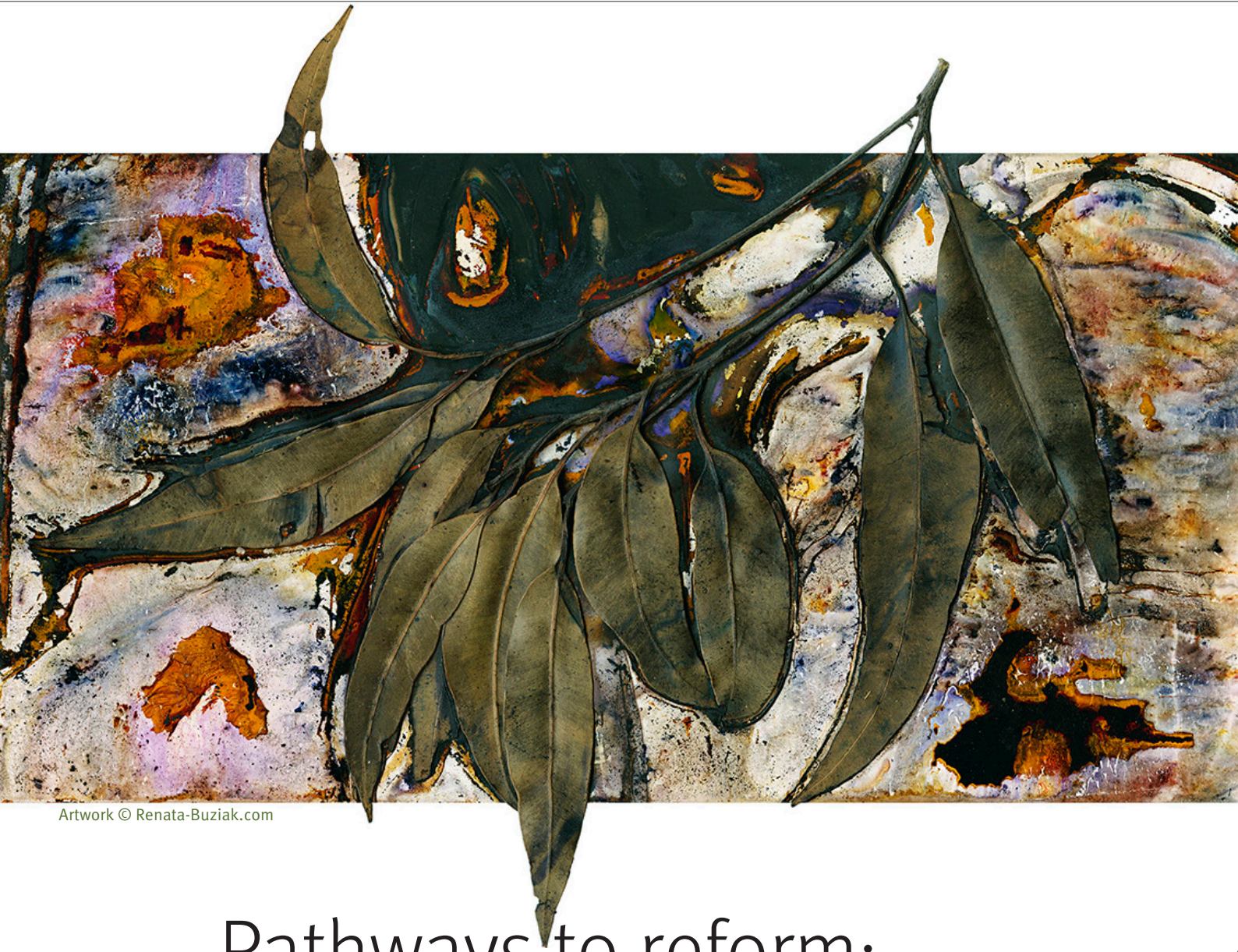

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Pathways to reform: *Biodiscovery Act 2004*

Options paper

31751-1118

Queensland Government

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***Corymbia gummifera* (bloodwood), 2012**
(aside from its healing properties, this corymbia is a bactericide).
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Contents

1. Foreword

Biodiscovery makes a valuable contribution to the State's economy. The Queensland Government is committed to stimulating and streamlining biodiscovery in Queensland and encouraging investment in the State's economy.

Reform of the *Biodiscovery Act 2004* (the Act) is a priority of this government to ensure Queensland's biodiscovery framework keeps pace with the biodiscovery industry and achieves Queensland Government goals to attract new investment and encourage businesses to start and grow in Queensland.

It is also a critical step towards recognising the rights that Aboriginal and Torres Strait Islander people hold in relation to their traditional knowledge, and ensuring biodiscovery entities are able to meet international obligations regarding access to genetic resources and the sharing of benefits resulting from their use.

The *2016 Statutory Review of the Biodiscovery Act 2004*[1] (the Review) and the Government Response are key inputs into reforming the Act, along with feedback received from Aboriginal and Torres Strait Islander people and biodiscovery entities who operate in Queensland.

Key issues emerging from the Review include implementation of the Nagoya Protocol and the rights of Aboriginal and Torres Strait Islander people regarding the use of their resources and traditional knowledge for biodiscovery, definitions of key terms and the regulatory framework for access and benefit sharing.

The government has developed options to address these issues and progress reform of the Act, based on analysis and consultation with stakeholders.

1. www.des.qld.gov.au/assets/documents/biodiscovery/statutory-review-biodiscovery-act-2004.pdf

2. Background

The Act currently regulates the take and use of native biological material collected from State land or Queensland waters for the purpose of biodiscovery. It provides the regulatory and contractual framework for Queensland to address, in part, international obligations regarding access to genetic resources and the sharing of benefits resulting from their use. It is also increasingly important in order to access international markets and maximise Queensland Government policies and initiatives, such as Advance Queensland, which aim to build global partnerships by attracting new investments and encouraging businesses to start and grow in Queensland.

When the Act commenced in 2004 following Commonwealth ratification of the international Convention on Biological Diversity (CBD), Queensland was the first jurisdiction to introduce best-practice biodiscovery legislation. This was important for attracting natural products research to the State. The CBD seeks to ensure the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of benefits arising from the utilisation of genetic resources.

Queensland's capability in biodiscovery is attributable to its unique biodiversity, its world-class research and commercialisation capabilities, and its commitment to efficient and effective regulation. The Department of Environment and Science regulates biodiscovery in Queensland.

As required by the Act, an initial review was undertaken in 2009 (the 2009 Review). The 2009 Review considered whether the provisions of the Act were appropriate. It concluded that the legislation had achieved its purpose within that five-year period and that no amendments were necessary. The 2009 Review recommended that international developments with respect to biodiscovery and benefit sharing models be monitored and that a further review of the Act should be undertaken to address international, national and industry development.

Following the 2009 Review, a supplementary agreement to the CBD was adopted in 2010—the *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization* (the Nagoya Protocol). Australia signed the Nagoya Protocol in 2012, committing Queensland to promote and safeguard the fair and equitable sharing of benefits arising from the utilisation of Queensland's genetic resources, including traditional knowledge associated with those resources. The Nagoya Protocol commenced in 2014, ten years after the Act. Although Australia has not ratified the Nagoya Protocol, alignment with its requirements is crucial for Queensland's biodiscovery industry to continue to be able to access international markets, as other jurisdictions are introducing requirements to demonstrate compliance with the Nagoya Protocol.

The Review was undertaken by Thomson Geer Lawyers in accordance with Terms of Reference set by the Queensland Government. The Review was informed by written submissions and face-to-face discussions with representatives from industry, biodiscovery entities, research institutions, Aboriginal and Torres Strait Islander people and relevant government departments.

The Government Response agreed with 30 of the Review's 45 recommendations, and agreed in principle with the remaining 15 recommendations on the basis that they were supported in their intent but required further investigation and analysis. This aimed to ensure that any shift in the policy direction underpinning the Act is evidence-based and consistent with the aspirations of the Queensland Government and key stakeholders.

The Review and the Government Response were released for public consultation in April 2018. See Attachment A for further information on consultation undertaken to date.

3. Purpose of this paper

This options paper has been developed following release of the Review and Government Response, and the options represent investigation, analysis, and consideration of previous stakeholder consultation (see Attachment A).

The purpose of this paper is to test options for reform with stakeholders and seek feedback on particular issues. Questions, shown in text boxes throughout the document, focus on finding out what stakeholders consider to be the most effective approach and why. The options and questions in this paper are not intended to limit feedback, and stakeholders are welcome to submit alternative approaches.

This options paper does not outline detailed proposals for the development of specific instruments; this will occur following consultation on the options paper.

By testing the options, the Queensland Government aims to reform the Act in a way that fosters development of the biodiscovery industry, whilst ensuring that benefits are equitably shared between parties and that traditional knowledge is appropriately recognised, protected and valued.

The Queensland Government invites all interested people to provide feedback on the options posed in this paper. Questions have been included to help guide feedback.

