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

THOMSON GEER
LAWYERS

The Hon Leeanne Enoch MP
Minister for Innovation, Science and the Digital Economy and Minister for Small Business

The Hon Dr Steven Miles MP
Minister for Environment and Heritage Protection and Minister for National Parks and the Great Barrier Reef

15 April 2016

Dear Ministers

Review of the *Biodiscovery Act 2004* (Qld)

Thomson Geer is pleased to submit its report on the review of the *Biodiscovery Act 2004* (Qld) (**the Act**) to you.

This Report details our analysis and recommendations arising out of the Terms of Reference together with the matters that were raised as part of submissions made to the review and face-to-face feedback sessions.

The recommendations arising out of the Review are listed commencing at page 10 of this Report.

We take this opportunity to thank those who participated in the process of the Review and now recommend the Report to you and your Ministerial colleagues.

Yours sincerely

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1 List of acronyms and abbreviations

Unless otherwise stated, the terms set out below have the meanings in the table below in this Report.

Capitalised terms not listed in the table below have the same meaning as in the Act unless otherwise stated.

ABS Clearing House	*Access and Benefit-sharing Clearing House established pursuant to the Nagoya Protocol.*
ABCS	*Australia's Biodiversity Conservation Strategy 2010 - 2030* prepared by the National Biodiversity Strategy Review Task Group convened under the Natural Resource Management Ministerial Council.
ABS	*Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization.*
Act	*Biodiscovery Act 2004* (Qld) (current as at 1 July 2014).
AIATSIS	Australian Institute of Aboriginal and Torres Strait Islander Studies.
AIATSIS Guidelines	Australian Institute of Aboriginal and Torres Strait Islander Studies *Guidelines for Ethical Research in Australian Indigenous Studies*.
ALRC	Australian Law Reform Commission.
BSA	A Benefit Sharing Agreement under the Act.
CBD	*United Nations Environment Program Convention on Biological Diversity (*ratified by Australia and coming into force in 1993).
CGEN	Genetic Heritage Management Council (Brazil).
Code of Ethics	*Queensland Biotechnology Code of Ethics.*
Commonwealth Nagoya Model	*A Model for Implementing the Nagoya Protocol in Australia* (published by the Australian Government, Department of Sustainability, Environment, Water, Population and Communities, 2013).
Commonwealth Regulations	Chapter 8A *Environment Protection and Biodiscovery Conservation Regulations 2000* (Cth).
Compliance Code	*Compliance code - Taking native biological material under a collection authority.*
DSITI	*Queensland Department of Science, Information Technology and Innovation.*
EHP	*Queensland Department of Environment and Heritage Protection.*
EU Regulation	*Regulation EU No 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union.*
FOEN	Federal Office for the Environment, Switzerland.

Gene Technology Act	*Gene Technology Act 2001* (Qld).
Government	The Queensland Government.
Nagoya Protocol	*Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS) to the Convention on Biological Diversity.*
NCA	*Nationally consistent approach for access to and the utilisation of Australia's native genetic and biochemical resources* (2002).
NC Act	*Nature Conservation Act 1992* (Qld).
NCHA	*Federal Act on the Protection of Nature and Cultural Heritage* (Switzerland).
New Brazilian Biodiversity Law	Brazil's new biodiversity legislation signed on 20 May 2015 (No. 13123/2015) which repeals the PM.
NTA	*Native Title Act 1993* (Cth).
NT Act	*Biological Resources Act 2006* (NT).
PM	Provisional Measure regulating access to genetic resources (No.2.186-16/2001) (Brazil), now repealed.
Report	This report setting out the outcomes of the Review.
2009 Review	The review of the Act undertaken in 2009.
Review	The review of the Act undertaken by Thomson Geer.
SCNAT	Swiss Academy of Sciences.
Terms of Reference	The Terms of Reference of the *'2015 Review of the Biodiscovery Act 2004 (Qld)'* as set out in Section 4 of this Report.
TOR	Terms of Reference of this Review.
TRIPS	Agreement on Trade Related Aspects of Intellectual Property Rights.
UNDRIP	United Nations Declaration on the Rights of Indigenous Peoples.
Updated Code	The proposed new combined code being the Compliance Code with the addition of the biodiscovery related aspects from the Code of Ethics.
WIPO	World Intellectual Property Organization.

2 Report

Thomson Geer was engaged by the Department of Science, Information Technology and Innovation to undertake a review of the *Biodiscovery Act 2004* (Qld) (**Act**).

The Review follows an earlier initial review of the Act which was conducted in 2009. The Government response to the initial review was published in 2010.

A recommendation of the initial review (which was supported by Government) was that a further review of the Act be undertaken five years after the initial 2009 review to ensure the Act continues to meet its aims and accommodates emerging trends and international developments.

The Review was guided by the Terms of Reference with particular regard to:

- The objectives and regulatory framework set out in the Act;
- The recommendations of the first review;
- The operation of the Act in the five years since that Review; and
- The Government's commitment to regulatory reform.

The Review has been informed by written submissions and face-to-face feedback sessions from a variety of organisations and bodies including government departments, industry representatives, private companies, research institutes, cultural groups and other interested parties.

This Report is divided into parts responding to the Terms of Reference for the Review.

3 The 2009 Review

3.1 Nature of the 2009 Review

Section 121 of the Act required a review to be undertaken within five years of the commencement of the Act (on 12 November 2004). This review was to consider whether the provisions of the Act remain appropriate in response to the Terms of Reference issued in July 2009.

A total of seven written submissions were received in response to a call from submissions made by the Queensland Government in August 2009. Roundtable discussions were also undertaken as part of the 2009 Review.

The 2009 Review considered the following areas (reflecting the Terms of Reference):

- *Purpose of the Act* – whether the policy objectives remain valid and whether any other issues may be included in the scope of the Act;
- *Act achieving its purposes* – 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* – the structure and effectiveness of the permitting regime, contractual framework for benefit sharing agreements and appropriateness of enforcement of compliance;
- *Regulatory Burden* – whether compliance and administrative costs are reasonable and justified and whether the system of approvals and application of regulatory requirements are commensurate to the level of risk;
- *Interface with other systems* – considering the interface with other legislation;
- *Changing circumstances* – examination of emerging trends and international developments and their impact on the Act; and
- *Changes to the legislation* – considering any amendments to the Act or alternatives to improve the effectiveness, fairness, timeliness and accessibility of the regulatory system.

The 2009 Review was tabled in the Queensland Parliament out of session on 1 December 2009. It suggested a number of changes directed towards operational aspects of the Act aimed at assisting the Act to continue to meet its purpose.

In broad terms, the 2009 Review included the following in its findings:

- The purpose of the Act remained valid and was being achieved;
- The Act should not be amended to extend its operation to private land, to specifically address any native title issues or indigenous knowledge or in respect of its treatment of genetic resources;
- International developments in relation to the regime and access to benefit sharing arrangements should be monitored;
- The regulatory framework of the Act was appropriate and should not be amended;
- The collection authority framework in the Act should be clarified including its application to samples which are transferred and also in respect of compliance by collection bodies including the Queensland Museum;
- The requirements regarding labelling and sorting of samples be considered as part of the review of the Compliance Code;
- It is appropriate for the State to negotiate benefit sharing agreements on a case by case basis with each biodiscovery entity;

- The application of the Act to educational and training institutions (including universities) should be clarified;
- The provisions of the Act dealing with enforcement of compliance are appropriate and should not be amended;
- The administrative and compliance system of the Act are appropriate;
- The system of approvals and application regulatory requirements are appropriate to the level of risk and does not require amendment;
- There is no regulatory overlap between the Act and the:
    - Commonwealth Regulations; and
    - NT Act

  and no amendments to the Act are required in this regard;
- Any peculiarities in the nature of the use of Native Biological Material may be able to be addressed through the individually negotiated benefit sharing agreements;
- No amendments to the Act were required in relation to international regimes; and
- A further review of the Act should be undertaken to address international, national and industry developments.

3.2 Queensland Government Response to the Review of the *Biodiscovery Act 2004* (Qld)

The Queensland Government issued its supportive response to the 2009 Review in July 2010.

Thirteen of the 2009 Review's recommendations were supported in full by the Queensland Government and the nineteen of the recommendations were either supported partially or in principle. The response noted that the policy intent or framework of the Act would not change based on the implementation of the 2009 Review's recommendations.

While the 2009 Review recommended a number of legislative changes to the Act, it was proposed by the Queensland Government that the Act and its operation be strengthened through a review of the Compliance Code and further education and stakeholder engagement. A copy of the Queensland Government Response to the 2009 Review is attached (Appendix 6).

4 Terms of Reference and other matters

4.1 Terms of Reference

In 2015, the Government issued the following Terms of Reference for the Review:

Terms of Reference

Purpose of the Act

1. Review the purposes of the Act to determine whether the policy objectives remain valid, the purposes of the Act are being achieved and whether the regulatory framework stipulated in the Act is still appropriate:

    (a) consideration of whether the current legislation is the most efficient means to achieve the policy objectives and if not, options for other mechanisms to achieve the objectives. In considering other options, gather evidence of the impacts of the other options on the regulated community to allow comparison to the current legislation and if there were no regulation.

    (b) consideration of developments internationally and nationally in relation to the implementation of the Nagoya Protocol and Australia's Biodiversity Conservation Strategy (ABCS) since the commencement of the Act and alignment with and any impact on its application.

    (c) examination of developments in native title law, indigenous knowledge and changes to IP law that may affect ownership of genetic resources.

Operation of the Act

2. Examine the overall structure and effectiveness of the Act including:

    (a) consideration of the effectiveness of the key features of the regulatory framework and opportunities to streamline the processes to reduce regulatory burden. In considering other options, gather evidence of the impacts of the other options on the regulated community to allow comparison to the current legislation and if there were no regulation.

3. Examine the structure and effectiveness of the permitting regime (Parts 3 and 4 of the Act) including:

    (a) consideration of whether the use of biodiscovery collection authorities compared to other types of environmental permits and authorities is effective and opportunities to streamline requests for access to native biological material for biodiscovery.

4. Examine the structure and effectiveness of the contractual framework for benefit sharing (Part 5 of the Act) including:

    (a) consideration of whether the framework is sufficiently adaptable to the different types of biodiscovery activities and entities and the range of pathways for commercialisation.

5. Examine the definitions in the Act and the need for the definition of any other terms including:

    (a) consideration of whether the operation of the Act is affected by the definition of biodiscovery and biodiscovery research which limit the application of the Act to research that is undertaken for the purpose of commercialising the native biological material.

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

Regulatory burden

7. 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.

8. Review the system of approvals and consider whether the application of regulatory requirements is commensurate with the level of risk.

Interface with other systems

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

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 including any consequential amendments that are required such as repeal of S119 due to the recent passing of the *Public Service and Other Legislation (Civil Liability) Amendment Act 2014*. In recommending other options, provide evidence of the impact of the recommended options on the regulated community to allow comparison to the current legislation and if there were no regulation. Guidance on this can be found in the Regulatory Impact Statement System Guidelines at http://www.treasury.qld.gov.au/office/knowledge/docs/ris-system-guidelines/index.shtml.

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

4.2 Written submissions

The Government made a call for submissions in May 2015. A total of five written submissions were received.

Below is a list of the organisations that made written submissions to the Review:

- Queensland Museum;
- Griffith University;
- James Cook University;
- Great Barrier Reef Marine Park Authority; and
- Chuulangun Aboriginal Corporation.

4.3 Face-to-face feedback

In July 2015, face-to-face feedback sessions were undertaken as part of the Review process.

Relevant stakeholders were identified as a result of their involvement or interest in the biodiscovery and biotechnology industry for the purposes of providing verbal feedback and comments to the Review.

Below are the organisations and individuals who participated in a face-to-face feedback session:

- EcoBiotics Limited;
- QIMR Berghofer;
- Griffith University;
- University of Queensland and UniQuest;
- Professor Ipek Kurtboke, University of the Sunshine Coast; and
- Professor Robert Henry, Director of Queensland Alliance for Food and Agriculture Innovation.

4.4 Summary of issues – Submissions and face-to-face feedback

A summary of the issues raised in submissions and during the face-to-face feedback sessions are set out in Appendix 1 to this Report.

This information will be addressed in the connection with the consideration of the relevant Terms of Reference in the Report.

4.5 Matters considered by the Review

The Review considered the following in reaching its recommendations:

- Submissions received in response to the call for submissions for the Review;
- Issues raised during face-to-face feedback sessions;
- The experience of the operation of the Act to date including operational issues;
- Feedback received from relevant Government departments;
- The experience and operation of similar legislation enacted in other jurisdictions;
- Emerging trends in the biodiscovery industry;
- International developments in biodiscovery and its regulation including the Nagoya Protocol; and
- Research, reports and other sources of information.

4.6 Recommendations arising out of the Review

Recommendations have been detailed in the Review corresponding to the Terms of Reference. Some recommendations relate to operational or policy matters and some recommendations relate to proposed amendments to the Act.

5 List of recommendations

5.1 Purpose of the Act (Term of Reference 1)

1. Review the purposes of the Act to determine whether the policy objectives remain valid, the purposes of the Act are being achieved and whether the regulatory framework stipulated in the Act is still appropriate:
   a. consideration of whether the current legislation is the most efficient means to achieve the policy objectives and if not, options for other mechanisms to achieve the objectives. In considering other options, gather evidence of the impacts of the other options on the regulated community to allow comparison to the current legislation and if there were no regulation.
   b. consideration of developments internationally and nationally in relation to the implementation of the Nagoya Protocol and Australia's Biodiversity Conservation Strategy (ABCS) since the commencement of the Act and alignment with and any impact on its application.
   c. examination of developments in native title law, indigenous knowledge and changes to IP law that may affect ownership of genetic resources.

Recommendation (Term of Reference 1)	
1	The Review recommends that the purpose of the Act be updated to reflect the: (a) special knowledge held by indigenous persons about the State's biological resources; and (b) rights of indigenous persons in relation to providing access to Native Biological Material on indigenous people's land. This change would reflect the amendments proposed to the Act in respect of this issue.
2	The objectives in Section 4 of the Act be updated to incorporate a reference to the Nagoya Protocol.
3	The Review recommends that consideration be given to incorporating the biodiscovery related sections of the Code of Ethics into the Compliance Code, compliance with which is regulated under the Act. Should this recommendation be accepted, the objectives of the Act may be updated to reflect the new Updated Code.
4	Subject to the proposed changes to the legislation as recommended by the Review, the current legislation remains the most effective mechanism to achieve the policy objective of the Act.
5	The Review recommends consideration be given to providing (in an Updated Code or alternative administrative instrument) guidelines for access and benefit sharing with private landowners or parties negotiating with them (including access and use of indigenous knowledge and on mutually agreed terms).
6	The Review does not recommend any amendment to the definition of State Land to the extent it relates to native title.
7	The Review recommends the State monitor the progress internationally and more importantly at a Commonwealth level regarding the protection of traditional and indigenous knowledge in the context of existing intellectual property regulation or by way of a sui generis system and the extent to which, once this occurs, consequential amendments to the Act are required.
8	The Review recommends: (a) the State give consideration to amending the Act to recognise the importance and

Recommendation (Term of Reference 1)	
	rights of indigenous people including in respect of their indigenous knowledge and access to Native Biological Material in indigenous people's land; and (b) except as set out below, the State adopt in general terms the approach of the Commonwealth Regulations regarding use of indigenous knowledge and access to Native Biological Material from indigenous people's land (including the requirement of prior informed consent on mutually agreed terms). Adopting this approach may include the Act being amended as follows: (a) recognising the importance and rights of indigenous people including in respect of their indigenous knowledge (wherever obtained) and access to Native Biological Material on indigenous people's land in the objectives of the Act; (b) including a definition of 'indigenous people'; (c) including a definition of indigenous people's land (for example, State land over which indigenous people have a claim but exclusive possession under the NTA has not been recognised); (d) incorporating a requirement for the giving of prior informed consent in relation to accessing Native Biological Material on land which is indigenous people's land and any use of indigenous knowledge; (e) the requirement for the giving of prior informed consent will be satisfied if a Statutory Declaration (or equivalent) confirming prior informed consent is provided in accordance with some accepted guidelines (for example the AIATSIS Guidelines). Entry into an ILUA under the NTA authorising the proposed action and providing the consent may be provided as an alternative to the statutory declaration; (f) the Department ought not be required to make its own assessment of whether the prior informed consent was satisfactory; and (g) incorporating a requirement that benefit sharing agreements include: a statement regarding use of indigenous knowledge including the source e.g. scientific or public documents or another group of indigenous persons and a statement regarding benefits to be provided in return for use of the indigenous knowledge. Implementation may also involve including direction to relevant guidelines and government portals, provision of contact details of land councils or individual traditional owners (to facilitate engagement).
9	The Review does not recommend any changes to the Act as a result of intellectual property law.
10	The Review does not recommend any changes to the Act as a result of gene technology legislation (with the exception of the proposed amendment to the definition of Native Biological Material – see Recommendation 33).
11	In the absence of a broader consideration of this issue, the Review does not recommend the scope of the Act be expanded to cover private land (with the effect that the State would be entitled to obtain Benefits of Biodiscovery from Native Biological Material collected from privately owned land).

5.2 Operation of the Act (Terms of Reference 2, 3, 4, 5 and 6)

2. Examine the overall structure and effectiveness of the Act including:
    a. consideration of the effectiveness of the key features of the regulatory framework and opportunities to streamline the processes to reduce regulatory burden. In considering other options, gather evidence of the impacts of the other options on the regulated community to allow comparison to the current legislation and if there were no regulation.

3. Examine the structure and effectiveness of the permitting regime (Parts 3 and 4 of the Act) including:
    a. consideration of whether the use of biodiscovery collection authorities compared to other types of environmental permits and authorities is effective and opportunities to streamline requests for access to native biological material for biodiscovery.

4. Examine the structure and effectiveness of the contractual framework for benefit sharing (Part 5 of the Act) including:
    a. consideration of whether the framework is sufficiently adaptable to the different types of biodiscovery activities and entities and the range of pathways for commercialisation.

5. Examine the definitions in the Act and the need for the definition of any other terms including:
    a. consideration of whether the operation of the Act is affected by the definition of biodiscovery and biodiscovery research which limit the application of the Act to research that is undertaken for the purpose of commercialising the native biological material.

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

Recommendation (Terms of Reference 2, 3, 4, 5 and 6)	
12	The Review recommends Biodiscovery Plans be removed from the regulatory framework of the Act and include relevant aspects previously contained in the Biodiscovery Plans in Collection Authorities and BSAs as appropriate.
13	In making this Recommendation, the Review has relied on Recommendation 26 - that the definition of Biodiscovery no longer has 'commercialisation' as a pre-requisite. The Review recommends the State give consideration to updating the permitting regime including the interaction between Collection Authorities and Benefit Sharing Agreements. Based on the alternatives considered by the Review, on balance the Review favoured an approach which is generally consistent with the process currently adopted by the Commonwealth: • retaining the Collection Authority under the Act; and • requiring a Benefit Sharing Agreement (commercial purposes) and declaration (non-commercial purposes). In order to meet the requirements of the Nagoya Protocol, the Review recommends the State Collection Authorities issued for non-commercial purposes also incorporate details of benefit sharing.
14	The Review recommends consequential amendments be made to the Act as are likely to be required to reflect an alternative approach to the Collection Authority and benefit sharing regime including but not limited to the need to update the model BSA to reflect the new framework.

Recommendation (Terms of Reference 2, 3, 4, 5 and 6)	
15	If the Biodiscovery Entity is engaging in Commercialisation, key information requirements (with the exception of the Benefits of Biodiscovery to be provided, as this is included in the BSA) in section 37 of the Act (previously included in the Biodiscovery Plan) may form part of the Collection Authority application.
16	Consistent with and in the manner noted in Recommendation 8, the Review recommends including as a pre-condition to the application for a Collection Authority the receipt of prior informed consent in relation to accessing Native Biological Material on land which is indigenous people's land (falling within the Act).
17	The Review recommends an education process be adopted to inform industry in relation to the changes in the permitting regime which may include updating the relevant code with a detailed explanation of the process.
18	The Review recommends that guidance notes (including contact persons and timeframes) setting out the Collection Authority pathway should be provided on the Department's website.
19	The Review recommends that the State consider whether the method of storage of samples requires amendment to reflect changes in scientific technologies – if so, updated requirements may be implemented using the Compliance Code (or updated equivalent).
20	The Review recommends updating the section 34 list of content of benefit sharing agreements to reflect the recognition of indigenous knowledge, access of Native Biological Material on indigenous people's land, and prior informed consent (see also Recommendation 8).
21	The Review recommends sections 35(2) and 54(2) and (3) be amended. The Review has determined that the State give consideration to adopting a licensing framework by which the head Biodiscovery Entity is permitted to enter into downstream arrangements in respect of the Commercialisation of Native Biological Material on certain conditions (as outlined in this Report). A breach of these conditions should be included in the offence provisions of the Act. If the head Biodiscovery Entity (which has entered the BSA with the State) is not able to comply with the conditions– the downstream entity must enter into a separate BSA in relation to the use of the Native Biological Material with the State on the usual terms. If this recommendation is adopted, the Review further recommends consequential amendments to the Model Benefit Sharing Agreement.
22	The Review recommends the change in the benefit sharing framework be supported by further explanation and examples to be included either on the department's website or in the Updated Code accompanying the Act.
23	The Review recommends the adoption of a contractual framework as described in Recommendation 21 (or similar), will enable the Act to be more adaptable to different types of biodiscovery activities, entities and pathways for commercialisation.
24	The Review does not recommend any amendment to the Act in relation to Benefits of Biodiscovery to be provided by institutions (including those that are also subject to funding loan terms with the State).
25	The Review does not recommend any amendment to the definition of Benefits of Biodiscovery.
26	The Review recommends delinking commercialisation from the definition of Biodiscovery. This may be achieved by deleting '*for the purpose of commercialising the material*' from the definition of Biodiscovery Research.

Recommendation (Terms of Reference 2, 3, 4, 5 and 6)	
27	The Review does not recommend a specific exclusion for particular industries from the definition of Biodiscovery. *However the State may wish to consider excluding 'non value-add' activities by amending subparagraph (b) of the definition of Biodiscovery.*
28	The Review recommends that paragraph (2) of the definition of 'Commercialisation' be amended to also exclude private research grants.
29	The Review recommends the State give consideration to extending the definition of Native Biological Material to cover underlying data, information or sequences of Native Biological Resources.
30	The Review recommends the State engage with providers of the underlying data, information or sequence to determine the most appropriate regulatory framework to permit and record the use of this information.
31	The Review recommends the State give consideration to extending the definition of Native Biological Resource to include *'extracts from samples*' in subparagraph (b) of that definition.
32	The Review recommends the State give consideration to extending the definition of Native Biological Material to include Native Biological Resources *'maintained in an ex situ collection'*.
33	The Review recommends the State give consideration to excluding from the definition of Native Biological Material the following: • A genetically modified organism for the purposes of section 10 of the *Gene Technology Act 2000* (Cth) or consistent state or territory legislation; or • 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).
34	The Review recommends the State give consideration to including some clear examples of the activities and material which would be covered by the Act in the Updated Code.
35	Consistent with the Commonwealth Regulations, the Review recommends the State give consideration to enabling the Minister to declare that the Act or part thereof not apply to specified Native Biological Material or a specified collection of Native Biological Material (including future additions to the collection) where use of the resources is required to be controlled under any international agreement or treaty to which Australia is a party.
36	As at the date of this Report, the powers of the Act allow enforcement of compliance which is effective and appropriate to the circumstances. However, the enforcement and monitoring provisions should be updated to ensure compliance with the broadening of the scope of the Act to cover indigenous knowledge and access to indigenous peoples' land. For example, the powers of the Act may be expanded to cover: • audit in relation to prior informed consent and benefit sharing in connection with the use of indigenous knowledge and access to indigenous peoples' land; • the right to request further information in relation to the provision of prior informed consent and benefit sharing in relation to the use of indigenous knowledge and access to indigenous peoples' land; • the use of indigenous knowledge and access to indigenous peoples' land other than with prior informed consent and benefit sharing to be an offence under the Act; and • the giving of false and misleading information regarding prior informed consent and benefit sharing in connection with the use of indigenous knowledge and access to indigenous peoples' land.

Recommendation (Terms of Reference 2, 3, 4, 5 and 6)	
	These powers may facilitate further enquiries to confirm the accuracy of the information provided to the State for example in circumstances where the State, for various reasons, may consider the information provided to be unreliable. The Act may also be amended to include offence provisions in relation to compliance with the Biodiscovery Register and also the giving of false and misleading information in connection with the Biodiscovery Register.

5.3 Regulatory Burden (Terms of Reference 7 and 8)

7. 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.

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

Recommendation (Terms of Reference 7 and 8)	
37	Other than the changes recommended elsewhere in this Report which may impact on the administrative and compliance costs, the Review considers the current compliance and administrative costs are reasonable and justified.

5.4 Interface with other systems (Term of Reference 9)

9. 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 (Term of Reference 9)
The Review does not make any recommendations in relation to this Term of Reference as all recommendations relating to this Term of Reference have been made in connection with other Terms of Reference.

5.5 Changes to the legislation (Term of Reference 10)

10. Recommend amendments to the Act, or alternatives to legislation, which improve the effectiveness, fairness, timeliness and accessibility of the regulatory system including any consequential amendments that are required such as repeal of S119 due to the recent passing of the Public Service and Other Legislation (Civil Liability) Amendment Act 2014. In recommending other options, provide evidence of the impact of the recommended options on the regulated community to allow comparison to the current legislation and if there were no regulation. Guidance on this can be found in the Regulatory Impact Statement System Guidelines at http://www.treasury.qld.gov.au/office/knowledge/docs/ris-systemguidelines/index.shtml

Recommendation (Term of Reference 10)	
38	The Review recommends the State engage with the Commonwealth to determine a consistent approach to compliance with Articles 15 and 16 of the Nagoya Protocol.
39	The Review recommends the State consider the following act as checkpoints (to establish provenance and prior informed consent on mutually agreed terms) for the purposes of compliance with the Nagoya Protocol: • At the time of application for Queensland government funding for research using Native Biological Material (including if accessed from indigenous people's land) and/ or associated indigenous knowledge (consistent with the proposed Commonwealth approach); • Issuing of Certificates of Compliance (from information lodged on Biodiscovery Register). In order to comply with the Nagoya Protocol, these checkpoints should also apply to Native Biological Material and genetic resources obtained outside the scope of the Act (nationally and internationally).
40	The Review recommends the State closely monitor any checkpoints implemented by the Commonwealth.
41	The Review confirms that subject to the extension of compliance with respect to indigenous peoples' land and indigenous knowledge (see Recommendation 8), the Review notes that the Collection Authority is likely to meet the standards required by the Nagoya Protocol. The Review recommends the State continue to engage with the Commonwealth in relation to the requirement for any standardised permits.
42	The Review recommends the State further examine (i) the viability of the implementation of a Biodiscovery Register as outlined in this Report with supporting enforcement provisions, (ii) the regulatory implications of establishing a Biodiscovery Register including, collecting information on the Biodiscovery Register and issuing International Certificates of Compliance to persons/entities covered by and outside the scope of the Act.
43	The Review recommends the State maintain close consultation with the Commonwealth so that the State may assess and appropriately implement any regulatory structure, policy or administration required in Queensland with respect to trusted collections.
44	The Review recommends the State maintain close and consistent engagement with the Commonwealth with respect to the implementation of the Nagoya Protocol and its impact on implementation or regulatory and administrative frameworks and policies in Queensland.
45	The Review recommends the State repeal section 119 of the Act.

6 *Biodiscovery Act 2004* (Qld)

6.1 General

The Act commenced on 12 November 2004.

On 11 October 2002 the Natural Resource Management Ministerial Council endorsed the *Nationally consistent approach for access to and the utilisation of Australia's native genetic and biochemical resources* (**NCA**). The Act was a response to the NCA.

The aim of the Act was to implement the objectives of Article 15 of the *United Nations Environment Program Convention on Biological Diversity* (**CBD**) (ratified by Australia in 1993) – to conserve biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising from the use of genetic resources. Further Article 15 recognises the sovereign rights of states over their natural resources and their authority to determine access to genetic resources, including fair and equitable sharing of benefits.

The benefits sought under the regulatory framework of the Act are intended to align with those set out in Appendix II to the *Access to Genetic Resources and Benefit-sharing Bonn Guidelines* of the CBD.

As described in the Explanatory Notes to the *Biodiscovery Bill 2004*, the Act adopts a regulatory framework that provides:

1. A regime authorising collection of native biological resources (taken from State land or Queensland waters) for biodiscovery; and

2. Mandatory benefit sharing agreements with the State.

In addition to the Act, the State implemented the Compliance Code which governs the collection of Native Biological Material. It a condition of the issue of a Collection Authority that the applicant complies with the Compliance Code (Section 14(2) of the Act).

The Code of Ethics (which is under review) also sets out requirements for the ethical practice of biotechnology in Queensland. Users of Native Biological Material under the Act are contractually bound to comply with the Code of Ethics in their benefit sharing agreements with the State.

The Act provides the Queensland Government with the authority to regulate the use of Native Biological Material (taken from State land or Queensland waters) for the purpose of Biodiscovery.

Drivers for reform

The principal drivers for reform of the Act are compliance with the Nagoya Protocol, consistency with Commonwealth Regulation (to make it easier for parties to operate in Australia), identifying a need for education about what Biodiscovery is, providing for workable administrative arrangements and reflecting changes in technology.

The impact of the Nagoya Protocol is discussed in Section 7 and throughout the Report generally. It is identified that to comply with the Nagoya Protocol some legislative changes are required. This will enable complying entities to meet international requirements in conducting their business.

To assist with ease of management of the Act there is a need for education to ensure that the community in general and the administering government departments have a consistent understanding of what Biodiscovery is, the need to obtain a Collection Authority and the requirement for a Benefit Sharing Agreement. The Review also considers the requirement for commercialisation is unnecessary and is a complicating factor in the administration of the Act (see Recommendation 26). Further, the Report addresses the current and proposed administrative arrangements and rationale is provided for a change in process. Changes in technology have meant that there is no longer a need to have a physical sample to carry out Biodiscovery and exploit that process. This is considered in the Report.

7 Purpose of the Act

7.1 Terms of Reference 1

1. Review the purposes of the Act to determine whether the policy objectives remain valid, the purposes of the Act are being achieved and whether the regulatory framework stipulated in the Act is still appropriate:
   a. consideration of whether the current legislation is the most efficient means to achieve the policy objectives and if not, options for other mechanisms to achieve the objectives. In considering other options, gather evidence of the impacts of the other options on the regulated community to allow comparison to the current legislation and if there were no regulation.
   b. consideration of developments internationally and nationally in relation to the implementation of the Nagoya Protocol and Australia's Biodiversity Conservation Strategy (ABCS) since the commencement of the Act and alignment with and any impact on its application.
   c. examination of developments in native title law, indigenous knowledge and changes to IP law that may affect ownership of genetic resources.

7.2 Purposes and objectives of the Act

The purpose of the Act is set out in Section 3:

- 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;
- To encourage the development, in the State, of value added Biodiscovery;
- 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
- To ensure Biodiscovery enhances knowledge of the State's biological diversity, promoting conservation and sustainable use of Native Biological Resources.

The Review acknowledges that since the commencement of the Act and the 2009 Review there have been significant developments both nationally and internationally with respect to policies relating to biological diversity, its conservation and the equitable sharing and access to genetic resources. In particular the Review refers to the Nagoya Protocol and the ABCS.

The Nagoya Protocol and the ABCS has driven the Review to give detailed consideration as to whether the current stated purposes of the Act are sufficient to reflect international and national developments.

Subject to the comments below, neither the face to face meetings nor the submissions received by the Review raised any significant concerns as to the current stated purposes of the Act.

The Review considered that the purposes of the Act were generally consistent with the NCA and the ABCS (with respect to the conservation of biodiversity). However, the Review was not able to conclude that the purposes of the Act met the principles espoused by the Nagoya Protocol or the ABCS to the extent the Act related to indigenous rights and prior informed consent.

In view of the recommendations in this Report, the Review has determined that the purposes of the Act be updated to include a recognition of the rights of indigenous people in particular, the protection of indigenous knowledge and framework for accessing Native Biological Material on indigenous people's land. The State should have regard to Regulation 8A.01 of the Commonwealth Regulations.

In doing so, the Act would acknowledge the special knowledge held by indigenous persons about the State's biological resources and also the rights of indigenous people in relation to accessing Native Biological Material from indigenous people's land – thereby reflecting the intent of the Nagoya Protocol and the ABCS (with respect to indigenous engagement).

Recommendation 1:

The Review recommends that the purpose of the Act be updated to reflect the:

(a) *special knowledge held by indigenous persons about the State's biological resources; and*

(b) *rights of indigenous persons in relation to providing access to Native Biological Material on indigenous people's land.*

This change would reflect the amendments proposed to the Act in respect of this issue.

The Review separately called for consideration as to whether the objectives of the Act are being achieved.

At the time the Act commenced, the reason for why the Act was enacted was to give effect to the CBD and in particular Article 15. This was set out in Section 4 of the Act.

While the purpose (specifically Article 15 of the CBD) remains a valid objective of the Act, the Review recommends that the objectives in Section 4 be updated to reflect the international context of the Nagoya Protocol insofar as it relates to State Land and Queensland waters. Collection of biological material from private land may be regulated by other Acts (such as the Nature Conservation Act 1992 (Qld), Forestry Act 1959 (Qld), Marine Parks Act 2004 (Qld) and Fisheries Act 1994 (Cth)) and be the subject of agreement with the private landholders (as discussed at 7.4 and Recommendation 5).

Recommendation 2:

The objectives in Section 4 of the Act be updated to incorporate a reference to the Nagoya Protocol.

7.3 Regulatory framework

The Review was asked to specifically consider whether the regulatory framework stipulated in the Act is still appropriate.

The regulatory framework of the Act is set out in Section 3(2) of the Act as follows:

> *(a) the following streamlined frameworks –*
>
> > *(i) a regulatory framework for taking and use 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.*

In the main, the regulatory framework of the Act is consistent with that of the Commonwealth and Northern Territory - regulation of the taking of resources, contractual benefit sharing and

monitoring and compliance. Further, the framework reflects that adopted internationally by those countries implementing the Nagoya Protocol.

With the exception of the application of the system relating to BSAs, no submissions were received which specifically argued against the framework adopted by the Act.

While there were some submissions which challenged the efficiency of the system of the process of applying for Collection Authorities pursuant to the Act, this appeared more to relate to operational matters connected with that process rather than the need to apply per se.

The Review also received some submissions from publicly funded organisations questioning whether they were bound by the benefit sharing agreement requirements of the Act on the basis that they were bound by other State agreements which required returns to be paid to the State. Again these comments concerned operational aspects rather than fundamental issues with the objectives of the Act.

It was noted by the Review that the Code of Ethics (under review) is not reflected in the regulatory framework in Section 3(2) of the Act. This is because Biodiscovery Entities are only bound to the Code of Ethics through the entry into a benefit sharing agreement.

The maintenance of both the Code of Ethics and Compliance Code (regarding collection protocols) increases the administrative burden on the State and creates a more complex structure for users. Further, the Review considers the biodiscovery aspects of the Code of Ethics should be given regulatory force.

To reduce the number of documents connected with the administration of the Act and to reduce complexity of structure, the Review recommends that the State give consideration to incorporating the biodiscovery sections of the Code of Ethics into the Compliance Code. The Code of Ethics has wider implications and should be separately maintained.

Recommendation 3:

The Review recommends that consideration be given to incorporating the biodiscovery related sections of the Code of Ethics into the Compliance Code, compliance with which is regulated under the Act. Should this recommendation be accepted, the objectives of the Act may be updated to reflect the new Updated Code.

7.4 Is the current legislation the most efficient means to achieve the policy objectives?

Whether the Act is the most efficient means to achieve the policy objectives is important in the national context but also in view of the emerging international trends flowing from the Nagoya Protocol.

After considering the Act, national and international approaches to achieve similar policy objectives, the Review is satisfied that, in broad terms, the current legislation is the most efficient means to achieve the policy objectives of the Act.

The Review notes there are some structural aspects of the Act which may be improved in an attempt to address some of the concerns raised by stakeholders in respect of the current legislation, for example, whether there is a need to enter into a benefit sharing agreement for non-commercial research and whether the exceptions for benefit sharing agreements should still apply – see Sections 8.3 and 8.4 of this Report.

These changes recommended by the Review (under separate Terms of Reference) do not alter the essence of the current legislation.

Recommendation 4:

Subject to the proposed changes to the legislation as recommended by the Review, the current legislation remains the most effective mechanism to achieve the policy objective of the Act.

Private land

In addition to considering whether the scope of the Act should be extended to private land in the context of ownership of genetic resources (as noted below), the Review also considered whether the Act should be amended to establish a framework governing access and benefit sharing arrangements with private landowners.

This approach could reflect the framework adopted in the Northern Territory for example, placing an obligation on parties to lodge with the State copies of benefit sharing agreements between private landowners and entities. This is further discussed in Section 7.14 of this Report.

The Review has determined that amending the Act in this way is likely to increase the regulatory burden of the Act. The Review found no compelling case for the extension of the Act in this way. In coming to this conclusion, the Review notes the continuing validity of the policy decision made at the commencement of the Act which determined that private land not be covered by the Act.