To provide your input, please:

- **email qldScience@des.qld.gov.au**
- **complete the survey at getinvolved.qld.gov.au/gi/consultation/5504/view.html**
- **send a voice or video-recording to qldScience@des.qld.gov.au or 0436 622 321. This recording does not need to be high-quality (e.g. it can be made using your phone), or**
- **post your response to:**
  Biodiscovery Reform Team
  Department of Environment and Science
  GPO Box 2454
  Brisbane Qld 4001

by midnight 1 February 2019.

To assist us to accurately assess your feedback, please specify the section of this paper and, if possible, which question number(s) your response relates to.

The Queensland Government will publish submissions received. For voice or video recordings, a transcript of the recording may be published. Please state in your submission if you do not agree to publication of all or parts of your submission.

Thank you in advance for taking the time to help improve Queensland's regulatory framework for biodiscovery.

4. Areas of reform

This section outlines the key areas of possible reform identified through the Review and consultation, and presents possible options to address them.

An overview of the key areas of reform that the Queensland Government is seeking input on is provided on the next page. Each reform area is then discussed in detail in the following subsections.

The options presented in this paper generally align with three different regulatory approaches:

1. Significant change to the existing framework, to maximise consistency with international and Commonwealth approaches and streamline processes where the opportunity exists
2. Moderate change to the existing framework, to better align with international and Commonwealth approaches, while retaining some regulatory features unique to Queensland
3. No or minimal change to the existing system.

Due to the wide variety of issues and the likely need for further policy analysis, consultation and coordination with the Commonwealth to develop and implement effective solutions, the Government anticipates that it may take a number of years to fully implement reforms to Queensland's biodiscovery framework. Consequently, development of a reform package may require that certain pieces of work are initially prioritised over others.

QUESTION

1. Which of the reform areas outlined on the next page are of the highest priority to you/your organisation, and which do you think could be implemented over a longer timeframe? Why?

Implementation of the Nagoya Protocol

Options addressing the extent to which Queensland's biodiscovery framework should be amended to be consistent with the Nagoya Protocol.

A. For access to Aboriginal and Torres Strait Islander peoples' resources and traditional knowledge, should consent and benefit sharing be required?

B. How should Aboriginal and Torres Strait Islander peoples' land and traditional knowledge be defined in the Act, if at all?

C. Should activities in exercise of native title rights be explicitly out of scope of the Act?

D. Should non-commercial activities be within scope of the Act?

E. Should freehold land and land with exclusive possession native title rights be within scope of the Act?

F. How can Australian entities show international partners that they have complied with international law?

Definitions

Options to clarify terms in the Act that may curently cause confusion.

G. 'Native biological material'—What materials and/or derivatives should be covered by the Act?

H. 'Commercialisation'—Which activities are commercial versus non-commercial?

Regulatory framework

Options for improving the effectiveness and efficiency of the permitting and contractual framework.

I. How can the approach to regulating commercial activities be more effective and efficient?

J. How should non-commercial activities by regulated (if at all)?

4.1 Implementation of the Nagoya Protocol

The Nagoya Protocol is an international agreement that implements and builds on one of the three core objectives of the CBD—the fair and equitable sharing of benefits arising from the utilisation of genetic resources. Australia signed the Nagoya Protocol in January 2012 but has not yet ratified it.

The Nagoya Protocol creates four broad categories of obligations for parties:

- Ensuring access to genetic resources is subject to prior informed consent, including from Indigenous people and local communities who have the established right to grant access to those resources
- Ensuring access to traditional knowledge associated with genetic resources is subject to prior informed consent or approval and involvement of Indigenous people and local communities and that mutually agreed terms have been established
- Ensuring the fair and equitable sharing of benefits from the utilisation of genetic resources, including from the use of traditional knowledge associated with genetic resources
- Ensuring compliance with the domestic legislation or regulatory requirements.

As it was enacted prior to the Nagoya Protocol, the Act currently does not explicitly recognise the Nagoya Protocol or its traditional knowledge requirements. Nevertheless, the Review concluded that the Act is consistent with many of the obligations in the Nagoya Protocol. The key areas the Review highlighted as having room for stronger alignment were:

- Updating the purposes of the Act to reflect the Nagoya Protocol (recommendations 1 and 2)
- Addressing access to Aboriginal and Torres Strait Islander peoples' land and use of traditional knowledge (and associated benefit sharing) (recommendation 8)
- Application of prior informed consent on mutually agreed terms to private land and to activities for non-commercial purposes (recommendations 5, 6, 11, and 26)
- Demonstrating provenance and compliance with prior informed consent requirements, including through:
  - a checkpoint system, including applications for State funding and International Certificates of Compliance (ICC) (recommendation 39),
  - introducing of a biodiscovery register (recommendation 42), and
  - developing a framework to accredit trusted institutions, subject to consultation with the Commonwealth (recommendation 43).

A range of possible reforms relating to these recommendations are addressed below.

The Queensland Government notes that Australia has not yet ratified the Nagoya Protocol but considers that, without alignment, Queensland's biodiscovery industry may encounter barriers to collaborating with overseas organisations. This is due to the adoption of requirements, for example in the European Union and India, that organisations that are providing samples or otherwise participating in biodiscovery be able to demonstrate the provenance of samples and compliance with the Nagoya Protocol, even if the sample is collected outside of that jurisdiction (e.g. in Queensland).

As such, the government will also consider issuing guidelines that:

- raise awareness of the importance of complying with the Nagoya Protocol if a biodiscovery entity intends to collaborate internationally with countries where it has been ratified
- facilitate engagement with Aboriginal and Torres Strait Islander people (such as details of representative groups and traditional owners)
- outlines the requirements (checkpoints) for compliance with the Nagoya Protocol.

The Review also recommended the Queensland Government engage closely with the Commonwealth regarding a consistent approach to implementing the Nagoya Protocol (recommendations 38 and 44). The Queensland Government has, and will continue to, engage with the Commonwealth to aid in the development of a consistent approach to implementing the Nagoya Protocol; and monitor international and national progress regarding the protection of traditional knowledge, to ensure the Act is not inconsistent with intellectual property regulation or *sui generis* system.

4.1.1 Purposes of the Act

The Review recommended (recommendation 1) that the purposes in section 3 of the Act be updated to reflect the:

a) special knowledge held by Aboriginal and Torres Strait Islander persons about the State's biological resources; and

b) rights of Aboriginal and Torres Strait Islander persons in relation to providing access to native biological material on Aboriginal and Torres Strait Islander peoples' land.

The Review also recommended section 4 of the Act, regarding why the Act was enacted, be updated to incorporate a reference to the Nagoya Protocol (recommendation 2).

These recommendations were unanimously supported by stakeholders during consultation on the Government Response, many of who outlined the crucial importance of protecting Aboriginal and Torres Strait Islander peoples' knowledge and enabling their social and economic futures. Submissions also noted that updating the purpose and objectives of the Act could support the international movement of traditional knowledge and is crucial to ensure Queensland researchers are able to access overseas markets.

The Queensland Government agreed in principle to the changes to section 3 of the Act, recognising that consultation and negotiation with Aboriginal and Torres Strait Islander peoples is essential to gain a proper understanding of the issues that relate to the use of their traditional knowledge. The Queensland Government agreed to update section 4 of the Act to reference the Nagoya Protocol.

QUESTION

2. Would you suggest any changes to the wording proposed in the Review (and set out above) for amending the purposes of the Act? Why?

4.1.2 Aboriginal and Torres Strait peoples' resources and traditional knowledge

The Nagoya Protocol sets out two main categories of prior informed consent and benefit sharing requirements in relation to Indigenous people:

- those relating to access to genetic resources where they have the established right to grant access to such resources, and
- those relating to access to traditional knowledge associated with genetic resources.

Although the Nagoya Protocol uses the term 'Indigenous people', this options paper refers to Australia's Indigenous peoples—Aboriginal and Torres Strait Islander people—for clarity.

The Act does not explicitly regulate access to, or the sharing of benefits from the use of, native biological material where Aboriginal and Torres Strait Islander people have the right to grant access or where traditional knowledge is used. However, in accordance with the *Queensland Biotechnology Code of Ethics*[2] (the Code of Ethics), biodiscovery entities with benefit sharing agreements must 'negotiate reasonable benefit sharing arrangements' with Aboriginal and Torres Strait Islander people whose traditional knowledge enables biodiscovery.

The Review recommended the State adopt, in general terms, the approach of the Commonwealth to use of traditional knowledge and access to native biological material from Aboriginal and Torres Strait Islander peoples' land (recommendation 8). In summary, this includes:

- recognising the importance and rights of Aboriginal and Torres Strait Islander people including in respect of their traditional knowledge (wherever obtained) and access to native biological material on Aboriginal and Torres Strait Islander peoples' land,
- incorporating a requirement for the giving of prior informed consent in relation to accessing native biological material on Aboriginal and Torres Strait Islander peoples' land and any use of traditional knowledge,
- incorporating a requirement that benefit sharing agreements include a statement regarding use of traditional knowledge and a statement regarding benefits to be provided in return for use of the traditional knowledge,
- incorporating definitions of 'Aboriginal and Torres Strait Islander people' and 'Aboriginal and Torres Strait Islander peoples' land'.