However, the Review notes that private landowners may benefit from some guidance in negotiating benefit sharing agreements. This guidance may be provided by the State in an Updated Code or alternative administrative instrument.

The Review also recommends that these guidelines for private landowners should also, where there is use of indigenous knowledge; address the need to obtain prior informed consent regarding access and use of indigenous knowledge and on mutually agreed terms – consistent with Articles 7 and 12 of the Nagoya Protocol. The existence of evidence of prior informed consent to access and use and appropriate benefit sharing agreements should assist with the grant of an International Certificate of Compliance.

A similar recommendation (in relation to providing guidance to private land owners) was made by the Review in 2009. However, the Review considers that providing guidance to private landowners is even more critical at this time in view of the Nagoya Protocol.

Entities engaging in biodiscovery will need to be able to confirm the existence of access arrangements and benefit sharing agreements with private landowners for the purposes of obtaining a Certificate of Compliance for access or benefit sharing which may be uploaded by the State to the ABS Clearing House. Such guidelines will also need to be cognisant of the requirements of other Acts (such as the Nature Conservation Act 1992 (Qld), Forestry Act 1959 (Qld), Marine Parks Act 2004 (Qld) and Fisheries Act 1994 (Cth)) and binding agreements as to the use of land (such as nature refuge conservation agreements, indigenous land use or management agreements).

Recommendation 5:

The Review recommends consideration be given to providing (in an Updated Code or alternative administrative instrument) guidelines for access and benefit sharing with private landowners or parties negotiating with them (including access and use of indigenous knowledge and on mutually agreed terms).

7.5 Nagoya Protocol

The Nagoya Protocol is a supplementary agreement to the CBD. It is aimed at providing a framework for the fair and equitable sharing of benefits arising out of the utilisation of genetic resources (one of the three objectives of the CBD).

The Nagoya Protocol was adopted on 29 October 2010 and entered into force on 12 October 2014, 90 days after the deposit of the fiftieth instrument of ratification.

The Nagoya Protocol applies to genetic resources (within the scope of Article 15 of the CBD), benefits arising from the utilisation of those resources, traditional knowledge associated with those resources and benefits deriving from the utilisation of those resources (Article 2 of the Nagoya Protocol).

The Review has considered the following countries/states in relation to the implementation of the Nagoya Protocol since the commencement of the Act:

Internationally

- European Union
- Switzerland
- Brazil
- Canada

Nationally

- Commonwealth
- Western Australia
- Northern Territory
- Other States (including Tasmania and Victoria)

Nagoya Protocol: First Meeting of the Conference of the Parties

The first meeting of the Conference of the Parties serving as the meeting of the parties to the Nagoya Protocol was held in the Republic of Korea in October 2014. The meeting was held concurrently with the twelfth meeting of the Conference of the Parties to the CBD.

In the Final Report tabled, two key initiatives were proposed, namely:

1. The development of a strategic framework for capacity building and effective implementation of the Nagoya Protocol; and
2. A strategy to raise awareness of the provisions of the Nagoya Protocol and general ABS obligations.

Strategic Framework for Capacity Building and Development

The Report found that most countries, particularly the least developed countries, lack the necessary capabilities to effectively implement the Nagoya Protocol. Many countries were identified as lacking clear and harmonised rules governing procedures for the obtaining of prior informed consent and mutually agreed terms. A lack of expertise in most countries to collect, manage and share information was also noted.

The strategic framework outlined in the Final Report focuses on capacity building and development at the individual, institutional and systemic levels and covers the following key areas:

- The capacity to implement and comply with the obligations of the Nagoya Protocol;

- The capacity to develop, implement and enforce domestic legislative, administrative or policy measures on access and benefit sharing;
- The capacity to negotiate Mutually Agreed Terms (Article 18 of the Nagoya Protocol); and
- The capacity of countries to develop endogenous research capabilities to add value to their own genetic resources.

The framework also provides for a number of supporting activities to the strategic measures including the organisation of workshops for key stakeholders, training on ABS Clearing House, provision of legal or technical assistance e.g. in preparation of model contracts, e-learning modules, documentation of case studies and development of guidelines for the establishment and strengthening of checkpoints at the national level.

Awareness Raising Strategy

A key concern arising from the conference was the general lack of awareness of ABS provisions amongst key stakeholders including government officials, indigenous and local communities and the private and public sector. This is largely attributable to the absence of an overall communications framework and a lack of predictable and long term funding for communications activities.

The awareness raising strategy outlined in the Final Report aims at providing a systemic and coherent approach to assist awareness-raising of ABS obligations.

The strategy is structured around 4 priority activities:

1. Communication situation analysis and the development of needs based awareness raising strategies at the national, regional and sub-regional levels;
2. Creation of a tool kit and awareness raising materials;
3. Training communicators and engage target group; and
4. Evaluation and feedback.

The strategy will be country driven but the Secretariat will carry out a number of supporting actions such as the creation of toolkits containing methodologies, templates and descriptive materials.

European Union

The European Union (**EU**) ratified the Nagoya Protocol on 16 May 2014.

To better align EU legislation with the provisions of the Nagoya Protocol, a new regulation was passed (Regulation EU No 511/2014). The Regulation came into force on the same day as the Nagoya Protocol. Users are however granted a one-year transitional period before the compliance measures take effect - all of its provisions applied from 12 October 2015.

The Regulation establishes an implementing framework for the Nagoya Protocol. It applies to all sovereign held genetic resources and indigenous knowledge accessed following the entry into force of the Nagoya Protocol.

The Implementing Regulation contains measures on some specific aspects, as provided for in Regulation EU No 511/2014 - it was adopted by the Commission on 13 October 2015, with entry into force on 9 November 2015.

Each Member State is required to designate a competent national authority in addition to a focal point to oversee implementation at a national level. To ensure uniform conditions of implementation, the Regulation confers on the European Commission broad implementing powers.

Due Diligence Requirement

Users must exercise due diligence to ensure that the genetic resources are accessed lawfully in accordance with the provider country's ABS legislation and any derived benefits are shared equitably on mutually agreed terms.

Where an International Certificate of Compliance has been issued to a user or the genetic material has been obtained from a recognised collection, users are considered to have satisfied the due diligence requirement.

Certificates must be maintained and subsequently transferred to third parties. Where no such certificate is available, users are required to maintain a detailed record of (amongst other things) the source and description of the genetic resources, any rights/obligations attaching to access, all mutually agreed terms and permits where applicable.

If the information held by the user is insufficient or there is uncertainty about the legality of access and utilisation persists, the user must obtain a new permit for access and establish mutually agreed terms, or discontinue utilisation.

Register of Trusted Collections

The Regulation (Article 5) provides for a system of 'Trusted Collections' to be established for the EU. The system is electronic and maintained by the European Commission. Member States are responsible for approving the collections to be included on the register.

Pursuant to Article 5(3) of the Regulation, in order to be accredited as a trusted collection, a collection will need to: (i) apply standardised procedures for exchange, (ii) only supply material and related information with documents providing evidence that they were accessed legally, (iii) keep records of all samples and information supplied to third parties, (iv) use unique identifiers for samples supplied and (v) use appropriate tracking and monitoring tools for exchanging samples with other collections.

Annexure I of the Implementing Regulation requires the following information (as part of a template form) to be provided with a request for inclusion in the register of collections:

(a) Information on the holder of the collection (name, type of entity, address, e-mail, telephone number);

(b) Information on whether the application concerns a collection or part of a collection.

(c) Information on the collection or the relevant part thereof (name; identifier (code/ number), where available; address (es), website, where available; link to the collection's online database of genetic resources, where available).

(d) A brief description of the collection or the relevant part thereof - where only part of a collection is to be included in the register, details on the relevant part(s) and its(their) distinctive features should be provided.

(e) Collection category - the application should provide information on the category to which the collection or part thereof belongs.

Annexure I also provides for a variety of documents including codes of conduct, guidelines or standards, relevant principles, or manuals of procedures, developed and applied within the collection, and any additional instruments for their application may be provided to evidence the requirements of Article 5(3) of the Regulation (summarised above).

Competent National Authorities are required to routinely verify compliance by collections with the above requirements. Pursuant to the Implementing Regulation, the verification may include:

(a) on-the-spot checks;

(b) examination of selected documentation and records of a collection or part thereof, which are relevant for demonstrating compliance with Article 5(3) of Regulation (EU) No 511/2014;

(c) examination of whether selected samples of genetic resources and related information of the collection concerned have been documented in accordance with Article 5(3) of Regulation (EU) 511/2014;

(d) examination of whether the collection holder has the capacity to consistently supply genetic resources to third persons for their utilisation in accordance with Article 5(3) of Regulation (EU) No 511/2014;

(e) interviews with relevant persons, such as the collection holder, staff, external verifiers, and users obtaining samples from that collection.

Remedial action is taken in instances of non-compliance and collections may be reported to the Commission with the possibility of deregistration.

Monitoring of User Compliance

The EU Regulation and Implementating Regulation identifies two main checkpoints for which users must declare and provide evidence (when requested) that they have exercised due diligence:

(a) When research funds are received for research involving the utilisation of genetic resources and traditional knowledge associated with genetic resources (where the same research project is funded from more than one source or involves more than one recipient, the recipient(s) may decide to make only one declaration); and

(b) At the final stage of utilisation, meaning prior to the first of the following events occurring:

i. market approval or authorisation is sought for a product developed via the utilisation of genetic resources and traditional knowledge associated with genetic resources;

ii. a notification required prior to placing for the first time on the Union market is made for a product developed via the utilisation of genetic resources and traditional knowledge associated with genetic resources;

iii. placing on the Union market for the first time a product developed via the utilisation of genetic resources and traditional knowledge associated with genetic resources for which no market approval, authorisation or notification is required;

iv. the result of the utilisation is sold or transferred in any other way to a natural or legal person within the Union in order for that person to carry out one of the activities referred to in points (a), (b) and (c);

v. the utilisation in the Union has ended and its outcome is sold or transferred in any other way to a natural or legal person outside the Union. 20.10.2015 L 275/8 Official Journal of the European Union

Competent National Authorities are also required to communicate user compliance to the ABS Clearing House and verify compliance by users of their obligations in provider countries on a periodical basis (with spot checks as appropriate). Special consideration is paid to cases of user non-compliance raised by Member States and remedial actions may be taken.

Switzerland

The Swiss Parliament ratified the Nagoya Protocol on 11 July 2014.

In order to implement the Nagoya Protocol on a national level, the *Federal Act on the Protection of Nature and Cultural Heritage* (**NCHA**) was amended. A new Section 3c was inserted dealing with the issue of genetic resources which came into force on 12 October 2014.

The NCHA was considered the most appropriate legislative instrument to introduce the legal provisions given that it was an instrument of the CBD and already includes the objectives of biological diversity and sustainable use.

Two key areas were introduced concerning due diligence and notification. Both areas also apply to indigenous knowledge associated with genetic resources, unless such knowledge is already freely available to the public.

Due Diligence Requirement

Before users can 'use' genetic resources or associated indigenous knowledge, or directly benefit from the utilisation of genetic resources, they must first comply with the domestic regulatory requirements of ABS of the Party to the Nagoya Protocol that has provided the resource or knowledge.

Specifically, they must ensure that the genetic resources have been accessed lawfully and that mutually agreed terms for the fair and equitable sharing of benefits have been established.

The definition of 'utilization' of genetic resources" is taken from Article 2 of the Nagoya Protocol and means:

> '*to conduct research and development on the genetic or biochemical composition of genetic resources including the application of biotechnology*'.

This includes both commercial and non-commercial activities undertaken mainly by researchers at universities, industry or other institutions.

The scope of the due diligence requirement under Swiss Law is particularly broad. It includes users who also derive direct benefits from biochemical substances based on the utilisation of a genetic resource (e.g. whoever obtains market authorisation for a biochemical active compound in a medicinal or cosmetic product).

Genetic resources utilised as consumption goods, accessed prior to when the Nagoya Protocol came into force in Switzerland or obtained outside of the limits of national jurisdiction remain outside the scope of due diligence requirement.

The Federal Council plans to provide additional regulation about the information to be recorded and where appropriate, passed on to future users, in compliance with this requirement.

In the interim, if it is found that the due diligence requirement has not been complied with, users are required to ensure that they are fulfilled at a later stage, or otherwise renounce using the genetic resources at stake.

Notification Requirement

To support the due diligence requirement, users in Switzerland must notify the Federal Office for the Environment (**FOEN**) of their compliance. The FOEN serves as a centralised checkpoint. Additional checkpoints have been set up at the market authorisation level with a number of smaller authorities designated the task of checking whether compliance with the due diligence requirement has been reported to the FOEN.

Notification must be made before market authorisation for utilised genetic resources, or if such authorisation is not required, before the genetic resource is commercialised.

'Commercialization' includes the sale of utilized genetic resources in addition to other legal instruments that derive monetary benefits from the use of genetic resources such as licences or pledge agreements.

To simplify the notification process, the FOEN have set up a simple electronic database into which users can enter information themselves.

Further checkpoints

Switzerland have established a number of other checkpoints including disclosure of the source of the genetic material at the time of applying for a patent and formal confirmation of compliance with the ABS requirements at the time of applying for public research grants.

Due to the limited number of patented inventions that reach the stage of commercialization, patent applicants are exempt from the notification requirement. However, at the point where legal transactions (such as the granting of licences) are used in connection with the patent, leading to monetary benefits, the notification requirement is triggered.

Penalties

Under the new provisions, any person who intentionally fails to provide information, or provides false information, will be liable to a fine of up to 100,000 francs. If the user's actions were negligent, the user faces a fine of up to 40,000 francs. A judge may also order the publication of the judgment.

Future considerations

A number of key measures still need to be considered by the Federal Council and defined more closely at the Ordinance level, including:

- Further refinements to the scope of the due diligence requirement e.g. defining the minimum information that needs to be recorded, stored and transferred to subsequent users;
- Provision of clear enforcement mechanisms;
- Provisions regarding access to genetic resources in Switzerland; and
- Recognition of ex situ collections ("trusted collections" under the EU) and best practices.

Non Commercial Research

In 2010 the Swiss Academy of Sciences (**SCNAT**) published a model *Agreement on Access to Genetic Resources and Sharing of Benefits in Non-Commercial Research*.

The Agreement contains model contractual clauses based on mutually agreed terms. It essentially serves as an ABS toolkit for nations and covers the most relevant issues that arise in the relationship between providers and non-commercial researchers.

In the negotiations leading up the publication of the Agreement a number of key issues were identified by the SCNAT relating to non-commercial academic research, including:

- Researchers are concerned that an overly restrictive ABS system for non-commercial public research will be counterproductive. Unfamiliarity of researchers with administrative processes and lack of resources for contractual negotiation may lead to difficulties in access. This is turn will reduce the flow of benefits back to providers as most if not all genetic resources that reach the stage of commercialisation have some foundation in non-commercial academic research.
- A main challenge in implementing the ABS system is controlling the flow of resources throughout the value chain, especially in the user country. The risk for provider countries is that users who access resources on a non-commercial basis enter the research and development sector without necessary mutually agreed terms for future commercial development.
- Public funding is crucial for non-commercial researchers. Funding is largely contingent on the publication of academic findings and collaborating with peers. Scholarly standards for disclosure and exchange of material may collide with the need for providers to control the use of the genetic resources. This in turn puts research at stake.

- Some fields of research, for example, ecological studies show very low probability of deriving results (whether commercial or otherwise). In these cases less control over uses will be needed by provider countries. User compliance could instead be monitored by requesting periodic reports on the progress of the research.

The Agreement takes into account these issues by proposing options for different situations of access, models of research cooperation and specific aspects of academic research such as the need to publish results, exchange data and store samples.

Brazil

Earlier ABS legislation – the PM (now repealed)

Brazil is considered to be one of the most biologically diverse countries in the world, with a fast developing biotechnology industry. Despite this, the country's ABS measures have evolved at a slow pace. Currently, the Member States of Amapa and Acre are the sole regions to enact their own ABS laws.

A Provisional Measure regulating access to genetic resources was in place since 2001 (No.2.186-16/2001) (**PM**). Over the years, the Brazilian government has had difficulty implementing the measure due to its undefined scope and lack of clear terms. The PM has now been repealed pursuant to new legislation introduced in May 2015.

The Report outlines information regarding the previously implemented PM for background purposes.

Under the PM, the Genetic Heritage Management Council (**CGEN**) is designated as the national competent authority. The CGEN is tasked with implementing national policies and, in conjunction with a number of other accredited bodies, authorising access for users.

Access to genetic heritage (under the repealed PM)

Access to genetic heritage was defined as the obtaining of a sample on a component of genetic heritage for the purposes of scientific research, technological development or bio prospecting with a view to industrial or another type of application.

The CGEN further clarified that access is activity undertaken on genetic heritage that seeks to isolate, identify or use information of genetic origin or molecules and substances deriving from the metabolism of living things and extracts obtained from such organisms. Access is thus different from collection under the New Brazilian Biodiversity Law.

Commercial v non-commercial activities (under the repealed PM)

Commercial and non-commercial activities were regulated quite differently under the PM.

Where access is sought for non-commercial scientific research including the evaluation of the evolutionary species or taxonomical groups, studies on the relationship/interactions of living beings and chromosomal or DNA analysis, among others, users are exempt from the authorisation requirements. In this case, only permission from the land owner is required. Where the research or recording involves the use of indigenous knowledge, researchers were required to obtain the prior informed consent of the indigenous and/ or local communities, and if placed in the public domain, were required to acknowledge the source of the knowledge.

Where the access activities involve commercial use (i.e. bio prospecting and technological development), users were required to obtain the following prior to applying for access:

- Prior informed consent of the provider (titleholder, indigenous community, local community or otherwise); and

- Contractual agreement (known as a CURB) setting out the mutually agreed terms with the provider. The terms need to be consistent with the terms of the prior consent agreement in particular in regards to benefit sharing and access and transfer of technology.

- If the provider agreed, the benefit sharing contract could be drawn up and signed at a later date so long as it is prior to the development of any commercial product or patent application (Presidential Decree (6159-2007).

Applications for access and/or associated indigenous knowledge could only be made by Brazilian institutions with a legal personality. These may be public, private, commercial or academic. Overseas institutions must enter into a partnership with a Brazilian entity, which will be the lead partner and assume full legal responsibility.

All institutions were required to show (i) prior expertise in research and development in the field of biology (ii) technical expertise to undertake the proposed activities and (iii) adequate infrastructure for handling the genetic resources. A trustee institution was also required to be identify who will receive and store ex situ voucher specimens of the genetic resources accessed.

Key checkpoints and user compliance (under the repealed PM)

The PM provided for a number of checkpoints and supplementary legal measures to assist in user compliance. For instance, applicant institutions had to provide a legally binding declaration that if access is sought for scientific research only, all activities were restricted to this end. Where potential economic benefits are realised for a product the institution was required to undertake to inform the CGEN (or other body that granted access authorisation) in order to put into effect a CURB.

Patent applicants were also required to inform the patent office of the origin of the genetic material accessed and/or associated indigenous knowledge and must provide evidence of the authorisation issued by the CGEN or other accredited body. However, this requirement only applied to genetic resources accessed in Brazil.

Finally, all university or research institutions were required to have a Technological Innovation Centre is responsible for helping researchers comply with the ABS legislation regarding the technology transfer to industry and patent application issues.

Penalties

The PM provided for a wide range of sanctions to address non-compliance. Products developed without the necessary authorisations were liable to pay a minimum of twenty five percent of the gross sales or royalties if developed by a third party. Other sanctions included the confiscation of samples and products developed, a partial or total ban on activities, including the suspension or cancelation of patent, licensee or authorisation, additional civil sanctions where necessary and fines ranging from USD $100 to 25,000,000 depending upon the gravity of the offence and the infringing party.

New biodiversity legislation

Brazil signed the Nagoya Protocol in 2011.

In the years following, national ABS laws were drafted and submitted to Congress aimed at overcoming the loosely drafted provisions of the PM. Of great concern to the scientific community was the requirement to negotiate commercial benefit sharing terms, irrespective of the commercial viability of the substances they produced.

On 20 May 2015 Brazilian President Dilma Rousseff signed new biodiversity legislation (No. 13123/2015) (**New Brazilian Biodiversity Law**) that provides a simplified, less bureaucratic legal framework for biodiversity research, development and commercialisation.

The New Brazilian Biodiversity Law repeals the 2001 PM and represents a fundamental shift in the regulation of access to genetic resources for key industry players such as cosmetics, food and pharmaceutical companies.

Like its predecessor, the New Brazilian Biodiversity Law regulates access to 'genetic heritage'. This includes information pertaining to the genetic origin of plant, animal, microbial species or

otherwise, including substances derived from the metabolism of living things, but excludes the access and/or subsequent use of human genetic material.

The law is focused on providing due recognition to indigenous community providers and the intellectual property surrounding plant based medicines which has been built up through their traditional practices.

The main changes introduced in the new biodiversity law include:

- Proof of prior consent will only be required in cases of access to associated indigenous knowledge;
- The power of federal bureaucrats controlling the CGEN is significantly constrained by forcing them to share 40% of their management with nominated representatives from civil society including the business sector, academia, indigenous population, traditional communities and farmers;
- Researchers/scientists are no longer required to obtain a license/authorisation from CGEN prior to undertaking commercial activities. Rather, these stakeholders now only have to register an interest on an online database so that royalties can be worked out later if the substances yield commercial potential. Where research is on associated indigenous knowledge, proof of registration will be a precondition to publication;
- Only the manufacturer of the finished product or the producer of the reproductive material will be required to notify the CGEN and enter into a benefit sharing agreement, regardless of who accessed the resources previously. The BSA must be filed within 365 days from the date of notification. Where the finished product is produced outside of Brazil, the foreign producer, importer, linked sales representative or otherwise is jointly liable with the manufacturer to share any economic benefits derived;
- Small companies, individual micro entrepreneurs and traditional farmers who do not exceed the income threshold are exempt from the benefit sharing obligations. Finished products, process or reproductive material that are the subject of a licence or intellectual property right are similarly exempt;
- Creation of a national benefit sharing fund (**FNRB**) to regulate the sharing of economic benefits arising out of indigenous and traditional plant-based knowledge. Where the indigenous knowledge has an identifiable origin, companies manufacturing products based on these remedies will be required to transfer of 1% of their net income into this fund for redistribution to the traditional communities. Where the knowledge obtained has an unidentifiable origin, companies may sign sectoral agreements with the Union providing for a transfer of net annual income of up to 0.1%.

The New Brazilian Biodiversity Law represents a much broader and more flexible approach to regulation that any of the other international jurisdictions considered and as compared with the earlier PM).

Canada

Canada is yet to ratify the Nagoya Protocol and implement a national ABS legislative framework.

While a number of agreements, policy statements and strategies have been adopted over the years, the actions taken by the Canadian Government have been mostly political, unsupported by specific legislative measures.

In 2010 the Canadian Government released a draft policy statement titled *'Managing Genetic Resources in the 21st Century: Domestic Policy Guidance for Canada'*. This policy statement is not legally binding, merely serving as a guide to the implementation of ABS policies at the federal, provincial and territorial levels.

Existing policies/practices

A federal permitting system is currently in place for research and collections from national parks. For all other areas, scientists and the respective land owners contract directly in relation to the collection of specimens. Agreements also exist regulating the transfer of material between academic institutions, researchers and private business. Industry sectors have also adopted a fragmented approach to ABS regulation with policy development left to the institutions themselves.

The Canadian territories of Yukon, the Northwest Territories and Nunavat have made the most progress in terms of implementing ABS measures. Each territory has passed research licensing legislation that serves as a form of access system. Despite this, the laws are largely inconsistent with the provisions of the Nagoya Protocol as:

- There is no distinction made between commercial and scientific research for licensing purposes;
- The laws do not require the State's (or indigenous/local communities) prior informed consent to use the genetic resources. The application process merely requires written confirmation from a researchers that they have discussed their plans with the agencies/communities affected and that they will provide support; and
- Obligations for benefit-sharing are largely limited to the reporting and sharing of research results.

Current ABS policy developments

In February of 2014, the Government adopted a number of biodiversity goals and targets for 2020. The goals and targets are designed to complement the Canadian Biodiversity Strategy and Biodiversity Outcomes Framework. Some of the key targets include:

- *Target 12: By 2020 customary use by Aboriginal peoples of biological resources is maintained, compatible with their conservation and sustainable use;*
- *Target 13: By 2020, innovative mechanisms for fostering the conservation and sustainable use of biodiversity are developed and applied;*
- *Target 14. By 2020, the science base for biodiversity is enhanced and knowledge of biodiversity is better integrated and more accessible; and*
- *Target 15. By 2020, Aboriginal indigenous knowledge is respected, promoted and, where made available by Aboriginal peoples, regularly, meaningfully and effectively informing biodiversity conservation and management decision-making.*

While this policy statement is a step closer to providing for a sustainable biodiversity framework for Canada, much work still needs to be done at the legislative level to ratify the Protocol and implement its key provisions.

Commonwealth - Australia

The Commonwealth Regulations (as described in Appendix 2 to this Report) currently implement the regulatory framework for access and benefit sharing for Commonwealth areas (as described in the Commonwealth Regulations).

In May of 2014 the Federal Government released a model for implementation of the Nagoya Protocol. Submissions were received up until the end of May. The Model is largely based on the EU approach to implementation with a focus on certification, successful biodiscovery and the establishment of a workable and cost effective system of checkpoints to monitor access and use of genetic resources.

Only those genetic resources and/or associated indigenous knowledge that were accessed after the Protocol comes into effect in Australia will be subject to the new compliance measures.

The following key changes to the legislation have been proposed:

- **International Certificates of Compliance**: The Commonwealth proposes to recognise these certificates as evidence of lawful acquisition of genetic resources and associated indigenous knowledge. Options for the certificate of compliance are currently being considered including using existing collection permits.

- **Establishment of a checkpoint**: Recipients of Commonwealth funding will be required to report on and provide evidence of the legal provenance of the genetic resources accessed. Where indigenous knowledge has also been accessed, users will have to provide evidence of an agreement with the holders of the knowledge.

- **Development and facilitation of codes of conduct**: These codes of conduct will contain the finer detail in regards to implementation including reporting obligations as well as standards for, and the circumstances where, due diligence processes should be undertaken.

- **Agreement with indigenous knowledge holders**: An agreement must be entered into between users and the indigenous people providing the indigenous knowledge in accordance with an applicable code of Conduct e.g. a community protocol, the AIATSIS Guidelines for the Conduct of Research in Indigenous Studies or a sui generis code. The government would not be a party to any agreement made.

- **Accreditation of trusted institutions**: To achieve accreditation, institutions will be required to satisfy a due diligence and administrative standard. Accreditation will warrant to international partners that the genetic resources and/or associated indigenous knowledge were accessed lawfully.

- **Inclusion of offence provisions under the Commonwealth Act**: It will be an offence to illegally acquire genetic resources and/or associated indigenous knowledge where the use was found to be reckless or resources were obtained in contravention of provider measures available on the ABS Clearing House. Users will not offend the provisions in cases where due diligence has been carried out in accordance with an agreed code of conduct or that on the evidence available it was reasonable to believe that access was lawful.

- **Option for remedy**: Users are allowed to remedy their non-compliance by obtaining written permission from the provider country and establishing mutually agreed terms.

- **Audit Powers**: Audit powers will be conferred on the Commonwealth to monitor compliance, using a risk-based approach.

Further considerations of the Commonwealth

In consultation with the Commonwealth Government, a number of issues were raised regarding ABS implementation. Consultation surrounding these issues is still underway and the proposed solutions do not in any way represent the concluded views of the Government.

Permitting regime

A key issue raised in consultation was the complexity of the current permitting regime. It was noted that the current permitting requirements creates excess layers of bureaucracy and is ineffective in ensuring that users come back for a commercial permit or to obtain a benefit sharing agreement.

Indigenous knowledge

To comply with the Nagoya Protocol, the Commonwealth is considering providing users with a certificate of compliance which confirms that an agreement is in place and that prior informed consent has been obtained from the holders of the indigenous knowledge. To receive the certificate, it is suggested the user must first demonstrate compliance with the AIATSIS guidelines.

Accreditation of Trusted Institutions

Uniform standards for accreditation may be published by the Commonwealth. It has been suggested that existing certifications be used, in order to reduce governmental bureaucracy.

Western Australia

Initial Attempts

In 2011, initial steps were taken by the Government of Western Australia to implement ABS measures. Draft bio-prospecting legislation was approved by the State Cabinet in August of 2011 and completed by the Parliamentary Counsel's Office in 2012.

The approach at the time was based on the NT Act and borrowed components from the Queensland and Commonwealth instruments, each with their own environmental protection legislation and agency structures. Initial legislation focused on regulating each and every interaction with biological material on the basis that bio-prospecting may occur even if that was not the primary purpose of access and highly unlikely.

The resultant Western Australian draft legislation was complicated, disjointed and raised a number of issues for key stakeholders. Future amendments to the legislation would also be difficult, given that all aspects of bio-prospecting were included in the body of the legislation, rather than provided for in subordinate regulations.

The Commonwealth, in consultation with the Western Australian Government, recognised that successful bio discovery is often unintended or accidental and that only approximately 1 in 1000 investigations may produce a result in the short term. They noted that a number of unusual discovery paths or legally available specimens under the control of private operators would be difficult to capture if a highly regulated approach was taken.

Current Attempt

It is understood that the Western Australian Government intends to table new bio-prospecting legislation. The exact form and content of the bill and legislation is yet to be released for public comment.

The current attempt considers what outcomes the Nagoya Protocol is trying to achieve and will attempt to deliver this using the existing powers of the Department of Fisheries and Department of Parks and Wildlife access regimes.

Focus is to be given to the following key provisions under the Nagoya Protocol:

- **Access to the material was legal**. The Review understands that the WA Government will facilitate this process by providing certificates of provenance.
- **There was prior informed consent**. The Review understands that this may be part of the licence issued to collect genetic resources.
- **Any indigenous knowledge used is recognised and reward provided**. The Review understands that the legislation may contain facilitating processes such as those needed to work with indigenous communities (i.e. mechanisms and powers to set up trusts to hold funds on behalf of indigenous groups).
- **Fair and equitable sharing of benefits with the State**. The Review understands that the Government plans to enter into the benefit sharing agreement and will manage any derived benefits. The terms of any agreement will be similar to the Commonwealth agreements to avoid "contract shopping" by users.

The Government has noted that successful implementation will ultimately depend upon the range of tools available to support the legislation including general advice on certification process, managing expectations with respect to benefit sharing and indigenous engagement, Commonwealth notification processes and model benefit sharing agreements.

Education will also play major role in raising awareness of need to be compliant and grant programs are intended to be used as a necessary checkpoint.

Northern Territory

The current regulatory framework for the Northern Territory is set out in the NT Act (see Appendix 3 to this Report).

The Review been unable to obtain any information from the Northern Territory Government in relation to its plans regarding the implementation of the Nagoya Protocol and whether any amendments to the NT Act are required.

However, it is noted by the Review that the NT Act already includes a number of measures which would comply with the principles of the Nagoya Protocol. This includes the framework in the NT Act regarding prior informed consent in relation to indigenous knowledge and certificates of provenance which may be issued by the CEO in respect of samples.

Other States and Territories

To date, no other States or Territories have enacted ABS legislation in this field. However, all have permit systems for the collection of genetic resources, regardless of whether the application is for biodiscovery or not.

At most, broad policy statements have been issued by Victoria and Tasmania on access to biological resources. Both statements provide a strategic framework for bio-discovery in way that supports the NCA of 2002.

7.6 **Does the Act meet the requirements of the Nagoya Protocol?**

With the exception of some specific aspects, in broad terms the Act meets the many obligations of the Nagoya Protocol. It provides for legal certainty, clarity and transparency of domestic access and benefit sharing frameworks (as required by Article 6(3)(a) of the Nagoya Protocol).

See the summary table below including comments on the Nagoya Protocol (where the Articles are relevant to the Act), the Act and relevant Recommendations in this Report.

Article 3 - scope	• The Schedule to the Act provides a clear definition of Native Biological Material which is sourced from State Land and Queensland waters – see also Recommendations 29, 31, 32, 33 and 35. • The Nagoya Protocol applies to associated traditional knowledge – this is not currently covered by the Act but is recommended to be included – see in particular Recommendation 8. • The Nagoya Protocol applies to private land – this is not covered by the Act (which only applies to Native Biological Material taken from State land and Queensland waters) but it is recommended that guidelines be provided for access and benefit sharing with private landholders. • As noted in respect of Article 15 below, the Act does not currently regulate the use in its jurisdiction of resources (including associated traditional knowledge) obtained from other countries - see further comments below in connection with Article 15 and also Recommendation 39. • The Nagoya Protocol to the 'utilization of genetic resources' which includes 'research and development'. The Act does not currently extent to 'research' as it is limited to use for the purposes of Commercialisation. The expansion of the Act to

	cover 'research' is detailed in Recommendation 26.
Article 5 – fair and equitable benefit sharing	• Part 5 of the Act sets out the requirements for benefit sharing through the BSA framework. The Act also sets out an inclusive list of Benefits of Biodiscovery in its Schedule. • While the Act does not apply to private landowners – the Review has recommended that guidelines be provided to guide private landowners so they may comply with the Nagoya Protocol including with respect to benefit sharing and indigenous knowledge – see Recommendation 5. • The Act does not currently address the sharing of benefits arising from the utilisation of indigenous knowledge and resources – the review has made recommendations in this regard and also in relation to prior informed consent to access indigenous peoples' land – see Recommendation 8.
Article 6 – access to genetic resources	• Part 3 of the Act sets out the requirements for Collection Authorities which meet the requirements of prior informed consent. • Though the Act does not currently reflect the need to obtain approval of indigenous communities with respect to access to resources (access to indigenous peoples' land and indigenous knowledge) – the Review has considered this issue and made a recommendation in respect of it – see Recommendation 8. Land over which there is a recognition of exclusive possession will be governed by the NTA and is subject to the ILUA framework. • Article 6(3) of the Nagoya Protocol sets out certain requirements regarding access. In the main, the Act, as currently drafted, meets those requirements with the exception of: o Implementation of notification of the administrating procedures including regarding the ABS Clearing House regarding access – see Recommendation 43. o Criteria for obtaining prior informed consent or approval and involvement of indigenous communities for access – see in particular Recommendation 8.
Article 7 – access to traditional knowledge associated with genetic resources	• The involvement and engagement with indigenous communities is not reflected in the Act in its current form. The Review has sought to address this in its recommendations – see in particular Recommendation 8.
Article 8 – special considerations	• The Act seeks to promote the taking of *'minimal quantities of native biological resources*' (See section 1(a) of the Act). This is further supported by the permitting regime and the Compliance Code.
Article 9 – contribution of conservation and sustainable use	• As the definition of Benefits of Biodiscovery is an expansive definition it is open to the State to direct benefits from the use of Native Biological Material towards conservation and sustainable use of biodiversity.
Article 12 – traditional knowledge associated with genetic resources	• These aspects are not currently reflected in the Act. These issues have been considered by the Review – see in

	particular Recommendation 8.
Article 13 – national focal points and competent national authorities Article 14 – ABS Clearing House and Information Sharing	• These aspects are not covered in the current terms of the Act. These are matters which in respect of which administrative regimes will need to be established by the State - see Recommendation 39, 42 and 43.
Article 15 – compliance with domestic legislation or regulatory requirements on access and benefit-sharing Article 16 - compliance with domestic legislation or regulatory requirements on access and benefit-sharing for traditional knowledge associated with genetic resources	• The Act does not currently regulate the use in its jurisdiction of resources (including associated traditional knowledge) obtained from other countries – in particular that those resources have been accessed in accordance with prior informed consent and mutually agreed terms. Recommendation 38 looks at the State engaging with the Commonwealth to determine a consistent compliance approach. • The Article requires measures to be implemented to address non-compliance with these user terms – see Recommendation 39. The implementation of Recommendation 39 would see the adoption of a checkpoint system which would apply to resources not falling within the scope of the Act (for example resources which are collected in Australia (outside the scope of the Act) or overseas.
Article 17 – monitoring the utilization of genetic resources	• The framework of the Act in granting Collection Authorities and BSA acts as a checkpoint for compliance with prior informed consent and mutually agreed terms (Article 17(1)). • The Review has recommended checkpoints be included with respect to access on indigenous people's land and with respect to indigenous knowledge – see in particular Recommendation 8. • Further checkpoints have been recommended as part of this Report – see Recommendations 38 and 39. • In relation to the sharing of information and cost effective communication tools and systems – see Recommendations 42, 43 and 44.
Article 18 – compliance with mutually agreed terms Article 19 – model contractual clauses	• The current Model BSA developed by the State meets the requirements of this Article as it includes an appropriate dispute resolution clause. • Recommendation 8 in this Report supports the use of standard terms to be adopted with respect to indigenous communities (for example the AIATSIS Guidelines.
Article 20 – codes of conduct, guidelines and best practices and/or standards	• The Act is currently supported by the Code of Ethics and Compliance Code. The Review has also made recommendations regarding additional information to be included in the codes – see for example Recommendations 3, 5, 17, 19, 22 and 34.
Article 21 – awareness-raising	• The Review has noted in this Report the importance of education in relation to the framework – see for example

Article 22 - capacity	Recommendation 17.

The following Articles of the Nagoya Protocol may be implemented by legislative, administrative or policy measures as appropriate:

- Article 5 – fair and equitable benefit sharing;
- Article 6 – access to genetic resources;
- Article 7 – access to traditional knowledge associated with genetic resources;
- Article 15 – compliance with domestic legislation or regulatory requirements on access and benefit-sharing; and
- Article 16 - compliance with domestic legislation or regulatory requirements on access and benefit-sharing for traditional knowledge associated with genetic resources.

As noted above, the Review has made numerous recommendations as to proposed amendments to the Act and its regulatory framework in order to comply with the Nagoya Protocol.

To the extent to which the Nagoya Protocol impacts on the Act - that is on the collection and use of Native Biological Material from State land and Queensland waters, the Review recommends implementation of Nagoya linked Recommendations (as noted in the table above) be implemented by legislation.

This approach:

- Is consistent with the approach taken in numerous jurisdictions in relation to the implementation of the Nagoya Protocol requirements;
- Facilitates enforceability;
- Encourages a stable regulatory environment to encourage investment, industry development and international engagement; and
- Consistency of application of the framework.

In particular, at Recommendation 42, the Review has recommended that consideration be given to (by means of legislation):

- The implementation of a Biodiscovery Register the uploading of information to which is compulsory for those persons / entities falling within the scope of the Act and voluntary otherwise; and
- The power to issue International Certificates of Compliance to persons or entities meeting the relevant requirements (based on information uploaded to the Biodiscovery Register) whether they fall within the scope of the Act or not.

Guidelines for persons or entities accessing material from private land and associated indigenous knowledge may be addressed in the administrative Updated Code (as per Recommendation 5) for the purpose of encouraging compliance with the Nagoya Protocol.

7.7 **Australia's Biodiversity Conservation Strategy (ABCS)**

The ABCS is a guiding framework for conserving Australia's biodiversity. The first 5 years of the ABCS is currently under review (with public consultation having closed on 11 September 2015) – the Review has not had the benefit of considering the outcomes of that review for the purposes of this Report.

The ABCS sets out the following priorities for action:

1. *Engaging all Australians* - mainstreaming biodiversity, increasing indigenous engagement and enhancing strategic investments and partnerships;

2. *Building ecosystem resilience in a changing climate* – protecting diversity, maintaining and re-establishing eco-system functions and reducing threats to biodiversity; and

3. *Getting measurable results* – improving and sharing knowledge, delivering conservation initiatives efficiently and implementing robust national monitoring, reporting and evaluation.

As noted in this Report, the Review has made recommendations regarding amendments to the Act in relation to indigenous knowledge and access to indigenous people's land.

Further, the Review notes that its purposes including the promotion of conservation and sustainable use of native biological resources (section 3(1) of the Act) is consistent with priority for action 2 of the ABCS.

The establishment of a Biodiscovery Register (see Section 11 of this Report) also reflects priority for action of reporting and evaluation and sharing knowledge.

The Review did not receive any submissions with respect to the ABCS.

In view of the recommendations in this Report and the Act as at the date of this Report, the Review has determined no amendments are necessary as a result of or for the purposes of the ABCS.

7.8 Native title law

In late 2012 the *Native Title Amendment Bill 2012* (Cth) was introduced into Federal Parliament. The bill proposed a number of amendments to the *Native Title Act 1993* (Cth) (**NTA**), including the streamlining of processes for Indigenous Land Use Agreements (**ILUAs**). While the proposed amendments do not appear to be controversial, the Bill ceased to be considered upon the prologuing of parliament and the election of the new Federal Government.

On 4 March 2014 Greens Senator Siewart introduced a revised bill titled *Native Title Amendment (Reform) Bill 2014* (Cth). The Bill is currently before the Senate. The Review has considered the proposed amendments and concludes that they do not impact the Act or the regulatory regime under it.

In 2013 and 2014 the Australian Law Reform Commission (**ALRC**) conducted an Inquiry into Commonwealth native title laws and legal frameworks. The Final Report was tabled in Parliament on 4 June 2015. In the Report, ALRC proposed a number of amendments to the NTA that would lower the threshold for proving native title rights and expand the scope of native title rights and interests capable of being recognised. Amendments were proposed relating to the connection requirements, scope of native title rights and interests, joinder and authorisation including:

- Clarifying that traditional laws and customs may adapt, evolve or develop over time;

- Confirming that it is not necessary to establish continuity of observance of laws and customs over time or by or generations;

- Removal of the word "traditional" from the definition of "native title"; and

- Expansion of native title rights to include rights in relation to "any purpose", which may include hunting, gathering, fishing, commercial activities and trade.

It is yet to be known whether the Commonwealth Government will implement the suggested reforms. The introduction of "commercial activities" and "trade" is significant particularly where the claim area contains valuable natural resources.

The Review also considered the *Cape York Peninsula Heritage Act 2007* (Qld) and the *Aboriginal Land Act 1991* (Qld). The *Aboriginal Land Act 1991* (Qld) was amended in 2011,

however, the amendments do not impact the operation of administration of the Act in any relevant way.

7.9 Indigenous Land Use Agreements

What is an ILUA?

An ILUA is an agreement (which among other things) enables a developer and the native title group for the relevant area to address future dealings affecting native title and set appropriate standards for those dealings.

There are three types of ILUAs regulated under the NTA (1) body corporate ILUA (2) area agreement ILUA and (3) alternative procedure ILUA. The vast majority of currently registered ILUAs are area agreements. An ILUA must cover one or more of the prescribed matters set out in the NTA (including, but not limited to the doing of future acts) and any consideration given and conditions imposed must be lawful. Aside from this, parties are largely free to agree on the content of the ILUA.

ILUAs have an advantage over reliance on other provisions of the NTA as they can be drafted to encompass the whole of a large and diverse project that may otherwise require separate consents to many interests or other statutory requirements relating to environmental or cultural heritage protection.

When may an ILUA be used?

Commonly, ILUAs have been used as part of settlement packages in relation to native title claims, operating in conjunction with consent determinations. ILUAs are also negotiated as 'stand-alone' agreements (independently and irrespective of whether there is a determination of native title).

On registration of an ILUA, an ILUA binds not only the parties, but also all persons who hold native title in relation to the ILUA area. Registration also confirms that the agreement has effect as if it were a contract, whether or not the usual indicia of contract are satisfied.

When must an ILUA be used?

The ILUA provisions are found in Part 2, Division 3, Subdivision B to Subdivision E of the NTA.

Section 24AA(3) of the NTA provides that a future act done pursuant to a consent in an ILUA will be valid if the details of the ILUA have been registered. An ILUA may also validate a future act that has already been invalidly done (other than an immediate period act).

Pursuant to the NTA, a registered ILUA is required if the parties intend to:

- Bind all native title holders for the agreement area;
- Contract out of the other future act provisions, including the right to negotiate provisions;
- Finalise compensation for the doing of future acts covered by the agreement;
- Give the agreement contractual effect if it does not otherwise have that effect;
- Validate future acts that have been done invalidly already; or
- Change the effect of a validation of an intermediate period act.

It is registration of the agreement by the Native Title Register that brings about these effects, not the making of an agreement.

ILUAs and Prior Informed Consent

See Recommendation 8 regarding ILUAs and the Act.

7.10 Interaction of the NTA with the Act

One of the central aims of the Act is to facilitate access by Biodiscovery Entities to minimal quantities of Native Biological Material on or in State land or Queensland waters for Biodiscovery.

As defined in the Act, 'State land' excludes (amongst others) *'land subject to a native title determination of exclusive possession*'. The Review notes that there is some current discussion as to exclusive native title as opposed to exclusive possession.

However, the Review did not receive any submissions requesting amendments to the definition of State land (in the context of native title) and concludes that the existing definition remains valid and appropriate for the Act. The Review does not propose an amendment to the definition of State Land to the extent it relates to native title.

Any land which is not the subject of a determination of exclusive possession (e.g. claim only or the subject of a non-exclusive determination) would still fall within the scope of the Act.

Recommendation 6:

The Review does not recommend any amendment to the definition of State Land to the extent it relates to native title.

7.11 Indigenous knowledge and Intellectual Property Protection

Current position under the Act and Code of Ethics

Other than via the Code of Ethics, the regulatory framework of the Act does not incorporate any protection for indigenous knowledge.

The Code of Ethics provides the following principles at paragraph 10:

> *We recognise that there may be culturally significant aspects of the knowledge of Aboriginal and Torres Strait Islander people, that we will treat in a sensitive and respectful manner if used in the course of biotechnology.*
>
> *Where in the course of biodiscovery we obtain and use indigenous knowledge from indigenous persons, we will negotiate reasonable benefit sharing arrangements with these persons or communities.*

Only parties to BSA's are required to comply with the Code of Ethics. This is a contractual right between the State and the Biodiscovery Entity which are parties to the relevant BSA.

The Review notes that in attaching the obligation to comply with the Code of Ethics to the BSA there is a risk that Biodiscovery Entities who do not enter a BSA as a required by the Act or are not required to enter a BSA will not be required to comply with the Code of Ethics.

The Review considers that recognition of indigenous knowledge and the rights of indigenous owners of that knowledge should form part of the regulatory framework of the Act (at the permitting and use level) rather than merely being enforceable as a result of the contractual arrangements of the BSA.

See below for Recommendation 8 of the Review.

Current international protections

At present, there is no accepted international definition or guidelines relating to the intellectual property protection of indigenous knowledge. While the Nagoya Protocol represents a significant step forward in regulating access to genetic resources, it does not go so far as to link failure to comply with access and benefit sharing obligations with intellectual property validity. Article 8(j) of the CBD requires the equitable sharing of benefits deriving from the use

of indigenous knowledge. However it does not place an obligation on the State to protect indigenous knowledge in terms of intellectual property.

The use of intellectual property to protect indigenous knowledge has been pushed in the last decade primarily by the World Intellectual Property Organization (**WIPO**) and the United Nations. The most significant instruments in this regard to which Australia is a signatory are the United Nations Declaration on the Rights of Indigenous Peoples (**UNDRIP**) and the Agreement on Trade Related Aspects of IP (**TRIPS**).

UNDRIP's Article 31.1 right of indigenous people to 'maintain, control, develop and protect their cultural heritage, indigenous knowledge and cultural expressions' and the TRIPS requirement that Australia allow patenting of 'all technologies' in order to meet the global standard of intellectual property causes some obvious tension.

In practice, patents are only used limited circumstances by indigenous holders. This is due in part to the high cost of filing a patent and the difficulties in meeting the "invention" or "novelty" threshold.

International Developments

Negotiations are currently underway by the WIPO Intergovernmental Committee to develop a model text for a multi-lateral treaty for the protection of genetic resources, indigenous knowledge and traditional cultural expressions. WIPO has also released a Traditional Knowledge Documentation Toolkit (Consultation Draft, November 1, 2012). The Toolkit is designed to help conceptualize and plan a traditional knowledge documentation process and understand its key intellectual property dimensions, as a means to assist in safeguarding the interests and protecting the rights of traditional knowledge holders, in particular, indigenous peoples and local communities. These endeavours by WIPO reflect the continued international momentum towards requiring international clarity in relation to this issue.

South Africa is one of the first developing nations to adopt sui generis legislation for the protection of indigenous knowledge. *The Protection, Promotion, Development and Management Knowledge Systems Bill 2014* was introduced into parliament in March 2015. A final draft of the Bill is yet to be submitted to the Minister of Science and Technology. Despite this, a number of concerns were raised during the public consultation period, including:

- The impact of the Bill on existing intellectual property laws, particularly their implementation and enforcement; and
- Limitations on who are considered 'beneficiaries' under the law - the Bill assumes that a community can identify those to whom the protection of indigenous knowledge is entrusted, that indigenous communities are homogenous and distinct persons can be identified.

The Review notes that in general terms (not limited to the context of this Act), development of international laws in relation to intellectual property protection of indigenous knowledge should be monitored in particular in the context of the IP Australia public consultation described below.

Current national protections

Indigenous knowledge is not currently regulated or protected under existing national intellectual property law (both statute and common law).

The Review notes that Australia has not passed legislation providing intellectual property protection for indigenous knowledge since the 2009 Review.

The Review received a submission noting that intellectual property, copyright and patent laws fail to adequately represent the ways in which indigenous knowledge is "owned", recorded and/or shared and is deficient in protecting the confidentiality of information shared. It was further argued that the present regime fails to set out how research will proceed, who will own the intellectual property of the research or how the results can be patented when indigenous knowledge is involved.

Given the lack of existing legal protections, indigenous people in Australia have generally relied on a system of administrative policies, community-based protocols and the goodwill of others to ensure that their information will be protected from unauthorised use.

The Australian Institute of Aboriginal and Torres Strait Islander Studies (**AIATSIS**) arguably provides the pre-eminent model of ethical standards for the access and use of indigenous knowledge. *The Guidelines for Ethical Research in Australian Indigenous Studies* (2012) comprise 14 principles which guide research projects undertaken covering broad items such as co-ownership of intellectual property, sharing of benefits, respect and negotiation, consultation, agreement and mutual understanding.

Research entities are guided by the *Australian Code for the Responsible Conduct of Research* and, in respect of publically funded research, the *National Principles of Intellectual Property Management for Publicly Funded Research.* Alternatively a number of research agencies also develop their own guidelines.

These codes and principles have regard for indigenous people and indigenous knowledge. However, there is a lack of a coordinated national approach, which is legally binding on institutions and those who access and use indigenous knowledge.

IP Australia public consultation

In 2012, IP Australia conducted a public consultation into the protection of indigenous knowledge. The consultation period is still currently open, with IP Australia having received 8 submissions in total to date.

The key issues raised in the submissions were:

- (**Gaps in existing domestic legal frameworks**) The legal concept of "confidential information and "confidentiality" is fundamentally incompatible with the nature of indigenous knowledge in that:

    i. Indigenous arts and culture are oral based, which does not meet the requirements of the *Copyright Act 1968* (Cth);

    ii. Indigenous cultural and intellectual property is fundamentally different from traditional legal constructs of intellectual property in that it is a communal, intergenerational right that evolves over time. An outcome of this is that individual members may commercially benefit from the exploitation of their knowledge to the exclusion of other members in the community;

    iii. Sunset clauses associated with copyright means that sensitive knowledge and cultural expressions could reside in the public domain against the wishes of indigenous holders; and

    iv. Customary laws regarding the sacredness and secrecy of information are inconsistent with current patent disclosure requirements.

- (**Government funding and contractual arrangements**) The nature of government funding and contractual arrangements leaves indigenous people with limited scope to amend funding contracts that significantly impair their rights to indigenous knowledge and commercial exploitation of that knowledge.

- (**National Indigenous Cultural Authority**) The Indigenous Advisory Council endorsed the idea of establishing a National Indigenous Cultural Authority, a body which could amongst other functions:

    i. Support the development of policy, protocols and agreement templates;

    ii. Provide a registration and certification mechanism to ensure that indigenous intellectual property have been appropriately acquired and are being used in line with any agreements that have been made with the Indigenous holders; and

    iii. Offer dispute resolution through mediation.

- (**Overarching policy framework**) The Indigenous Higher Education Advisory Council recommended that an over-arching ethical policy framework is developed with guidelines covering aspects such as consent, attribution, benefit-sharing and integrity issues.

- (**Sui generis legislation**) Adoption of sui generis legislation is submitted to be the only way in which adequate protection of indigenous knowledge can be achieved.

At the time the Review was completed the IP Australia consultation remained open. The Review therefore did not have the benefit of considering the outcomes of the IP Australia public consultation on this critical issue.

Commonwealth power to legislate

While the outcomes of the IP Australia public consultation should be closely monitored by the Queensland Government, the Review notes that protection of indigenous knowledge and indigenous cultural heritage, from an intellectual property perspective, falls within the Commonwealth head of powers.

Section 51(xviii) of the Commonwealth Constitution grants the Commonwealth the right to make laws in respect of 'copyright, patents of inventions and designs, and trade marks'. This power has been extended to cover intellectual property regimes not listed in the Constitution for example plant breeder's rights (*Grain Pool of Western Australia v Commonwealth* (2000) 202 CLR 479).

Establishing sui generis legislation in relation to the protection of intellectual property rights in indigenous knowledge and indigenous cultural heritage is beyond the scope of the Act. Such legislation should stand on its own and merely interact with other relevant regulatory schemes such as this Act and the NTA.

The Review does not consider the Queensland Government has the necessary power to legislate in relation to intellectual property protection of indigenous knowledge and indigenous cultural heritage. To do so is likely to create ambiguity and confusion.

Submissions to the Review – indigenous knowledge

The Review received the following recommendations for greater enhancement of intellectual property protection for indigenous knowledge:

- Establishment of an indigenous knowledge database as a protective measure to ensure others cannot, without consent, obtain patents based on custodial knowledge (this could be incorporated into the Cultural Heritage database);

- Development of biodiscovery community protocols to guide prior informed consent and facilitate involvement of traditional owners with biodiscovery entities; and

- Reform of related legislation such as the *Aboriginal Cultural Heritage Act 2003* (Qld), *Cape York Peninsula Heritage Act 2007* (Qld) and *Aboriginal Land Act 1991* (Qld) to include provisions for protection of "bio-cultural" rights of indigenous peoples.

Further, the Review received a submission proposing that a framework for prior informed consent, benefit sharing and permitting system be adopted similar to that of the Northern Territory, NT Act. Specifically, it was submitted that the Act should incorporate the following provisions in relation to the content of a BSA:

- A statement regarding any use of indigenous people's knowledge, including details of the source of knowledge, such as, for example, whether the knowledge was obtained from the resource access provider or from other indigenous persons;

- A statement regarding the benefits to be provided or any agreed commitments given in return for the use of the indigenous people's knowledge;

- The details of any proposals of the applicant to benefit biodiscovery conservation in the area if access is granted; and

- Details of the benefits that the resource access provider will receive in return for the taking of resources.

It was further noted that a substantive rights system approach should be adopted that could include:

- Indigenous spatial identities (clan and clan family cultural mapping);
- Customary governance and decision making underpinning genetic resources;
- Land use and occupancy mapping of genetic resources at relevant customary landscape scales regarding 'relationships with a resource' and 'control over access to a resource';
- Documentation of genetic resource data within an indigenous intellectual property framework; and
- Customary permit system established as part of the Act's permit approach through a 'competent authority' similar to the NT Act.

By contrast, the Review notes that a number of consulted stakeholders expressed practical concerns in extending the Act this way. It was raised in a face to face meeting that the consultation process (where conducted) with traditional land owners was long, uncertain and often quite difficult. A broad range of people need to be consulted, with the potential for other groups or individuals to claim the same knowledge.

It was submitted that that the inclusion of indigenous knowledge (prior informed consent) to the Act would arguably add a degree of complexity to the existing transaction model. This in turn may increase supply chain costs and provide a disincentive for international investment.

The Review has considered the above submissions in relation to indigenous knowledge and its impact on the policy objectives and regulatory framework of the Act. The Review has also considered this issue in the context of the Nagoya Protocol and in particular Articles 7 and 12.

As noted above the Review:

- Does not consider the scope of this Review extends to making recommendations relating to the intellectual property protection of indigenous knowledge as this falls within the Commonwealth powers; and
- Only extends to considering the impact of indigenous knowledge in the context of Biodiscovery under the regulatory framework under the Act.

Accordingly, while the Review supports the introduction of sue generis legislation in relation to indigenous knowledge by the Commonwealth, the Review does not recommend the introduction of any such legislation by the Queensland Government.

The Review is also supportive of submissions made by interested stakeholders in relation to the recognition of indigenous knowledge and benefit sharing with the indigenous owners of that knowledge in the context of the Act.

It notes the concerns of stakeholders with respect to the complexity of engaging in consultation regarding indigenous knowledge. However, the Review does not consider this burden outweighs the need to recognise indigenous knowledge of indigenous people and their need to give prior informed consent to access to indigenous areas and use of their knowledge.

Further, the recognition of indigenous knowledge, prior informed consent and benefit sharing on mutually agreed terms is a central tenet of the Nagoya Protocol to which the State must have regard in any legislative reform.

In making its recommendations regarding indigenous knowledge the Review has also considered the current position under other existing Australian legislation (Commonwealth and Northern Territory).

Commonwealth Regulations and NT Act – indigenous knowledge

As noted, the Review has taken into account the critical inclusion of indigenous knowledge in both the NT Act and the Commonwealth Regulations.

A comparison between the Act and the NT Act is set out in Appendix 3 to this Report. In summary, the Northern Territory's position in the NT Act regarding indigenous knowledge is as follows:

- A party entering into a benefit sharing agreement must make a statement regarding any use of the 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 (section 29(1)(h));
- A statement regarding benefits to be provided or any agreed commitments given in return for the use of the indigenous people's knowledge (section 29(1)(i));
- 'indigenous knowledge' is limited to knowledge obtained from an indigenous person and not obtained from scientific or other public documents, or otherwise from the public domain (section 29(2)); and
- A condition of a benefit sharing agreement is that the CEO must be satisfied that the resource access provider which may include land councils, aboriginal communities or native title body corporates have given prior informed consent to the terms of a benefit-sharing agreement (sections 6 and 28).

The NT Act does not specifically address indigenous knowledge at the permitting level but the NT Act notes at section 11 that a permit to take indigenous flora or fauna is issued by the Agency responsible for administering the *Territory Parks and Wildlife Conservation Act*.

Similarly, the Commonwealth Regulations specifically recognises indigenous knowledge (at both the access and the benefit sharing level):

- Benefit sharing agreements must include:
    - A statement regarding use of indigenous knowledge including the source e.g. scientific or public documents, the access provider or another group of indigenous persons (Regulation 8A.08(h));
    - A statement regarding benefits to be provided in return for use of the indigenous knowledge (Regulation 8A.08(i)); and
    - Copy of an agreement or terms of any oral agreement regarding the use of the indigenous knowledge (Regulation 8A.08(j)).
- If biological resources are in an area which is indigenous people's land, access providers (including land owners or native title holders) must give informed consent regarding access to the biological resources (Regulation 8A.10 – se also Regulation 17.03A).
- The Minister is required to determine whether the informed consent for access has been given – considering adequacy of knowledge to negotiate, adequacy of time, whether a land council or representative body should have been consulted. The Minister may be satisfied if an ILUA meeting the requirements of regulation 8A.10 is met.

In its response regarding the implementation of the Nagoya Protocol the Commonwealth also notes the need to require an agreement between users of indigenous knowledge and indigenous providers of that knowledge – in accordance with community protocols, the AIATSIS Guidelines or another agreed code.

Consideration by the Review

The Review considers that the approaches adopted by the Commonwealth and Northern Territory goes some way to recognising the importance of protecting indigenous knowledge, the rights of indigenous people in relation to that knowledge and also access to indigenous

peoples' land. However, the Review has the concerns relating to those regulatory frameworks including:

- The fact that more than one indigenous community may claim ownership of the relevant indigenous knowledge;
- The fact the CEO (under the NT Act) and Minister (under the Commonwealth Regulations) must be satisfied with the arrangements places a significant administrative obligation to be comfortable with the arrangements;
- The difficulty in determining (under the NT Act) whether the indigenous knowledge is in the public domain (in order to assess whether it is in fact indigenous knowledge');
- The requirement that the indigenous knowledge be obtained from an indigenous person (under the NT Act); and
- The need for informed consent (under the Commonwealth Regulations) appears to only be in relation to access not use of indigenous knowledge.

The Review is also aware of the need to meet:

- Nagoya Protocol obligations in recognising and establishing a checkpoint of compliance regarding indigenous knowledge and informed consent; and
- Article 15, paragraph 5 of the CBD - access to genetic resources is subject to prior informed consent given by the contracting party providing such resources, unless otherwise determined by that party.

The Review recognises the importance of adopting a framework in the Act to recognise indigenous knowledge and rights of access granted by indigenous people. This is consistent with the Nagoya Protocol and the Priority for Action 1 (indigenous engagement) in the ABCS.

After considering the submissions to the Review, the Commonwealth Regulations and NT Act, international responses and the international landscape including the impact of the Nagoya Protocol, the Review recommends that consideration be given to adopting a framework similar to that in the Commonwealth Regulations in the Act with the following:

- The giving of prior informed consent must apply in relation to:
    - accessing Native Biological Material on land which is indigenous people's land (land over which a native title claim exists but in respect of which exclusive possession has not been recognised); and
    - using the indigenous knowledge (wherever obtained).
- If the State has been involved in compliance and has information as to whether there has been compliance then it must act appropriately in informing itself or requiring compliance before being satisfied as to informed consent. Otherwise, the Minister is not required to satisfy him or herself in relation to whether informed consent has been appropriately given, rather confirmation must be provided (by the Biodiscovery Entity) by Statutory Declaration or equivalent that prior informed consent has been given.

It should be noted that if the nature of the use of the indigenous knowledge fundamentally changes or there is no use of indigenous knowledge or such indigenous knowledge is already freely available to the public then consideration should be given as to whether updated prior informed consent is required.

Compliance with Nagoya Protocol – indigenous knowledge

The Review's recommendation is consistent with the Nagoya Protocol including:

- *Article 7* – requiring measures to be adopted with the aim of ensuring traditional knowledge associated with genetic resources that is held by indigenous communication is

accessed with prior informed consent or approval in accordance with mutually agreed terms; and

- *Article 12* – establishing mechanisms to inform potential users of traditional knowledge associated with genetic resources about their obligations arising from the utilisation of such knowledge.

The approach proposed by the Review is also consistent with the approach internationally as evidenced in the countries considered in the context of this Review (see Section 7.5 of this Report).

The recognition of indigenous rights is reflective of the Code of Ethics and paragraph 4.9 of the Compliance Code regarding the protection of indigenous cultural heritage resources.

The Review also notes that the recommendation is consistent with the principle of the NCA, that the need to ensure the use of traditional knowledge is undertaken with the co-operation and approval of the holders of that knowledge on mutually agreed terms.

Recommendation 7:

The Review recommends the State monitor the progress internationally and more importantly at a Commonwealth level regarding the protection of traditional and indigenous knowledge in the context of existing intellectual property regulation or by way of a sui generis system and the extent to which, once this occurs, consequential amendments to the Act are required.

Recommendation 8:

The Review recommends:

(a) the State give consideration to amending the Act to recognise the importance and rights of indigenous people including in respect of their indigenous knowledge (wherever obtained) and access to Native Biological Material in indigenous people's land; and

(b) except as set out below, the State adopt in general terms the approach of the Commonwealth Regulations regarding use of indigenous knowledge and access to Native Biological Material from indigenous people's land (including the requirement of prior informed consent on mutually agreed terms).

Adopting this approach may include the Act being amended as follows:

(a) recognising the importance and rights of indigenous people including in respect of their indigenous knowledge and access to Native Biological Material on indigenous people's land in the objectives of the Act;

(b) including a definition of 'indigenous people';

(c) including a definition of indigenous people's land (for example, State land over which indigenous people have a claim but exclusive possession under the NTA has not been recognised);

(d) incorporating a requirement for the giving of prior informed consent in relation to accessing Native Biological Material on land which is indigenous people's land and any use of indigenous knowledge;

(e) the requirement for the giving of prior informed consent will be satisfied if a Statutory Declaration (or equivalent) confirming prior informed consent is provided in accordance with some accepted guidelines (for example the AIATSIS Guidelines).

Entry into an ILUA under the NTA authorising the proposed action and providing the consent may be provided as an alternative to the statutory declaration;

(f) the Department ought not be required to make its own assessment of whether the prior informed consent was satisfactory; and

(g) incorporating a requirement that benefit sharing agreements include: a statement regarding use of indigenous knowledge including the source e.g. scientific or public documents or another group of indigenous persons and a statement regarding benefits to be provided in return for use of the indigenous knowledge.

Implementation may also involve including direction to relevant guidelines and government portals, provision of contact details of land councils or individual traditional owners (to facilitate engagement).

7.12 Intellectual property Law

The Review notes that there have been no significant changes in relation to the regulation of biological material under intellectual property law.

Amendments to the Act were considered in 2010 with the introduction of the *Patent Amendment (Human Genes and Biological Materials) Bill 2010 [No.2]* into Federal Parliament. The Bill proposed to further exclude biological materials (including their components and derivatives) from the application of the Act. The Bill was subsequently discontinued.

In July 2015, the High Court of Australia heard an appeal (*D'Arcy v Myriad Genetics*) from the Full Federal Court considering the patentability of isolated genetic material (the Full Federal Court having ruled that isolating nucleic acid was patentable under section 18(1) of the *Patents Act 1990* (Cth).

On 7 October 2015, the High Court handed down its decision allowing the appeal ruling that isolated genetic material is not patentable under the *Patents Act 1990* (Cth). While a significant decision for intellectual property law, this decision (in the absence of any Commonwealth legislative response) does not have any impact on the Act.

Recommendation 9:

The Review does not recommend any changes to the Act as a result of intellectual property law.

7.13 Gene Technology in Queensland

The *Gene Technology Act 2001* (Qld) (**Gene Technology Act**) commenced on 1 November 2001 and is part of the national scheme established by the States, Territories and Commonwealth legislation to protect the health and safety of people and to protect the environment from risks associated with gene technology.

The Gene Technology Act was most recently reviewed in 2013, following a review of the Commonwealth legislation. The principal findings arising from this review included (amongst others):

- (**Operation of the Act**) The Gene Technology Act was seen as operating as an effective and efficient component of the nationally consistent gene technology regime.
- (**Lock step**) There is overall strong support amongst researchers and industry for Queensland to adopt a "lock step" approach similar to that adopted by New South Wales and the Northern Territory which automatically and immediately adopt any changed gene technology regulation by the Commonwealth. However, the review recommended that this

should only proceed if there are legislated provisions accompanying the change to lock-step which provide adequate safeguards for Queensland.

- (**Definitions**) Review of the definition of "dealings" in the Commonwealth legislation was considered timely in order to clarify the scope of the regulatory regime.

The Government provided its response to the review in April 2014, largely agreeing with all proposed recommendations. It should be noted that proposed changes to the Queensland gene technology legislation will require consideration by Parliament.

This Review has considered the proposed changes to the Gene Technology Act (in line with the Commonwealth changes) and concludes that they do not impact the Act or the administrative and regulatory regime under it. For this reason, no consequential amendments to the Act are required.

Recommendation 10:

The Review does not recommend any changes to the Act as a result of gene technology legislation (with the exception of the proposed amendment to the definition of Native Biological Material – see Recommendation 33).

7.14 Ownership of genetic resources

The issue of ownership of genetic resources has significant relevance for determining whether the Act should be broadened to regulate biodiscovery activities conducted on private land.

At present, private land owners in Queensland engage resource or biodiscovery companies privately. The State is neither a party nor a beneficiary of any of the benefits flowing from these contractual arrangements. This approach is consistent with the common law principles of ownership of biological resources on private land. Please also see commentary in Section 7.4.

Submissions were received proposing an expansion of the Act (and its benefit sharing obligations) to private land.

The Northern Territory has expanded the scope of its biodiscovery law in this way. Section 6 of the NT Act defines the owner of the fee simple (including where the land is subject to a lesser interest such as a lease or licence) as a 'resource access provider' – details of benefit sharing agreements with these private landowners must be retained in a register maintained by the CEO.

International law (Andean Community)

Many international countries have adopted progressive legislation in this field, expanding sovereign ownership to all genetic resources irrespective of the source or location.

Decision 391 establishes that genetic resources and their derivatives found in the Andean Community (Columbia, Ecuador and Peru) are considered goods or patrimony of the State depending on the country's national legislation. This applies to resources found in private, public and indigenous lands and in situ and ex situ collections.

Similarly in Costa Rica, their Law of Biodiversity states that genetic and biochemical resources are considered to be in the public domain, independent of any private ownership of the land where they are located.

Having examined the position in Queensland, the Review does not consider the determination of the ownership of resources found on private land to be so clear.

Property Ownership (Australia)

In considering whether the Act should be extended to cover private land, the Review has considered the nature of property rights attaching to flora and fauna sourced from private land.

So far as landholding is concerned, in Australia land is held by way of grant from the Crown. The grant may be a freehold estate, a Crown lease or some lesser interest or right in the land. Freehold land is held by grant from the Crown. What the landholder is said to hold is an interest in the land for a particular period of time. This interest is described as a landholder's 'estate' in land. There are two freehold estates in Queensland, the fee simple and the life estate and one non-freehold estate (the leasehold estate).

The fee simple estate gives to its owner rights akin to an absolute owner. At common law, the owner in fee simple of the land surface owns all of the subsoil, including minerals, down to the centre of the earth in addition to the airspace above: *Wade v NSW Rutile Mining Co Pty Ltd (1969) 121 CLR 177.*

The owner also owns all natural things (including biological resources) attached to land or growing on it (or in it), whether cultivated or not. In a contract for sale or will, these natural things must be expressly excluded or granted separately from the land: *Eastern Constructions Co Ltd v National Trust Co Ltd & Schmidt (1914) AC 197.*

The courts have held that the benefits derived from flora can also create an interest in land for the private land owner. For example, where the owner derives a benefit from the further growth of trees of further vegetation and from nutrients provided to the land, an interest in them is an interest in land: *Marshall v Green (1875) 1 CPD 35.*

At common law, there is no absolute property in wild animals while they are alive. A person may only gain a qualified property that can be defeated. However, when a wild animal is killed or dies, absolute property vests in the owner or the occupier of the land upon which the animal dies, or in the grantee or licensee of the shooting or sporting rights: *Yanner v Eaton [1999] HCA 93.*

The Review also notes that the 2000 Commonwealth Public Inquiry (known as the Voumard Inquiry) commented that, subject to valid legislation or agreements with the private landowner to the contrary, biological resources generally that are attached to or growing on or in land would be regarded as the property of the landowner.

Property 'use' vs 'ownership'

The common law has recognised very few restrictions on a landowner's right to use and enjoy land. There are only very limited circumstances where landowners rights have been restricted from their rights at law, for example:

(a) All jurisdictions have legislated to ensure Crown ownership over minerals and petroleum under private land. Minerals is defined narrowly under the *Mineral Resources Act 1989* (Qld) and does not include biological resources;

(b) Precious minerals lying beneath private land belongs to the Crown, together with the right to enter, dig and such other powers; and

(c) Restrictions are also placed on landowners from a conservation standpoint for example, a restriction on clearing of certain protected species of vegetation on land.

Nature Conservation Act 1992 (Qld)

Set out below are relevant sections from the *Nature Conservation Act 1992* (Qld) (the **NC Act**):

83(1) Subject to subsections (2) to (5), sections 85 and 86 and the provisions of any captive breeding agreement, all protected animals are the property of the State.

84(1) Subject to subsections (2) to (4), section 86 and the provisions of any captive breeding agreement, all protected plants (other than protected plants on private land) are the property of the State.

84(5) In this section—
***private land** means—*
(a) freehold land; or
(b) land the subject of a lease under any Act containing an entitlement to a deed of grant in fee simple.
***protected plant** means a protected plant that is in the wild.*

86 Sections 83 and 84 do not affect property rights a person (other than the State) has in native wildlife immediately before the wildlife becomes protected wildlife.

Section 86 of the NC Act supports the position at common law - a private landowner retains its rights in native wildlife (defined as any taxon or species of wildlife indigenous to Australia) before the wildlife becomes protected.

The protected wildlife is then regulated by the NC Act (subject to the provisions of any captive breeding agreement):

(a) Section 83 provides that *'all protected animals are the property of the State'*; and

(b) Section 84 provides that '*all protected plants (other than protected plants on private land) are the property of the State'.*

A protected animal or plant is one that is prescribed under the Act that is threatened, near threatened or least concern wildlife. This means that under the Act:

(a) Plants (including *'protected plants'* on private land) on private land remain the property of private landowners (section 84(1));

(b) *'protected animals'* are the property of the State (Section 83(1)) but only from the time they become *'protected'* (Section 86); and

(c) The State does not have any property rights in native wildlife immediately before the wildlife becomes protected wildlife.

What does 'property of the State' mean?

A prima facie review of the case law has revealed that the reference to a right of 'property' with respect to the State's rights may not amount to 'ownership' of those resources. We have outlined the key concepts from the leading case on this issue. There are many cases which have considered this decision. A full review of the case law on this issue is outside the scope of the Independent Review.

Yanner v Eaton [1999] HCA 93

The High Court considered the meaning of section 7(1) of the *Fauna Conservation Act 1974* (Qld) which provided that property in all native fauna in Qld vested in the State. The *Fauna Conservation Act 1974* (Qld) was the predecessor to the *Nature Conservation Act 1992* (Qld).

The Court rejected a conclusion that full or beneficial ownership was vested in the State, noting that "*the Crown's control and possession of wild animals is, as theorised at common law, inherently limited'.*

It was held (among other aspects) that:

(a) The use of the term "*property*" merely conferred a regime forbidding the taking and keeping or property not the actual property in that fauna;

(b) '*property*' created by legislation is nothing more than the aggregate of various rights of control by the executive and those rights are less than full, beneficial or absolute ownership;

(c) Regulating the way in which rights and interests may be exercised is not inconsistent with their continued existence – in fact seeking to regulate those rights presupposes that the right exists;

(d) So called State ownership is only a sort of State guardianship for social purposes;

(e) The rights granted to the State (expressed in a similar way to rights granted over minerals) may give rise to an ability to claim a royalty; and

(f) The interests in fauna differ in nature from the ordinary understanding of property in a chattel conferred by the common law.

Yanner v Eaton is the seminal case in respect of this issue. Since the decision was handed down by the High Court in 1999, it has been considered, applied and followed by numerous cases.