The Government Response agreed in principle to these recommendations, recognising that consultation and negotiation with Aboriginal and Torres Strait Islander peoples is essential to gain a proper understanding of the issues that relate to the use of their traditional knowledge. The Minister for Science proposes to establish a stakeholder roundtable to facilitate this consultation. Further input from all stakeholders is welcome.

Stakeholder submissions were heavily in favour of ensuring that the Act addresses access to Aboriginal and Torres Strait Islander peoples' land and traditional knowledge, and that appropriate consultation is undertaken on these matters.

Recognition of the importance and rights of Aboriginal and Torres Strait Islander people is considered in section 4.1.1 regarding the purposes of the Act.

The Review also recommended that the Act's enforcement and monitoring provisions be updated to ensure compliance with the broadening of the scope of the Act to cover traditional knowledge and access to Aboriginal and Torres Strait Islander peoples' resources (recommendation 36). Options for this are considered in section 4.4.4 regarding compliance with the Act and enforcement.

2 www.business.qld.gov.au/industries/science-it-creative/science/scientific-research/regulation-ethics

Aboriginal and Torres Strait Islander peoples' resources

As outlined above, the Nagoya Protocol requires parties to ensure access to genetic resources is subject to prior informed consent from Indigenous people and local communities who have the established right to grant access to those resources.[3]

In Australia, exclusive possession native title aligns broadly with the Nagoya Protocol's right to grant access:

> Exclusive possession native title is the right to assert sole possession, occupation, use and enjoyment in relation to the land or waters. It includes a right to make decisions about the land or waters and a right to control access.[4]

Freehold title, including under the *Aboriginal Land Act 1991* and *Torres Strait Islander Land Act 1991*, would also confer a right to grant access to native biological material unless the State has retained ownership of the resource through a reservation or declaration.[5] However, non exclusive possession native title and tenures such as Deeds of Grant in Trust do not confer a right to grant access to resources, such as native biological material.

As a result, those areas where an Aboriginal or Torres Strait Islander person could have an established right to grant access to the resources (i.e. exclusive possession native title and freehold titles) are currently out of scope of the Act, as they do not meet the definition of 'State land' in the Act. Therefore, to address the Nagoya Protocol requirements relating to access to genetic resources, the Act would need to be amended to apply to areas currently out of scope. Further discussion of potential reforms to the scope of the Act is in section 4.1.3 below.

The Commonwealth approach appears to go beyond the requirements of the Nagoya Protocol, by establishing any native title holder as an 'access provider' (i.e. holders of both exclusive and non exclusive possession native title rights).[6] As the Review's recommendation was based on adopting the Commonwealth's approach, it also appears to go beyond the Nagoya Protocol by suggesting, as an example, that 'Aboriginal and Torres Strait Islander peoples' land' could be defined as 'State land over which Aboriginal and Torres Strait Islander people have a claim but exclusive possession has not been recognised' (recommendation 8(c)).

Although it may not amount to prior informed consent, an alternative option may be to amend the Compliance Code's definition of 'land/water manager', which currently includes for example occupiers, residents, trustees, and lessees. Including native title holders as 'land/water managers', would require biodiscovery entities to negotiate access arrangements with native title holders (regardless of whether exclusive or non-exclusive possession). This would assist with making connections between biodiscovery entities and native title holders.

3 Nagoya Protocol, art 6
4 COAG, *Investigation into Indigenous Land Administration and Use* (Australian Government 2015) 74, https://www.pmc.go.au/sites/default/files/files/COAG_Investigation_into_Indigenous_Land_Administration_and_Use.pdf
5. For example, under the *Forestry Act 1959* or a reservation under the *Land Act 1994*
6. Environment Protection and Biodiversity Conservation Regulations 2000 (EPBC Regulations) reg. 8A04(i)

QUESTIONS

3. What types of rights, such as land tenures and/or native title rights, do you think should give rise to requirements for prior informed consent from, and benefit sharing with, Aboriginal and Torres Strait Islander peoples?
4. Are there other types of rights you think should give rise to requirements to be notified or consulted regarding access to the land (as opposed to the resources)?

Traditional knowledge

Traditional knowledge relevant to biodiscovery may be held by Aboriginal or Torres Strait Islander people with or without an established right to grant access, or it may be held by different people from those who have the rights to grant access. Therefore, requirements relating to traditional knowledge could be incorporated without any change to the land tenures covered by the Act.

The Review recommended broadly adopting the Commonwealth approach to use of traditional knowledge (recommendation 8). The Commonwealth Regulations do not require prior informed consent for use of traditional knowledge for non-commercial biodiscovery, but the permit application must contain information about the use of traditional knowledge and any agreement regarding that use.[7] For commercial biodiscovery, the Commonwealth requires:

> A benefit sharing agreement must provide for reasonable benefit sharing arrangements, including protection for, recognition of and valuing of any Indigenous peoples' knowledge to be used, and must include the following:
>
> ...
>
> (h) a statement regarding any use of Indigenous peoples' 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 peoples' knowledge;
>
> (j) if any Indigenous peoples' 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.[8]

The Northern Territory legislation requires similar information in benefit sharing agreements. However, instead of a copy of any agreement, it requires details of the benefits that the access provider will receive in return for the taking of resources.[9] This may be more limited than the Commonwealth's approach, as it focusses on access providers only.

In Victoria, a policy states that parties must enter into a benefit sharing agreement, with any benefits resulting from use of native biological and genetic resources being shared in a fair and equitable manner, including with respect to the use of traditional knowledge.[10]

These requirements apply to the use of traditional knowledge by biodiscovery entities. They would not apply where Aboriginal and Torres Strait Islander peoples hold knowledge about particular native biological material but do not share it with the biodiscovery entity prior to that entity discovering the information through alternative means, such as through analysis of samples.

The Review recommended that prior informed consent requirements could be satisfied through either a Statutory Declaration (or equivalent) confirming prior informed consent has been provided in accordance with accepted guidelines (for example the AIATSIS Guidelines[11]), or entry into an Indigenous Land Use Agreement authorising the proposed action and providing the consent.

Provision of this evidence could be required as a precondition to granting a collection authority or entering into a benefit sharing agreement. Submissions generally supported this recommendation, with a suggestion that detailed consultation with Aboriginal and Torres Strait Islander people is needed.

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7. EPBC Regulations, reg 17.02(2)(ga)
8. EPBC Regulations, reg 8A.08
9. *Biological Resources Act 2006* (NT), s.29
10. *Biodiscovery in Victoria: A framework for managing access to and use of our native biological resources*, https://www.cbd.int/doc/measures/abs/msr-abs-au8-en.pdf
11. AITSIS 2012, *Guidelines for Ethical Research in Australian Indigenous Studies*, https://aiatsis.gov.au/research/ethical-research/guidelines-ethical-research-australian-Indigenous-studies

Option 1: Amend the Act to require prior informed consent on mutually agreed terms for use of traditional knowledge, including through statutory declarations, entry into Indigenous Land Use Agreements, benefit sharing agreements, and/or other mechanism as appropriate.

Option 2: Release guidance to raise awareness and guide compliance with the Nagoya Protocol's requirements regarding access to traditional knowledge.

Option 3: Do not amend the Act or release guidance regarding access to traditional knowledge.

Note that none of these options is intended to address the application of these requirements to non-commercial activities or non-State land. Section 4.1.3 addresses these issues in dealing with the scope of the Act.

QUESTIONS

5. Which option or combination of options do you prefer? Why?
6. For options 1 or 2:
   a. What, if any, changes would you suggest to the Commonwealth/Northern Territory requirements for the content of benefit sharing agreements or are there other examples that could be used?
   b. Are there any other ways a biodiscovery entity could demonstrate they have obtained prior informed consent on mutually agreed terms, or the holder of traditional knowledge provide prior informed consent on mutually agreed terms?
7. What would the implications for you or your organisation be if requirements for prior informed consent and benefit sharing regarding traditional knowledge were introduced?

Definition of traditional knowledge

A draft glossary of key terms and concepts under the CBD, which will likely be adopted at the 14th Conference of Parties in November 2018, defines 'traditional knowledge' as:

> The knowledge, innovations and practices of Indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity.[12]

The term 'traditional knowledge' as it relates to genetic resources is not defined by legislation in Queensland; however the Queensland Government's business portal 'Business Queensland' states:

> Traditional knowledge refers to:
> - knowledge or practices
> - passed down from generation to generation
> - that part of the traditions or heritage of Indigenous communities
> - knowledge or practice for which Indigenous communities act as the guardians or custodians.
>
> The type of knowledge that is considered within this scope includes:
> - knowledge about the medicinal properties or effects of flora and fauna
> - knowledge about hunting or fishing techniques.[13]

The Nagoya Protocol states that it is the right of Indigenous people and local communities to identify the rightful holders of their traditional knowledge associated with genetic resources, within their communities.[14] It further requires parties to support the development by Indigenous people and local communities of:

- community protocols in relation to access to traditional knowledge and fair and equitable sharing of benefits arising from utilisation of that knowledge,
- minimum requirements for mutually agreed terms, and
- model contractual clauses for benefit sharing.[15]

Any approach to determining what constitutes traditional knowledge and who holds it will need to consider the State's role. For example, whether the State should have a decision-making, gate keeping, or facilitation role.