Other than some limited exceptions as noted above (for example in relation to minerals and petroleum), the Review notes that common law has recognised few restrictions on a private landowners rights in land and what is on it.

The NC Act states that 'protected animals' and 'protected plants' (other than protected plants on private land) are the 'property' of the State. The NC Act also regulates the access to and use of certain protected plants and animals.

However, as case law has indicated, the reference to 'property' in the NC Act does not equate to full, absolute or beneficial ownership. Rather, this concept of 'property' relates to the authority to regulate the way in which items (over which a property right is granted in the legislation) is exercised. The Courts clearly draw the distinction between ownership rights and the State's right to regulate the use/access.

Impact on the Act – Benefit Sharing

The Act currently does not extend to private land.

This was a clear policy decision stemming from the commencement of the Act – the Explanatory Notes to the Biodiscovery Bill 2004 confirmed that private landowners may enter their own benefit sharing agreement in respect of resources sourced from his/her land. The intention of the Act is not to alter the access rights or intellectual property rights of landowners which may be generated by biodiscovery.

Based on the current position as to the resources in which the State is granted 'property' rights and in the absence of any comprehensive review of the law surrounding this issue, the Review does not consider there is any clear basis to recommend that the State be entitled to benefits of biodiscovery in relation to wildlife or plants (taken from private land) other than possibly with respect to protected plants and animals over which it is granted 'property' rights under the *Nature Conservation Act 1992* (Qld). This is because of the way the Courts have interpreted the State's 'property' right such that it does not amount to full ownership (as noted above).

The Review has determined that a change in policy by the State to obtain Benefits of Biodiscovery from plants or animals deriving from private land would require:

(a) The State to claim property rights in respect of those plants and animals (in the context of private land);

(b) For clarity, the State to confirm its rights over protected plants and animals pursuant to sections 83 and 84 of the NC Act;

(c) The resolution of the confusion which is likely to arise as between the NC Act and the Act with respect to the claiming of property rights in the State, for example:

    (i) Protected animals taken under licence, permit etc cease to become property of the State (irrespective of where they are taken) – section 83(2) of the NC Act;

    (ii) Protected plants taken under licence, permit etc cease to become property of the State (irrespective of where they are taken) – section 84(2) of the NC Act; and

(iii) Rights in native wildlife immediately before the wildlife becomes protected wildlife - section 86 of the NC Act.

Any recommendation providing the State with rights to Benefits of Biodiscovery in relation to Native Biological Material (taken from private land) will have broader implications as to the:

(a) Rights of private landowners; and

(b) The State's interpretation and policy surrounding the concept of 'property' as noted in the NC Act and interpretation by the Courts.

Such a change is also likely to represent a fundamental change to the Act, serving to increase regulatory burden and administrative oversight.

Impact on the Act – Collection Authorities

As distinct from the State obtaining Benefits of Biodiscovery from plants or animals deriving from private land, for completeness, the Review notes that:

(a) Collection of biological material from private land may be regulated by other Acts in specific circumstances (such as the Nature Conservation Act 1992 (Qld), Forestry Act 1959 (Qld), Marine Parks Act 2004 (Qld) and Fisheries Act 1994 (Cth));

(b) The extension of the Collection Authority regime to private land (in addition to State land and Queensland waters) would require a fundamental change in policy under the Act;

(c) It would be complicating to have the Collection Authority regime applying to the 'collection' of Native Biological Material on private land but not the sharing of benefits in connection with the collection as noted above; and

(d) As with the above, the implementation of any such change is likely to increase regulatory burden and administrative oversight.

Recommendation 11:

In the absence of a broader consideration of this issue, the Review does not recommend the scope of the Act be expanded to cover private land (with the effect that the State would be entitled to obtain Benefits of Biodiscovery from Native Biological Material collected from privately owned land).

As previously noted in the context of Recommendation 5, despite not falling within the scope of the Act, the Review notes that private landowners may benefit from some guidance (in an Updated Code) in relation to specific matters including negotiating benefit sharing agreements and obtaining prior informed consent regarding access and any use of indigenous knowledge and on mutually agreed terms. This guidance should also assist with the process of granting International Certificates of Compliance.

8 Operation of the Act

8.1 Terms of Reference 2, 3, 4, 5 and 6

2. Examine the overall structure and effectiveness of the Act including:
    a. consideration of the effectiveness of the key features of the regulatory framework and opportunities to streamline the processes to reduce regulatory burden. In considering other options, gather evidence of the impacts of the other options on the regulated community to allow comparison to the current legislation and if there were no regulation.

3. Examine the structure and effectiveness of the permitting regime (Parts 3 and 4 of the Act) including:
    a. consideration of whether the use of biodiscovery collection authorities compared to other types of environmental permits and authorities is effective and opportunities to streamline requests for access to native biological material for biodiscovery.

4. Examine the structure and effectiveness of the contractual framework for benefit sharing (Part 5 of the Act) including:
    a. consideration of whether the framework is sufficiently adaptable to the different types of biodiscovery activities and entities and the range of pathways for commercialisation.

5. Examine the definitions in the Act and the need for the definition of any other terms including:
    a. consideration of whether the operation of the Act is affected by the definition of biodiscovery and biodiscovery research which limit the application of the Act to research that is undertaken for the purpose of commercialising the native biological material.

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

8.2 *TOR 2* - Examine the overall structure and effectiveness of the Act - the effectiveness of the key features of the regulatory framework and opportunities to streamline the processes to reduce regulatory burden

The Review has considered the structure and effectiveness of the Act. It has considered the key features of the regulatory framework and opportunities to streamline the processes to reduce regulatory burden. The following sections of this Report address the key features of the current regulatory framework:

- Permitting – see Section 8.3 of this Report; and
- Benefit sharing - see Section 8.4 of this Report.

Biodiscovery Plan

A central part of the regulatory framework of the Act is the requirement for the Biodiscovery Entity to complete (and have approved) a Biodiscovery Plan (Section 36 of the Act). The Biodiscovery Plan is a pre-requisite for the granting of a Collection Authority and the entry into a BSA under the Act.

The Biodiscovery Entity may only undertake activities which are the subject of an approved Biodiscovery Plan (section 35(1) of the Act).

Pursuant to Section 37 of the Act, the Biodiscovery Plan must include the following details:

(a) Commercialisation activities proposed to be undertaken;

(b) Proposed timetable for undertaking the activities;

(c) The parts of any activities the entity proposes carrying out outside the State;

(d) The types of 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 BSA;

(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; and

(g) Other details prescribed under a regulation.

The Review received only minimal comments on the effectiveness or otherwise of the Biodiscovery Plan. For those stakeholders who were advanced with their Commercialisation activities or their Commercialisation plans, the Biodiscovery Plan was said to provide an opportunity to formalise those plans.

However, in the context of the high levels of regulation in the Act with respect to permitting and BSAs, the Review is concerned that the requirement of the Biodiscovery Plan imposes another hurdle to compliance with the Act which may result in a stifling of the industry. Consistent with the submissions by interested parties in relation to BSAs, it is the case that the commercial potential of a use may not be known at the initial collection stage.

On analysing the regulatory structure of the Act, the Review considered that pertinent information currently included in the Biodiscovery Plan may be adopted as part of other aspects of the Act's framework.

The obligations for the Minister to review and decide applications for Biodiscovery Plans (Division 2 of the Act) is also administratively burdensome. This administrative burden outweighs the benefit of the maintaining Biodiscovery Plans as part of the regulatory framework.

For example the information regarding Commercialisation may be included in the BSA or Collection Authority. This is consistent with Recommendation 13 regarding the proposed change to the permitting regime (commercial vs non-commercial activities).

Neither the Commonwealth Regulations nor the NT Act incorporate a requirement equivalent to the Biodiscovery Plan in their framework.

The removal of this requirement from the Act, would also represent a move to further consistency between the Australian jurisdictions (decreasing the risk of forum shopping'). Such consistency is also important in the context of the implementation of the Nagoya Protocol which prefers a nationally consistent approach (also expected from large companies seeking to do business in Australia).

The removal of the regulatory burden of the Biodiscovery Plan also responds to feedback provided in submissions to the Review that the legislation should be amended to reduce regulatory barriers to facilitate industry participation.

Recommendation 12:

The Review recommends Biodiscovery Plans be removed from the regulatory framework of the Act and include relevant aspects previously contained in the Biodiscovery Plans in Collection Authorities and BSAs as appropriate.

Summary of proposed recommendations regarding the structure of the Act

In response to specific Terms of Reference, the Review has sought to where appropriate:

(a) Confirm the current structure and framework of the Act; or

(b) Where necessary, provide recommendations to either improve the structure and effectiveness of the Act or reduce the regulatory burden of the Act.

For ease of reference, we set out below a summary (including the relevant Recommendation where relevant) of the proposed regulatory framework assuming the Recommendations set out in this Report are supported and adopted by the State:

Framework	Recommendation
Note: It is recommended that Biodiscovery Plans not form part of the regulatory framework of the Act.	Recommendation 12
Biodiscovery Research – delinked from Commercialisation	Recommendation 26
Biodiscovery Entities to obtain a Collection Authority where Native Biological Material to be used for commercial or non-commercial purposes. Where the Biodiscovery Entity proposes to access indigenous knowledge or access Native Biological Material from indigenous people's land, the Collection Authority will be conditional on receipt of prior informed consent (including on mutually agreed terms) from the relevant indigenous group. See below for further conditions regarding Statutory Declarations.	Recommendation 8 Recommendation 13 Recommendation 16
Where Native Biological Material is being used for non-commercial purposes, the Biodiscovery Entity must provide a Statutory Declaration confirming the use of Native Biological Material for non-commercial purposes (precondition to Collection Authority). In relation to non-commercial use the Biodiscovery Entity: (a) Commit to a regular reporting structure in relation to the use of the Native Biological Material (may be undertaken via the Biodiscovery Register); (b) Not be permitted to pass on the material to a third party unless that third party agrees to report as to the use of the material; and (c) Enter into a BSA if the material is to be commercialised.	Recommendation 13
Where Native Biological Material is being used for commercial purposes, the Biodiscovery Entity must enter into a Benefit Sharing Agreement with the State (precondition to Collection Authority). The Benefit Sharing Agreement will including an ongoing reporting structure (which may be undertaken via the Biodiscovery Register).	Recommendation 13
Biodiscovery Entity may enter into downstream arrangements in respect of the Commercialisation of Native Biological Material on certain conditions (as outlined in this Report). If the head Biodiscovery Entity is not able to comply with the conditions– the downstream entity must enter into a separate BSA in relation to the use of the Native Biological Material with the State on	Recommendation 21

Framework	Recommendation
the usual terms.	
Information to be included in Biodiscovery Register including provider, proof of prior informed consent (e.g. permit for collection and where necessary statutory declaration or equivalent), relevant Native Biological Material and whether the use is commercial or non-commercial. [The State may require additional information to be included to track activities]	Recommendation 42
Existing collections or libraries may be authorised by the State issuing International Certificates of Compliance in respect of those collections. In order for the State to be able to issue an International Certificate of Compliance in relation to existing collections or libraries, those collections or libraries will need to provide the required information for assessment by the State via the Biodiscovery Register or come to an appropriate arrangement for the provision of that information.	Recommendation 42
Accessing material which is not governed by the Act: (a) Updated Code or alternative administrative instrument which provides guidelines for access and benefit sharing with private landowners and accessing indigenous knowledge; (b) Entities accessing material from private land or internationally may voluntarily upload information to the Biodiscovery Register in order to obtain an International Certificate of Compliance from the State.	Recommendation 5
State may issue International Certificates of Compliance based on information included on Biodiscovery Register.	Recommendation 39
Trusted Collections may, subject to further consultation with the Commonwealth, be accredited to grant access to genetic resources.	Recommendation 43

Appendix 7 of this Report sets out a simple diagram reflecting the Recommendations in relation to the regulatory framework.

Reporting

The Review has given consideration to the reporting requirements under the Act and also the reporting requirements in connection with the proposed regulatory framework.

The Review has summarised the reporting requirements in the table below for ease of reference. The proposed changes to the reporting framework arising out of the Review are highlighted in the table so they can be easily identified.

Trigger	Reporting requirements	Recommendations
Biodiscovery Plan (Section 37 of the Act)	Section 37 sets out information to be included in the Biodiscovery Plan. Biodiscovery Entities are required to continually ensure their Biodiscovery Plan is up to date as it forms the basis for the authority to conduct Biodiscovery in relation to the Native Biological Material.	The Review recommends the Biodiscovery Plan be removed from the regulatory framework of the Act (Recommendation 12).
Material Disposal Report (Section 32 of the Act)	The holder of a collection authority must give to the DSDI chief executive, within 15 business days after each 30 June and 31 December, a material disposal report about all Native Biological Material.	No recommended changes. However, consideration should be given as to whether the practical implementation of Section 32 is viable in view of the current facilities and technologies available to produce these reports.
Giving a sample of material (Section 32 of the Act)	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 and required information to the relevant authority in accordance with Section 30.	State to consider whether this is the most effective means of storage of samples in view of updated scientific technologies (Recommendation 16).
Collection Authority - general (Part 3 of the Act)	Reporting in relation to collection pursuant to Compliance Code: requirement to lodge collection report with the State within 10 business days of request (2.11 of the Compliance Code).	Subject to any changes in the Compliance Code, there is no proposal to change this requirement as a result of the Review. This obligation will apply to Collection Authorities for commercial and non-commercial activities.
Collection Authority – non-commercial activities.	Not specifically addressed in the current regulatory framework of the Act.	Statutory declaration as to non-commercial use (which may be uploaded to the Biodiscovery register). The Review recommends a regular reporting structure in relation to the use of the Native Biological Material (this may be undertaken using the Biodiscovery Register) and Biodiscovery Entity not be permitted to pass on the material to a third party unless that third party agrees to report as to the use of the material (see Recommendation 13).

Trigger	Reporting requirements	Recommendations
Benefit Sharing Agreement (Section 34 of the Act)	Section 34 sets out the required content of a BSA which includes reportable matters. The Biodiscovery Entity must report annually in relation to royalties. – Financial information – Outline of Biodiscovery Research – Outline of Commercial activities – Disposals of intellectual property – Benefits of Biodiscovery – Other items as agreed	The Report recommends the BSA be retained for use of Native Biological Material for commercial purposes. Reporting under the BSA will continue but will be able to be undertaken by uploading material to the Biodiscovery Register (see Recommendations 13 and 42). Further reporting will also be required if downstream licence model adopted (see Recommendation 21).
Prior informed consent on mutually agreed terms to use indigenous knowledge and access material on indigenous people's land.	Not specifically addressed in the current regulatory framework of the Act.	It is recommended that this information be uploaded to the Biodiscovery Register (Recommendation 8 and 42).
Voluntary reporting by those not falling within the scope of the Act for the purposes of obtaining an International Certificate of Compliance.	Not specifically addressed in the current regulatory framework of the Act.	The Review recommends that the voluntarily uploading of information by persons or entities to the Biodiscovery Register for the purposes of the State issuing International Certificates of Compliance (see Recommendation 42).

The removal of the Biodiscovery Plan from the regulatory framework will result in a reduction in reporting to the State by Biodiscovery Entities and a consequent lessening of the resources required to be applied by the State in assessing and processing those Biodiscovery Plans.

However, the Review notes that additional reporting burden will be placed on users as outlined above – specifically in connection with:

Providing material in relation to prior informed consent on mutually agreed terms to use indigenous knowledge and access material on indigenous people's land - however, this is required to meet Nagoya Protocol requirements which would otherwise not be satisfied;

- Statutory declaration as to non-commercial use and associated reporting; and
- Voluntary reporting by entities not falling within the scope of the Act for the purposes of obtaining an International Certificate of Compliance.

It is proposed that this reporting (as well as existing reporting requirements) be undertaken by uploading the required information to the Biodiscovery Register which forms part of the legislated regulatory framework under the Act (see Section 7.6 of this Report and Recommendation 42 and associated commentary).

The Review considers that the use of the Biodiscovery Register as the reporting solution under the Act will assist in streamline the operation of the Act. It will also assist in reducing the regulatory burden from both the perspective of the State and the persons/entities uploading the information as it:

- Serves as one clear repository of information allowing for efficiencies in streamlining the Act;
- A certain means and online portal for users to provide information as required by the Act; and
- A means by which the State can adopt a checking mechanism to review and store information based on which International Certificates of Compliance are issued or refused.

It may impose greater burden on the holders of collections in dealing with use of materials by researchers and others. Consideration should be given to how best to appropriately streamline the gathering and storing of information without imposing an unnecessary administrative burden on the holders of collections or the State.

Consideration should be given, in liaison with the Commonwealth whether some of these collection holders have the status of trusted collections (see Recommendation 43). Guidance can be taken from the information to be submitted and verification procedures as described in the EU Implementing Regulation (see Section 7.5 of this Report).

8.3 *TOR 3* - Examination of the structure and effectiveness of the permitting regime

A Collection Authority may be issued under Part 3 of the Act. The Department of Environment and Heritage Protection is responsible for the issue of Collection Authorities under the Act.

Section 10 of the Act provides that, 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.

The issue of the effectiveness and structure of the permitting regime was a significant one for those stakeholders who made submissions to the Review in respect of this issue.

Current process under the Act

If an entity intends to undertake Biodiscovery then the entity may apply for a Collection Authority.

A proposed or approved Biodiscovery Plan is required to be lodged with the application for a Collection Authority (section 11(2) of the Act) and no material is able to be collected under a Collection Authority unless the entity has entered into a BSA with the State in relation to that material (Section 17(1) of the Act).

The Review notes that Biodiscovery (as currently defined in the Act) requires a link to 'commercialisation' (see definition of Biodiscovery in the Act).

The practical effect of this is that in order to apply for a Collection Authority the Biodiscovery Entity must intend engaging in 'commercialisation' of the Native Biological Material as a pre-requisite for obtaining a Collection Authority.

This requirement of 'commercialisation' has meant historically that entities have not applied for Collection Authorities as it is 'too early' to determine whether any 'commercialisation' will occur. If the entity does not intend to commercialise the material, then the entity may apply for a different permit which is not governed by the Act, for example a Scientific Purposes Permit. Consequently it has been difficult to track the use of that material and to determine whether Biodiscovery is actually occurring and whether a BSA under the Act is required.

The Review has considered the appropriateness of the definition of Biodiscovery in Section 8.5 of this Report.

Considerations of the Review

For the purposes of the Review, consideration has been given to several alternatives in relation to permitting under the Act. The alternatives have been driven by the Review seeking to achieve an alternative to the current process which improves the structure and effectiveness of the permitting regime.

Holders of samples of Native Biological Material, the taking of which has not been appropriately permitted with a valid Collection Authority may be subject to enforcement pursuant to the enforcement provisions in the Act. The Review does not recommend an embargo on Biodiscovery Entities who have previously failed to comply with the Collection Authority regime under the Act.

The authorisation of existing collections or libraries is described in Section 11 of this Report (including in particular the concept of trusted institutions).

For the purpose of these alternatives it is assumed that the Recommendation 26 has been adopted such that the definition of Biodiscovery no longer has a pre-requisite of Commercialisation.

Alternative A *- Benefit sharing agreement (commercial and non-commercial purposes) a precondition to Collection Authority*

Alternative A may operate as follows:

- Entities are required to sign up to a BSA in standard terms at the time of applying for a Collection Authority.
- Where the entity is not using the material for commercialisation purposes then the clauses in the BSA dealing with payment of monetary benefits and provision of non-monetary benefits will not apply. However, reporting and other provisions will apply.
- The BSA will require the entity to report regularly on activities including on matters which will enable a determination to be made as to whether the entity is engaging in commercialisation.
- Where no commercialisation is occurring at the time the BSA is entered into, DSITI will be relying on the reporting mechanism under that BSA to determine whether commercialisation is being undertaken.
- EHP will be required to administer the entering into the standard form BSAs at the time permitting and ensure that it is signed at the time a Collection Authority is issued.

Alternative B *- Benefit sharing agreement (commercial and non-commercial purposes) a precondition to other permits (in addition to Collection Authorities)*

Alternative B is an addition to Alternative A whereby entities applying for permits are required to enter into a standard form BSA (as per Alternative A) in the event the use of the material collected under those permits falls under the scope of the Act.

Alternative C *– Retaining the Collection Authority - Benefit sharing agreement (commercial purposes) and declaration (non-commercial purposes)*

This alternative reflects the approach undertaken under the Commonwealth Regulations.

Alternative C may operate as follows:

- At the time an entity applies for a Collection Authority it must state whether it is using the material for commercial or non-commercial purposes. A different permit may need to be issued for commercial vs non-commercial purposes (as per the Commonwealth approach).
- If the material is being used for commercial purposes, the entity must enter into a BSA as a pre-condition for issuing the Collection Authority.

- If the material is being used for non-commercial purposes then a statutory declaration or equivalent must be signed (before the Collection Authority is issued) stating that is the case and among other obligations the entity must:
    - Commit to a regular reporting structure in relation to the use of the Native Biological Material (this may be undertaken using the Biodiscovery Register);
    - Not be permitted to pass on the material to a third party unless that third party agrees to report as to the use of the material (this will assist with establishing the chain of title as required for provenance purposes under the Nagoya Protocol and will assist the tracking of the use of the material) – the administering department will be able to cross check the transfer of samples via the material disposal report lodged pursuant to section 32(1) of the Act; and
    - Enter into a BSA if the material is to be commercialised and as part of the entry into the BSA an updated Collection Authority to use the relevant Native Biological Material for commercial purposes should be issued.
- A Collection Authority which is issued for non-commercial purposes must also incorporate terms for benefit sharing on mutually agreed terms. This may be achieved by including a list of benefits which may arise for the non-commercial use of the Native Biological Material – the Biodiscovery Entity could then tick or insert (in the 'other' field) the most relevant benefits as part of the application process for the Collection Authority (non-commercial purposes).

Alternative D *- No Collection Authorities under the Biodiscovery Act – permitting completely disconnected*

- The concept of Collection Authorities to be completely removed from the Act and EHP and other relevant departments will continue to be responsible for issuing all permits – there will be no specific permit dealing with material collected for Biodiscovery purposes.
- EHP will review reports to be provided by permit holders to determine whether Biodiscovery is being undertaken by the permit holders.
- Reporting mechanism to be put in place between EHP and DSITI to advise of circumstances which fall within the Act – for example, EHP permitting team to advise DSITI team (using information obtained from permit reports) whether:
    - Commercial activity is occurring in relation to the collected material; or
    - Transfer of material for commercial purposes.
- The reporting under the permitting system would need to be ongoing and would require sufficient resource allocations internally to ensuring relevant information is being shared.

Consideration of permitting alternatives

Assuming the definition of Biodiscovery has been amended to delink it from Commercialisation (Recommendation 26), on balance, the Review considers that the preferred option to which further consideration should be given by the State is Alternative C - *Retaining the Collection Authority - Benefit sharing agreement (commercial purposes) and declaration (non-commercial purposes.*

This Review has reached this conclusion in consideration of the following:

1. Alternative C is:
    a. Generally consistent with the process currently adopted by the Commonwealth Regulations; and
    b. Responds to the key issue raised by stakeholders that the entry into a BSA at an early stage is problematic as it is difficult to ascertain whether the initial research will be commercialised;

2. The Review is informed that the Commonwealth is considering an approach similar to Alternatives A or B. However, the Review considered that the requirement to enter into a BSA as a precondition for obtaining a permit (Collection Authority under the Act or otherwise) under Alternatives A and B is likely to be administratively burdensome for entities applying for permits as well as for the department issuing the permit. Further, it has the risk of slowing down the application process as applicants may be unwilling to agree to terms of a BSA at application stage. The Review considers that if the Commonwealth were to adopt Alternatives A or B, the State should review its approach only after the new approach has been used by the Commonwealth for some time; and

3. The Review has also considered the possibility of Biodiscovery Entities entering into BSA by virtue of a:

    a. 'shrink wrap' agreement (acceptance and use of the Native Biological Material is deemed acceptance of the BSA terms); or

    b. 'click wrap' agreement (ticking a box online confirming acceptance of the BSA terms).

    This is the approach adopted in the Standard Material Transfer Agreement in connection with the International Treaty on Plant Genetic Resources for Food and Agriculture. The Review makes the following observations in respect of the 'shrink wrap' and 'click wrap' models:

    a. As between the two options the Review favours the 'click wrap' model.

    b. The 'click wrap' model involves the Biodiscovery Entity taking an active step to accept the terms and conditions of the BSA which would assist in its enforceability. The State would also be able to retain an electronic log as to the time the Biodiscovery Entity clicked 'accept' forming a legal contract between the State and entity.

    c. While the 'shrink wrap' model is often used with software products (not downloadable from the cloud), enforceability of an agreement of this nature is unclear. There remains the concern that unless the terms and conditions of the BSA are printed on the Collection Authority to be issued, there may be some uncertainty as to whether the BSA terms have been provided to the Biodiscovery Entity or in fact whether the BSA entity has had sufficient opportunity to consider the terms before being deemed to have accepted them. This may be of limited concern if the Native Biological Material is collected some time after the Collection Authority with the BSA terms are issued. Subject to reporting, the State is also unable to be clear on exactly when the terms are accepted by the entity as there is no set time for collection of the Native Biological Material which will trigger the commencement of the legal agreement between the State and the entity.

    d. The Review reiterates its concern (as noted above) that Biodiscovery Entities may be unwilling to accept standard terms for BSAs including pursuant to a 'click wrap' agreement and may seek the relevant material elsewhere if available.

    e. There may be some resistance to entering into standard form 'click wrap' agreements in light of the recent introduction of the unfair contract terms in the Australian Consumer Law. However, a consumer would be required to establish the Native Biological Material is being acquired wholly or predominantly for personal, domestic or household use or consumption in order for the unfair contract terms to apply.

4. The deletion of the Collection Authority (as per Alternative D) is, based on the current State permitting system (including under other legislation) not workable - the Review is informed that:

    a. The Collection Authority serves a purpose of covering 'take' not authorised under other legislation (for example permitting collection in a park for the purpose of commercialisation); and

b. Permits under available under other legislation may not permit commercialisation activities falling within the scope of Biodiscovery under the Act.

5. The Review notes that the Commonwealth has indicated that its current structure remains a challenge to administer as entities are resistant to entering into a BSA when commercialisation occurs. However, the Review considers the proposed approach together with the implementation of the Biodiscovery Register (see Section 11 of this Report) will assist the State in monitoring progress from research to commercialisation.

This approach recognises the need for an efficient permitting regime supports research, but still allows for more sophisticated regulation via a BSA in the event of Commercialisation.

Impact of the Nagoya Protocol

The Nagoya Protocol governs the utilisation of resources including for 'research'. The obligations of prior informed consent and benefit sharing on mutually agreed terms will also apply to activities undertaken on Native Biological Material for non-commercial purposes.

The Review has concluded that to reflect the obligations of the Nagoya Protocol with a minimum of regulatory burden, the Collection Authorities issued for non-commercial purposes also incorporate terms for benefit sharing on mutually agreed terms. This may be achieved by including a list of benefits which may arise for the non-commercial use of the Native Biological Material for example:

- Institutional capacity building;
- Contribution in scientific research;
- Collaboration, co-operation and contribution in education and training;
- Development of institutional and professional relationships; and
- Other (to be inserted by the Biodiscovery Entity).

The Biodiscovery Entity could then tick or insert (in the 'other' field) the most relevant benefits.

It will be open to the State to determine the most efficient and effective way of meeting this requirement.

Recommendation 13:

In making this Recommendation, the Review has relied on Recommendation 26 - that the definition of Biodiscovery no longer has 'commercialisation' as a pre-requisite.

The Review recommends the State give consideration to updating the permitting regime including the interaction between Collection Authorities and Benefit Sharing Agreements.

Based on the alternatives considered by the Review, on balance the Review favoured an approach which is generally consistent with the process currently adopted by the Commonwealth:

- *retaining the Collection Authority under the Act; and*
- *requiring a Benefit Sharing Agreement (commercial purposes) and declaration (non-commercial purposes).*

In order to meet the requirements of the Nagoya Protocol, the Review recommends the State Collection Authorities issued for non-commercial purposes also incorporate details of benefit sharing.

This adoption of an alternative approach will also give rise to consequential amendments to

the Act – for example, removing the need to have a BSA in order to collect under a Collection Authority (Section 17(1) of the Act).

Recommendation 14:

The Review recommends consequential amendments be made to the Act as are likely to be required to reflect an alternative approach to the Collection Authority and benefit sharing regime including but not limited to the need to update the model BSA to reflect the new framework.

Collection Authorities – additional information

Information previously included in Biodiscovery Plans

As noted in Recommendation 12, the Review has recommended the deletion of the requirement for Biodiscovery Entities to lodge a Biodiscovery Plan.

If the Biodiscovery Entity is engaging in Commercialisation as described above, key information requirements (with the exception of the Benefits of Biodiscovery to be provided, as this is included in the BSA) in section 37 of the Act (previously included in the Biodiscovery Plan) may form part of the Collection Authority application. This will inform the Department of the nature of the Commercialisation.

Recommendation 15:

If the Biodiscovery Entity is engaging in Commercialisation, key information requirements (with the exception of the Benefits of Biodiscovery to be provided, as this is included in the BSA) in section 37 of the Act (previously included in the Biodiscovery Plan) may form part of the Collection Authority application.

Prior informed consent – indigenous people's land

The Review refers to Recommendation 8 regarding the proposed requirement for the giving of prior informed consent in relation to accessing Native Biological Material on land which is indigenous people's land.

This is not a current requirement of the Act but the Review recommends should be included (for the reasons set out in Section 7.11 of this Report) as a pre-condition to the application for a Collection Authority under the Act.

Recommendation 16:

Consistent with and in the manner noted in Recommendation 8, the Review recommends including as a pre-condition to the application for a Collection Authority the receipt of prior informed consent in relation to accessing Native Biological Material on land which is indigenous people's land (falling within the Act).

Education process

Should the above recommendations be supported by the State, the Review considers an education process be adopted to inform industry in relation to the changes in the permitting regime. This may also include updating the relevant code with a detailed explanation of the process.

Recommendation 17:

The Review recommends an education process be adopted to inform industry in relation to the changes in the permitting regime which may include updating the relevant code with a detailed explanation of the process.

Administration of the Collection Authority system

Some of the key issues raised with the Review by stakeholders are set out below:

- There was general uncertainty in relation to the administration of the Collection Authority regime in terms of the relevant departments and contact persons; and
- There was limited intra-departmental awareness of the permitting process in particular in relation to Collection Authorities issued under the Act, its timeframes and authorisations required.

The Review noted that these issues are likely to have arisen as a result of the limited number of Collection Authorities which have had to be issued pursuant to the Act. As a result there is minimal history or retained knowledge about the administration of assessing applications for Collection Authorities.

The Review concluded that operational matters such as these could be addressed by further information being provided to applicants for Collection Authorities. This would assist in clarifying the application pathway and would encourage (rather than dissuade) Biodiscovery Entities to apply (as required) for Collection Authorities under the Act.

Recommendation 18:

The Review recommends that guidance notes (including contact persons and timeframes) setting out the Collection Authority pathway should be provided on the Department's website.

Storage of samples

The 2009 Review highlighted the evolution of scientific methods may mean that the storage of samples pursuant to section 30 of the Act may not be the most appropriate method of retaining Native Biological Material which has been collected.

While the current Review has not received submissions in respect of this issue, the Review considers it is an important issue to ensure the State maintains currency with technology – in particular in view of the proposed amendment to the definition of Native Biological Material to include 'underlying data, information or sequences of Native Biological Resources' (see Recommendation 29).

Recommendation 19:

The Review recommends that the State consider whether the method of storage of samples requires amendment to reflect changes in scientific technologies – if so, updated requirements may be implemented using the Compliance Code (or updated equivalent).

8.4 *TOR 4* – Examination of the structure and effectiveness of Benefit Sharing Agreements

Pursuant to section 33 of the Act, the Minister may, for the State, enter into a BSA with a Biodiscovery Entity in 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.

The application of section 33 is that, in the absence of a BSA, the Biodiscovery Entity will not have the right to use of the Native Biological Material for the purposes of Biodiscovery.

This right to use and the requirement to provide Benefits of Biodiscovery is consistent across the Commonwealth Regulations and the NT Act. It is also consistent with the requirement for mutually agreed terms as required in Article 18 of the Nagoya Protocol.

The Review did not receive any specific feedback in relation to the requirement (in principle) of having to enter into a BSA with the State.

Content of Benefit Sharing Agreements

Section 34 sets out the requirements of the Act as to the content of a BSA:

(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.

The Review supports the content of the BSA as described in section 34(2).

In addition to these requirements, the Review recommends the State (in light of Recommendation 8) update the content requirements of the BSA to include reference to:

- The use of indigenous knowledge (if any) including details of the source of that knowledge;
- Whether any Native Biological Material has been accessed on indigenous people's land (see Recommendation 8); and
- The benefits to be provided or any agreed commitments given in return for the use of indigenous people's knowledge including confirmation of prior informed consent having been given.

These inclusions reflect the Commonwealth Regulations (Regulation 8A.08) and the NT Act (section 29).

As noted in Recommendation 12, the BSAs may also include, where appropriate, information which was previously incorporated in the Biodiscovery Plans.

Recommendation 20:

The Review recommends updating the section 34 list of content of benefit sharing agreements to reflect the recognition of indigenous knowledge, access of Native Biological Material on indigenous people's land, and prior informed consent (see also Recommendation 8).

Changes to the interaction between the permitting regime and the BSA framework

As noted in Recommendation 13, it is proposed by the Review that BSAs only be required when Native Biological Material is being Commercialised and statutory declaration (or equivalent) are to be used when Native Biological Material is to be used for non-commercial (including research) purposes.

This approach is consistent with the Commonwealth Regulations and addresses the concerns of stakeholders who informed the Review that the obligation to enter into BSAs should only be triggered when Native Biological Material is being Commercialised.

The Review repeats Recommendation 13 and as described in that recommendation, the Act should be updated to reflect the new proposed structure.

Multi-layered benefit sharing model

Section 35(2) of the Act provides as follows:

It is also a condition of the [benefit sharing 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.

Concern has been raised in relation to the operation of section 35(2) and in particular the application of this clause together with the offence provisions (section 42). In practical terms - a Biodiscovery Entity may not use the Native Biological Material for Biodiscovery unless the other person is:

- Acting for the Biodiscovery Entity (section 35(2)(a));
- Is undertaking one of the following activities:
    - Classifying the material scientifically (section 54(2)(a));
    - Verifying research results concerning the material (section 54(2)(b));
    - Biodiscovery to which a BSA concerning the material applies, carried out for a person who is a party to the agreement (section 54(2)(c));
    - Use by an educational institution (as defined in section 54(3)), or a person at the institution, for educational or training activities not involving Commercialisation of the material (section 54(3)); or
- A party to a BSA concerning the material (section 35(2)(b)).

The Review understands that confusion has arisen as a result of the meaning of these terms (for example, when is an entity 'acting for' the Biodiscovery Entity). This has led to uncertainty in the application of the Act.

As currently drafted, if the entity does not fall within one of the exceptions in section 54(2) and (3) or section 35(2)(a), the entity will be required to enter into a separate BSA in relation to the use of the Native Biological Material (**multi-layered model**).

The challenges associated with this framework have been raised by interested stakeholders including:

- The requirement that entities enter into separate BSAs raises uncertainty about the terms of the BSA entered to be into with the State and the length of the process;
- The multi-layered model increases transaction costs and complexity (including from an accounting point of view when compared with sharing benefits through a single pathway); and
- The multi-layered model also increases the resources required by the State to administer and negotiate additional BSAs.

To address these issues, one Stakeholder proposed a principal/agent model whereby the head Biodiscovery Entity would enter a BSA with respect to the Native Biological Material and would licence the right to use the Native Biological Material to other entities – it was submitted that this model would have the following benefits:

- Easy and clear transactional structure - there would be a single point of engagement through a head entity and obligation to remit royalty payments, including those from all downstream participants;
- Clear rules as to what is to be licensed; and
- Risk of compliance falling on the head entity.

The stakeholder proposed that the principal/agent model be implemented through an amendment to sections 34 and 54 to remove any interpretation of requiring the multi-layered approach. This could be achieved on the basis that the downstream participants would:

- Explicitly acknowledge the Biodiscovery is subject to the Act;
- Downstream participants will bear similar obligations to the principal entity;
- Ownership of samples will not be transferred to downstream participants but they will be granted a very specific right to use;
- Downstream participants may act as the exclusive commercialisation partner;
- Downstream participants will pay milestones and royalties to the principal who will account to the State. The State will receive one payment from the principal together with financial information to verify calculations;
- Downstream participants will report to the principal who in turn will report to the State; and
- Downstream participants will be entitled to onward contract provided the onward arrangement is consistent with the principal's Biodiscovery Plan and benefits shared with the principal who then shares them with the State.

The Review has considered the concerns raised by the stakeholder and notes the application of the exceptions in sections 35(2) and 54(2) and (3) may:

- Lead to uncertainty (in particular when determining whether an entity is 'acting for' the Biodiscovery Entity); and
- Impose restrictions on the effectiveness of the Act by increasing the burden on Biodiscovery Entities seeking to Commercialise the Native Biological Material (which is likely to act as a disincentive to potential commercial partners of those entities).

On the other hand, the Review acknowledges the value of the conditions in sections 35(2) and 54(2) and (3) such that it is a mechanism by which the State seeks to be able to trace the use of Native Biological Material and Benefits of Biodiscovery.

The Review also notes that the position in sections 35(2) and 54(2) and (3) do not align with the framework set out in the Commonwealth Regulations and NT Act in relation to benefit sharing agreements.

To enhance the effectiveness of the Act and to streamline the process in relation to BSAs the Review has concluded that sections 35(2) and 54(2) and (3) should be amended. A change to these sections will amount to a significant update to the current contractual framework set out in the Act. The Review has determined that the State should give consideration to adopting licensing framework which, in general terms, is consistent with the principal/agent model proposed by stakeholders.

Proposed approach

If the head Biodiscovery Entity (which has entered the BSA with the State) is not able to comply with the conditions below – the downstream entity must enter into a separate BSA in relation to the use of the Native Biological Material with the State on the usual terms.

The head Biodiscovery Entity may licence the right to use the Native Biological Material on minimum terms including:

- The sub-licence is for the limited purpose of use the Native Biological Material for Biodiscovery (with a right to sub-licence on the same terms), including granting rights (for example intellectual property rights) in the Native Biological Material or products of Biodiscovery Research;
- The sub-licence must acknowledge the right to use the Native Biological Material for Biodiscovery is subject to the Act and the head BSA;
- The sub-licence would be on at least the same terms to enable the Biodiscovery Entity to continue to meet the obligations of the head BSA (including audit reach through provisions);
- Ownership of samples will not be transferred to sub-licensee but they will be granted a very specific right to use (the disposal of any Native Biological Material will also be able to be tracked via the material disposal report in section 32 of the Act);
- The Biodiscovery Entity (licensor under the head BSA) will be fully responsible for all the acts or omissions of the licensee (with respect to the Native Biological Material);
- The licensee will pay milestones and royalties (if agreed) to the Biodiscovery Entity (licensor under the head BSA) who will account to the State. The licence must ensure that the State continues to receive an equitable share of benefits The State will receive one payment together with financial information to verify calculations;
- The licensee will report to the principal who in turn will report to the State (on matters to be set out in the head BSA);
- The licensee will be entitled to onward contract provided the onward arrangement is consistent with the above including the sharing of benefits; and
- The Biodiscovery Entity will report to the State in relation to each downstream arrangement entered into in relation to the Native Biological Material (this information may be provided as part of the Biodiscovery Register (if implemented) – see Section 11 of this Report).

The external driver to comply with these requirements exists in the form of the Nagoya Protocol. The State will not be able to issue International Certificates of Compliance in respect of these downstream arrangements in the absence of confirmation being provided that these conditions have been met.

This approach reflects the framework adopted by the Commonwealth in its *'Model Deed of Agreement in relation to Access to Biological Resources in Commonwealth Areas for Commercial or potential Commercial Purposes and Benefit-Sharing*' based on the requirement in Regulation 8A.08(g) requiring the benefit sharing agreement to include details regarding the 'agreed disposition of ownership of the samples, including details of any proposed transmission of samples to third parties'.

The NT Act in section 29(c) requires the same information to be included in the benefit sharing agreement (as Regulation 8A.08(g) of the Commonwealth Regulations). The Review has not had access to a model benefit sharing agreement from the Northern Territory and is therefore unable to comment or consider how this issue has been addressed in that document.

Although not a position adopted by the State under the current model, it is anticipated this change will provide greater comfort to Biodiscovery Entities as this model will not allow for

'double dipping' through the imposition through BSAs (in relation to the use of the same Native Biological Material).

If adopted this change would benefit from further explanation and examples to be included either on the department's website or in the code accompanying the Act.

Recommendation 21:

The Review recommends sections 35(2) and 54(2) and (3) be amended. The Review has determined that the State give consideration to adopting a licensing framework by which the head Biodiscovery Entity is permitted to enter into downstream arrangements in respect of the Commercialisation of Native Biological Material on certain conditions (as outlined in this Report). A breach of these conditions should be included in the offence provisions of the Act.

If the head Biodiscovery Entity (which has entered the BSA with the State) is not able to comply with the conditions– the downstream entity must enter into a separate BSA in relation to the use of the Native Biological Material with the State on the usual terms.

If this recommendation is adopted, the Review further recommends consequential amendments to the Model Benefit Sharing Agreement.

Recommendation 22:

The Review recommends the change in the benefit sharing framework be supported by further explanation and examples to be included either on the department's website or in the Updated Code accompanying the Act.

Benefit sharing framework – adaptability to different types of biodiscovery activities and entities and the range of pathways for commercialisation

The Review has given consideration as to whether the contractual framework of BSAs are adaptable to different types of Biodiscovery activities, entities and commercialisation pathways.

As noted above submissions have indicated that the current structure may be hindering entry into commercialisation arrangements due to the complexity and confusion in relation to the application of sections 35(2) and 54(2) and (3) of the Act.

The Review has concluded that the proposal set out above in Recommendation 21, is adaptable to various types of Biodiscovery activities, from individual companies to collection libraries and research institutes. The Review also notes that the State has considered this issue and holds several forms of Model BSAs which have been adapted to specific types of entities or institutions.

Despite the conditions on downstream arrangements (which are in broad terms consistent with an arm's length sub-licence arrangement), it is anticipated that this approach should encourage the entry into Commercialisation arrangements.

The Review also received feedback from stakeholders as to whether publically funded institutions (including those that are also subject to funding loan terms with the State) should be required to provide Benefits of Biodiscovery in the form of royalty payments to the State.

Further, the Review has given consideration to the New Brazilian Biodiscovery Law which exempts small companies, individual micro entrepreneurs and traditional farmers who do not exceed income thresholds. Similarly, exemptions apply to finished products the subject of a licence or intellectual property right. The Review does not consider this an appropriate measure to be adopted in the Act as it would serve to further limit the application of the Act in Queensland. A distinction can be drawn between the size of the Queensland biodiscovery

industry and that of Brazil where those mechanisms may be appropriate for commercial reasons and to reduce regulatory burden.

The Review has analysed the issues described in this Section of the Report and notes that the Act does not include an exclusion for those institutions. The view of the Review is that, subject to the conditions in the Act regarding BSAs, it is open to the State to negotiate the terms of BSAs (including Benefits of Biodiscovery to be provided) with each independent Biodiscovery Entity.

Recommendation 23:

The Review recommends the adoption of a contractual framework as described in Recommendation 21 (or similar), will enable the Act to be more adaptable to different types of biodiscovery activities, entities and pathways for commercialisation.

Recommendation 24:

The Review does not recommend any amendment to the Act in relation to Benefits of Biodiscovery to be provided by institutions (including those that are also subject to funding loan terms with the State).

8.5 *TOR 5* – Examination of the definitions in the Act and the need for the definition of any other terms

Throughout the consultation process, limited submissions were made in relation to the operation and scope of the definitions under the Act. Most stakeholders regarded the definitions (save for those outlined below) as sufficient and scoped appropriately in relation to biodiscovery activities.

Definition of 'Benefits of Biodiscovery'

The Schedule to the Act includes a definition of Benefits of Biodiscovery - the definition is an inclusive definition which provides guidance to Biodiscovery Entities and the State in administering the contractual BSA framework. The Review has considered the definition of Benefits of Biodiscovery in the Act and does not recommend any amendment to it.

Recommendation 25:

The Review does not recommend any amendment to the definition of Benefits of Biodiscovery.

Definition of 'Biodiscovery'

The Act defines Biodiscovery as follows:

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 considered the impact of this definition on the operation of the Act – in particular, whether the definition of Biodiscovery and Biodiscovery Research which limit the application of

the Act to research that is undertaken for the purpose of commercialising the Native Biological Material.

The definition of Biodiscovery has far reaching consequences in relation to the application of the Act and whether users of Native Biological Material fall within the scope of the Act for example:

- Section 10 of the Act provides that a Collection Authority authorises the taking and keeping of Native Biological Material for Biodiscovery; and
- Section 33(1) of the Act provides that the State (pursuant to a BSA) gives the right to use Native Biological Material for Biodiscovery.

This means that (subject to the exceptions in the Act in relation to when a BSA is required), a Biodiscovery Entity will not fall within the ambit of the Act (for the purposes of a Collection Authority or a BSA) unless engaging in or proposing to engage in Biodiscovery.

The Review has determined and has been informed by stakeholders that the critical element of the definition of Biodiscovery is the pre-requisite that it be undertaken for the purpose of Commercialisation of the Native Biological Material (as the reference to Commercialisation is present in both elements of the definition of Biodiscovery – in the definition of Biodiscovery Research and in subparagraph (b)).

The Review has determined that the Biodiscovery Entities which are undertaking research in relation to Native Biological Material and are unsure whether that research will be commercialised do not fall within the scope of the Act. As a result the State has not been able to trace that research to determine whether it develops into Commercialisation of Native Biological Material which would trigger a requirement for a Collection Authority and BSA under the Act. Historically, it has been suspected that those entities have been unlikely to meet their obligations under the Act, even when Commercialisation has commenced.

The linking of Commercialisation to the definition of Biodiscovery is also distinct from the approach of both the Commonwealth Regulations and the NT Act which do not incorporate a commercial pre-requisite into their regulatory framework (see Tables 1 and 2 annexed to this Report for further detail).

By broadening the definition of Biodiscovery so that it covers both commercialisation and research activities, the scope of the Act will be expand so that activities both commercial and research will be covered by the Act. This change in the definition is required for the proposed change in the permitting regime and circumstances in which a BSA is required (see Section 8.3 of this Report).

As a result of the delinking of Commercialisation from the definition of Biodiscovery, more entities (engaging in research into Native Biological Material) will be required to apply for Collection Authorities (as their activities will be covered by the Act) – this will increase the engagement of the Department with these entities and the industry generally. The proposed change is consistent with approach taken in both the Commonwealth Regulations and NT Act. A change in this approach means that administrators of the Act and the regulatory framework will be required to be fully appraised in relation to the proposed change.

The expansion of the Act in this way is also consistent with the requirements of the Nagoya Protocol which covers the 'utilization of genetic resources' which extends to 'research and development'.

In making this recommendation the Review is cognisant of the fact that making this change in the Act may require interdepartmental co-operation to formulate a consistent approach (before any final change is agreement). Consideration is likely required to be given (at a policy level) to the interaction between Collection Authorities and permits issued under other legislation.

The Review considers the delinking of Commercialisation from the definition of Biodiscovery can be achieved by deleting the words 'for the purpose of commercialising the material' from the definition of Biodiscovery Research. The updated definition of Biodiscovery Research will therefore be:

*'**Biodiscovery Research** means the analysis of molecular, biochemical or genetic information about Native Biological Material*'.

The Review did not receive submissions in respect of any other aspect of the definition of Biodiscovery.

Recommendation 26:

The Review recommends delinking commercialisation from the definition of Biodiscovery. This may be achieved by deleting ' for the purpose of commercialising the material' from the definition of Biodiscovery Research.

Exclusions of specific industries from the definition of 'Biodiscovery'

The Review is being undertaken at a time where the biodiscovery industry (which the Act has sought to cover) has continued to evolve.

Industry

Undertaking Biodiscovery begins with the collection of samples (of Native Biological Material in the context of the Act). It then involves Biodiscovery Research or Commercialisation of Native Biological Material or a product of Biodiscovery Research.

As described above, the Act provides a definition of what is considered to be Biodiscovery in order to fall within the ambit of the legislation. The current definition includes a requirement that there is a link to Commercialisation (as defined in the Act).

The impact of the definition of Biodiscovery means that in order for an industry to be undertaking Biodiscovery (as defined) within the scope of the Act - the activities are:

(a) An analysis of the information relating to samples taken from State land or Queensland waters; or

(b) Undertaken for the purposes of Commercialisation (that is, for gain); or

(c) Be Commercialisation of Native Biological Material or a product of Biodiscovery Research.

Commercialisation has no requirement to value-add, improve or vary the Native Biological Material, the only requirement is the use of the Native Biological Material for gain.

As a result, the biodiscovery industries covered by the Act include the following, provided the required link to Commercialisation is satisfied:

- Medical including the development of pharmaceuticals, tools in biomedical research, drug-screening and hygiene-monitoring, treatments and identification of human disease and medical conditions for example vaccines and antibiotics.
- Environmental including oil/mineral recovery, environmental protection, waste reduction, improved detergents, chemicals, stronger textiles.
- Agricultural including improved foods, pest control, plant and animal disease control, improved food production, new crop traits, propagation.
- Industrial including the use of living cells or enzymes in chemical transformations, to develop biofuels, biomaterials (for example the development of biopolymers from plants), products based on enzymes (for example to be used as pesticides) or the use of biomass to produce products including fuels.

This is not an exhaustive list.

Under the Act as it currently is drafted, a range of persons and entities may potentially be obliged to comply. It becomes a factual question as to whether a Biodiscovery Entity in one of these industries is involved in Biodiscovery.

If nursery propagators or gardening/landscaping businesses, purveyors of native/bush tucker, suppliers of native bees meet the criteria above including the Commercialisation element, then they are currently subject to the Act.

Some of the relevant entities involved in Biodiscovery have been broadly identified already.

The Queensland Government has established a Queensland Biotechnology Directory and has also produced material relating to Queensland life sciences. The entities involved in Commercialisation of Biodiscovery are an important subset of Biotechnology in Queensland. However, the persons and entities caught may be much broader than those recorded in this list.

Impact of delinking Commercialisation from Biodiscovery

A critical difference between the current Act and the proposed change to the meaning of Biodiscovery (with the removal of the requirement for Commercialisation from the definition of Biodiscovery Research) is that a range of entities currently involved in biodiscovery research will fall under the purview of the Act.

Research institutes, universities and Co-operative Research Centres and companies will become subject to the Act to the extent that they currently or, in the future, engage in Biodiscovery in respect of Native Biological Material from State land or Queensland waters and do not currently do so for the purposes of Commercialisation.

In this respect it is noted that this Report recommends that:

- Different treatment for applications for Collection Authorities by those seeking to commercialise and those not seeking to do so at the time of Collection Authority issue (see Recommendation 13); and

- An education process be undertaken to inform to assist in compliance with the Act (see Recommendations 17, 18 and 22).

Industry exclusions

The Review was also asked to consider whether specific exclusions for specific industries should be excluded from the definition of Biodiscovery.

The Review has not been able to determine a compelling reason to recommend a change to the definition to exclude specific industries from the application of the Act.

Further, the Review notes that:

- The exclusions of particular industries from the ambit of the Act does not reflect the application of the Nagoya Protocol which does not include exclusions for specific industries;

- The fact that specific industries (for example nurseries propagating Native Biological Material) have not historically complied with the Act may be a reflection of the fact that they have not been made aware of the Act and its requirements; and

- An approach (without numerous exclusions) is likely to provide greater scope to the State to collect important information in relation to the Biodiscovery industries as all industries conducting activities which fall within the scope of the will be required to comply.

Should the State wish to exclude particular industries or activities from the definition of Biodiscovery in the Act, a change in policy on this issue will be required.

Should the State wish to address the peculiarities of specific industries, it is open to the State to do so by negotiating tailored arrangements (in particular in relation to Benefits of

Biodiscovery to be provided) under specific BSAs with Biodiscovery Entities in those industries.

Consideration has also been given as to alternatives which may be adopted by the State if the State wishes to exclude (from the operation of the Act) specific activities which do not 'value-add' to the Native Biological Material (for example, the sale of snakes for recreation). This exclusion would be consistent with the Nagoya Protocol as it sits outside the definition of 'Utilization of genetic resources' in the Protocol which limits utilisation in part to activity involving research and development.

The Review considers that the exclusion of 'non value-add' activities from the operation of the Act in this way would (as noted above) require a policy change by the State.

If such a policy decision is made, and the State wishes to exclude 'non value-add' activities, the State may consider deleting the reference to 'Native Biological Material or a product of' from subparagraph (b) of the definition of Biodiscovery in the Act. The updated definition of Biodiscovery may read:

'Biodiscovery means-

(a) Biodiscovery research; or

(b) The commercialisation ~~of native biological material or a product of~~ biodiscovery research'.

Recommendation 27:

The Review does not recommend a specific exclusion for particular industries from the definition of Biodiscovery. However the State may wish to consider excluding 'non value-add' activities by amending subparagraph (b) of the definition of Biodiscovery.

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 face to face meetings, it was submitted that the definition of Commercialisation is too broad. It was argued that a more narrow definition would aid in clarifying the stage in which activities reach 'commercialisation'.

Specifically, concerns were raised by research institutions and universities that private and research funding would be captured under the definition. This issue was also raised in the previous review undertaken in 2009. It was argued that funding sources are constantly subject to change, with funding commonly being granted by non-government entities and charities. It was also noted that many academic publications receive funding, and this too may potentially be caught under the Act as a form of 'gain'.

These issues were raised in the context of section 54(3) of the Act which excludes educational institutions or individuals from that institution from the need to enter into a BSA in relation to non-commercial activities. The Review has made specific recommendations in relation to these exclusions later in this Report.

To provide research institutions and universities with greater clarity in relation to the application of the Act, the Review recommends that paragraph 2 of the definition of Commercialisation be amended to exclude private research grants.

The same recommendation was put forward to the State Government in the 2009 Review. The Government, in its response, supported the amendment 'in principle' noting that *'any confusion in relation to the definition can be clarified through stakeholder engagement activities'*.

Recommendation 28:

The Review recommends that paragraph (2) of the definition of 'Commercialisation' be amended to also exclude private research grants.

Definition of 'Native Biological Material' and 'Native Biological Resource'

The Schedule to the Act provides the following definition of Native Biological 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;*

(b) *a living or non-living sample of the organism or virus.*

As with the Commonwealth Regulations, the NT Act and international legislation (for example, the New Brazilian Biodiversity Law), human organisms are excluded from material governed by the regulatory framework.

Subject to the comments below, the Review does not propose any further amendments to the definitions of Native Biological Material or Native Biological Resource.

The structure of the definitions, specifically the use of the definition of Native Biological Resource within the definition of Native Biological Material serves to simplify the definition of Native Biological Material from the perspective of the reader. Further, should the definition of Native Biological Resource be deleted (with the wording being incorporated directly into the definition of Native Biological Material, then further consequential amendments to the Act will be required as Native Biological Resource is referenced separately in Sections 3, 4, 9, 44 and in the Long Title of the Act.

The Review considered the following issues with respect to the definition of Native Biological Material and Native Biological Resource:

- *sequenced genetic information and underlying data or information of Native Biological Material*

  It was submitted in a number of face to face meetings that the scope of the Act should be broadened to include the underlying data of the physical substance or Native Biological Resource sourced. It was argued that as data use is becoming more prevalent in traditional pharmaceutical development, there is a need for appropriate legislative protections.

  In this context the Review has also considered whether the definition of Native Biological Material should be extended to cover sequenced genetic information.

The Review examined this issue and notes:

(c) The definition of Native Biological Material does not specifically cover the underlying data, information or sequence of Native Biological Resources;

(d) Research has indicated that there has been no agreement internationally in relation to whether the definition of 'genetic resources' in the Nagoya Protocol extends to sequenced genetic information or underlying data (as noted in the 2015 United Kingdom Government response to the *'Consultation on implementing the Nagoya Protocol in the UK*');

(e) Despite the lack of clarity in relation to the application of the Nagoya Protocol, it is open to the State to include underlying data, information or sequences of Native Biological Resources in the definition of Native Biological Material;

(f) It is considered that in view of scientific developments and changes in the way information and data is accessed, the Act should cover the underlying data, information or genetic sequence arising from Native Biological Resources – in doing so it is hoped the State will limit the opportunity of Biodiscovery Entities to deliberately by-pass the Act;

(g) If this recommendation is adopted, the use of the underlying data, information or sequences will be governed by the regulatory framework of the Act; and

(h) If this recommendation is adopted, it is likely the permitting regime will need to be updated to account for the access and rights to use this intangible information. The Review recommends the State engage with providers of this information to determine the most appropriate regulatory framework to permit and record the use of this information.

- *Extracts of Native Biological Resources*

  The Review considered whether the definition of Native Biological Resource should be amended to specifically refer to 'extracts from samples'. For clarity, the Review recommends the definition of Native Biological Resource be extended to cover 'extracts from samples'.

- *Native Biological Resources sourced from ex situ collections*

  In its definition of 'bioprospecting' the NT Act includes a reference to samples 'maintained in an ex situ collection'. Industry trends have revealed that samples are increasingly accessed from 'collections' as well as directly from State land and Queensland waters. For clarity it is recommended that the definition of Native Biological Material be amended to ensure it clearly covers Native Biological Resources including Native Biological Resources 'maintained in an ex situ collection'. If this recommendation is implemented, the State may consider incorporating the NT Act definition of 'ex situ collection' set out in section 5(4) of the NT Act. The State may also wish to consider whether to apply this recommendation prospectively to existing collections rather than retrospectively.

- *Exclusions - genetically modified organisms and plant breeders rights*

  Both the Commonwealth Regulations (Regulation 8A.03) and the NT Act (section 5) specifically exclude:

  - A genetically modified organism for the purposes of section 10 of the *Gene Technology Act 2000 (Cth)*; or
  - 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)*.

  These exclusions are not currently incorporated into the Act. The Review is informed that these exclusions were implemented in the Commonwealth Regulations as the genetically modified organisms and plant varieties in respect of which plant breeders rights have been granted are separately regulated by specific regulatory frameworks and are

therefore no longer Native Biological Material falling within the scope of the Act. For clarity and consistency with the Commonwealth Regulations and NT Act, the Review recommends these exclusions be incorporated into the definition of Native Biological Material.

- *Exemption for specified Native Biological Material or collections*

  Regulation 8A.05 of the Commonwealth Regulations provides that the responsible Minister may declare that the provisions in Part 8A of the Commonwealth Regulations (Access to biological resources in Commonwealth areas) not apply to specified biological resources or a specified collection of biological resources (including future additions to the collection) on grounds (among others) where use of the resources is required to be controlled under any international agreement to which Australia is a party.

  The Review was informed that this process is important in respect of material which is controlled under treaties for example the International Treaty on Plant Genetic Resources for Food and Agriculture, to which Australia is a signatory.

  This is also likely to be relevant in relation to free trade agreements. The Commonwealth of Australia is a party to a number of free trade agreements including with the United States of America, Thailand Singapore, New Zealand, Chile, ASEAN – and said, Malaysia, Korea, Japan and China.

  It is open to make a specific determination at the time of amendment to include particular named agreements (including free trade agreements or treaties) which would fall under this category. However, the Review considers it would be preferable to enable the Minister to determine which international agreements or treaties on a case by case basis.

  The free trade agreements typically provide that the regulatory framework of parties to the agreement (and for Australia, its States) not discriminate against the free trade partner. The Act as currently drafted and as modified to conform with the Nagoya Protocol it is generally not discriminatory in nature but, to the extent possible, there should be a discretion retained under which the Queensland Government so the Minister can exercise discretion to provide for exceptions.

  In doing so, the structure will continue to reflect the Commonwealth Regulations in relation to the issue and the Minister will retain the flexibility to determine whether the exclusion from the Act will apply to permitting and the entry into a BSA or the other.

- *Education regarding application of framework*

  The Commonwealth Regulations and NT Act contain specific inclusions and exclusions regarding the activities covered by the Act. In order to maintain the simplicity of the definitions the Review does not consider the Act should be amended to reflect this additional detail in the definitions.

  In reaching this conclusion the Review took into consideration the fact that no submissions were received which challenged the definitions of Native Biological Material or Native Biological Resources. In fact stakeholders contended that the Act was easier to navigate than other state and territory frameworks.

  However, the Review considers it would be beneficial to include some clear examples of the activities and material which would be covered by the Act in the Updated Code (see Recommendation 5).

- *Value for humanity*

  It has been also noted by the Review that the Commonwealth Regulations and NT Act incorporate a concept of 'value for humanity' in relation to resources and use thereof governed by the relevant legislation. This reference appears to be derived from the definition of 'biological resources' in the CBD. This qualification is not used in the definition of Native Biological Resources in the Act.

'Genetic resources' governed by the Nagoya Protocol are defined as "means genetic material of actual or potential value' (Article 2 of the CBD). The definition is not qualified by value to 'humanity'. In seeking consistency with the Nagoya Protocol the Review does not consider that the definition of Native Biological Resources should be qualified by a concept of 'value for humanity'.

Recommendation 29:

The Review recommends the State give consideration to extending the definition of Native Biological Material to cover underlying data, information or sequences of Native Biological Resources.

Recommendation 30:

The Review recommends the State engage with providers of the underlying data, information or sequence to determine the most appropriate regulatory framework to permit and record the use of this information.

Recommendation 31:

The Review recommends the State give consideration to extending the definition of Native Biological Resource to include 'extracts from samples' in subparagraph (b) of that definition.

Recommendation 32:

The Review recommends the State give consideration to extending the definition of Native Biological Material to include Native Biological Resources 'maintained in an ex situ collection'.

Recommendation 33:

The Review recommends the State give consideration to excluding from the definition of Native Biological Material the following:

- *A genetically modified organism for the purposes of section 10 of the Gene Technology Act 2000 (Cth) or consistent state or territory legislation; or*
- *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).*

Recommendation 34:

The Review recommends the State give consideration to including some clear examples of the activities and material which would be covered by the Act in the Updated Code.

Recommendation 35:

Consistent with the Commonwealth Regulations, the Review recommends the State give consideration to enabling the Minister to declare that the Act or part thereof not apply to specified Native Biological Material or a specified collection of Native Biological Material (including future additions to the collection) where use of the resources is required to be controlled under any international agreement or treaty to which Australia is a party.

8.6 ***TOR 6*** **- Examination of powers of the Act to allow effective and appropriate enforcement of compliance with the Act**

The Review has considered the powers of the Act in relation to enforcement of compliance and is of the view that they remain effective and appropriate in the circumstances. The Review did not receive any submissions from relevant stakeholders on this point.

Appendices 4 and 5 provide a comparative analysis of the offence and enforcement provisions under the Act, the NT Act, Commonwealth Regulations and also internationally.

Offence Provisions

General

The offence provisions are set out in Divisions 1 to 3 to Part 7 of the Act, and include offences about compliance with Collection Authorities, Biodiscovery Plans and using Native Biological Material without a BSA. To date there has been no prosecutions under the Act.

As compared to the NT Act and the Commonwealth Regulations, in general terms the offence provisions under the Act are more substantial and carry greater penalties. For example, use of Native Biological Material without a BSA in place carries a penalty of a maximum of 5000 penalty units or the full commercial value of any commercialisation of the material (whichever is the greater) (section 54 of the Act).

In contrast, the breach of the terms of a permit or a benefit sharing agreement under the NT Act carries only a maximum penalty of 500 penalty units (Sections 40 and 41 of the NT Act).

Arguably, the Act provides greater deterrence to non-compliance by potentially stripping infringers of their commercial gains. Criminal sanctions may also be imposed where a person has collected material regulated under the *Nature Conservation Act 1992* (Qld) for Biodiscovery without the required Collection Authority (Section 50(1) of the Act).

The penalties for breach under the Act are also commensurate to other legislation regulating natural resources including the *Mineral Resources Act 1989* (Qld) and *Petroleum and Gas (Production and Safety) Act 2004* (Qld).

In order to give detailed consideration of this issue, the Review undertook a limited comparison of the offence and enforcement provisions of the following jurisdictions with the Act:

- Northern Territory;
- Commonwealth;
- Switzerland;
- European Union; and
- Brazil.

As noted previously, these comparisons are set out in Appendices 4 and 5 of the Report. Our summarised comments are set out below.

NT Act

In comparison to the Act, the enforcement provisions in the NT Act are very limited and principally relate to bioprospecting under the NT Act except in accordance with a permit registered with the CEO (Section 38 of the NT Act), the giving of false information (Section 39 of the NT Act) or the breach of permit conditions or benefit sharing agreement (Sections 40 and 41 of the NT Act).

Commonwealth

There are limited offence provisions provided for under the Commonwealth Regulations. Part 8A.06 provides that it is an offence to access biological resources without a permit.

Commonwealth – proposed Nagoya Protocol response

In order to meet the obligations prescribed under the Nagoya Protocol, the Commonwealth Government (as set out in the Commonwealth Nagoya Model) is proposing to introduce a number of offence provisions.

For example, it is proposed that it will be an offence to use illegally acquired genetic resources and/or associated indigenous knowledge, where such use is reckless to the source and in contravention of provider measures under the Nagoya Protocol unless:

- Due diligence was conducted in accordance with an agreed code of conduct; or
- On the evidence it is reasonable to believe the genetic resources / indigenous knowledge was legally obtained.

As noted above the Act already includes detailed offence provisions relating to the taking of Native Biological Material without a Collection Authority and use of Native Biological Material without a BSA.

The Review notes the offence provisions in the Act should be updated to reflect the proposed amendments to the Act regarding indigenous knowledge (in particular the requirement for prior informed consent on mutually agreed terms). This is consistent with the approach the Commonwealth is proposing to adopt in line with the Nagoya Protocol.

Switzerland

Article 24 of the NCHA provides a number of criminal law sanctions. These include a fine of up to 100,000 francs where a person intentionally fails or provides false information when notifying authorities of compliance with the due diligence requirement. The court may also order publication of the judgment.

It should be noted that in the European Union the offence provisions are regulated at state level.

Brazil

The administrative sanctions which may be levied in Brazil include the provision of a warning, imposition of a fine or seizure of samples, instruments used in obtaining or processing genetic resources or associated indigenous knowledge and temporary suspension of manufacture and sale of the finished product or reproductive material derived from the access to genetic resources and associated indigenous knowledge (Article 24 of the New Brazilian Biodiversity Law).

The New Brazilian Biodiversity Law goes further than the Act in including the right to suspend manufacture and sale. Providing this power is enforceable and is actually enforced by the Brazilian authorities, this provision would provide a significant incentive for compliance (as distinct from the right under the Act to strip infringers of their commercial gains (Section 54(1)(b) of the Act)).

However, the Review does not consider it necessary to include such an extensive power in the Act in view of the existing offence and monitoring provisions.

Enforcement Provisions

General

The enforcement and monitoring provisions are contained in Part 8, Division 1 of the Act.

This Part provides that the Chief Executive or DSDI (now DSITI) Chief Executive may appoint an inspector to investigate breaches or likely breaches of the Act. The relevant inspector is provided with broad powers including, powers of entry, powers to stop and search vehicles and powers to search, inspect and seize likely offending materials. These powers are specific to the Act and have not been incorporated or replicated in the NT Act or Commonwealth Regulations. In this respect, the Act provides a more comprehensive enforcement and monitoring regime than other comparable legal frameworks in Australia.

However, the Review notes that these enforcement and monitoring provisions will need to be updated to reflect the compliance measures required by the Nagoya Protocol. Examples of these enforcement measures are set out in the Swiss and European Union approaches are summarised in Appendix 5 to this Report.

The structure implemented by Switzerland and the European Union adopt a 'checking system' by way of required notifications of compliance for the purposes of the relevant legislative framework and also to permit compliance to be notified to the ABS Clearing House.

Commonwealth and Northern Territory

The enforcement powers in the Act have not been incorporated or replicated in the NT Act or Commonwealth Regulations. In this respect, the Act provides a more comprehensive enforcement and monitoring regime than other comparable legal frameworks in Australia.

Commonwealth - proposed Nagoya Protocol response

In conjunction with the offence provisions, the Commonwealth (in the Commonwealth Nagoya Model) is proposing to provide enhanced audit powers to the Commonwealth to monitor for potential breaches of an offence (in the nature described above) in relation to the use of genetic resources and/or indigenous knowledge. This would be through a "risk based approach". A person or institution in good standing with the relevant code of conduct would be regarded as "low risk" for audit purposes.

The current audit powers of inspectors in Part 8 of the Act reflect the proposal by the Commonwealth to provide audit powers to meet Nagoya Protocol requirements.

The Review considers that the existing provisions in Part 8 of the Act providing audit powers to appointed inspectors may be able to be expanded to enable monitoring of compliance with new measures to be included in the Act in particular in relation to the incorporation of indigenous knowledge in the Act.

Switzerland

In Switzerland, the Confederation (i.e. the Federal Office for the Environment (**FOEN**)) serves as a centralised checkpoint to which compliance with the due diligence requirement must be notified before market authorisation can be granted, or before commercialisation (if market authorisation is not required) (Article 23o NCHA). Other federal agencies may also be delegated the responsibility of ensuring that notification of compliance has been made to the FOEN.

Further "checkpoints" are established in existing procedures to ensure that the necessary notification to the FOEN has taken place (e.g. in the authorisation procedure for pharmaceuticals). These checkpoints are arguably more effective and less burdensome administratively than systematic monitoring of companies at an "enterprise level".

Information relating to the due diligence requirement, including the name of the notifying person, the product to be commercialised, the utilised genetic resource and its source, may be then passed onto the ABS Clearing House and made publicly available. This increases the level of transparency in the due diligence process.

European Union

The European Union has implemented legislation that closely accords with the requirements of the Nagoya Protocol with respect to enforcement.

Articles 7 and 9 of the EU Regulation provide a number of obligations on the part of the competent authorities to monitor and check user compliance, including transmitting the relevant compliance information (in the form of an internally recognised certificate of compliance) to the ABS Clearing House.

Checks are to be carried out using a "risk based approach" and must be effective, proportionate and dissuasive in relation to the relevant offence. Ultimately, the degree and method for which enforcement is carried out is regulated at the implementation level by the individual Member States.

Recommendation 36:

As at the date of this Report, the powers of the Act allow enforcement of compliance which is effective and appropriate to the circumstances. However, the enforcement and monitoring provisions should be updated to ensure compliance with the broadening of the scope of the Act to cover indigenous knowledge and access to indigenous peoples' land.

For example, the powers of the Act may be expanded to cover:

- *audit in relation to prior informed consent and benefit sharing in connection with the use of indigenous knowledge and access to indigenous peoples' land;*
- *the right to request further information in relation to the provision of prior informed consent and benefit sharing in relation to the use of indigenous knowledge and access to indigenous peoples' land;*
- *the use of indigenous knowledge and access to indigenous peoples' land other than with prior informed consent and benefit sharing to be an offence under the Act; and*
- *the giving of false and misleading information regarding prior informed consent and benefit sharing in connection with the use of indigenous knowledge and access to indigenous peoples' land.*

These powers may facilitate further enquiries to confirm the accuracy of the information provided to the State for example in circumstances where the State, for various reasons, may consider the information provided to be unreliable.

The Act may also be amended to include offence provisions in relation to compliance with the Biodiscovery Register and also the giving of false and misleading information in connection with the Biodiscovery Register.

9 Regulatory burden

9.1 Terms of Reference 7 and 8

7. 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.

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

9.2 *TOR 7* - Examination of costs of the Act are reasonable and justified compared with benefits of the Act

It is critical for legislation and regulatory requirements to operate in such a way so that (as far as possible) the purposes and objectives of the Act may be met while not stifling productivity of the industry.

The Review received comments from stakeholders to the effect that the Queensland legislation was on balance easier to navigate than comparable legislation in other jurisdictions.

However, some stakeholders reported that the Collection Authority regime was challenging. Their concerns did not arise from the need to actually comply with a Collection Authority in the first instance but rather related to a lack of clarity and understanding around the process for applying for an authority, who to contact in relation to the authority and other practical aspects. The Review noted that these concerns related to management and administration of the Act rather than the fact that the Collection Authority process was in place as part of the Act's regulatory framework. See Recommendation 18 in relation to this issue.

Universities addressed the regulatory burden of having to comply with the Act including having to enter into benefit sharing agreements when discoveries have a very long pipeline. The Review has noted this issue and tried to clarify it by recommending an amendment to the definition of Biodiscovery (with respect to its link to commercialisation) and recasting the requirements of the entry into benefit sharing agreements (see Section 8.3 of this Report).

In response to Term of Reference 2 (Section 8.2 of this Report), the Review has recommended that the Biodiscovery Plan be removed from the regulatory framework of the Act. This recommendation was not made in response to submissions made in respect of this issue by stakeholders but was a determination made in view of the overall operation of the Act.

The Recommendations of the Review to cover non-commercial as well as commercialisation Biodiscovery (reflecting the Nagoya Protocol's extension to 'research') together with the requirements to upload information to the Biodiscovery Register is likely to increase the compliance costs for Biodiscovery Entities. The extent of the increase in compliance is unclear and may require further review after its implementation when any increase will be apparent. However, it is expected there will be substantial benefits for Biodiscovery Entities as these proposed reforms will enable the State to issue Biodiscovery Entities with International Certificates of Compliance for the purposes of the Nagoya Protocol. This will assist Biodiscovery Entities to engage internationally in relation to their activities in compliance with the international regulatory framework.

On balance, the administrative and compliance costs in the Act are consistent and no more burdensome than those of the Commonwealth Regulations and NT Act. Further, the compliance requirements in the Act reflect the existing and developing international approach in legislation.

Subject to the recommendations made in other sections of this Report, the Review is not aware of any matters which would make the current compliance and administrative costs unreasonable.

Accordingly, there is no apparent need to consider possible alternatives to legislation. Further, doing so would move away from the national and international approach to regulate in respect of the matters covered by the Act.