The administrative burden for all stakeholders, and resourcing and workload implications for the State would also need to be considered.

A submitter suggested that the *Aboriginal Cultural Heritage Act 2003* (Qld) and *Torres Strait Islander Cultural Heritage Act 2003* (Qld) provide a sufficient process for Aboriginal and Torres Strait Islander communities to identify the rightful holders of their traditional knowledge. This legislation sets up a database of cultural heritage, which assembles information about Aboriginal and Torres Strait Islander cultural heritage in a central and accessible location. The database is not available to the public but may be made available to someone who requires the information to satisfy their cultural heritage duty of care.[16] The database is not an authoritative and complete record but may be of assistance in meeting obligations under the cultural heritage legislation.

Any approach that involves a government department as an arbiter, such as the example above, may create conflict over who can submit traditional knowledge, their rights, and whether their registered information was used in a biodiscovery project. Extensive and in-depth consultation with relevant stakeholders would therefore be required.

An alternative approach may be for the State to provide assistance to biodiscovery entities in identifying the Aboriginal or Torres Strait Islander people who may hold traditional knowledge in relation to a particular area. The biodiscovery entity would then have responsibility for agreeing with those or other relevant people about the traditional knowledge that may be used, where it was sourced, and who should share in any benefits of the biodiscovery. This option would reduce the State's role in determining the holders of traditional knowledge.

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12 Ad hoc open-ended inter-sessional working group on Article 8(j) and related provisions of the *Convention on Biological Diversity*, recommendation adopted by the working group, 10/2 glossary of relevant key terms and concepts within the context of Article 8(j) and related provisions www.cbd.int/doc/recommendations/wg8j-10/wg8j-10-rec-02-en.pdf

13 www.business.qld.gov.au/running-business/protecting-business/ip-kit/browse-ip-topics/traditional-knowledge-and-Indigenous-cultural-expression/definitions

14 Nagoya Protocol preamble

15 Nagoya Protocol article 12(3)

16 Cultural heritage database and register www.datsip.qld.gov.au/people-communities/aboriginal-torres-strait-islander-cultural-heritage/cultural-heritage-database-register

A submitter also noted that there are important aspects of traditional knowledge about native biological material that are of spiritual or religious significance and which are not readily captured by intellectual property law principles. These include the status of native flora and fauna as totems, the use of native flora and fauna in initiation and other ceremonies.

The submitter suggested that the State give consideration to a broader regime which recognises and protects these aspects of traditional knowledge, with this possibly done in a similar way to the principles adopted as the foundation for Queensland's cultural heritage legislation.

These principles acknowledge, for example, that Aboriginal and Torres Strait Islander people should be recognised as the primary guardians of cultural heritage and the importance maintaining knowledge and practices of Aboriginal and Torres Strait Islander people.[17]

17 s.5 *Aboriginal Cultural Heritage Act 2003*, s.5 *Torres Strait Islander Cultural Heritage Act 2003*.

Option 1: Define 'traditional knowledge' by reference to the determination by the relevant Aboriginal and Torres Strait Islander people as to what constitutes their traditional knowledge.

Option 2: Adopt the CBD's definition of 'traditional knowledge', with minor changes to make it appropriate to Queensland.

Option 3: Develop guidance that includes principles regarding traditional knowledge, using those set out in section 5 of the *Aboriginal Cultural Heritage Act 2003* and *Torres Strait Islander Cultural Heritage Act* 2003 as a starting point.

QUESTIONS

8. Which options or combination of options do you prefer? Why?
9. Are there other definitions that could be used as the basis for a definition in the Act or guidance?
10. For option 1, do you think the cultural heritage legislation provides an appropriate process to identify the rightful holders of traditional knowledge?
    a. If not, are there any other existing processes that could be used?
11. For option 3, what do you think are the key principles that should be included?

Definitions of Aboriginal and Torres Strait Islander people and their land

The Review recommended including definitions of 'Aboriginal and Torres Strait Islander people' and 'Aboriginal and Torres Strait Islander peoples' land' in the Act (recommendation 8). The Review did not propose definition of 'Aboriginal and Torres Strait Islander people' but suggested as an example that 'Aboriginal and Torres Strait Islander peoples' land' could be defined as 'State land over which Indigenous people have a claim but exclusive possession has not been recognised'. As discussed above in relation to Aboriginal and Torres Strait Islander peoples' resources, this definition appears to go beyond the Nagoya Protocol.

If added, these definitions would be relevant for any new requirements around prior informed consent from Aboriginal and Torres Strait Islander people for access to resources on their land and/or use of

their traditional knowledge (see section 4.1.2). This section is not intended to address the application of Act requirements to non-State land, such as to land over which a native title determination of exclusive possession has been granted—see section 4.1.3 regarding the scope of the Act.

The Commonwealth uses the following definitions of 'Indigenous people' and 'Indigenous peoples' land':

> A person is an Indigenous person if he or she is:
> (a) a member of the Aboriginal race of Australia; or
> (b) a descendant of an Indigenous inhabitant of the Torres Strait Islands.
>
> Land is Indigenous peoples' land if:
> (a) a body corporate holds an estate that allows the body to lease the land to the Commonwealth or the Director; and
> (b) the body corporate was established by or under an Act for the purpose of holding for the benefit of Indigenous persons title to land vested in it by or under that Act.[18]

In Queensland, the *Aboriginal Land Act 1991* (Qld) and the *Torres Strait Islander Land Act 1991* (Qld) (the Land Acts) include definitions of Aboriginal people and Torres Strait Islander people, respectively, which align with the Commonwealth definition of 'Indigenous person'. The definitions of Aboriginal land and Torres Strait Islander in the Land Acts land are linked to the processes under those acts for transferring or granting land.[20]

Other relevant Queensland legislation, such as the cultural heritage legislation, does not define Aboriginal or Torres Strait Islander people.

The CBD and the Nagoya Protocol have intentionally abstained from defining Indigenous people or their land. However, the Protocol's requirements for Indigenous peoples' prior informed consent apply to resources over which they have 'an established right to grant access to'.[21]

18 EPBC Act, s 363
19 The *Aboriginal Land Act 1991*, s.5 states that 'Aboriginal people are people of the Aboriginal race of Australia'.
20 The *Torres Strait Islander Land Act 1991*, s.5 states that 'A Torres Strait Islander is a person who is a descendant of an Indigenous inhabitant of the Torres Strait Islands'.
21 The *Aboriginal Land Act 1991*, s.8 states that 'Aboriginal land is transferred land or granted land', and s.9 states that 'Transferred land is land that is granted under part 4 without a claim being made under this Act for the land'.

Option 1: Amend the Act to include definitions of 'Aboriginal and Torres Strait Islander people' and 'Aboriginal and Torres Strait Islander peoples' land' modelled off the Commonwealth definitions.

Option 2: Amend the Act to include definitions of 'Aboriginal and Torres Strait Islander people' and 'Aboriginal and Torres Strait Islander peoples' land' that cross-reference other Acts (such as the *Aboriginal Land Act 1991* and the *Torres Strait Islander Land Act 1991*). This could effectively create a list of tenures that would be 'Aboriginal and Torres Strait Islander peoples' land'.

Option 3: Amend the Act to define 'Aboriginal and Torres Strait Islander peoples' land' as on which 'they have the established right to grant access' to native biological materials, in accordance with the Nagoya Protocol.

Option 4: Do not amend the Act to include definitions of 'Aboriginal and Torres Strait Islander people' and Aboriginal and Torres Strait Islander peoples' land'.

QUESTIONS

12. Which options or combination of options do you prefer? Why?
13. What, if any, other examples of relevant definitions could be used?
    a. What are the benefits of these definitions?

Activities in exercise of native title rights

One submission raised a concern that the Act does not currently provide any exception for exercise of native title rights and interests on State land. They were concerned that this could mean that the Act infringes the native title rights of people who have a determination of non exclusive possession, or native title claimants.

Article 12(4) of the Nagoya Protocol states that, 'Parties, in their implementation of this Protocol, shall, as far as possible, not restrict the customary use and exchange of genetic resources and associated traditional knowledge within and amongst Indigenous and local communities in accordance with the objectives of the Convention.'

The *Native Title Act 1993* (Cwth) already provides an overarching exemption from a law of the Commonwealth, a State or a Territory that requires a permit, where the activity is the exercise of native title rights and is for the purpose of satisfying personal, domestic or non-commercial communal needs.[22] However, this exception does not apply where the permit can only be granted for research, environmental protection, public health or public safety purposes. It is therefore unclear whether this exemption applies to the Act. It may also not exempt the native title holder from requirements to enter into a benefit sharing agreement. This exemption is also limited to non-commercial uses.

The Commonwealth Regulations provide a broader exemption from requiring a permit for the taking of biological resources by Indigenous persons in the exercise of their native title rights and interests.[23] This does not contain any restriction on the purpose being non-commercial.

Creating an exemption for the exercise of native title rights could lead to difficulty satisfying biodiscovery partners or collaborators that the resources were collected in compliance with international law, as there would be no permit to demonstrate compliance. However, it may be possible to support this through statements of provenance similar to any other activities outside the scope of the Act (see options in section 4.1.3 regarding scope of the Act).

Option 1: Amend the Act or develop regulations to state that activities carried out pursuant to native title rights are not within the scope of the Act.

Option 2: Develop guidance on the interaction between the Act and the exercise of native title rights.

Option 3: Do not amend the Act or develop regulations or guidelines.

QUESTIONS

14. Which options or combination of options do you prefer? Why?
15. For option 1, do you have suggestions on the specific scope of an exemption?
16. Are there any other measures that would be required to support biodiscovery activities undertaken by native title holders?

22 s.211 *Native Title Act 1933* (Cwth)
23 r.8A.03 EPBC Regulations

4.1.3 Scope of the Act

The Review found that the requirements for collection authorities meet the Nagoya Protocol's requirements of prior informed consent, with the exception of access to Aboriginal and Torres Strait Islander peoples' resources and traditional knowledge (see section 4.1.2). However, the Nagoya Protocol's requirements to obtain prior informed consent on mutually agreed terms and ensure fair and equitable sharing of benefits are not limited, as the Act currently is, to only commercial uses or to only State land.

Non-commercial activities

The current definition of 'biodiscovery' in the Act means that only research undertaken on native biological material for commercial gain is captured:

> ***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 recommended delinking commercialisation from the definition of biodiscovery. This would be consistent with the Nagoya Protocol, which extends to research utilising genetic resources, and the Commonwealth Regulations that regulate the use of biological resources in Commonwealth areas without prerequisite commercialisation activities. Inclusion of non-commercial activities within the scope of the Act may also aid Queensland organisations to collaborate with overseas partners, who may require demonstration of compliance with international requirements (such as the Nagoya Protocol).

The Review recommended utilising the Commonwealth's approach to regulating non-commercial activities, using a permit and statutory declaration. Possible approaches to permitting or otherwise regulating non-commercial activities are discussed further in section 4.3.1.

The submissions received in response to the review and Government Response contained varying points of view, such as that removing commercialisation as a prerequisite of biodiscovery:

- is consistent with the usual research and development process and the Nagoya Protocol
- may restrict or deter research, due to increased administrative burden and high transaction costs on research collaborations
- is unnecessary, as there are no realistic scenarios where a commercial organisation would invest time and money into research in isolation of potential commercial gain
- would, if implemented using the Commonwealth approach, create a challenge in identifying when there is a change of intent from non-commercial to commercial and disincentivise a company renegotiating a benefit sharing agreement after the resources have already been used.

The department's experience is that the issue of determining when an activity is considered commercial is relevant regardless of the whether the definition of biodiscovery in the Act is amended or not. Options regarding this issue are outlined in section 4.2.2 regarding the definition of commercialisation.

Option 1: Remove the linkage between commercialisation and biodiscovery by redefining 'biodiscovery' and/or 'biodiscovery research'. This would require consequential amendments to the Act to require prior informed consent for non-commercial activities (for example, through a collection authority or permit under the *Nature Conservation Act 1992*—see s.4.3.1 for detail on options).

Option 2: Provide guidance to biodiscovery entities on the requirements for prior informed consent for non-commercial activities.

Option 3: Do not amend the Act or provide guidance.

QUESTIONS

17. Which option or combination of options do you prefer? Why?
18. What are the likely impacts for your organisation if non-commercial activities were included (and quantify where possible)?
    a. To what extent would it change the administrative burden of complying with the Act?

Land tenures

The Act currently applies only to 'State land', which is defined as:

> **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.

This is narrower than the Nagoya Protocol, which also requires prior informed consent from, and benefit sharing with, Indigenous peoples and local communities where 'they have an established right to grant access' to the native biological material. The Nagoya Protocol sets up detailed requirements for land that is subject to the State's 'sovereign rights', such as granting a permit as evidence of compliance. However, the requirements are less prescriptive for other tenures, simply requiring governments to take legislative, administrative or policy measures aimed at ensuring that prior informed consent is obtained and that benefits are shared in a fair and equitable way.

The Review did not recommend any amendment to the definition of State land to the extent it relates to native title (recommendation 6) or to capture freehold land (recommendation 11), in the absence of broader consideration. This is because, in Australia, an owner of a fee simple estate owns all natural things (including biological resources) attached to land or growing on it,[24] although there is no absolute property ownership in wild animals while they are alive.

24 Unless the State has retained ownership of the resource through a reservation or declaration, for example under the *Forestry Act 1959* of a reservation under the *Land Act 1994*

The explanatory memorandum for the Act outlines that the intent was not to alter the access rights or intellectual property rights of landowners which may be generated by biodiscovery. Therefore, the Review concluded that there is no basis for the State to be entitled to obtain benefits from biodiscovery on freehold land or land with an exclusive native title determination.

Although the Government Response agreed with the Review's recommendation not to amend the scope of the Act in terms of tenures, consultation on the Review and the Government Response indicated that further consideration of this issue is required. The Government also considers that this is a key issue relevant to the broader commitment to investigate options for implementation of the Nagoya Protocol.

Submissions on this topic varied, and included:

- support for the continued exclusion of land over which native title rights to exclusive possession had been determined.
- support for the Act applying to all land tenures in Queensland. This was stated to be because it would be compliant with the Nagoya Protocol, reduce forum-shopping, reduce confusion, and improve ability to meet requirements from international partners to demonstrate compliance with the Nagoya Protocol.
- that the State should not be party to benefit sharing agreements involving private landholders, nor receive benefits from the biodiscovery, and the State should record only basic information about the benefit sharing agreement.
- that 'established right to grant access' is a complex concept and that the interpretation of this should be clearly spelt out in the Act.

It may be possible to extend the Act to non-State land, without extending the rights of the State to share in the benefits of biodiscovery on that land. This could be done by requiring that biodiscovery entities obtain the prior informed consent of, and negotiate benefit sharing with, the owners of the land or the native title holders. For example, the Northern Territory requires that, where the access provider is not the Territory, the access provider and the biodiscovery entity must confirm to the relevant department that a benefit sharing agreement that meets legislative requirements is in place.[25] This would increase both regulatory burden for biodiscovery industry and administrative burden for the Queensland Government. On the other hand, it may assist biodiscovery entities to demonstrate compliance with international requirements to potential international collaborators and partners, and it would protect the rights of those landholders.

An alternative to extending the Act's application is for the State to provide guidance to landowners, native title holders, and biodiscovery entities about conducting biodiscovery on non-State land (as per recommendation 5 of the Review). This would assist in ensuring biodiscovery entities obtain the prior informed consent of, and share benefits with, private landowners and native title holders, without increasing regulatory burden or detracting from those landholders' rights.

The Act could also be amended to explicitly acknowledge that it does not intend to displace the Nagoya Protocol's obligations to obtain prior informed consent on mutually agreed terms on non-State land, and that these obligations continue. Furthermore, compliance with the Nagoya Protocol could be checked if the biodiscovery entity were to apply for an ICC or equivalent certificate at any time (see section 4.1.4). This provides incentive for the entity to comply, as the entity may be unable to work with overseas partners without such evidence of compliance with the Nagoya Protocol.

25 s.19 *Biological Resources Act 2006* (NT)

Option 1: Amend the Act to cover non-State land (i.e. freehold land, freeholding leases and/or land with a native title determination of exclusive possession) without providing for the State to be entitled to the benefits of the biodiscovery.

Option 2: Amend the Act to acknowledge that the Act does not displace the Nagoya Protocol's requirements in relation to non-State land, and acknowledge the rights of landowners regarding access and benefit sharing.

Option 3: Provide guidance on the Nagoya Protocol's requirements for owners of non-State land and holders of exclusive-possession native title rights, and biodiscovery entities working on this land.

Option 4: Do not amend the Act or issue guidance.

QUESTIONS

19. Which option or combination of options do you prefer? Why?
20. What are the likely impacts for your organisation if requirements relating to freehold land and exclusive possession native title were included (and quantify where possible)?
    a. To what extent would it change the administrative burden of complying with the Act?

4.1.4 Demonstrating provenance and prior informed consent on mutually agreed terms

The Nagoya Protocol requires that checkpoints collect or receive information related to prior informed consent, the source of the genetic resource, establishment of mutually agreed terms, and the utilisation of genetic resources.[26] In turn, parties to the Nagoya Protocol require users of genetic resources to provide the required information. This information is to be made available to relevant national authorities and to the Access and Benefit sharing Clearing-House.