The Review notes that some of the recommendations arising out of the Review will lead to increased resourcing requirements for the State, for example: preparing the Updated Code, engaging in the educational process arising out of the proposed changes to the regulatory framework, establishing and monitoring the Biodiscovery Register (see Term of Reference 10) and implementing the administration requirements to ensure compliance with the Nagoya Protocol

In particular, the Review notes that while incorporating indigenous knowledge (including concepts of Indigenous people and Indigenous people's land) will ensure consistency with the Nagoya Protocol, this may lead to additional complexity and administration. From the Review's perspective, these outcomes are justified in the context of the international landscape and feedback received in relation to the importance of recognising indigenous contributions.

While the aspects described above will likely increase the administrative burden on the State, the proposed changes leading to the increased regulatory burden are either recommended to comply with the Nagoya Protocol or to promote workable compliance with the Act.

Recommendation 37:

Other than the changes recommended elsewhere in this Report which may impact on the administrative and compliance costs, the Review considers the current compliance and administrative costs are reasonable and justified.

9.3 *TOR 8* – Review the system of approvals and application of regulatory requirements commensurate to the level of risk

The Review has considered this issue in the context of the other recommendations made in respect of the Act. Recommendations of the reforms have also been made in the context of the overarching objectives of the reforms including to:

- Contemporise the Act so it reflects the evolution of new technologies which are likely to relate to the Act;
- Reflect the changing international landscape in relation to the implementation of the Nagoya Protocol;
- To the extent possible reducing the regulatory burden of the Act by removing unnecessary (and administratively intense) parts of the regulatory framework; and
- Streamlining processes in the Act to facilitate ease of reporting, information management and development of a stable regulatory environment for the Biodiscovery industry.

In light of the recommendations and comments in Section 8 of this Report, the Review does not have any further recommendations in relation to the approvals and application of the regulatory requirements of the Act in response to this Term of Reference.

10 Interface with other systems

10.1 Terms of Reference 9

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

10.2 Feedback from stakeholders

Limited feedback was received from key stakeholders in relation to the interface between the Act, Commonwealth Regulations and the NT Act. It was submitted by one stakeholder that there is a prevailing need for consistency across the jurisdictions, particularly in relation to the definitions of key terms and the permitting system in order to reduce overlap and compliance costs. It was also noted that generally greater consistency between the Act, Convention and the Commonwealth Regulations would be preferred.

The Review has made numerous recommendations in this Report aimed at improving the consistency between the Act, Commonwealth Regulations and the NT Act.

10.3 Interface between the Commonwealth Regulations, NT Act and the Act

Purpose

In general, all three legislative regimes seek to promote benefit sharing, the conservation of biological resources and the establishment of a regulatory framework for accessing biological resources.

However, the Act diverges from the Commonwealth Regulations in two principal ways:

(a) Indigenous knowledge is neither recognised nor protected under the Act; and

(b) The focus is on regulating the commercialisation of biological resources (i.e. the end point of the use) as opposed to the initial access and control of the resources.

The NT Act has mirrored the Commonwealth's approach and also recognises and protects indigenous knowledge.

These departures have been addressed in this Report including in Recommendations 8 and 26.

Scope of regulation

Arguably, the scope of the Commonwealth Regulations is wider than the Act because the definitions of biological resources do not refer to concept of 'commercialisation'. Furthermore, what constitutes a 'benefit' of biodiscovery is not specifically addressed in the Commonwealth Regulations or the NT Act. Under the Act, benefits may include broad economic, environmental or social benefits, together with monetary benefits.

Despite this, the Commonwealth Regulations and NT Act impose a number of limitations on its application, which are not reflected in the Act, including:

(a) Material/resources falling under the definition of 'biological resources' are required to have 'value for humanity'; and

(b) There are a number of specific exclusions in in respect of the taking of material by indigenous persons, or material which fall under *Gene Technology Act 2000* (Cth) or *Plant Breeder's Rights Act 1994* (Cth) .

The extent to which certain types of land are regulated under the access provisions of the Act, NT Act and Commonwealth Regulations also differ substantially. For example, the Act only

applies to State land, specifically excluding freehold land and land subject to a native title determination of exclusive possession (indigenous land). In contrast, the Commonwealth Regulations apply to indigenous land. The NT Act also applies to various types of freehold land, including indigenous land, land subject to leases and private land.

These issues have been addressed in this Report including in Recommendations 8, 11, 26 and 33.

Permits and Collection Authorities

Unlike the Commonwealth Regulations, the Act requires applicants to submit a proposed or approved Biodiscovery Plan (specifically identifying proposed Commercialisation activities) with the Collection Authority application. The Review considers this requirement to be administratively burdensome and practically ineffective, as in most cases, the commercial potential of a use may not be known at the initial collection stage.

Although not contained in a separate document, certain information is required under the NT Act in a BSA, which must be entered into before a permit is granted. The NT Act does not however include a specific requirement that information about commercialisation be provided at this stage (but the CEO may request this information to be provided).

These issues have been addressed in this Report including in Recommendation 12.

Benefit Sharing Agreements

Both the Act, the NT Act and the Commonwealth Regulations include the concept of benefit sharing agreements, with the designated collection authority/ permitting system being linked to those agreements. The key differences under the Act include the fact that BSAs:

(a) Have a more commercial focus (as opposed to the protection of indigenous knowledge and requirement for informed consent) and are limited to approved activities specified in the Biodiscovery Plan; and

(b) Can only be entered into with the State (whereas the NT Act covers resource access providers include the State and private landowners).

Please see Section 8.4 of this Report in relation to BSAs.

11 Changes to the legislation

11.1 Term of Reference 10

> 10. Recommend amendments to the Act, or alternatives to legislation, which improve the effectiveness, fairness, timeliness and accessibility of the regulatory system including any consequential amendments that are required such as repeal of S119 due to the recent passing of the Public Service and Other Legislation (Civil Liability) Amendment Act 2014. In recommending other options, provide evidence of the impact of the recommended options on the regulated community to allow comparison to the current legislation and if there were no regulation.

The earlier Sections of this Report set out those areas in which it is considered that amendments to the Act and regulatory framework would assist in improving the effectiveness, fairness, timeliness and accessibility of the regulatory system on the community following feedback from the community and from the Departments administering its operation.

Considerations of the Nagoya Protocol and its implementation have also been examined as part of this Review. Recommendations have been made which reflect the requirements of the Nagoya Protocol, for example with respect to indigenous knowledge, prior informed consent and mutually agreed terms (see Recommendation 8).

There are several additional aspects determined by the Review as important in relation to effectiveness of the regulatory system or for the purposes of compliance with the Nagoya Protocol (and in some instances both). These further aspects are set out in the Review's response to Term of Reference 10.

Genetic resources and traditional knowledge obtained outside Australia

Articles 15 and 16 of the Nagoya Protocol seek to regulate the use in its jurisdiction of resources (including associated traditional knowledge) obtained from other countries. This is not currently covered by the Act (see also Section 7.6 of this Report).

In practical terms this will mean that, International Certificates of Compliance will travel with the relevant resources to enable the competent authorities to determine whether those resources or traditional knowledge have been accessed in accordance with the Nagoya Protocol.

It is not yet clear how the Commonwealth proposes to address this issue including measures to address non-compliance as required by the Nagoya Protocol. The Review regards this as a matter to be determined in conjunction with the Commonwealth to ensure consistency of approach and implementation (whether through policy or regulation).

Recommendation 38:

The Review recommends the State engage with the Commonwealth to determine a consistent approach to compliance with Articles 15 and 16 of the Nagoya Protocol.

Checkpoints

The Nagoya Protocol requires measure to be taken to monitor and enhance transparency of resources. Article 17(1)(a)(iv) of the Nagoya Protocol provides that these measures include the implementation of one or more checkpoints.

According to Article 17(1)(a)(iv) the *'checkpoints … should be relevant to the utilization of genetic resources, or to the collection of relevant information at, inter alia, any stage of research, development, innovation, pre commercialization or commercialization'*.

The framework of the Act in granting Collection Authorities and BSAs acts as a checkpoint for compliance with prior informed consent and mutually agreed terms. The Review has also recommended checkpoints be included with respect to access on indigenous people's land and with respect to indigenous knowledge – see in particular Recommendation 8.

The Review has given further consideration of this requirement and its implementation in other jurisdictions and recommends that the following act as checkpoints (to establish provenance and prior informed consent on mutually agreed terms):

- At the time of application for Queensland Government funding for research using Native Biological Material and/ or associated traditional knowledge (consistent with the proposed Commonwealth approach);
- Issuing of Certificates of Compliance (from information lodged on Biodiscovery Register) – see below.

In order to comply with the Nagoya Protocol, these checkpoints should apply to Native Biological Material and genetic resources and traditional knowledge) obtained outside the scope of the Act (nationally and internationally). These checkpoints are likely to be able to be met through an International Certificate of Compliance which should travel with the resources.

In addition to the time at which research funds are received the EU Regulation identifies other checkpoints, for example at the time the final stage of utilisation, meaning at the stage of final development of a product before requesting market approval for a product developed via the utilisation of genetic resources or indigenous knowledge associated with such resources.

In Australia, it is likely that market approval for a product is regulated by Commonwealth legislation (for example for pharmaceutical products). The State should monitor any additional checkpoints proposed by the Commonwealth and should amend its requirements accordingly (to the extent they are effective within the Queensland regime).

Alternatively, it is open to the Commonwealth to implement a checkpoint (as is the case in Switzerland) at the time of patenting.

Recommendation 39:

The Review recommends the State consider the following act as checkpoints (to establish provenance and prior informed consent on mutually agreed terms) for the purposes of compliance with the Nagoya Protocol:

- *At the time of application for Queensland government funding for research using Native Biological Material (including if accessed from indigenous people's land) and/ or associated indigenous knowledge (consistent with the proposed Commonwealth approach);*
- *Issuing of Certificates of Compliance (from information lodged on Biodiscovery Register).*

In order to comply with the Nagoya Protocol, these checkpoints should also apply to Native Biological Material and genetic resources obtained outside the scope of the Act (nationally and internationally).

Recommendation 40:

The Review recommends the State closely monitor any checkpoints implemented by the Commonwealth.

International Certificates of Compliance

Queensland legislation including the Act requires a permit for collection and use of genetic resources. Subject to the extension of compliance with respect to indigenous land and knowledge (see Recommendation 8), the Review notes that the Collection Authority is likely to meet the standard required by the Nagoya Protocol.

Article 17(2) of the Nagoya Protocol confirms that the published permits will be recognised as International Certificates of Compliance - serving as evidence that the genetic resource which it covers has been accessed in accordance with prior informed consent and that mutually agreed terms have been established.

Subject to continued engagement with the Commonwealth, the Review considers that an International Certificate of Compliance may also be issued by Queensland based on the information included on the Biodiscovery Register (see below). Further consideration may also be given as whether Trusted Institutions (once accredited) will be able to issue their own International Certificates of Compliance.

The Commonwealth is yet to advise whether nationally consistent formats will be required for permitting documentation.

Although Australia has signed the Nagoya Protocol, it is not legally bound by its provisions until ratification occurs. However, this should not prevent International Certificates of Compliance from being issued before ratification. However, the Review notes that this approach should be confirmed within Government to ensure such an approach is consistent with the Commonwealth's response to ratification and associated processes.

Recommendation 41:

The Review confirms that subject to the extension of compliance with respect to indigenous peoples' land and indigenous knowledge (see Recommendation 8), the Review notes that the Collection Authority is likely to meet the standards required by the Nagoya Protocol. The Review recommends the State continue to engage with the Commonwealth in relation to the requirement for any standardised permits.

Biodiscovery Register

Consideration has been given by the Review to the implementation of a Biodiscovery Register to be maintained by the State.

This proposed register could function as a central repository for information regarding activities falling within the scope of the Act and could be made up of information which is both private and publically available.

It may be also be used as a register for information regarding activities outside the Act, such as private and public collections (see later).

Based on preliminary consideration by the Review, the Biodiscovery Register may operate as follows:

- Entry of required information - at a minimum:
    - Provider;
    - Proof of prior informed consent (for example permit under which material was collected – this may include Collection Authorities issued under the Act);
    - The person or entity to whom prior informed consent was granted;
    - Identification of the relevant resources or subject matter;

- Evidence in the form of an uploaded statutory declaration or equivalent that prior informed consent has been obtained and mutually agreed terms were established;
- Whether the use is commercial or non-commercial,

This information is the minimum required for the State to be able to issue an International Certificate of Compliance in accordance with Article 17 of the Nagoya Protocol.

- The State may also include other fields of information in order to effectively track activities and include fields to enable the reporting functions under the Act to be satisfied – for example, information relating to the material disposal report (Section 32 of the Act) or whether the relevant entity has received funding including non- Government funding for example private or philanthropic funding within Australia or from overseas and reporting in relation to activities being undertaken by the Biodiscovery Entity (with a view to tracking whether activities to determine when commercialisation is imminent or occurring).

- Compulsory entry of information by Biodiscovery Entities whose activities fall within the scope of the Act.

- Voluntary entry of information from other entities or individuals (including persons accessing material from private land or using material accessed internationally) who wish to obtain an International Certificate of Compliance. The Department will require at least the information described above to be able to grant an International Certificate of Compliance in relation to material accessed from private land – evidence of the prior informed consent as described above may include permits issued in relation to collection of material on private land under for example the NC Act or evidence of prior informed consent with private landowners.

The implementation of a register of this nature may eliminate the need for the public register described in section 18 of the Act.

If implemented the Biodiscovery Register be given legislative force in the Act including:

- Requiring Biodiscovery Entities undertaking Biodiscovery under the Act to upload specific information to the Biodiscovery Register (including for example ongoing reporting under the statutory declaration (or equivalent) for non-commercial use or under a BSA);

- Enabling the State to collect information voluntarily uploaded to the Biodiscovery Register by persons or entities which do not fall within the scope of the Act (for example those accessing material from private land or internationally); and

- Providing the State with the power to issue International Certificates of Compliance based on the information uploaded to the Biodiscovery Register to Biodiscovery Entities and persons/entities not falling within the scope of the Act as described above.

Collections and libraries

Further, if adopted, the Biodiscovery Register will provide a mechanism pursuant to which private collections or public collections (for example the Museum and the Herbarium) may be able to obtain International Certificates of Compliance with respect to their collections (until they become Trusted Collections).

Samples of Native Biological Material in existing libraries or collections will be able to be authorised by the State via the Biodiscovery Register.

The Biodiscovery Entities may upload the required information in relation to the samples of Native Biological Material held in their collections or libraries into the Biodiscovery Register. Provided this information meets the requirements for an International Certificate of Compliance including provenance, the State may issue an International Certificate of Compliance in relation to the relevant materials in the collection or library.

Even in the absence of a valid Collection Authority in respect of the Native Biological Material housed in collections or libraries, the operator of those collections or libraries may enter a BSA

with the State to Commercialise. Compliance with the requirements in the Act in relation to Collection Authorities may be dealt with under the enforcement provisions of the Act.

Should the register be implemented it should also be supported by appropriate enforcement provisions with respect of Biodiscovery Entities required to comply with the Act.

The Review is advised that the Herbarium and Museum maintain an existing internal database of collection users and other collection holders maintain similar databases. As part of the implementation of a Biodiscovery Register the Review contends that consultation be undertaken with these collection holders in relation to the development of the Register.

Recommendation 42:

The Review recommends the State further examine (i) the viability of the implementation of a Biodiscovery Register as outlined in this Report with supporting enforcement provisions, together (ii) the regulatory implications of establishing a Biodiscovery Register, including collecting information on the Biodiscovery Register and issuing International Certificates of Compliance to persons/entities covered by and outside the scope of the Act.

Trusted collections

In its *'Response to the Department of Environment Consultation on A Model for Implementing the Nagoya Protocol in Australia'* the Queensland Government supported in principle the recognition of trusted institutions that are accredited to provide genetic resources.

The Review is informed that the Commonwealth is working with interested collections to advance this framework. Organisations such as the Herbarium, Museum and other large collection holders would seem to be appropriate bodies (subject to an ability to comply with all the requirements) to be accorded the status of 'Trusted Institutions'.

While the Review supports the establishment of this structure but notes that (as is the case in the European Union), as a result of the need for consistency, these collections should be accredited based on a national accreditation framework. The EU Implementing Regulation has provided some further guidance as to accreditation of trust collections and their verification (see Section 7.5 of this Report).

This is another matter in respect of which it is recommended that the State maintain close consultation with the Commonwealth so that the State may assess and appropriately implement any regulatory structure, policy or administration required in Queensland with respect to trusted collections.

Recommendation 43:

The Review recommends the State maintain close consultation with the Commonwealth so that the State may assess and appropriately implement any regulatory structure, policy or administration required in Queensland with respect to trusted collections.

Other issues arising out of compliance with the Nagoya Protocol implementation

It is clear to the Review that there is an ongoing need for close and consistent engagement with the Commonwealth with respect to the implementation of the Nagoya Protocol for example to determine consistent administrative systems to provide notification in at the time permits are issued (Article 6(3)(e) of the Nagoya Protocol) and whether the systems will apply to resources and knowledge acquired after the Nagoya Protocol comes into effect in Australia.

Recommendation 44:

The Review recommends the State maintain close and consistent engagement with the Commonwealth with respect to the implementation of the Nagoya Protocol and its impact on implementation or regulatory and administrative frameworks and policies in Queensland.

Consequential amendments

Term of Reference 10 has also directed the Review to the *Public Service and Other Legislation (Civil Liability) Amendment Act 2014 (Qld)*.

The Review has considered the *Public Service and Other Legislation (Civil Liability) Amendment Act 2014 (Qld)* and to avoid any confusion recommends that section 119 of the Act be repealed.

Recommendation 45:

The Review recommends the State repeal section 119 of the Act.

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Appendix 1

Summary – Submissions and Face-to-Face Feedback

Summary of Issues

Submissions and Face-to-Face Meetings

Issue	Points raised/discussed
Publicly funded institutions	• (**General**) • One stakeholder suggested that a different regulatory system be implemented in relation to 'trusted parties' (for example statutory bodies). This system may include such things as standardized licensing terms. However, it was acknowledged that this could represent too much of a significant change at this point.

Extension to Private Land	• (**General**)
	  • The Review received submissions calling for the inclusion under the Act of biota samples collected on private land and land under native title.
	  • This would increase uniformity in relation to access conditions as between jurisdictions.
	  • It was submitted that the Act should stipulate minimum terms and conditions for Benefit Sharing Agreements between the State and private or traditional land owners.

Native Title and Traditional Knowledge	• (**General**)
	  • While the concept is largely supported and the value of traditional knowledge to the industry acknowledged, a number of stakeholders expressed practical concerns in extending the Act in this way.
	  • The inclusion of native title and traditional knowledge considerations was argued would add a degree of complexity to the existing transaction model.
	  • It was submitted that a framework for prior informed consent, benefit sharing and permitting system be adopted similar to that of the *Northern Territory Biological Resources Act 2006*. Specifically, the Act should incorporate the following provisions in relation to the content of a BSA:
	  • A statement regarding any use of indigenous people's knowledge, including details of the source of knowledge, such as, for example, whether the knowledge was obtained from the resource access provider or from other indigenous persons;
	  • A statement regarding the benefits to be provided or any agreed commitments given in return for the use of the indigenous people's knowledge;

Issue	Points raised/discussed
	• The details of any proposals of the applicant to benefit biodiscovery conservation in the area if access is granted; and • Details of the benefits that the resource access provider will receive in return for the taking of resources. • It was further noted that a substantive rights system approach should be adopted that could include: • Indigenous spatial identities (clan and clan family cultural mapping). • Customary governance and decision making underpinning genetic resources. • Land Use and occupancy mapping of genetic resources at relevant customary landscape scales regarding "relationships with a resource" and "control over access to a resource". • Documentation of genetic resource data within an Indigenous intellectual property framework. • Customary permit system established as part of the Act's permit approach through a 'competent authority' similar to the Northern Territory *Biological Resources Act* 2006.
	• (**Prior Informed Consent**) • Consultation process with traditional owners (where conducted) was noted as long, uncertain and quite difficult. A broad range of people needed to be consulted, with the potential for other groups or individuals to claim the same knowledge. • It was further noted that it is difficult to define an exact stage in which negotiations with traditional land-owners should be conducted, due to the different requirements and biological materials sourced for each activity. • It was proposed that collectors consult with only the respective Land Council's or individual traditional owners.
	• (**IP Protection for traditional knowledge**) • Traditional knowledge (namely its origins, transference and nature) is fundamentally incompatible with western constructs of intellectual property, making it difficult for traditional knowledge to be afforded any meaningful IP protections. E.g the focus of the Act is on material (physical) resources. • It was raised in a submission that the Nagoya Protocol is silent on IP and allows for exploitation of traditional knowledge by innovations registered through the patent system. • It was submitted that intellectual property, copyright and patent law fails to adequately represent the ways in which traditional knowledge is 'owned', recorded and/or shared and is deficient in protecting the confidentiality of information shared. Neither does it set out how research will proceed, who will own the IP of the research nor how the results can be

Issue	Points raised/discussed

	patented when traditional knowledge is involved.
	• The following was proposed in a submission:
	  • Establishment of a traditional knowledge database as a protective measure to ensure others cannot, without consent, obtain patents based on custodial knowledge (this could be incorporated into the Cultural Heritage database);
	  • Development of Biodiscovery community protocols to guide prior informed consent and facilitate involvement of Traditional Owners with bio prospecting entities (could follow the NICA model proposed by IP lawyer Terri Janke); and
	• Reform of related Acts such as the Cultural Heritage Act, Cape York Peninsula Heritage Act and Aboriginal Land Act to include provisions for protection of "bio-cultural" rights of Indigenous peoples.

Definitions	• (**General**) • Limited comments were made when this issue was raised in the face-to face meetings
	• (“**biodiscovery**”) • The definition of “bio-discovery” was noted by one stakeholder as appropriate and much clearer in comparison to other jurisdictions

	• (“**commercialisation**”)
	  • Comments were raised by three stakeholders in relation to the breadth of the definition of “commercialisation”. It was also submitted that it was not clear what amounted to a 'gain'.
	  • Concerns were raised that both private and public research funding (e.g from industry via research contracts) would be captured by the Act as being for “gain”.
	  • The Review received a proposal that the definition of 'commercialisation' should be triggered by income resulting from royalties or upfront payments less commercialisation expenses.
	  • Proposed that the definition specifically exclude private and public research funding.
	  • Funding sources constantly change and commonly come from non-government entities and charities. Academic institutions also receive funding that could be captured under the current definition.

Issue	Points raised/discussed
	• It was noted that a more narrow definition would aid in clarifying the "trigger point" under the Act for commercialisation. • One submission proposed the following inclusions to the definition of "gain": *"upfront payments, milestone payments, royalties, license fees, revenue from start up companies generated from the use of biological resources, but excluding donations, gifts, bequests, in kind/non-cash benefits and funds for further research (including private or industry funding/grants)*
	• ("**native biological material**") • It was raised in two face to face meetings that the Act should regulate not just physical samples of the biological resources, but also the underlying data from which synthetic products can be made. • Data use is becoming more prevalent in traditional pharmaceutical development and it was argued that there needs to be adequate legislative protections to cover the molecular advancements in this field.
Exclusions	• (**International treaties**) • The interaction between the Act and other international treaties e.g FAO Treaty was noted by one stakeholder to be unclear. • Under the FAO Treaty material is exchanged through standard material transfer agreements. If commercialisation is achieved, a 1.4% fee is required to be deposited into the FAO Trust Fund. • ("**fundamental research and education**") • One stakeholder proposed excluding general research, education and training activities from the requirements of the Act to reflect the rapidly changing nature of research funding (e.g funding from government or NGOs, philanthropic entities or industry) • (**"screening"**) • One stakeholder recommended that section 35(2)(a) of the Act be clarified to include 'screening' as an activity which may be undertaken while 'acting for the entity'.
Purposes	• (**General**) • The Act is seen as the forefront in the biodiscovery field from both a national and international perspective and is generally working well. • The Act provides a better-structured process than the Northern Territory *Biological Resources Act* 2006 and provides an

Issue	Points raised/discussed
	incentive for institutions and private companies alike to conduct their bio-discovery activities in QLD. • The regulatory burden of the Act is not high and it sets a reasonable set of requirements. • A submission was made to the Review proposing the inclusion of biocultural values in the objects of the Act, as starting point for acknowledgement of traditional knowledge and a foundation for a supporting legal framework. • It was further raised by one stakeholder in the face to face meetings that the purpose of the Act should be clarified as relating to only inter-country use of native biological resources but not intra-country and intra-state use of native biological resources.
	• (**Removal of regulatory barriers**) • It was widely held by participants in the face to face meetings that the objectives of the legislation should be focused on removing regulatory barriers to entry in a way that facilitates industry participation and attracts international investment. • The current legislation does not fully achieve these aims. There is a need to make the legislation more competitive internationally to create value for Queensland. • A number of stakeholders proposed the inclusion of monetary as well as non-monetary incentives to encourage overseas investment. • It was argued that this would alleviate some of the indirect costs incurred by overseas investors/partners in the supply chain (caused largely by Australia's geographical isolation).
	• (**Application of the Act**) • There was a general uncertainty across State and publicly funded entities (who have private commercialisation agreements in place) as to the interaction with the Act and requirement to have a BSA in place. • It was submitted that public organisations should not be subject to benefit sharing arrangements as they are inherently suited to benefitting the State. • Two stakeholders raised the point that the philosophical approach and objective of benefit sharing under the Act does not fit with these particular types of entities as the arrangements in place inherently benefit the State. • Layered royalty payments were considered to be a discencentive for commercialisation and research. One stakeholder advocated for a form of "reinvestment" of biodiscovery related income directly in biodiscovery research or other suitable fields, in lieu of royalty payments. It is argued that this would avoid the significant administrative and regulatory burden of having to account for income and royalties which would facilitate more immediate benefits to the State.

Issue	Points raised/discussed
	• There was a general misconception amongst these stakeholders that if they had private commercialisation agreements in place with the State, they were largely excluded from the requirements of the Act (including reporting and other non-monetary obligations). • Greater clarity required as to application of the Act to publicly funded or government affiliated bodies. • Educational programs to be set up to raise awareness of requirements
Appropriateness of regulatory framework	• (**General**) • There was general uncertainty amongst stakeholders as to which State Government department administers the Act and the relevant contact person to deal with. • (**Permitting**) • One stakeholder expressed the need for greater integration between State government departments, responsible for administering permits and the department responsible for administering the Act. For example, it was noted that the period granted for a Biodiscovery Plan is in some cases, different to the period of the underlying collection permit. • Greater intra-departmental awareness and knowledge of the permitting process was considered to be needed, particularly in relation to the biodiscovery permit, its timeframes and the authorisations required. • The research institutions noted that there is currently no coordinated approach at the institutional level, in applying for collection permits (i.e no central register). The collection objectives within the relevant departments of the institution were noted as too disparate to progress a uniform approach. • Collection permits for these institutions are generally applied for under the name of the institution, but carried out by the individual department. • Some stakeholders had little experience with the permitting system because they would obtain the material directly from a compound library and screen against the library's samples. • One stakeholder supported the continued joint permitting arrangement which covers both the Great Barrier Reef Marine Park and the Great Barrier Reef (Coast) Marine Park – these permitting arrangements do not extend to formal benefit sharing and proponent must resolve benefit sharing agreements prior to accessing the marine parks. • Section 17 of the Act requires a benefit sharing agreement be place before material can be taken under a collection authority. One stakeholder considered this was impractical as at the time of wishing to obtain a collection authority there is uncertainty as to whether the product of the biodiscovery research will be commercialised or not. It is therefore impractical to enter into a benefit sharing agreement at this time and for this to be a pre-requisite for collecting under a

Issue	Points raised/discussed
	collection authority. • Where there is existing legislation regulating collection of resources then that legislation should regulate collection and the focus of the Act should merely be on ensuring benefits are provided to the State when commercialization occurs. • Update Queensland Government website – include: a. contact details for department and relevant person/s b. General profile of biotechnology in Queensland i.e what the institutes and private companies have to offer – important for international investment and also cross- institutions collaboration • One submitter proposed the following: • specific examples to guide research institutes and universities involved in the sourcing and use of native biological material. The examples would assist entities in determining whether the Act applies. • flow chart /decision tree outlining the BSA process, royalty payments – this will aid in referring only those complex scenarios to DSITIA • Q&A section in the form of an online "yes/no" questionnaire as to the applicability of the Act in commonly encountered scenarios
Effectiveness of Collection Authorities	• This was generally not raised as an issue by the research institutions as they were not involved in sourcing the native biological material. They have long standing relationships with their partners (who hold the collection permits) • It was noted that formalizing a permitting system is the first step in creating valid and provable chain of title. This is particularly important for downstream partnerships.
Structure and effectiveness of Benefit Sharing Agreements	• (**General**) • Lack of enforcement and oversight of the BSA process. There is currently great difficulty in making sure applicants either commercializing, or at the stage of commercialisation, enter into a BSA. • It was raised in one submission that regulating the collection of native biological materials up front is problematic because it is difficult to ascertain when research becomes commercial. This stakeholder advocated for a wholly independent permitting/collection system (i.e application only through the Nature Conservation Act or other legislation). • They noted that the Act and associated BSA obligations should only be triggered once commercialisation has been achieved and should be focused solely on regulating this process (as opposed to the collection regime). It was submitted that this would reduce regulatory burden on the biodiscovery entity.

Issue	Points raised/discussed
	• One stakeholder recommended the entry into a head benefit sharing agreement with research institutions/universities as a whole rather than individual agreements.
	• (**Biodiscovery Plan**) • Comments in relation to this issue varied. • The Plan was described by some on the one hand as useful as it sets out important internal processes eg what the applicant is doing, why they are doing it, informing the State about applicant is doing, the spill over benefits which may arise and the contribution which is to be made to the community. • The template Biodiscovery Plan placed on the Queensland Government website was also found to be a useful, increasing accessibility and simplicity in the process. • On the other hand, the Plan was viewed as a hindrance to research as it requires entities to set out expected commercialisation outcomes, which is often difficult to assess • Concern was expressed by one stakeholder that the plan itself would need to be drafted quite broadly due to the breadth of activities it may need to cover in the future.
	• (**Multi-Layered Benefit Sharing Model**) • Concerns were raised in relation to the multi-layered model under the Act. It was noted that pharmaceutical companies want the freedom to operate and create international distribution networks. There is currently uncertainty about the terms of the BSA entered into with the State and the length of the process. • It was noted that the multi-layered model increases transaction costs and complexity (including from an accounting point of view when compared with sharing benefits through a single pathway). This in turn is a disincentive for pharmaceutical companies from investing in naturally based products (as opposed to the less risky synthetic products). • The multi-layered model also increases the resources required by the State to administer and negotiate these agreements • One stakeholder submitted that the mechanism by which royalties are obtained should not allow for 'double dipping' through the imposition on multiple licence holders or infrastructure funding loan terms. • A principal/agent model was proposed by one stakeholder which replaces multi-layered agreements with a licensing arrangement. It was argued that a licensing model would have the following benefits: (i) Easy and clear transactional structure - There would be a single point of engagement through a head entity (e.g at the

Issue	Points raised/discussed
	research institution level) and obligation to remit royalty payments, including those from all downstream participants. (ii) Clear rules as to what is to be licensed; and (iii) Risk of compliance falls on the head entity • It was proposed that the principal/agent model be implemented through an amendment to sections 34 and 54 to remove any interpretation of requiring the multi-layered approach and replacing it with a mandate the principal/agent approach. This could be achieved on the basis that the downstream participants would: (i) Explicitly acknowledge the biodiscovery is subject to the Act. (ii) Downstream participants will bear similar obligations to the principal entity. (iii) Ownership of samples will not be transferred to downstream participants but they will be granted a very specific right to use. (iv) Downstream participants may act as the exclusive commercialisation partner. (v) Downstream participant will pay milestones and royalties to the principal who will account to the State. The State will receive one payment from the principal together with financial information to verify calculations. (vi) Downstream participants will report to the principal who in turn will report to the State. (vii) Downstream participant will be entitled to onward contract provided the onward arrangement is consistent with the principal's biodiscovery plan and benefits shared with the principal which then shares them with the State.
	• (**Trigger Point for Commercialisation**) • One stakeholder noted that the trigger point for commercialisation and the associated benefit sharing process should be sufficiently set out in the regulations or the Compliance Code. • E.g Trigger point for one institution was whether the research resulted in a "stated disclosure" • It was raised in one submission that the appropriate point for entities to enter into a BSA is at the point when biological material or product discovery/research is about to be commercialized. This would reduce the regulatory burden on the entity.
Enforcement and Compliance	• (**Reporting Requirements**) • The Nagoya Protocol will have implications for the Act in relation to regulatory oversight and administration • One stakeholder noted that the administration arrangements under the existing legislation needed to be improved. To

Issue	Points raised/discussed
	properly regulate BSA's and associated royalty payments from all downstream participants, the government would need separate departments for reporting as well as well-versed accountants to verify royalty statements. • It was recommended by one stakeholder that (if a licensing model was to be adopted), there should be one collated report and royalty payment per annum provided by the "primary entity" to the State. • One stakeholder noted that there are significant collections of Queensland material already held outside the State (nationally and internationally) – the stakeholder queried how this would impact on compliance with the Act.
Consistency with other States, the Commonwealth and Internationally	• (**General**) • One stakeholder commented on the need for consistency across jurisdictions (particularly in relation to the definitions of key terms and the permitting system) to reduce overlap and compliance issues. • It was also noted that generally greater consistency of the Act with the Convention and the Commonwealth regime under the EPBC Act would be preferred. • (**International consistency**) • There is a need for clear alignment with the principles and objectives of the Nagoya Protocol, to make the legislation more attractive to overseas partners and investors. • It was noted that Australia should build upon its alliances e.g with NZ. A comparison was made to Asia, in which an already established network of benefit sharing is in place between countries such as Thailand, Japan and Malaysia. • The Act was seen to not fit with the intention of the Convention, namely the regulation of inter-country relationships (as opposed to intra-state relationships).

Appendix 2

Comparison of the Act to the Commonwealth Regulations

THOMSON GEER
LAWYERS

Comparison of the QLD Act to the Commonwealth Regulations

Environment Protection and Biodiversity Conservation Regulations 2000 (**Commonwealth Regulations**)
Biodiscovery Act 2004 (**QLD Act**)

Section	QLD Act	Reg	Commonwealth Regulations	Comments
Purposes				
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 of native biological resources. (2) The purposes are achieved mainly by providing for – (a) the following streamlined frameworks - (i) a regulatory framework for	8A.01	**8A.01 Purpose of Part 8A** For section 301 of the [*Environment Protection and Biodiversity Conservation Act 1999*], the purpose of this Part is to provide for the control of access to biological resources in Commonwealth areas to which this Part applies by: (a) promoting the conservation of biological resources in those Commonwealth areas, including the ecologically sustainable use of those biological resources; and (b) ensuring the equitable sharing of the benefits arising from the use of biological resources in those Commonwealth areas; and (c) recognising the special knowledge held by indigenous persons about biological resources; and (d) establishing an access regime designed to provide certainty, and minimise administrative cost, for people seeking access to biological resources; and (e) seeking to ensure that the social, economic and environmental benefits	Both the QLD Act and the Commonwealth Regulations have similar purposes including promoting the: - sharing of benefits; - establishing a regulatory framework for access; and - conservation of biological resources. However the significant difference is that the Commonwealth Regulations refers to the recognition of the special knowledge held by indigenous persons. Indigenous knowledge is not addressed in the QLD Act. A further significant difference is that the Commonwealth Regulations is directed towards 'control of access to biological resources' rather than commercialisation (emphasised in the QLD Act).

Section	QLD Act	Reg	Commonwealth Regulations	Comments
	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.		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				
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.	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	The QLD Act is focussed on the definition of 'biodiscovery' which includes research ('biodiscovery research') and 'the commercialisation of native biological material or a product of biodiscovery research'. Although the definition is split into 2 limbs both limbs embed a 'commercial' element, and a definition of commercialisation is provided (i.e. there is commercialisation where there is use for 'gain' with some very limited exceptions). The material which is the subject of the 'biodiscovery' is

Section	QLD Act	Reg	Commonwealth Regulations	Comments
	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.		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. (***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 that has actual or potential value for humanity.* ***native species*** *means a species:* *(a) that is indigenous to Australia or an external Territory; or* *(b) that is indigenous to the seabed of the coastal sea of Australia or an external Territory; or* *(c) that is indigenous to the continental shelf; or* *(d) that is indigenous to the exclusive economic zone; or* *(e) members of which periodically or occasionally visit:* *(i) Australia or an external Territory; or* *(ii) the exclusive economic zone; or* *(f) that was present in Australia or an external Territory before 1400.* Note: A reference to Australia or an external Territory includes a reference to the coastal sea of Australia or the Territory. See section 15B of the *Acts Interpretation Act 1901*.	'native biological material' which does not expressly include genetic resources (which is referred to in Regulation 8A.03(1)). By comparison, the Commonwealth Regulations refers to the 'access to biological resources' which expressly refers to 'genetic resources'. There are 2 fundamental differences between these corresponding definitions in the Commonwealth Regulations and the QLD Act, being: 1. the critical description of 'biological resources' in the Commonwealth Regulations requires the material to have 'actual or potential value for humanity' – the QLD Act does not incorporate this limitation; and 2. The Commonwealth Regulations definitions do not refer to the concept of 'commercialisation' in its definitions of 'biological resources'. The Commonwealth Regulations refer to 'potential commercial product development' in the example of 'access to biological resources', however, 'commercial purposes' are not included in the main part of the definition. The absence of this reference is a significant distinction from the QLD Act's and requirement of commercialisation

Section	QLD Act	Reg	Commonwealth Regulations	Comments
			(2) A person is taken to have access to biological resources if there is a reasonable prospect that 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); (d) the taking of public resources for a purpose other than a purpose mentioned in subregulation (1); (e) the taking of a biological resource that is: (i) a genetically modified organism for the purposes of section 10 of the *Gene*	for 'biodiscovery'. In addition, subregulation (3) includes a long list of exclusions to the definition of 'access to biological resources' including the taking of biological resources by indigenous persons for specific purposes. Subregulation (4) elaborates on the taking of public resources and what that means. If the resources listed in (4) are taken for purposes other than those listed in subregulation (1), it does not constitute 'access to biological resources'. See comments below in this table in relation to the exemption for 'access to biological resources specified in a declaration under regulation 8A.05'. Other than a specific exclusion with respect to 'land subject to a native title determination granting rights of exclusive possession' (in the definition of 'State Land'), the QLD Act does not include any specific exclusions with respect to the taking of material by indigenous persons (3)(a) as is the case in the Commonwealth Regulations. The QLD Act also does not exclude the taking of material which fall within the Gene Technology Act 2000 or Plant Breeder's Rights Act 1994 or other regimes (see 8A.05). There is some overlap between the QLD Act and the Commonwealth

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			Technology Act 2000; 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;* (iii) access to biological resources specified in a declaration under regulation 8A.05. (4) For paragraph (3)(d), taking of public resources includes the following activities: (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.	Regulations as to what can and cannot be collected. Both exclude the collection of material of human origin/remains. The QLD Act includes a broader definition of the nature of the research to be undertaken as it includes a reference to 'molecular' information which is not specifically covered in the Commonwealth Regulations.

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Schedule	***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.	8A.04	**8A.04 Meaning of access provider** (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 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	There is a significant difference between the QLD Act and the Commonwealth Regulations in the context of the definition of the land to which the Commonwealth Regulations apply and the relevant access provider for the purposes of the regulations. Under the QLD Act the State of Queensland will always be the provider of access as the QLD Act only applies to State land which specifically excludes freehold land and land subject to a native title determination granting rights of exclusive possession (indigenous land). However, the position is different under the Commonwealth Regulations. The application of the Commonwealth Regulations means that the access provider may be the Commonwealth or another party, depending on who owns or controls access to the land. There is a provision for multiple Access Providers for the one piece of land. It should also be noted that the Commonwealth Regulations do not go as far as the Biological Resources Act 2006 (NT) as the Regulations do not extend to private land except to the extent there is a connection to the Commonwealth (for example a lease but only where the Commonwealth has a usage right in relation to the land that entitles the lessee to control

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			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.	access to the biological resources in and on the land – see Regulation 8A.02).
		8A.02	**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	

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			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?* (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;	

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			(d) the coastal sea of Australia or an external Territory; (e) the continental shelf, and the waters and airspace over the continental shelf; (f) the waters of the exclusive economic zone, the seabed under those waters and the airspace above those waters; (g) any other area of land, sea or seabed that is included in a Commonwealth reserve. *Territory Land in 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	

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			4 of the *Coastal Waters (Northern Territory Title) Act 1980*; and (c) the subsoil under the seabed described in paragraph (a) or (b); and (d) any water and airspace over seabed described in paragraph (a) or (b).	
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 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		**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.* Unlike the QLD Act which includes a clear description of what may constitute a benefit of biodiscovery, the Commonwealth Regulations do not specifically outline what may amount to a benefit (other than as detailed in Regulation 8A.08). Regulation 8A.08 does require benefit-sharing arrangements to be reasonable and to include protection for, recognition of and valuing of any indigenous people's knowledge. The benefit-sharing agreement must include (as separate aspects): - statement of benefits in return for the use of indigenous people's knowledge (Regulation 8A.08(i)); and

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	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.			- details of the benefits the access provider will receive for having granted access (Regulation 8A.08(l)).
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**	Neither the Commonwealth Regulations or the enabling Act (Environmental Protection and Biodiversity Conservation Act 1999) provide a definition of 'commercialisation' or 'commercial' purposes. The absence of this definition in the Commonwealth Regulations reflects the distinction between the QLD Act and the Commonwealth Regulations – with the QLD Act seemingly placing an emphasis on commercialisation and commercial purposes as a theme through the QLD Act. The Commonwealth Regulations acknowledge the difference between commercial and non- commercial purposes, but do not elaborate on commercialisation as part of the access to biological resources process.
Permits and Application Procedure				
10	**10 What collection authority authorises**	8A.06	**8A.06 Access to biological resources**	A person must apply for a permit

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	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.		**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.	pursuant to Part 17 of the Commonwealth Regulations to obtain access to biological resources in a Commonwealth area to which Part 8A applies. The QLD Act refers to a collection authority authorising 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.
11	**11 Procedural requirements for application** (1) An application for a collection authority 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;	8A.06 8A.15 – 17 17.02(2)	**Regulation 8A.06** points to Part 17 of the Act. **Regulation 17.02(2)(ga)** – the application for the permit under Part 8A must include the following information: (i) whether the relevant purpose is commercial or non-commercial; and (ii) the name of each access provider or, if an access provider for the biological resources is the Commonwealth or a Commonwealth agency, the name of the Commonwealth Department or Commonwealth agency that administers the Commonwealth area in which the access is proposed; and	<u>Queensland</u> In addition to other information in relation to material to be collected and identity of the applicant, the QLD Act requires a proposed or approved biodiscovery plan (identifying proposed commercialisation activities) to be provided with the application for a collection authority. The collection authority may be issued in the absence of a benefit sharing agreement in Queensland, 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

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	(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 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 Stateland or Queensland waters to which the application relates; Example— the real property description or geographic coordinates of the land or		(iii) the biological resources to which the applicant seeks access; and (iv) the amount of biological resources that is proposed to be taken; and (v) the use that is proposed to be made of indigenous people's knowledge in determining the biological resources to be accessed or the particular areas to be searched, and details of any agreements made with indigenous persons in relation to use of specialised information or information otherwise confidential to the indigenous people of the area; and (vi) the use the applicant proposes to make of the biological resources and how access will benefit biodiversity conservation within the area; and (vii) details of any other person for whose benefit access is sought or who proposes to use the samples obtained; and (viii) how the access is to be undertaken, including details of vehicles and equipment to be used; and (ix) whether the applicant thinks that further access to the biological resources will be sought; and (x) details of any other application by the applicant for a permit under this Part;	agreement has been entered into. <u>Commonwealth</u> Part of the application process under Part 17 requires the applicant to advise whether the relevant purpose is commercial or not commercial. Further, the applicant must advise the use that is proposed to be made of indigenous people's knowledge in connection with determining the biological resources to be accessed or areas to be searched and whether any agreement has been reached with the indigenous people of the area. There is a distinction under the Commonwealth Regulations as to whether the permit is to be issued for commercial purposes [see regulation 8A.15(2)] and applications for a permit for 'non- commercial purposes' [see 8A.15(3)]. ***Commercial purposes*** A permit must not be issued if the permit is to be issued for commercial purposes unless a benefit-sharing agreement(s) is in place, a copy has been provided and if the resources are in indigenous people's land – the owner has given informed consent for access to that land. By way of contrast, the collection authority under the QLD Act is able to be issued before a benefit sharing agreement is entered into but collections can not be made using

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	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 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.		**Regulation 17A03A(6):** For paragraph 17.03(1)(a), the requirements are: (a) for an application for access to biological resources for **commercial** purposes: (i) the applicant has entered into a benefit-sharing agreement for the biological resources with each access provider; and (ii) the applicant has given to the Minister a copy of each benefit-sharing agreement; and (iii) if the resources are in an area that is indigenous people's land and an access provider for the resources is the owner of that land — the Minister is satisfied that the owner has given informed consent to the benefit-sharing agreement; and (b) for an application for access to biological resources for **non-commercial** purposes: (i) the applicant has permission from each access provider for the area in accordance with subregulation 8A.12 (1); and (ii) the applicant has given to the Minister a copy of the statutory declaration required under regulation 8A.13; and (c) the Minister believes, on reasonable grounds, that some of the benefits of	that authority until a benefit sharing agreement is signed. Despite the timing of issue of the permit being slightly different, no collection can be made under the permit (for commercial purposes in the Commonwealth) or the collection authority (under the QLD Act which assumes a purpose of commercialisation) until a benefit sharing agreement is in place. ***Non-commercial purposes*** In addition to information requirements regarding biodiversity conservation etc, a pre-requisite for the issue of the permit for non-commercial purposes is the provision of a statutory declaration (among other aspects) stating that the applicant does not intend to use the biological resources, to which the application relates, for commercial purposes. Subject to the requirements being met, a permit may be issued and resources may be collected for non-commercial purposes. This authority may be similar to a collection under a scientific purposes permit in Queensland. As the QLD Act requires a clear connection with commercialisation for the collection authority to be granted (part of biodiscovery) then it seems a collection authority would not be issued for non-commercial purposes.

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	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; 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 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 Act 1959,* the chief executive must consult with any plantation licensee for a licence area in the State plantation forest when considering 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		access to the biological resources will, if practicable, be used for biodiversity conservation in the area from where the resources were taken; and (d) for proposed access in a Commonwealth reserve, access would be consistent with any management plan in operation for the reserve; and (e) for proposed access in Kakadu National Park, Uluru-Kata Tjuta National Park or Booderee National Park, access would be consistent with any lease of indigenous people's land in the park; and (f) the proposed access will, taking into account the precautionary principle, be ecologically sustainable and consistent with the conservation of Australia's biological diversity. *Note* For the meaning of ***precautionary principle***, see the Act, section 391. (7) In considering whether the requirement in paragraph (6) (f) is met, the Minister must consider whether the proposed access may adversely affect: (a) the conservation status of any species or population; or (b) any ecosystem or ecological community. **Division 8A.4 Assessment of applications** **8A.15 Assessment by Minister**	The Commonwealth Regulations are less prescriptive than the QLD Act as to the content of an application for a permit, but does include a public notice for assessment for controlled actions where there may be more than 'negligible' environmental impact.

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	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— ***licence area,*** in a State plantation forest, see the *Forestry Act 1959*, schedule 3, ***plantation licensee,*** for a licence area in a State plantation forest, see the *Forestry Act 1959*, schedule 3, **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 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		(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 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,	

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	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— (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.		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 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	

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			days); and (iii) publish on the Internet any documents relevant to public consideration of the proposed access and its environmental 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, www.deh.gov.au; and (c) in a daily newspaper that circulates throughout Australia. (3) The Minister must register any person	

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			who applies in writing for registration. (4) Registration has effect for the period specified in the notice.	
Benefit Sharing Agreements				
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. **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;	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. (2) If an access provider is the Commonwealth, the Secretary of the	Both the Commonwealth Regulations and the QLD Act require a benefit sharing agreement to be entered into for commercial purposes. Both frameworks require the benefit sharing agreement to detail the benefits to be provided. Commonwealth Regulations 8A.07 embed the connection with 'commercial purposes or potential commercial purposes'. The connection with commercialisation is not part of the description of 'access to biological resources'. By contrast, the QLD Act incorporates the reference to commercialisation at the grass roots level of the definition of 'biodiscovery' so the concept then flows throughout the QLD Act. Unlike the QLD Act, the Commonwealth Regulations do not include a concept of the biodiscovery plan and therefore the activities to be undertaken under the benefit sharing agreement are not limited to those approved under the biodiscovery plan (as the commercial activities listed in the plan become a condition of the agreement). The emphasis on the recognition,

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	(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. **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		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 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 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	protection and valuing of indigenous 'knowledge' in the formation of Benefit- sharing agreements is borne out in Regulation 8A.08. This approach is further highlighted in Regulation 8A.10 (requirement of 'informed consent' if the access provider is indigenous with the Minister having to make a determination as to whether appropriate informed consent has been provided. As noted previously, the QLD Act does not provide for the recognition of indigenous knowledge or for informed consent. 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 the QLD Act. The Commonwealth Regulations (8A.08(g)) also notes that the benefit sharing agreement must provide for the agreed disposition of ownership in the samples. This seems to be at odds with the QLD Act which clearly only grants a right to the biodiscovery entity to 'use' (rather than own) (Section 33(1)).

Section	QLD Act	Reg	Commonwealth Regulations	Comments
	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 (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).		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 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	

Section	QLD Act	Reg	Commonwealth Regulations	Comments
			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 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-	

Section	QLD Act	Reg	Commonwealth Regulations	Comments
			sharing agreement; (b) whether the access provider was given adequate time: (i) to consider the application for the permit, including time to consult with relevant people; and (ii) if the biological resources are in an area that is indigenous people's land and an access provider for the resources is the owner of the land, to consult with the traditional owners of the land; and (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 anybody performing the functions of a	

Section	QLD 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.* **8A.11 Requirement for permit** A benefit-sharing agreement takes effect only if a permit for the proposed access is issued under Part 17.	

Section	QLD Act	Reg	Commonwealth Regulations	Comments
Non-commercial purposes				
Part **7 Division 1**	**Division 1Offences about collection authorities and biodiscovery plans** **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. (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. **Division 2 Offences about benefit sharing agreements** **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	8A.12	**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 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.	<u>Queensland:</u> The QLD Act requires a collection authority to take native biological material for biodiscovery from State land or Queensland waters. To do so in the absence of a collection authority will trigger an offence provision (Section 50). Unless a person is: (a) classifying 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 (d) an educational institution for educational or training activities not involving commercialisation of the material, a person must not, unless the person is a party to a benefit sharing agreement, use native biological material for biodiscovery (otherwise the section 54 (offence provision) will be triggered.

Section	QLD Act	Reg	Commonwealth Regulations	Comments
	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; or (b) a registered higher education provider under the *Tertiary Education Quality and Standards Agency Act 2011* (Cwlth); or		(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 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	However, despite these exemptions in those circumstances a collection authority will still be required if person wishes to collect under the QLD Act. However, in the case of educational institution it is likely that (due to the lack of commercial purpose) the access would be achieved under a different permit. <u>Commonwealth:</u> The Commonwealth Regulations do not include exemptions in the same format as under the QLD Act. The Regulations draw a distinction between applications for a permit for 'commercial purposes' and applications for a permit for 'non-commercial purposes' Regulation 8A.13(e) requires a benefit-sharing agreement to be signed if access to biological resources is going to involve a commercial purpose.

Section	QLD Act	Reg	Commonwealth Regulations	Comments
	(c) a registered training organisation under the *National Vocational Education and Training Regulator Act 2011* (Cwlth).		collected for permanent loan; and (d) undertakes not to give a sample to any person, other than an institution referred to in paragraph 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.	

Section	QLD Act	Reg	Commonwealth Regulations	Comments
Providing samples to the State - Act				
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. (2) However, subsection (1) does not apply if the sample is held by the holder for the State under an agreement between the holder and the State. (3) The sample must be – (a) of a sufficient size and quality to enable scientific classification of the material; and (b) fixed and preserved in a way approved by the receiving entity; and		**Nil direct equivalent**	The QLD Act and the Commonwealth Regulations differ in this respect with the QLD Act requiring samples to always be provided to the appropriate 'receiving entity'. However, Regulation 8A.13(c) only requires the person to offer a sample to an Australian public institution that is a repository of similar specimens.

Section	QLD Act	Reg	Commonwealth Regulations	Comments
	(c) labelled in an appropriate way, including for example, by bar coding, stating – (i) the number, or other identification, of authority under which the material was taken; and (ii) the date on which it was taken; and (iii) if the holder is reasonably able to classify the material by using current scientific nomenclature – its classification to the lowest taxonomic level reasonably possible; and (iv) the geographic location from which the material was taken, including, for example, by reference to geographical coordinates. (4) If the sample is not labelled as required by subsection 3(c)(iii), the receiving entity may - (a) classify the material to the lowest possible taxonomical level, and (b) recover from the holder, as a debt, the costs reasonably incurred by the entity.			

Section	QLD Act	Reg	Commonwealth Regulations	Comments
Biodiscovery Plan - Act				
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 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		**Nil direct equivalent**	The Commonwealth does not include an equivalent concept as the biodiscovery plan in its access framework. By contrast, the biodiscovery plan is central to the regulatory framework in Queensland as it underpins the approval of the collection authority and benefit sharing agreement (only commercialisation activities in the approved biodiscovery plan may be undertaken under the benefit sharing agreement)

Section	QLD Act	Reg	Commonwealth Regulations	Comments
	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. (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. (c) The chief executive may require the information or document to be verified by a statutory declaration. (d) 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 without conditions; or			

Section	QLD Act	Reg	Commonwealth Regulations	Comments
	(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, 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;			

Section	QLD Act	Reg	Commonwealth Regulations	Comments
	(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 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				
	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 agency in a manner that is consistent with the purpose of	The Regulations also allow the Minister to give specific exemptions. There is no equivalent in the QLD Act. Therefore the QLD Act does not provide for a scenario where samples are collected and benefits shared pursuant to an international treaty which has been ratified by Australia.

Section	QLD Act	Reg	Commonwealth Regulations	Comments
			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). (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*.	

Appendix 3

Comparison of the Act to the NT Act

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Comparison of the QLD Act to the Northern Territory Legislation

Biological Resources Act 2006 (**NT Act**)
Biodiscovery Act 2004 (**QLD Act**)

Definitions				
Section	**QLD 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. See below Section 34 regarding the content of the benefit sharing agreement.	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, and must include the 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	The NT Act has a clear emphasis on reasonable benefit sharing including multiple provisions that require recognition and protection for indigenous people's knowledge (to the extent that the knowledge is obtained from an indigenous person or persons. The concept of indigenous knowledge is not currently addressed in the QLD Act.

Definitions				
Section	**QLD Act**	**Section**	**NT Act**	**Comments**
			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 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 was obtained from scientific or other public documents, or otherwise from the public domain.	

Definitions				
Section	**QLD Act**	**Section**	**NT Act**	**Comments**
Schedule Dictionary	***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 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; (viii) (viii)improved knowledge of the State's biological diversity or natural environment; and	Section 29(i)and (k)	(i) a statement regarding benefits to be provided or any agreed commitments given in return for the use of the indigenous people's knowledge. (k) Details of the benefits that the resource access provider will receive in return for the taking of the resources.	The 'benefits of biodiscovery' under the QLD Act reflects 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.* The definition of 'benefits of biodiscovery' in the QLD Act provides that benefits may include broad economic, environmental or social benefits (examples provided in the definition) together with monetary benefits. While the definition in the QLD Act is a broad 'includes' definition, the fact that the monetary and non-monetary benefits are listed in the definition may lead to a suggestion that the biodiscovery entity should provide both as benefits to the State. The NT Act has a less descriptive approach to what may constitute a 'benefit' as there is no specific definition giving any indication of the benefits which may be provided. However, section 29 provides that the benefit-sharing agreement must provide a statement as to the benefits to be provided in return for indigenous knowledge used and benefits to the resource provider.

Definitions				
Section	**QLD Act**	**Section**	**NT Act**	**Comments**
	(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)	"**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.	The NT Act treats the research ('biodiscovery') as separate to the taking for the purposes of research ('bioprospecting'). Any research to be undertaken (biodiscovery) must be for the purposes of discovering and exploiting resources of actual or potential value for humanity (see definition below). The QLD Act treats 'biodiscovery' as both the research and the taking of the sample for the research. The QLD Act separates the definition of 'biodiscovery' into 'biodiscovery research' and 'commercialisation of native biological material or a product of biodiscovery research'. Both limbs of this definition are connected to the concept of commercialisation including the definition of 'biodiscovery research' which must also be 'for the purpose of commercialising the material' (see definition below). This highlights the focus of the QLD Act on commercialisation. The QLD Act does not require the research conducted to be of value to humanity to fall within the definition of 'biodiscovery research'. The QLD Act does not specifically

Definitions				
Section	**QLD Act**	**Section**	**NT Act**	**Comments**
				refer to the use of 'extracts' of 'native biological material' as is contemplated by the definition of 'biodiscovery' in the NT Act. However, the QLD Act does refer to 'a substance sourced, whether naturally or artificially, from a native biological resource'
		Section 5	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: (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	The NT Act has a long list of what is not considered to be 'bioprospecting' for the purposes of the Act and is mindful of the indigenous population's traditional cultural activities. Other than a specific exclusion with respect to 'land subject to a native title determination granting rights of exclusive possession' (in the definition of 'State Land'), the QLD Act does not include any specific exclusions with respect to the taking of material ' from an area of land or water by indigenous people' as is the case in the NT Act. The QLD Act also does not exclude the taking of material which fall within the Gene Technology Act 2000 or Plant Breeder's Rights Act 1994 (as set out in para (f) of the definition of 'bioprospecting' in the NT Act). There is some overlap between the QLD Act and the NT Act as to what

Definitions				
Section	**QLD Act**	**Section**	**NT Act**	**Comments**
			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 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.	can and cannot be collected. Both Acts, through the definition of 'bioprospecting' (in the NT Act and through the definition of 'native biological material' in the QLD Act specifically exclude the collection of material of human origin. The definition of 'bioprospecting' in the NT specifically covers the taking of samples which are maintained in an *ex situ* collection (for example a sample bank). This concept is not specifically addressed in the QLD Act. The QLD Act includes a broader definition of the nature of the research to be undertaken as it includes a reference to 'molecular' information which is not specifically covered in the NT Act.

Definitions				
Section	**QLD Act**	**Section**	**NT Act**	**Comments**
			(3) The following activities, if undertaken for a purpose other than biodiscovery, also do not constitute bioprospecting: (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 resources exist within ecosystems and natural habitats within the Territory.	
	Nil direct equivalent	Section 4(3)	A resource has **value for humanity** if an extract or compound derived from the resource is used, directly or indirectly, with advantage in any field of human endeavour, whether agricultural, industrial, veterinarian, pharmaceutical or other.	The QLD Act does not incorporate this limitation on the definition of 'biodiscovery research' or 'commercialisation'.

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Definitions				
Section	**QLD Act**	**Section**	**NT Act**	**Comments**
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 QLD Act concept of the 'plan component' is included in the requirements of NT benefit-sharing agreement or approval process. This includes the requirements outlined in Section 37 (b), (d), and (e) of the QLD 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 benefit sharing agreement.
		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 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	In the NT Act, during the approval process, the CEO of the administering agency may request extra material to support the application for a permit, which may include the nature of the biodiscovery activities and a proposed timetable.

Definitions				
Section	**QLD Act**	**Section**	**NT Act**	**Comments**
			appropriate.	
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	The reference to 'samples' or 'extracts' in the NT Act definition are covered in the definition of 'native biological material' in the QLD Act. Unlike the NT Act, the QLD Act covers molecular information. The research in the QLD Act must be for the purpose of commercialising the material. However, under the NT Act there must be a 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 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.	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: (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").	There are no substantive differences in these definitions.

Definitions				
Section	**QLD Act**	**Section**	**NT Act**	**Comments**
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 example, a government grant.		**Nil equivalent**	The NT Act or Regulations does not focus or require commercialisation through biodiscovery or bioprospecting.
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 Section 24(2)(d) as to quantity. For the purposes of the issue of a Certificate of Provenance the NT Act requires that the biological resource was collected under a permit scheme intended to minimise negative impacts on biodiversity (Section 36(2)). The NT Act does state in its purposes that it is committed to promoting conservation of and ecologically sustainable use of biological resources.
Schedule	***native biological material*** means—			See comments below for

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Definitions				
Section	**QLD Act**	**Section**	**NT Act**	**Comments**
Dictionary	(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.			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.	Section 4(1)	"**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; and (c) an organism that has died.	The Queensland definition for "***native biological resource"*** encompasses part of the definitions of resources and organisms in the NT Act, but does not explicitly include genetic resources or 'populations and any other biotic component of an ecosystem'. The definition of 'organism' in the NT is addressed in part in the QLD Act definition of 'native biological resource' as follows: (a) a virus is referred to separately from an organism; and (b) an organism which has died is covered by the reference to 'living or non-living sample'. The QLD Act definition of 'native biological resource' does not refer to 'the reproductive material of an organism'.
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	Section 6	**Resource access provider** (1) Resource access provider, for biological resources in the Territory to which this Act applies, means the following:	This is a significant difference between the QLD Act and the NT Act. The NT Act includes the concept of

Definitions				
Section	**QLD Act**	**Section**	**NT Act**	**Comments**
	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.		(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 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	resource access provider rather than the concept of the State/ Territory only. The NT Act also applies to 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. The NT Act does not grant rights to the Territory to negotiate on behalf of the other landholders. However, it does set out the requirements which apply to the Territory and other landholders alike and provides that the bioprospector must comply with those requirements in relation to the other landholders in order to comply with the NT Act.

Definitions				
Section	**QLD Act**	**Section**	**NT Act**	**Comments**
			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)* *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.*	
Schedule Dictionary; Section 11	The relevant agency for the issue of a collection authority under the QLD Act is the department which administers the *Nature Conservation Act 1992*	Section 4(1)	"**permit issuing authority**" means any of the following: (a) the Agency responsible for issuing permits under the Territory *Parks and Wildlife Conservation Act*; (b) the Agency responsible for issuing permits under the *Fisheries Act*; (c) any other body as prescribed;	The NT Act contemplates a number of different agencies to whom applications for a permit may be made. There is no specific permit issued under the NT Act. The QLD Act provides that the department administering the *Nature Conservation Act 1992* will be responsible for issuing collection authorities under the QLD Act.
	Nil equivalent	Section 4(2)	A person is an indigenous person if the person is: (d) A member of the Aboriginal race of Australia; or (e) A descendant of an indigenous inhabitant of the Torres Strait Islands.	The QLD Act does not refer to indigenous persons.

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Purposes of the Act and General Provisions				
Section	**QLD Act**	**Section**	**NT Act**	**Comments**
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 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	Section 3	**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 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	Both the QLD Act and the NT Act have similar purposes and objects. Both Acts were enacted to: - facilitate biodiscovery/ bioprospecting; - establish a regulatory and contractual framework for the equitable sharing of benefits with resource providers (State or private); - promote the conservation of / taking of minimal quantities of resources; - attempt on a National basis to streamline principles and laws for biodiscovery/bioprospecting. The NT Act specifically refers to indigenous knowledge and the QLD Act explicitly refers to the CBD and the sovereign rights of the states over natural resources.

Purposes of the Act and General Provisions				
Section	**QLD Act**	**Section**	**NT Act**	**Comments**
	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.		Territory; (f) contributing to a nationally consistent approach to bioprospecting in Australia.	
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. (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			As above where NT 'Objects' are discussed.

Purposes of the Act and General Provisions				
Section	**QLD Act**	**Section**	**NT Act**	**Comments**
	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. (5) In this section – ***Convention on Biological Diversity*** means the convention – (a) opened for signature on 5 June 1992 at the United Nations Conference on Environment and Development (the Rio de Janeiro 'Earth Summit'); and (b) entered into force on 29 December 1993.			
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. **7. Relationship with other Acts** (1) This section applies in relation to any other Act to the extent the other Act— (c) requires a person to obtain a licence, permit or other authority to	**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 (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*	Section 7 of the QLD Act provides comfort in relation to potential conflicts between the permitting/ licence provisions under other legislation and the QLD Act such that a collection authority granted under the QLD Act operates so that another permit / licence is not required to take the same material for the same purposes under another act and does prohibit the taking of the material. Both the QLD Act and the NT Act apply to material (covered by each of the Acts) which are outside Queensland (for example, this confirms that QLD or NT samples in

Purposes of the Act and General Provisions				
Section	**QLD Act**	**Section**	**NT Act**	**Comments**
	take native biological material for which a collection authority may be issued under this Act; or (d) 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. **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		*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;* *(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:* *(a) the seabed vested in the Northern Territory under section 4 of the*	sample banks outside QLD/ NT remain subject to the relevant regulatory requirements under the Acts).

Purposes of the Act and General Provisions				
Section	**QLD Act**	**Section**	**NT Act**	**Comments**
	than this provision, if— (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.		*Coastal Waters (Northern Territory Title) Act 1980; and* *(b) the subsoil under the seabed described in paragraph (b); and* *(c) any water and airspace over seabed described in paragraph (b).* (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	**QLD Act**	**Section**	**NT Act**	**Comments**
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 (or the agency administering the *Nature Conservation Act 1992* at the relevant time). The application must be accompanied with information including the proposed or approved biodiscovery plan (Section 11(2)) or a benefit sharing agreement under the QLD Act (Section 11(3)). However, the EPA may refuse the application for a	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*) (Section 11). From there, if the permit issuing authority (Section 12(1)): (a) receives an application for a permit to take biological material; and (b) is satisfied, in terms of the authority's regulatory role, it would be appropriate to issue the permit; and (c) considers the applicant's proposed activity may comprise	The QLD Act requires a proposed or approved biodiscovery plan to be lodged with the application for a collection authority. Although not a separate document, similar information is required under the NT Act in the benefit-sharing agreement which is required to be entered into before the permit is granted. While a collection authority may be granted under the QLD Act without an approved biodiscovery plan, no material may be collected under the authority unless there is a benefit sharing agreement in place (which requires an approved biodiscovery

Permits and Application Procedure				
Section	**QLD Act**	**Section**	**NT Act**	**Comments**
	collection authority even if a benefit sharing agreement or approved biodiscovery plan is in place 9Section 14(4)). The EPA chief executive may ask for further information or documents required to decide the application (Section 13). The collection authority may only be granted if the proposed taking and use of the native biological material is for biodiscovery only and conforms with the compliance code and other collection protocols to the extent they are consistent with any conditions imposed (Section 14(2)). Only one application is necessary to cover a number 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 and the authority expires at the end of the term (Section 16(2)). If there is no Benefit- Sharing Agreement with the State, the authority lapses after one year (Section 16(4)). Native biological material is not permitted to be taken under a sample in the absence of a benefit-sharing agreement (Section 17(1)).		bioprospecting, the application is referred to the CEO of the administering Agency. If the application is referred to the CEO, the applicant must at this stage be advised that the application has been approved in principle and has been referred to the CEO for consideration in relation to bioprospecting matters (Section 12(2)). The CEO must considers the application with reference to various criteria and refers the approval or denial for 'bioprospecting' back to the original agency (Section13). The CEO may request various further information to support the application, including consultation with other government Agencies (for example the Commonwealth) (Section 14(1)). If the CEO considers the proposed activities may comprise bioprospecting the CEO may request information in relation to the proposed activities, proposed timetable and other details the CEO considers appropriate (Section 15). The existence of a valid benefit-sharing Agreement is a pre-condition for the grant of a permit (Section 18) and the CEO is responsible for entering the agreement on behalf of the Territory (Section 16). If no benefit-sharing Agreement is entered into (Section 18(1)): (a) the CEO must advise the permit	plan per Section 33). It is important to note that Section 37 of the QLD Act requires that the Biodiscovery Plan identify the proposed commercialisation activities. The NT Act does not include a specific requirement that information about commercialisation be provided at this stage however it is open to the CEO to request this information under the general power in Section 15). Under the NT Act a permit is not able to be issued unless a benefit-sharing agreement is in place. In a practical sense it seems at first glance that this means that both Acts lead to the same outcome – no material is able to be collected (for biodiscovery / bioprospecting purposes) in the absence of a benefit sharing agreement being signed. However, under both Acts material may be collected under permits under other legislation for other purposes (for example scientific purposes) with a benefit sharing agreement being entered into later on (see Section 30 NT Act) or before native biological material is able to be used for biodiscovery and subject to the exceptions in that section (Section 54 of the QLD Act).

Permits and Application Procedure				
Section	**QLD Act**	**Section**	**NT Act**	**Comments**
			issuing authority of that fact; and (b) the authority must decline to issue a permit. The reason that no Agreement was entered should be recorded in the register (Section 18(2)). A benefit-sharing Agreement must be with the informed consent of the land owner (called Resource Access Provider) (Section 27(3)). As per Section 19, if the resource access provider is not the Territory, the resource access provider and the applicant must confirm to the CEO that a benefit-sharing agreement that meets the requirements of this Act (Section 29) has been negotiated and is in place. The permit issuing authority may issue the permit (including any conditions imposed by the CEO) on receiving confirmation from the CEO that a benefit-sharing Agreement is in place (Sections 20 and 21). The authority must provide the CEO with details of the permit and conditions or advise why the permit is not to be issued (Section 22).	

Report and Accountability Requirements				
Section	**QLD Act**	**Section**	**NT Act**	**Comments**
Part 4, Division 1	**29. Identifying native biological material** (1) The holder of a collection authority must, as soon as practicable after taking 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.	Section 24	**24. When samples taken** (1) When the bioprospector has taken the biological resource samples, the 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.	The QLD Act in Part 4, Division 1 details a number of procedural requirements (not all excerpted) for the reporting of removal of materials and resources. The NT Act has a broader approach and is less prescriptive than the QLD Act.
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	Section 24(3)	(3) If it is a condition of the permit, the bioprospector must lodge samples of the biological resources taken with the Territory Herbarium or Museum of Arts and Sciences, as appropriate.	The QLD 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. However this is only required in NT if it is made a condition of the permit.

Report and Accountability Requirements				
Section	**QLD Act**	**Section**	**NT Act**	**Comments**
	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.			
		Section 25	**25. Information to CEO** (1) The permit issuing authority must provide the CEO with details of the samples taken. (2) The permit issuing authority must also inform the CEO if the authority has any concerns the bioprospector has not complied with any of the conditions under which the permit was issued.	
Section 27	The EPA chief executive must keep a register of collection authorities.	Section 26	**26. CEO to enter details in register** The CEO must enter in the register the details provided by the permit issuing authority.	This is generally consistent in both Acts with some aspects of the register being available to the public or for government purposes (Section 34 NT Act). The QLD Act makes specific provision for publicly available information on the register (Section 27(3) QLD Act).

Biodiscovery Plan				
Section	**QLD Act**	**Section**	**NT Act**	**Comments**
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**	Unlike the QLD Act, the NT Act does not include a concept of a biodiscovery plan. However, section 15 of the NT Act enables the CEO to request information in relation to the activities to be conducted with the material collected, timeline and other information the CEO considers appropriate. Some of this information is covered in the aspects required to be included in the biodiscovery plan in the QLD Act (see section 37). Unless the CEO specifically requests it at the time of considering the application for the permit under the NT Act, section 15 does not contemplate the provision of information relating to commercialisation and benefits of biodiscovery (as is required under the QLD Act). The information to be included in the biodiscovery plan under the QLD Act is much more comprehensive (see Section 37).
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.		**Nil equivalent**	Note Section 35(1) of the QLD Act which provides that 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

Biodiscovery Plan				
Section	**QLD Act**	**Section**	**NT Act**	**Comments**
	(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.			out are the activities detailed in the entity's current approved biodiscovery plan. This limitation is not included in the NT Act.
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; (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.		**Nil equivalent**	See comments above in relation to the content of the biodiscovery plan pursuant to the QLD Act. As noted above, pursuant to the NT Act, at its discretion the CEO may request information under Section 15 of the NT Act including the a plan for the research (biodiscovery) to be undertaken, the proposed timetable and any other information the CEO considers appropriate. As noted above, unless specifically requested by the CEO pursuant to the CEO's general power to request information under Section 15(c), the NT Act does not list information regarding proposed commercialisation or benefits to be provided at the permitting stage.

Benefit Sharing Agreements				
Section	**QLD Act**	**Section**	**NT Act**	**Comments**
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 (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; (b) the agreement's term;	Section 17 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. (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;	Both Acts include the concept of benefit sharing agreements. The collection authority / permitting system in connection with the Acts are both linked to the benefit sharing agreements. Under the QLD Act, a biodiscovery entity is not able to collect material under a collection authority granted under the QLD Act without a signed benefit sharing agreement with the State. In the Northern Territory, the CEO must agree for a permit to be granted under the NT Act unless a benefit sharing agreement has been entered into with a resource access provider. A key difference is that the QLD Act only deals with benefit sharing agreements with the State, whereas the NT Act covers resource access providers including the State and private landowners. The QLD Act is much more comprehensive in its requirements in relation to the benefit sharing agreement The benefit sharing agreements under the QLD Act includes a specific focus on monetary aspects – this is not specifically mentioned in the NT Act (although could fall broadly within the description of benefits) The NT Act requirements for benefit

Benefit Sharing Agreements				
Section	**QLD Act**	**Section**	**NT Act**	**Comments**
	(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. **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		(b) whether the resource access provider 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 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	sharing agreements (consistent with the approach in the rest of the NT Act) provides that any indigenous knowledge must be recognised and reciprocally rewarded. The NT Act also includes the concept of prior informed consent by the resource access provider (which may or may not be the Territory) under section 28. In determining whether prior informed consent the CEO must consider the matters in Section 28(2) of the NT Act. This requires the CEO to undertake an assessment (including of benefit sharing agreements where the resource access provider is not the Territory) thereby placing a further administrative burden on the CEO. The NT Act also allows for an applicant to retrospectively enter into a benefit-sharing agreement (section 30), but does not exclude liability for the offence of sampling without authority. The QLD Act also includes specific conditions in Section 35 which are not present in the NT Act. Section 35(2) includes specific limitations in relation to the use of the native biological material by other parties. Unlike the NT Act in Section 17 which specifically provides that the CEO must not enter into a benefit-sharing agreement unless the CEO is satisfied

Benefit Sharing Agreements				
Section	**QLD Act**	**Section**	**NT Act**	**Comments**
	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).		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; (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	the terms of the agreement are fair to the Territory. This concept of 'fairness' is not included in the benefit sharing provisions of the QLD Act but is included in the purposes of the QLD Act in Section 3. The QLD Act does not specifically enable consideration of 'reputation' of the applicant in determining whether a benefit sharing agreement should be entered into by the Territory (compare Section 17 of the NT Act).