To facilitate international transfer of samples and products, the Nagoya Protocol sets up that permits issued in accordance with article 6 of the Protocol constitute an ICC. This serves as evidence that genetic resources covered by the ICC have been accessed in accordance with the Nagoya Protocol. The Nagoya Protocol outlines standard information that should be on the ICC, so long as it is not confidential.[27]

The Review made a range of recommendations relating to mechanisms to record and demonstrate provenance of samples and that requirements for prior informed consent on mutually agreed terms have been met. These recommendations included that:

- the following checkpoints should be used to establish provenance and prior informed consent:
  - application for Queensland Government funding for research using native biological material
  - issuing ICCs (recommendation 39).
- implementation of a biodiscovery register may assist with compliance with the Nagoya Protocol (recommendation 42)
- trusted collections may, subject to further consultation with the Commonwealth, be accredited to grant access to genetic resources (recommendation 43).

Applications for Queensland Government funding

At present, organisations undertaking biotechnology (which includes biodiscovery) that receive State Government funding or assistance must comply with the Code of Ethics. The Code of Ethics requires negotiation of reasonable benefit sharing where traditional knowledge is used.[28] As the Code of Ethics is not a legislative instrument, failure to comply with it will not attract legal sanctions. However, the State reserves the right to review and withdraw funding provided to any organisation undertaking biotechnology which is found to be in breach of the Code of Ethics.

However, to fully meet the recommendation and align with the Nagoya Protocol, this checkpoint would also need to apply to:

- obtaining prior informed consent for use of traditional knowledge, and
- obtaining prior informed consent for, and sharing benefits of, material sourced from non-State land, or from other jurisdictions nationally or internationally.

26 Nagoya Protocol article 17(1)
27 Nagoya Protocol article 17(1)
28 Biotechnology Code of Ethics

QUESTION

21. What impact do you think a requirement to demonstrate compliance for material sourced outside of Queensland, or from non-State land within Queensland, would have on applications for funding? For example, would it act as a deterrent?

International Certificates of Compliance

The Review noted that collection authorities are likely to meet the standard required to be considered an ICC. However, subject to the extension of the Act (recommendation 8), the Review notes that Queensland may be able to issue its own ICCs (recommendation 39).

At present, Australian biodiscovery entities cannot obtain official ICCs under the Nagoya Protocol, as Australia has not ratified the Nagoya Protocol. Furthermore, the Queensland Government is not aware of any plan by the Commonwealth to ratify the Nagoya Protocol. As a result, the Commonwealth does not provide a framework for issuing ICCs; and the Northern Territory has independently adopted a system that allows the chief executive to issue certificates of provenance for samples, which act in a similar capacity to ICCs.

Submissions received agreed with both recommendations relating to ICCs and the need to monitor Commonwealth progress on Australia's ratification of the Nagoya Protocol and any position on ICC's.

The Queensland Government notes the importance of ICCs in the checkpoint process, and their role in enabling Queensland biodiscovery entities to be competitive in international markets. Continued monitoring and collaboration with the Commonwealth is essential to develop nationally consistent permits that provide regulatory certainty for Queensland researchers operating in the international marketplace.

QUESTIONS

22. Should the Queensland Government wait to develop a certification framework that is consistent with the Commonwealth or should it develop its own system independently?
    a. What are the benefits and costs to you of each approach?
23. How important is adoption of ICCs or alternative proof of compliance with the Nagoya Protocol for maintaining international competitiveness of Queensland's biodiscovery entities? Why?

Biodiscovery register

In support of the adoption of a checkpoint system and ICCs, the Review also recommended that the government further examine:

- the viability of implementing a biodiscovery register with supporting enforcement provisions
- the regulatory implications of establishing a biodiscovery register, including collecting information on the biodiscovery register and issuing ICCs to persons/entities covered by and outside the scope of the Act (recommendation 42).

The review proposed that a biodiscovery register could function as a central repository for information about activities that fall within the scope of the Act, and could contain private and publically available information, sufficient to allow issuance of ICCs. It could also contain information about activities not in scope of the current Act (e.g. activities on freehold land) where this information is volunteered. The register would enable the Queensland Government to monitor the progress of biodiscovery activities (e.g. whether it is commercial or non-commercial), provide a platform for simpler reporting under benefit sharing agreements, and help biodiscovery entities to meet international obligations, including the use of native biological material obtained from non-State land.

During consultation, no specific comments on the biodiscovery register were received.

Development and maintenance of a register is standard business of government, and important for the accurate management of applications and for increased transparency. Further work would be required to determine the specific format and costs of establishing and maintaining a register.

QUESTIONS

24. What are the key considerations you think are important in the development of a biodiscovery register? Why?
25. What is the key information you think is important to include in a biodiscovery register?
    a. Is there information you think is important to be included in a biodiscovery register but not made public?

Trusted institutions

The Review recommended that trusted institutions may, subject to further consultation with the Commonwealth, be accredited to grant access to genetic resources (recommendation 43). This would be intended to reduce the regulatory burden for those organisations that deal with a large volume of samples. The types of organisations that would likely be candidates for accreditation include herbaria, museums and other large collection holders.

An official register of trusted institutions is maintained by the CBD's Access and Benefit sharing Clearing House. At present, Australian biodiscovery entities cannot obtain official status as trusted institutions under the Nagoya Protocol, as Australia has not ratified the Nagoya Protocol. As stated above, the Queensland Government is not aware of any plan by the Commonwealth to ratify the Nagoya Protocol.

Queensland could create its own trusted institution framework, modelled on the European Union's system of registered collections. Collections included in the system apply measures restricting the supply of genetic resources to third parties and are able to provide documentary evidence of legal access and mutually agreed terms where required. Users that obtain a genetic resource from a registered collection are considered to have exercised due diligence.[29] To be included on the register a collection must:

- apply standardised procedures for exchange,
- only supply material and related information with documents providing evidence that they were accessed legally,
- keep records of all samples and information supplied to third parties,
- use unique identifiers for samples supplied, and
- use appropriate tracking and monitoring tools for exchanging samples with other collections.[30]

Accreditation may confer benefits such as exemption from permits for the collection of native biological material. The institution would likely still be required to enter into a benefit sharing agreement with the State in relation to any commercial use they undertake. Trusted institutions would likely be subject to regular audits of ongoing compliance with the requirements for accreditation.

The Review highlighted the importance of a consistent approach to accreditation and thus recommended a national accreditation framework. The Commonwealth has proposed amending its framework to allow for such a system, but this work has not yet progressed.

Submissions received during consultation expressed support for a different regulatory system for trusted parties (although the submissions also noted that this may represent too significant a change at this time) and also for consulting with the Commonwealth.

29 Regulation (EU) No. 51/2014, preamble para 28
30 Regulation (EU) No. 41/2014, article 5(3)

QUESTIONS

26. Should the Queensland Government wait to develop a truisted institution framework that is consistent with the Commonwealth or should it develop its own system independently?
27. What do you consider to be key requirements of a framework that accredits trusted institutions?
28. What would the consequences of this system be for your organisation?
    a. How would it change the administrative burden of complying with the Act?

4.2 Definitions

4.2.1 Native biological material

The Act regulates the use of native biological material for the purpose of biodiscovery. Relevant definitions currently in the Act are:

> '**Native biological material** means—
> a) a native biological resource; or
> b) a substance sourced, whether naturally or artificially, from a native biological resource; or
> c) soil containing a native biological resource.
>
> **Native biological resource** means—
> a) a non-human living organism or virus Indigenous to Australia and sourced from State land or Queensland waters; or
> b) a living or non-living sample of the organism or virus.

The Review recommended the State consider the following amendments to these definitions:

- extending the definition of native biological material to:
  - cover underlying data, information or sequences of native biological resources (recommendation 29).
  - include 'extracts from samples' in subparagraph (b) of the current definition (recommendation 31).
  - include native biological resources 'maintained in an ex situ collection' (recommendation 32).
- excluding from the definition of native biological material the following (recommendation 33):
  - a genetically modified organism for the purposes of section 10 of the *Gene Technology Act 2000* (Cwth) 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* (Cwth).

Terminology used across Australia and internationally is not consistent. For example, the CBD and Nagoya Protocol uses the term 'genetic resources', which means 'genetic material of actual or potential value'; and, 'genetic material' means 'any material of plant, animal, microbial or other origin containing functional units of heredity'.[31] The Commonwealth uses the term 'biological resources', which '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'.[32] This inconsistency can create issues about the scope of requirements, with digital sequence information and synthetic biology being most contentious examples.

Submissions on proposed amendments to the definition of native biological material included:

- that 'native biological material' is broader than 'genetic resources' as used in the Nagoya Protocol.
- that it is unclear why it is necessary to include 'extracts from samples'. The submission provides an alternative that the definition should include 'derivatives of samples'.
- support for extending the Act to resources in ex situ collections, on the basis that this would keep Queensland consistent with international practice and the Nagoya Protocol. The submission noted that in making such a change, key matters such whether new and continuing uses of ex situ material is captured, how to capture the origin of the material and how to manage the flow of genetic resources through intermediaries.
- objection to extending the Act to resources in ex situ collections, on the basis that doing so would unnecessarily complicate the definition and could cause inconsistencies within the Act. The submitter suggested that an educational program or guidance notes would be a more appropriate means of communicating to biodiscovery entities the scope of the Act.
- the need for greater clarity on specific exclusions from the Act, for example, native biological material where a plant breeders permit has been granted under section 44 of the *Plant Breeders Rights Act 1994*.

Inclusion of digital sequence information was the most contentious element of the Review's recommendations on the definition of native biological material. Submissions on digital sequence information included:

- concern about inconsistency with the CBD and Nagoya Protocol's definition of genetic resources.

31 CBD, article 2
32 EPBC Regulations, regulation 1.03

- concern that the broad exchange and wide accessibility of this information would create a huge burden and adversely affect innovation, and may complicate operation of the Act.
- that there is considerable risk of unintended consequences if a broad definition is adopted (which includes non-tangibles), such as researchers avoiding the use of underlying data, with detrimental impacts for science.
- that it would be necessary to think carefully about how digital sequence information is defined (i.e. whether it includes non-confidential descriptive information), how the information would be tracked and recorded, and how it can be linked to the physical samples when it is used by subsequent users.

The issue of digital sequence information is yet to be fully debated, let alone resolved, in an international context and is unlikely to be resolved in the short to medium term. Some parties to the CBD consider that digital sequence information is included in the CBD's definitions of genetic resources and genetic material, and are of the view that the terms include both tangible and intangible components. However, the Commonwealth's position is that digital sequence information on genetic resources is a distinct entity from tangible physical genetic resources and material. The Commonwealth considers that, as digital sequence information does not contain functional units of heredity or genes, the CBD and the Nagoya Protocol would need to be renegotiated to redefine the term 'genetic resources', if the intent was to include digital sequence information.

On the other hand, Queensland's model benefit sharing agreement presently includes digital sequence information within scope. It defines 'product' (in the context of a product of biodiscovery) as:

> '… any thing (physical or non-physical, for example, data including sequence information) in relation to which property rights (including Intellectual Property rights) which incorporates, is created, produced, extracted or derived from the Native Biological Material.'

Despite this, the Review 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. The rationale for this was limiting the opportunity of biodiscovery entities to deliberately by-pass the Act. The Review noted this would have consequential impacts on the permitting regime, and recommended working with providers of digital sequence information to determine the most appropriate framework.

A key issue that would need to be resolved is the ability to monitor and enforce biodiscovery regulation for activities that do not include tangible material, and subsequent use of that intangible material. There may be no physical component of the native biological material, or evidence of it, in the final product.

Option 1: Replace the term 'native biological material' with 'genetic resources', as defined in the CBD and Nagoya Protocol, in the Act. This would mean any international decisions regarding whether the term includes digital sequence information (or not) would be 'automatically' reflected in Queensland laws.

Option 2: Amend the Act's definition of 'native biological material' to incorporate changes regarding some or all of:

a) inclusion of underlying data, information or sequences of native biological resources;
b) inclusion of 'extracts from samples';
c) inclusion of 'derivatives of samples';
d) inclusion of ex-situ collections;
e) exclusion of a genetically modified organism for the purposes of section 10 of the *Gene Technology Act 2000* (Cwth) or consistent state or territory legislation; and/or
f) exclusion of a plant variety for which a plant breeder's right has been granted under section 44 of the *Plant Breeder's Rights Act 1994* (Cwth); and/or
g) exclusion of 'man-made materials'.

Option 3: Provide further guidance around the interpretation and application of the term 'native biological material' (or equivalent term if amended).

QUESTIONS

29. Which option or combination or options do you prefer? Why?
30. For option 2, which components of the amendments do you support? Why?
31. What would the implications of any of these changes be to your organisation (and quantify where possible)?
    a. How would it change the administrative burden of complying with the Act?

4.2.2 Commercialisation

The point at which an activity changes from non-commercial to commercial has been contentious and confusing in Queensland (under the current Act) and other jurisdictions, for both regulators and researchers. Section 4.1.3 discusses the options relating to expanding the scope of the Act to cover non-commercial activities. If the Act is amended to incorporate non-commercial activities, the definition of commercialisation will continue to be an issue for determining whether a benefit sharing agreement must be entered into. If the Act is not amended, the definition remains relevant to determine whether the Act applies at all.

The Act currently defines 'commercialisation' as:

> *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.[33]

The Compliance Code further states that 'commercial purposes include situations where one or more of the research objectives are commercially motivated, and/or where commercialisation and/or intellectual property protection of selected research outcomes is an expectation of the employer, collaborator, or funding body'.[34]

Many other jurisdictions either do not have a requirement for commercialisation or have not provided any further guidance about the point at which an activity becomes commercial. The most useful examples on this topic appear to be from South Africa and the European Union (EU).

In South Africa, the *National Environmental Management: Biodiversity Act 2004* differentiates between the 'discovery phase' and the 'commercialisation phase' of biodiscovery.

33 *Biodiscovery Act 2004*, schedule (Dictionary)
34 Compliance Code

The supporting regulations provide that:

> "Commercialisation" includes the following activities in relation to Indigenous biological resources—
>
> - The filing of any complete intellectual property application, whether in South Africa or elsewhere;
> - Obtaining or transferring any intellectual property rights or other rights;
> - Commencing clinical trials and product development, including the conduct of market research and seeking pre-market approval for the sale of resulting products; or
> - The multiplication of Indigenous biological resources through cultivation, propagation, cloning or other means to develop and produce products, such as drugs, industrial enzymes, food flavours, fragrance, cosmetics, emulsifiers, oleoresins, colours and extracts.[35]

The EU has released guidance on the implementation of EU Regulation No. 511/2014 on compliance measures for users from the Nagoya Protocol.[36] This guidance provides a non-exhaustive set of example activities that would and would not invoke the regulations, rather than providing a definition of 'utilisation' (which is at the core of the EU Regulation).

The examples are activity-based and do not address the situation where the result of the research is not known at the outset, as commercialisation is not a requirement under the EU Regulation. However, this guidance provides an alternative model that could be used, whereby guidance material would provide a non-exhaustive list of example activities that do and do not represent commercialisation.

The Review's only recommendation regarding the definition of 'commercialisation' was that private research grants should be excluded, as well as the existing exemption for government grants (recommendation 28). This was in response to submissions that there is significant private investment in research that should not be considered commercial.

Further consideration would be required on the boundaries for this, to ensure that commercial activities are not indirectly funded through grants.

The department's experience administering the Act is that the definition of commercialisation, in the context of knowing when certain regulatory requirements apply (or not), is problematic. Submissions received during consultation on the Review and Government Response included that:

- the Act should focus on commercial 'outcome' rather than commercial 'intent'. This would mean that the obligations under the Act should be triggered once an identifiable benefit is accrued (outcome) rather than just an intention to gain a benefit.
- the trigger point for commercialisation and the associated benefit sharing process should be sufficiently set out in the regulations or the Compliance Code.

35 National Environmental Management: *Biodiversity Act 2004*: Regulations on Bio-pProspecting, Access and Benefit Sharing, regulation 1 www.wipo.int/wipolex/en/text.jps?file_id=179663

36 Official Journal of the European Union C313, volume 49, 27 August 2016

Option 1: Amend the definition of *commercialisation* in the Act, using as a starting point:

a) the South African definition, or

b) reference to whether there has been a commercial outcome.

Option 2: Develop and release guidance that assists in understanding tyhe current definition of *commercialisation*, using as a starting point:

a) the South African definition,

b) a non-exhaustive set of examples demonstrating interpretation of the term *commercialisation*, or

c) reference to whether there is a commercial outcome.

Option 3: Do not amend the Act or release guidance.

QUESTIONS

32. Which option do you prefer? Why?

33. What do you think are the triggers that an activity has shifted from non-commercial to commercial? Why?

4.3 Regulatory framework

The primary purpose of the Act is to assist biodiscovery entities to access and use sustainable quantities of native biological material for biodiscovery, whilst ensuring that the State obtains a fair and equitable share in the benefits that result. A permitting and approvals system exists under the Act to administer this process.

Under the Act, an approved biodiscovery plan, collection authority and benefit sharing agreement are required prior to taking and using small quantities of native biological material from State land or Queensland waters for biodiscovery. A short summary of each requirement is outlined below.

Biodiscovery plan

A biodiscovery plan is the first step of the approvals process and must accompany an application for a collection authority. It also forms the basis of the benefit sharing agreement.

The proponent must provide details about the proposed commercialisation activities and the proposed benefits to be delivered to the State.

A biodiscovery plan is taken to be approved if a decision has not been made within 20 business days of its receipt by the department.[37]

Collection authority

A collection authority allows the take of minimal quantities of native biological material from State land and Queensland waters. The holder of the collection authority and/or their agents may collect the native biological material from areas specified on the authority.

Collection authorities have conditions attached and it is an offence to not comply with the conditions. In addition, these permits override any other State authority, such as a permit to take or interfere with flora and fauna under the *Nature Conservation Act 1992* (NCA).