Benefit Sharing Agreements				
Section	**QLD Act**	**Section**	**NT Act**	**Comments**
			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 was obtained from scientific or other public documents, or otherwise from the public domain. **17. Matters CEO may consider** (1) The CEO must not enter into a benefit-sharing agreement unless the CEO is satisfied the terms of the agreement are fair to the Territory. (2) The CEO may consider the reputation of the applicant in relation to the following matters when deciding to enter into a benefit-sharing agreement on behalf of the Territory: (a) compliance with recognised standards of operation; (b) commitment to ecological sustainability; (c) compliance with conditions imposed in relation to permits and approvals (for example, approval by an ethics	

Benefit Sharing Agreements				
Section	**QLD Act**	**Section**	**NT Act**	**Comments**
			committee); (d) honouring commitments under benefit-sharing agreements. **30. Retrospectively entering into benefit-sharing agreement** (3) 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. (4) 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 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	

Benefit Sharing Agreements				
Section	**QLD Act**	**Section**	**NT Act**	**Comments**
			relation to the benefit-sharing agreement. (5) 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. (6) The legitimising of a sample does not prevent a prosecution for a breach of the Act.	

Record keeping				
Section	**QLD Act**	**Section**	**NT Act**	**Comments**
Section 43	**43 Records to be kept by biodiscovery entity** (1) A biodiscovery entity that has entered into a benefit sharing agreement must keep each record or document evidencing the results of biodiscovery research carried out under the agreement for 30 years after the record or document is created. Maximum penalty—50 penalty units. (2) The entity must also keep each record or account necessary for working out amounts of money payable by the entity to the State under the agreement for 30 years after the record or account is created.	Section 42	**42. Bioprospector to keep records** (4) A bioprospector issued a permit in relation to bioprospecting must keep the following records for each sample taken: (a) for each record about a sample – a unique identifier for the sample that is also on a label attached to the sample or its container; (b) the date the sample was taken; (c) the location from which the sample was taken; (d) an indication of the quantity or size of the sample (for example, approximate weight or physical dimensions of the sample); (e) the scientific name of, or given to,	In addition to the provision of information in relation to the collection of samples under Section 24, the NT Act also includes further record keeping requirements in Section 42. However, the QLD Act focuses on the records to be kept in connection with the benefit sharing agreement (including in relation to the calculation of monetary amounts payable).

Record keeping				
Section	**QLD Act**	**Section**	**NT Act**	**Comments**
	Maximum penalty—50 penalty units. (3) In this section— biodiscovery entity, that has entered into a benefit sharing agreement, includes the entity's successors and assigns.		the sample; (f) the location of the sample when first entered in the record; (g) the details of any subsequent disposition of the sample, including the names and addresses of others having possession of the sample or a part of the sample. Maximum penalty: 100 penalty units. (5) A copy of the records must be sent to each relevant resource access provider, the permit issuing authority and the CEO within a reasonable time after the sample is taken. Maximum penalty: 100 penalty units. (6) A record mentioned in subsection (1) for a sample must be retained by the bioprospector while the sample is in the bioprospector's possession. Maximum penalty: 100 penalty units.	
Section 32	**32 Giving material disposal report to DSDI chief executive** (1) The holder of a collection authority must give to the DSDI chief executive, within 15 business days after each 30 June and 31 December, a material disposal report about all native biological material— (a) taken under the authority; and (b) given to someone else, whether or		**43. Disposal of samples** (1) If a bioprospector does not intend to keep a sample for which the bioprospector has a record of the type mentioned in section 42 (1), the bioprospector must offer the sample and record to each resource access provider. Maximum penalty: 100 penalty units. (2) If no resource access provider agrees to take the sample and record, the bioprospector may dispose of the	Both Acts include an obligation to report on material disposal. The NT Act includes an additional obligation to offer the sample and record to the resource access provider where it does not intend to keep the sample.

Record keeping				
Section	**QLD Act**	**Section**	**NT Act**	**Comments**
	not for gain; and (c) for which the holder has not previously given a material disposal report to the chief executive. *Maximum penalty—100 penalty units.* *Note—* *This provision is an executive liability provision—see section 115.* (2) Subsection (1) does not apply if the holder has a reasonable excuse for not giving the report as required under the subsection.		sample and, at that time, must send the record and details of the disposal of the sample to the CEO. Maximum penalty: 100 penalty units.	

Exemptions				
Section	**QLD 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*	No equivalent provision in the QLD Act other than the sections regarding specific types of land in Division 4 of the QLD Act.

Exemptions				
Section	**QLD Act**	**Section**	**NT Act**	**Comments**
			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.* *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		**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. A benefit sharing

Exemptions				
Section	**QLD Act**	**Section**	**NT Act**	**Comments**
	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			agreement is required even for educational and scientific purposes.

Exemptions				
Section	**QLD Act**	**Section**	**NT Act**	**Comments**
	material. (4) In this section— ***educational institution*** means— (a) a school; or (b) a registered higher education provider under the *Tertiary Education Quality and Standards Agency Act 2011 (Cwth);* or (c) a registered training organisation under the *National Vocational Education and Training Regulator Act 2011* (Cwlth).			

Certificate of Provenance – NT Act				
Section	**Act**	**Section**	**NT Act**	**Comments**
	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	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. There is no equivalent in the QLD Act.

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Certificate of Provenance – NT Act				
Section	**Act**	**Section**	**NT Act**	**Comments**
			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 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:	

Certificate of Provenance – NT Act				
Section	**Act**	**Section**	**NT Act**	**Comments**
			(a) a unique identifier of the certificate; (b) the date of issue of the certificate; (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. (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	

Certificate of Provenance – NT Act				
Section	**Act**	**Section**	**NT Act**	**Comments**
			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**	**Comments**
	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 specific equivalent provision in QLD Act 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. However, section 33(1) of the QLD Act gives the entity the right to use native biological material for biodiscovery. As the QLD Act does not specifically address the granting of exclusive rights, no exclusive rights are granted.

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Offences and Legal Provisions				
Section	**Act**	**Section**	**NT Act**	**Comments**
Part 7	The Act creates a number of offences relating to breaches of the Act and other offences relating to false or misleading information, 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, false or misleading 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**	

Appendix 4

Offence and Enforcement Provisions

Comparison of the Act to the Commonwealth Regulations and NT Act

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Offence and Enforcement Provisions

Comparison of the QLD Act to the Commonwealth Regulations and NT Act

Environment Protection and Biodiversity Conservation Regulations 2000 (**Commonwealth Regulations**)
Biodiscovery Act 2004 (**QLD Act**)
Biological Resources 2006 (**NT Act**)

Sec	QLD Act	Sec	NT Act	Reg	Commonwealth Regulations
Offence Provisions					
Part 7	**Division 1 Offences about collection authorities and biodiscovery plans** **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. (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	**Part 6**	**38 Bioprospecting without permit** (1) A person must not engage in bioprospecting except in accordance with a permit registered with the CEO. Maximum penalty: 500 penalty units. (2) A person is taken to engage in bioprospecting if there is a reasonable prospect that 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. **39. Giving false information** A person, in making an application to a permit issuing authority, or in providing information to the CEO under section 15, must not knowingly	**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. (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.

Sec	QLD Act	Sec	NT Act	Reg	Commonwealth Regulations
	meaning of the *Nature Conservation Act 1992*; or (b) native wildlife mentioned in section 97 of that Act. **51 Contravening a condition of a collection authority** A person must not contravene a condition of a collection authority, unless the person has a reasonable excuse. Maximum penalty—100 penalty units. Note—this provision is an executive liability provision—see section 115. **52 False or misleading information given by applicant** (1) A person, in making an application for a collection authority, must not state anything to the EPA chief executive that the person knows is false or misleading in a material particular. Maximum penalty—100 penalty units. Note—This provision is an executive liability provision—see section 115.		give information that is false or misleading in a material particular. Maximum penalty: 500 penalty units. **40 Breach of permit conditions** A bioprospector must not breach the conditions of a permit relating to bioprospecting and registered with the CEO. Maximum penalty: 500 penalty units. **41 Breach of benefit sharing agreement** A person who is bound by the terms of a benefit sharing agreement under this Act must not breach a condition of the agreement. Maximum penalty: 500 penalty units.		

Sec	QLD Act	Sec	NT Act	Reg	Commonwealth Regulations
	(2) A person, in making an application for approval of a biodiscovery plan, must not state anything to the DSDI chief executive that the person knows is false or misleading in a material particular. Maximum penalty—100 penalty units. **53 False or misleading documents given by applicant** (1) A person, in making an application for a collection authority, must not give the EPA chief executive a document containing information the person knows is false or misleading in a material particular. Maximum penalty—100 penalty units. Note—This provision is an executive liability provision—see section 115. (2) A person, in making an application for approval of a biodiscovery plan, must not give the DSDI chief executive a document containing information the person knows is false or misleading in a material particular.				

Sec	QLD Act	Sec	NT Act	Reg	Commonwealth Regulations
	Division 2 Offences about benefit sharing agreements **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— (c) classifying the material scientifically; (d) verifying research results concerning the material;				

Sec	QLD Act	Sec	NT Act	Reg	Commonwealth Regulations
	(e) 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; or (b) a registered higher education provider under the *Tertiary Education Quality and Standards Agency Act 2011* (Cwlth); or (c) a registered training organisation under the *National Vocational Education and Training Regulator Act 2011* (Cwlth). **55 Contravening a condition of a benefit sharing agreement** A biodiscovery entity must not contravene a condition of a benefit sharing agreement imposed under section 35(1) or (2). Maximum penalty—100 penalty units.				

Sec	QLD Act	Sec	NT Act	Reg	Commonwealth Regulations
	56 False or misleading information given by person seeking benefit sharing agreement A person, in seeking a benefit sharing agreement, must not state anything to the DSDI Minister that the person knows is false or misleading in a material particular. Maximum penalty—100 penalty units. **57 False or misleading documents given by person seeking benefit sharing agreement** (1) A person, in seeking a benefit sharing agreement, must not give the DSDI Minister a document containing information particular. Maximum penalty—100 penalty units. (2) Subsection (1) does not apply to a person who, when giving the document— (a) informs the Minister, to the best of the person's ability, how it is false or misleading; and (b) gives the correct information to				

Sec	QLD Act	Sec	NT Act	Reg	Commonwealth Regulations
	the Minister if the person has, or can reasonably obtain, the correct information. **58 False or misleading information about reportable matters** A person must not state anything about a reportable matter to the DSDI Minister that the person knows is false or misleading in a material particular. Maximum penalty—100 penalty units. **Division 3 Other offence provisions** **59 Claims by persons about holding a collection authority** A person who is not the holder of a collection authority must not claim to hold, or hold himself or herself out as holding, the authority. Maximum penalty—100 penalty units. **60 Collection authority to be available for immediate inspection** The holder, or a person acting for the holder, of a collection authority must have a copy of the authority available for immediate inspection under part 8 while the holder or other person is taking				

Sec	QLD Act	Sec	NT Act	Reg	Commonwealth Regulations
	native biological material under it. Maximum penalty—20 penalty units.				
Enforcement Provisions					
Part 8	**Division 1 Inspectors** **61 Appointment and qualifications** (1) The EPA chief executive or the DSDI chief executive (each the appointing chief executive) may appoint any of the following persons as an inspector— (a) a public service employee; (b) a local government employee; (c) a person holding an appropriate accreditation by the (d) National Association of Testing Authorities, Australia ABN 59 004 379 748; (e) another person prescribed under a regulation. (2) However, the appointing chief executive may appoint a person as an inspector only if the chief executive is satisfied the person is qualified for appointment because the person has the		**Nil equivalent**		**Nil equivalent**

Sec	QLD Act	Sec	NT Act	Reg	Commonwealth Regulations
	necessary expertise or experience. **Division 2 Powers of inspectors** **Subdivision 1 Entry of places** **68 Power to enter places** (1) Subject to section 74(2), an inspector may enter a place if— (a) its occupier consents to the entry; or (b) it is a public place and the entry is made when it is open to the public; or (c) the entry is authorised by a warrant; or (d) it is a person's place of business stated in the person's (e) collection authority and is—				

Appendix 5

Offence and Enforcement Provisions

Comparison of International Jurisdictions

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Offence and Enforcement Provisions

Comparison of International Jurisdictions

Federal Act on the Protection of Nature and Cultural Heritage (NCHA) (**Switzerland**)
Regulation EU No 511/2014 of the European Parliament and of the Council of 16 April 2014 (**European Union**)
Law No.13, 123 of 20 May 2015 (**Brazil**) (Non-official English translation)

Section	Switzerland	Art	European Union	Chp	Brazil
Offence Provisions					
Section 4 Criminal Law Provisions	**Article 24** 1 Any person who wilfully and without authorisation a. destroys or seriously damages a natural or cultural monument protected under this Act, a protected historical site, a protected natural landscape or a protected biotope; b. clears, covers up or otherwise destroys riparian vegetation as specified in Article 21; c. destroys or seriously damages buried natural objects or antiquities of substantial scientific value82 (Art. 724 para. 1 Civil Code83); d. ... shall be liable to a term of imprisonment not exceeding one year or to a monetary penalty.	**Article 11**	**Nil equivalent offence provisions – regulated at the State level** **Article 11 Penalties** Member States shall lay down the rules on penalties applicable to infringements of Articles 4 to 7 and shall take all measures necessary to ensure they are applied. The penalties provided for shall be effective, proportionate and dissuasive.	**Chp VI**	**Chapter VI (Administrative Sanctions)** **Article 27** 1 Subject to applicable civil and criminal sanctions, the [infra's administrative] will be punished with the following sanctions: I. warning; II. fine III. seizure of: a. samples containing genetic resources accessed; b. the instruments used in obtaining or processing genetic resources or associated traditional knowledge accessed; c. products derived from access to genetic

Section	Switzerland	Art	European Union	Chp	Brazil
	2 In cases of negligence, the penalty shall be a fine not exceeding 40,000 Swiss francs.85 **Article 24a** **Any person who:** a. fails to comply with a condition or requirement that makes specific reference to this provision that is related to the provision of a federal subsidy; b. contravenes an implementation regulation issued under Articles 16, 18, 18a, 18b, 18c, 19, 20, 23c, 23d or 25a, where infringements have been declared to be offences; c. performs an action without authorisation where approval is required as specified in Articles 19, 22 paragraph 1, or 23 shall be liable to a fine not exceeding 20,000 Swiss francs. **……** 2 Any person who intentionally fails to provide information or provides false information under Article 23o *(Notification Requirement)* shall be liable to a fine not exceeding 100,000 francs; if the offender acts through				resources and associated traditional knowledge; or d. the products obtained from reports [will on] associated traditional knowledge; IV. temporary suspension of manufacture and sale of the finished product or the reproductive material derived from access to genetic resources and associated traditional knowledge. V. the specific embargo activity will be below; VI. [will interdi partial or total establishment, activity or undertaking] VII. Suspension certificate or [authorise will of this Law]; or VIII. Cancellation certificate or authorization shall be dealt with in this Act. 2 In granting the administrative sanction, the competent authority shall observe: I. the seriousness of the fact; II. the antecedents of the offender [as will the enforcement of legislation related to genetic resources and associated

Section	Switzerland	Art	European Union	Chp	Brazil
	negligence, the penalty is a fine not exceeding 40,000 francs. The court may order publication of the judgement.				traditional knowledge; III. [recidivism]; IV. the economic situation of the offender in the case of a fine. …. 5 The fine mentioned in item II of 1 to be arbitrated by the competent authority for infrastructure and may vary: I. R $1,000.00 (one thousand reais) to R $100,000.00 (one hundred thousand reais) when the infrastructure will be committed by an individual; or II. R$10,000.00 (ten thousand reais) the R$10,000,000 (ten million Reais) when the infrastructure will be committed by a legal entity, or your competition. …...
Enforcement Provisions					
Section 3C	**Article 23o (Notification Requirement)** 1 Compliance with the due diligence requirement must be notified to the Federal Office for the Environment FOEN before market authorisation has been obtained, or if such authorisation is not required, before commercialisation of products	**Articles 7 and 9**	**Article 7 (Monitoring user compliance)** 1 The Member States and the Commission shall request all recipients of research funding involving the utilisation of genetic resources and traditional knowledge associated with genetic	**Ch VI**	**Article 28** The relevant federal agencies will oversee the exercise, the intercept and seizure of samples containing the genetic resources accessed, products or reproductive materials arising from access to genetic resources or associated traditional knowledge where access or explores the economic will

Section	Switzerland	Art	European Union	Chp	Brazil
	developed on the basis of utilised genetic resources. 2 Information relating to compliance with the due diligence requirement may be passed on to the international clearing house described in Article 14 of the Nagoya Protocol. The name of the notifying person, the product to be commercialised, the utilised genetic resource, the date on which it was accessed and its source are made publicly available. 3 The Federal Council shall designate the authorities responsible for verifying compliance with the notification requirement. It may provide for exemptions to the notification requirement if the verification of compliance with the due diligence requirement is ensured by other means. **Article 24d** 1 The cantons are responsible for prosecution. ….. **Article 24f** The cantons shall implement this Act unless implementation is assigned to the Confederation. They shall issue the required regulations.		resources to declare that they exercise due diligence in accordance with Article 4. 2 At the stage of final development of a product developed via utilisation of genetic resources or traditional knowledge associated with such resources, users shall declare to competent authorities referred to in Article 6(1) that they have fulfilled the obligations under Article 4 and shall simultaneously submit: a. the relevant information from the internationally recognised certificate of compliance; or b. the related information referred to in Article 4(3)(b)(i)-(v) and Article 4(5), including information that mutually agreed terms were established, where applicable. Users shall further provide evidence to the competent authority on request. 3 The competent authorities shall transmit the information received on the basis of paragraphs 1 and 2 of this Article to the Access and Benefit Sharing Clearing House, established under Article 14(1) of the Nagoya Protocol to the Commission and where appropriate		have been in violation of the dispositions of this Act and its regulations.

Section	Switzerland	Art	European Union	Chp	Brazil
			to the competent national authorities referred to in Article 13(2) of the Nagoya Protocol. ….. **Article 9 Checks on User Compliance** 1 The competent authorities referred to in Article 6(1) shall carry out checks to verify whether users comply with their obligations under Articles 4 and 7, taking into account that the implementation by a user of a best practice in relation to access and benefit-sharing, recognised under Article 8(2) of this Regulation or under Article 20(2) of the Nagoya Protocol, may reduce that user's risk of non-compliance. 2. Member States shall ensure that the checks carried out pursuant to paragraph 1 are effective, proportionate, dissuasive and detect cases of user non-compliance with this Regulation. 3. The checks referred to in paragraph 1 shall be conducted: (a) in accordance with a periodically reviewed plan developed using a risk-based approach; (b) when a competent authority is in possession of relevant information,		

Section	Switzerland	Art	European Union	Chp	Brazil
			including on the basis of substantiated concerns provided by third parties, regarding a user's non-compliance with this Regulation. Special consideration shall be given to such concerns raised by provider countries. 4. The checks referred to in paragraph 1 of this Article may include an examination of: (a) the measures taken by a user to exercise due diligence in accordance with Article 4; (b)documentation and records that demonstrate the exercise of due diligence in accordance with Article 4 in relation to specific use activities; (c) instances where a user was obliged to make declarations under Article 7. On-the-spot checks may also be carried out, as appropriate. 5. Users shall offer all assistance necessary to facilitate the performance of the checks referred to in paragraph 1. 6. Without prejudice to Article 11, where, following the checks referred to in paragraph 1 of this		

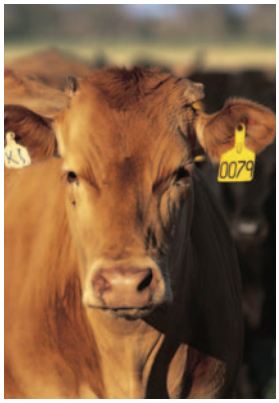
Section	Switzerland	Art	European Union	Chp	Brazil
			Article, shortcomings have been detected, the competent authority shall issue a notice of remedial action or measures to be taken by the user. Depending on the nature of the shortcomings, Member States may also take immediate interim measures.		

Appendix 6

Queensland Government Response to 2009 Review









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A response to the Review of the ***Biodiscovery Act 2004 (Qld)***

July 2010

A response to the Review of the Biodiscovery Act 2004 (Qld)

Contents

Preface

The *Biodiscovery Act 2004* (Qld) commenced by proclamation on 12 November 2004. The legislation 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 of the Act 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
- monitoring and enforcement provisions.

In developing the Act, Queensland became the first jurisdiction in Australia – and indeed remains one of only a handful of jurisdictions internationally – to legislate access to, and benefit sharing for native biological resources. The Act helps fulfil Queensland's commitment to Article 15 of the international *Convention on Biological Diversity*, and the *Nationally Consistent Approach for Access to and Utilisation of Australia's Native Genetic and Biochemical Resources*, ratified by all states and territories in October 2002.

The Act seeks to provide legal certainty for both individuals and entities undertaking biodiscovery while promoting benefit sharing in favour of the State. It was hoped that the framework would encourage research and commercialisation using Queensland's rich biodiversity.

Section 121 of the Act requires a review to be undertaken within five years of the commencement of the Act to consider whether the provisions of the Act remain appropriate. The Act requires the outcome of the review to be tabled in the Queensland Parliament as soon as practicable after its completion.

Terms of Reference of the Review

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 Terms of Reference of the Review were as follows:

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 Indigenous 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 (including but not limited to the parameters around determining when a benefit sharing agreement is required).
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 alternative mechanisms to improve the effectiveness, fairness, timeliness and accessibility of the regulatory system.

Recommendations of the Review

The Review of the Act was conducted in 2009 and the report of the independent reviewer was tabled out of session to Queensland Parliament on 1 December 2009.

On balance the Review found that the legislation had worked well in the five years following introduction, however it suggested a number of minor changes aimed at improving the operation of the legislation whilst ensuring that it continued to achieve its purpose.

The main findings of the Review are:

- The purpose of the Act is being achieved and the regulatory framework of the Act is appropriate.
- The policy objectives and scope of the Act remain valid.
- Scope of the Act should not be extended to private land or land over which a native title determination of exclusive possession has been made.
- The Act should not be amended to afford legislative protection of traditional Indigenous knowledge.
- Implementation of an international regime on access and benefit sharing arrangements should be closely monitored.

To increase industry understanding of the scope of the Act and to improve compliance with the legislation the Review recommends:

- Some provisions of the Act be amended and the *Compliance code for taking native biological material under a collection authority* reviewed.
- Further education and clarification as to the operation of the Act be provided.

The Review makes 32 recommendations and the Queensland Government response to them is as follows:

Purpose of Act (Terms 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 Indigenous knowledge and ownership of genetic resources are considered
e. the definitions in the Act, and the need for the definition of other terms.

No.	RECOMMENDATION	RESPONSE
1	The Review recommends that the policy objectives remain valid and the scope of the Act should be maintained.	**Supported** The government supports the findings from which this recommendation has been made. The Review considers that the purposes of the Act adequately address the issues of conservation and sustainability and industry development. The Review concluded that the scope of the Act should not be extended to private land or land over which a native title determination of exclusive possession has been made, or amended to afford legislative protection of traditional Indigenous knowledge (see below).
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.	**Supported** The government supports this recommendation which is intended to provide certainty of access to interested parties undertaking biodiscovery on private lands. The *Queensland Biotechnology Code of Ethics* (the Code) reflects the government's policy in this area. The Code states 'before collecting samples from privately owned land, we (the entity) will ensure that the prior informed consent of the landowner is obtained and we will negotiate reasonable benefit sharing arrangements with the landowner in return for access to the samples'. To give effect to the recommendation, the government will publish information in relation to the access and benefit sharing rights of interested parties (the accessing entity and private landowners). The information will be provided on agency websites as part of any explanatory material in relation to the Act. Responsible agency: Department of Employment, Economic Development and Innovation (DEEDI)

No.	RECOMMENDATION	RESPONSE
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.	**Supported** Although outside the scope of the Act, the government agrees that interested parties should be able to access information in respect of negotiating access arrangements (Indigenous Land Use Agreements, ILUA) for lands subject to native title determination of exclusive possession. As such, the government will provide its current publicly available *Guidelines for negotiation of an ILUA (area agreement)* on agency websites as part of any explanatory material in relation to the Act, as well as direction to the National Native Title Tribunal which currently offers assistance to parties at all stages of the ILUA process. Responsible agency: DEEDI
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).	**Supported in principle** To give effect to this recommendation, a provision will be included in the *Compliance code for taking native biological material under a collection authority* (the Compliance Code) to place a positive obligation on the holder of a collection authority to notify Indigenous occupiers of State lands (where those contact details are available) prior to accessing those lands pursuant to a collection authority. The obligation would be in addition to the current requirement of the Compliance Code for the holder of a collection authority to provide notification to the relevant land manager. Responsible agency: Department of Environment and Resource Management (DERM)
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.	**Supported** The government notes the move towards an international regime on access and benefit sharing from genetic resources and the legislative protection of traditional Indigenous knowledge. The *Queensland Biotechnology Code of Ethics* (the Code) reflects the government's policy in this area. The Code states 'where in the course of biodiscovery we (the entity) obtain and use traditional knowledge from Indigenous persons, we will negotiate reasonable benefit sharing arrangements with these persons or communities'. Any legislation dealing with the protection of traditional Indigenous knowledge will be a matter for the Commonwealth, as the Commonwealth has Constitutional responsibility for intellectual property laws. Should legislation dealing with traditional Indigenous knowledge be developed, the government will examine its impact on the Act to determine whether legislative change is required.

No.	RECOMMENDATION	RESPONSE
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.	**Supported** To give effect to this recommendation, a provision will be included in the *Compliance code for taking native biological material under a collection authority* to place a positive obligation on the holder of a collection authority to comply with the biodiscovery principles of the government's *Queensland Biotechnology Code of Ethics*. Responsible agency: DERM
7	The Review recommends that the movement towards the development of an international regime be closely monitored.	**Supported** The Commonwealth leads Australia's participation in the international negotiations towards an international regime on access and benefit sharing from genetic resources and the protection of traditional knowledge. The aim of the negotiations is to adopt a protocol to effectively implement the provisions of Article 15 of the international *Convention on Biological Diversity*. The government will continue to monitor the progress of the draft protocol, as well as continue to contribute input to Australia's approach in the international negotiations through the Commonwealth Government.
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'.	**Supported in principle** The government notes the Review's suggestion to broaden the definition of 'biodiscovery research' to capture potential new commercial applications of native biological materials, for example nutraceuticals, cosmeceuticals and food extracts. The government has considers that the definition of 'biodiscovery' is sufficiently broad to capture these applications. 'Biodiscovery' is defined under the Act as — biodiscovery research (the analysis of molecular, biochemical or genetic information about native biological material for the purpose of commercialising the material); or — the commercialisation of native biological material or a product of biodiscovery research.
9	The Review recommends that paragraph (1) of the definition of 'commercialisation' be amended to clarify 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.	**Supported in principle** The government notes the Review's suggestion to amend the definition of 'commercialisation' to capture the actual receipt of monies and exclude the use of native biological materials to obtain private research grants. While the government supports the intent of these recommendations any confusion in relation to the definition can be clarified through stakeholder engagement activities. Responsible agency: DEEDI
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.	

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.

No.	RECOMMENDATION	RESPONSE
11	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.	**Supported** The government supports the findings from which this recommendation has been made. The Review considers that the purposes of the Act are being achieved and the regulatory framework stipulated in the Act is appropriate.

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

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

Examine the structure and effectiveness of the contractual framework for benefit sharing agreements stipulated in Part 5 of the Act (including but not limited to the parameters around determining when a benefit sharing agreement is required).

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

No.	RECOMMENDATION	RESPONSE
12	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.	**Supported in principle** The government supports the intent of this recommendation. The use of material transfer agreements would evidence a clear chain of title to samples of native biological materials, as well as provide certainty to acquiring parties, and government that the samples were collected pursuant to a collection authority under the Act. The government will consider the most appropriate way of implementing this recommendation as part of the review of the *Compliance code for taking native biological material under a collection authority.* Responsible agency: DERM
13	The Review recommends that the publicly available part of the collection authority register be converted into a publicly available online format.	**Supported** In the interest of transparency and openness, the government agrees that interested parties should be able to access the publicly available part of the collection authority register on agency websites. As such, the government will provide this information as part of any explanatory material in relation to the Act. Responsible agency: DERM

No.	RECOMMENDATION	RESPONSE
14	The Review recommends the Queensland Museum and Queensland Herbarium be able to apply for and hold collection authorities under the Act.	**Supported in principle** The government supports this recommendation which is intended to give confidence and certainty about the compliance of the Queensland Herbarium and the Queensland Museum with the permitting framework of the Act. The government will consider the most appropriate way of implementing this recommendation as part of the review of the *Compliance code for taking native biological material under a collection authority*. Responsible agency: DERM
15	The Review recommended that issues of labelling and storage of samples of material be considered as part of the review of the Compliance Code.	**Supported in principle** This recommendation will be addressed by the Department of Environment and Resource Management as part of the review of the *Compliance code for taking native biological material under a collection authority*. Consideration will be given to the inclusion of provisions to streamline requirements in relation to the depositing, labelling and storage of samples of native biological materials, and any samples of, or substances sourced from the material. Responsible agency: DERM
16	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.	**Supported in principle** The government agrees that the storage of samples may not always be the most appropriate method of retaining information in relation to native biological materials held pursuant to s30 of the Act. Should advancements in scientific methods or technologies necessitate a change in the way this information should be provided under the Act, the government will consider the most appropriate way of addressing the issue without significantly increasing the regulatory burden or cost to relevant parties. This may involve amendment to the *Compliance code for taking native biological material under a collection authority*. Should s30 of the Act require review, consultation would be undertaken with receiving entities and relevant parties on the appropriate format/s for the information. Responsible agency: DERM

No.	RECOMMENDATION	RESPONSE
17	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.	**Supported in principle** The government supports this recommendation which is intended to make clear for receiving entities the length of time samples of native biological materials must be held pursuant to s30 of the Act. A policy position will be developed by the Department of Environment and Resource Management as part of the review of the *Compliance code for taking native biological material under a collection authority*. Consultation with receiving entities would be undertaken. Responsible agency: DERM
18	The Review recommends that the State investigate options for the storage of microorganisms and microbes. This may take the form of an independent repository.	**Supported in principle** The Act does not specifically address the storage of State samples of microorganisms and microbes deposited pursuant to s30 of the Act. The government will give consideration to options for the storage of State samples of microorganisms and microbes as part of the review of the *Compliance code for taking native biological material under a collection authority*. The establishment or identification of a repository would not require amendment to s30 of the Act as the legislation already provides for an entity other than the Queensland Museum or Queensland Herbarium to receive samples. Responsible agencies: DERM and DEEDI
19	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.	**Supported in principle** The government notes the Review's suggestion to reformat the Act to convey the existing offence provisions in a simpler form and introduce a positive obligation provision on educational and training institutions to make clear their obligations in respect to benefit sharing under the Act. While the government supports the intent of these recommendations any confusion in relation to the provisions can be clarified by government through stakeholder engagement activities. Legislative amendment is not necessary. Responsible agency: DEEDI
20	The Review recommends section 54(3) of the Act be redrafted to reflect the exclusion in section 17 of the Act.	
21	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.	

No.	RECOMMENDATION	RESPONSE
22	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.	**Supported in principle** This recommendation intends to facilitate the management of benefit sharing agreements (agreement) with educational and training institutions by removing the need to negotiate a new agreement each time biodiscovery commences by a researcher or department of the institution. The government supports the policy that educational and training institutions enter into head agreements with the State pursuant to s33 of the Act. However, contrary to the recommendation the government will continue its current requirement that the head agreement specifies the benefits of biodiscovery to be provided to the State. This will remove the need for addendums and the associated administrative burden or cost for their negotiation. Responsible agency: DEEDI
23	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.	**Supported in principle** The government agrees there may be circumstances where native biological materials collected pursuant to a licence or permit other than a collection authority could be used for biodiscovery. Irrespective of the initial licence or permit, these circumstances mean a benefit sharing agreement with the State is required under the Act. Any confusion in relation to this concept will be clarified by government through stakeholder engagement activities. Legislative amendment is not necessary. Responsible agency: DEEDI
24	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.	**Supported in principle** As indicated in the response to recommendations 19 and 20, the government notes the Review's suggestion to reformat the Act to convey the existing offence provisions in a simpler form. This would make clear to interested parties the circumstances in which they are exempt from benefit sharing under the Act in relation to the use of native biological materials. While the government supports the intent of these recommendations any confusion in relation to the provisions can be clarified by government through stakeholder engagement activities. Legislative amendment is not necessary. Responsible agency: DEEDI
25	The Review recommends section 54(2) of the Act be redrafted to reflect the exclusion in section 17 of the Act.	

No.	RECOMMENDATION	RESPONSE
26	The Review does not recommend that the enforcement or compliance provisions of the Act be amended.	**Supported** The government supports the findings from which this recommendation has been made. The Review considers the provisions in the Act dealing with enforcement and compliance are appropriate and should not be amended.

Regulatory burden (Terms of Reference 6, 7)

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.

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

No.	RECOMMENDATION	RESPONSE
27	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.	**Supported in principle** Although outside the scope of the Act, the government is committed to undertaking all it can to ensure that interested parties are able to access information on collection authorities, as well as licences or permits allowing the commercial collection or non-commercial use of native biological materials from State lands or Queensland waters (e.g. scientific purposes permits and commercial harvesting licences under the *Nature Conservation Act 1992*). The Ecoaccess website of the Department of Environment and Resource Management provides comprehensive information for interested parties with licensing and permitting enquiries (application forms, information sheets and guidelines). The website is supported by the Ecoaccess customer service unit. Responsible agency: DERM
28	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.	**Supported in principle** This recommendation will be addressed by the Department of Environment and Resource Management as part of the review of the *Compliance code for taking native biological material under a collection authority* (the Compliance Code). At present, the sample of native biological material to be deposited pursuant to s30 of the Act and the sample required for biodiscovery must be provided from the maximum allowable sample sizes set out in Schedules 1 to 5 of the Compliance Code. As such, consideration will be given to the inclusion of provisions for circumstances where the maximum allowable sample size is not sufficient in quantity for the interested party to conduct biodiscovery as well as fulfil the requirements of s30 of the Act.

No.	RECOMMENDATION	RESPONSE
		Consultation with receiving entities would be undertaken should the maximum allowable sample sizes require amendment. Responsible agency: DERM
29	The Review does not recommend any amendments to the compliance and administrative costs under the Act.	**Supported** The government supports the findings from which this recommendation has been made. The Review considers the compliance and administrative costs of the Act are appropriate in the context of the level of certainty and commercial advantage provided by compliance with the Act.
30	The Review does not recommend any change to the regulatory requirements in the Act.	**Supported** The government supports the findings from which this recommendation has been made. The Review considers the regulatory requirements of the Act are comparable to the legislative and regulatory requirements interested parties face in respect of other corporate matters.

Interface with other systems (Terms of Reference 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.

No.	RECOMMENDATION	RESPONSE
31	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).	**Supported** The Act represents Queensland's implementation of the principles under which access to native biological resources should be granted in Australia as agreed to by all States and Territories on 11 October 2002. These principles are set out in the *Nationally Consistent Approach for Access to and Utilisation of Australia's Native Genetic and Biochemical Resources*. While there are differences between the Act and the Commonwealth *Environment Protection and Biodiversity Conservation Regulations 2000* and Northern Territory *Biological Resources Act 2006*, the Review found no compelling case to amend the Act with either for the sake of consistency. The government supports the findings from which this conclusion has been made. In the context of the international biodiversity community, the Review found that Queensland and Australia are well advanced in their consideration of issues relating to access and benefit sharing of genetic resources under the *Convention of Biological Diversity*. Consistent with the government's response to recommendation 7, the government will continue to monitor the progress of the international negotiations for an international regime.

Changing circumstances (Terms of Reference 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 (Terms of Reference 10)

Recommend amendments to the Act, or alternative mechanisms to improve the effectiveness, fairness, timeliness and accessibility of the regulatory system.

No.	RECOMMENDATION	RESPONSE
32	The Review recommends that the Act be reviewed again, within five years, to accommodate emerging trends and international developments.	**Supported** Subsequent five-yearly reviews are consistent with current practice.

Next steps

The Queensland Government response to the Review is largely supportive of the recommendations made by the independent reviewer. The Queensland Government supports in full 13 of the report's recommendations and, either partially or in principle supports another 19 recommendations. On balance, implementation of the recommendations would not change the underlying policy intent or overall legislative framework of the regulatory scheme.

The Review suggests a number of minor legislative changes intended to improve compliance of the Act and clarity of its application. While the Queensland Government response supports the intent of these recommendations, amendment to the Act as proposed by the Review is not considered the sole option for achieving implementation of these recommendations. Instead the Act is proposed to be further strengthened through:

- the review of the *Compliance code for taking native biological material under a collection authority* by the Department of Environment and Resource Management
- further education and stakeholder engagement, as to the operation of the Act, by the Department of Employment, Economic Development and Innovation.

Appendix 7

Regulatory Framework