An application for a collection authority is taken to be refused if a decision has not been made within 40 business days of the receipt of the application or any further information requested by the department.[38]

Benefit sharing agreement

A benefit sharing agreement formalises the way that benefits of biodiscovery (economic, social and environmental) will be shared between the State and the biodiscovery entity.

Biodiscovery cannot commence until a benefit sharing agreement is executed. An approved biodiscovery plan is required prior to entering into a benefit sharing agreement.

Where a biodiscovery entity has entered into an agreement with another downstream entity (i.e. a subsequent user of the native biological material), they may enter into a subsequent use agreement. In this case, the prescribed minimum terms[39] must be included in any subsequent use agreement entered into under the benefit sharing agreement.

37 s.40(3) *Biodiscovery Act 2004*
38 s.19(1) *Biodiscovery Act 2004*
39 See https://publications.qld.gov.au/dataset/biodiscovery-plan-guidelines-and-template/resource/bf74808c-1231-4015-9b59-bc757211b963

4.3.1 Authorisation to collect and use native biological material

The Review recommended several changes to the existing permitting framework, which, in broad terms, relate to two key recommendations. These are:

1. That biodiscovery plans should be removed from the Act (recommendation 12). Key requirements of the biodiscovery plan that relate to both commercial and non-commercial uses would be incorporated in the collection authority, whilst aspects relating to benefits of biodiscovery would be incorporated into benefit sharing agreements (recommendation 15).
2. That collection authorities are retained and that benefit sharing agreements are only required for commercial purposes, whilst a statutory declaration is sufficient for non-commercial biodiscovery (recommendation 13). To meet the requirements of the Nagoya Protocol, the Review also recommended that collection authorities issued for non-commercial purposes incorporate details of benefit sharing. This recommendation is dependent on the Act being expanded to cover non-commercial biodiscovery and to require prior informed consent for access to Aboriginal and Torres Strait Islander peoples' resources and traditional knowledge. Options regarding these issues are discussed in sections 4.1.3 and 4.1.2, respectively.

The Queensland Government recognises that biodiscovery plans add administrative burden at the early stages of a project, when the scope of the research and potential commercial outcomes are not known. It supports in principle both of these key recommendations, and agrees that much of the information within a biodiscovery plan can be effectively captured in the benefit sharing agreement once commercialisation is proposed to be undertaken and likely benefits better understood. Further discussion of *commercialisation* is provided in section 4.2.2.

Removal of the biodiscovery plan would necessitate minor amendments to content of both collection authorities and benefit sharing agreements. To support biodiscovery entities, guidance material would be developed where any changes to the permitting framework are made. This material would support navigation of the revised permitting framework and clarify the necessary process to demonstrate prior informed consent.

Submissions received supported removal of biodiscovery plans on the basis that commercialisation pathways and expected benefits are not known. Submissions were also received regarding possible changes to the permitting process if the Act was expanded to include non-commercial biodiscovery. The chief concerns raised in the submissions were that a split approval process could increase regulatory complexity, increase transaction costs where downstream entities engage in commercialisation and discourage entry into the industry. Submissions noted that other, more effective temporary alternatives such as material transfer agreements may suffice instead.

To minimise regulatory duplication for both commercial and non-commercial biodiscovery, a further option is to remove the collection authority from the regulatory framework as much as possible. Instead, the biodiscovery-specific requirements could be integrated into existing NCA Act permits, such as scientific purposes permits, or another appropriate form. Such an approach would still ensure that the relevant requirements concerning collection of native biological material and traditional knowledge are recognised.

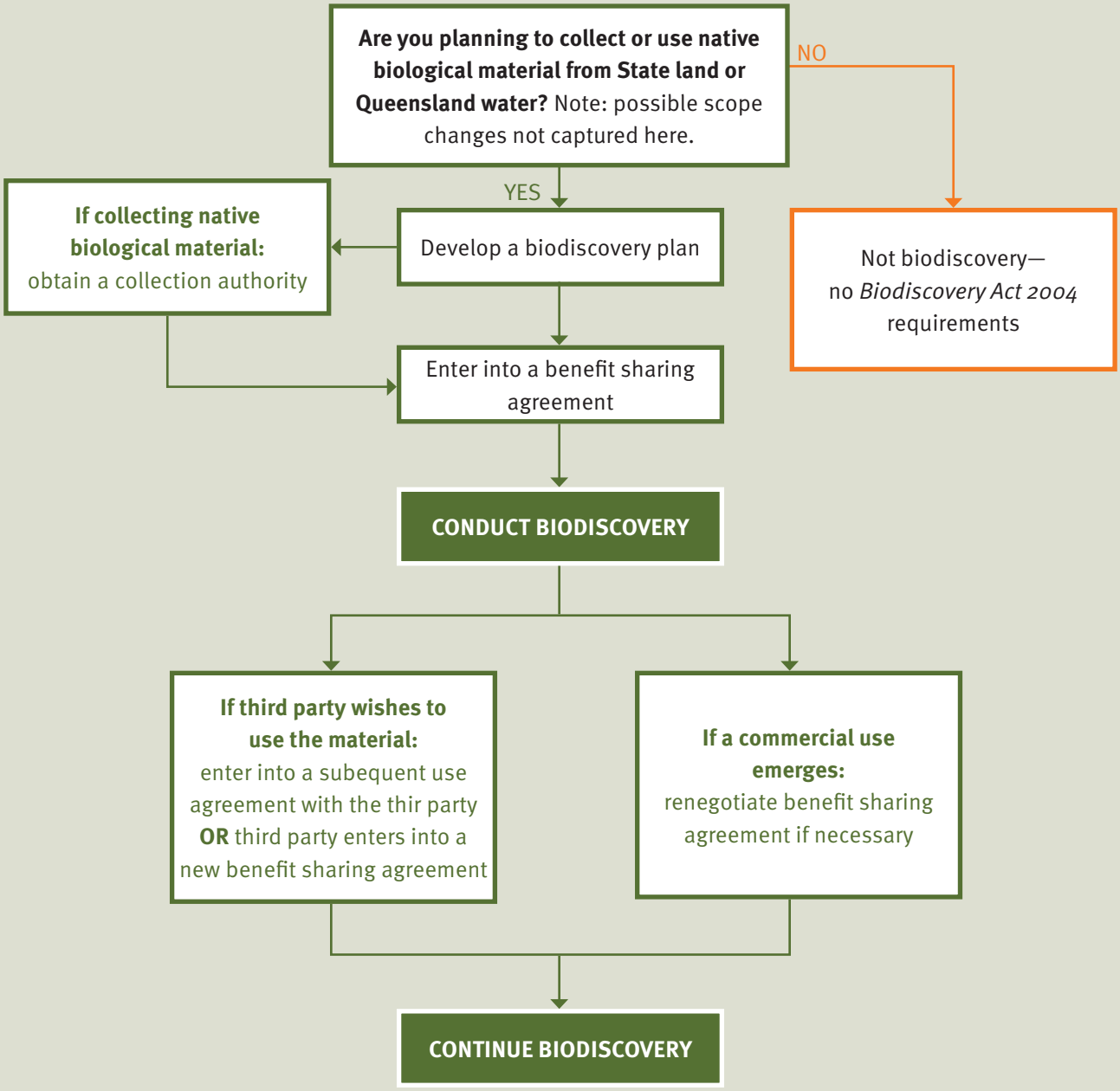
To allow fair comparison of all options detailed below, each has been developed to demonstrate how non-commercial activities could be regulated if they were to be within the scope of the Act. This is not intended to pre-judge the outcome of consultation on that question (see section 4.1.3).

Option 1: Keep the existing framework, including the requirement for biodiscovery plans, and extend it to non-commercial activities in the same way it currently applies to commercial biodiscovery.

This would require a benefit sharing agreement even for non-commercial biodiscovery. The benefit sharing agreement may then need to be amended if the benefits of biodiscovery change due to commercialisation activities.

A flow chart of option 1 is shown in Figure 1.

Figure 1. Flow chart for Option 1: Retain the current process, but apply also to non-commercial activities



PROS:

- Maximum coverage of permits, as evidence of compliance with Nagoya Protocol
- Minimal changes to the existing permit framework

CONS:

- Minimal streamlining of regulatory framework; biodiscovery plan retained
- Complex process for transition from non-commercial to commercial biodiscovery

Option 2: Recommended by the Review, this approach removes the requirement for a biodiscovery plan but retains the collection authority, regardless of whether the material is used for commercial or non-commercial purposes. This approach intends to reduce upfront administrative burden by removing the biodiscovery plan, but still requires determination of whether entities are undertaking commercial or non-commercial biodiscovery up front.

Where the proposed use is for non-commercial purposes, the biodiscovery entity would be required to:

- provide a statutory declaration confirming the use of native biological material is for non-commercial purposes
- obtain a collection authority
- report regularly (possibly through a biodiscovery register)
- not pass on the material to a third party unless that third party agrees to report as to the use of the material
- enter into a benefit sharing agreement if the material is to be commercialised.

Where the proposed use is for commercial purposes, the biodiscovery entity would be required to:

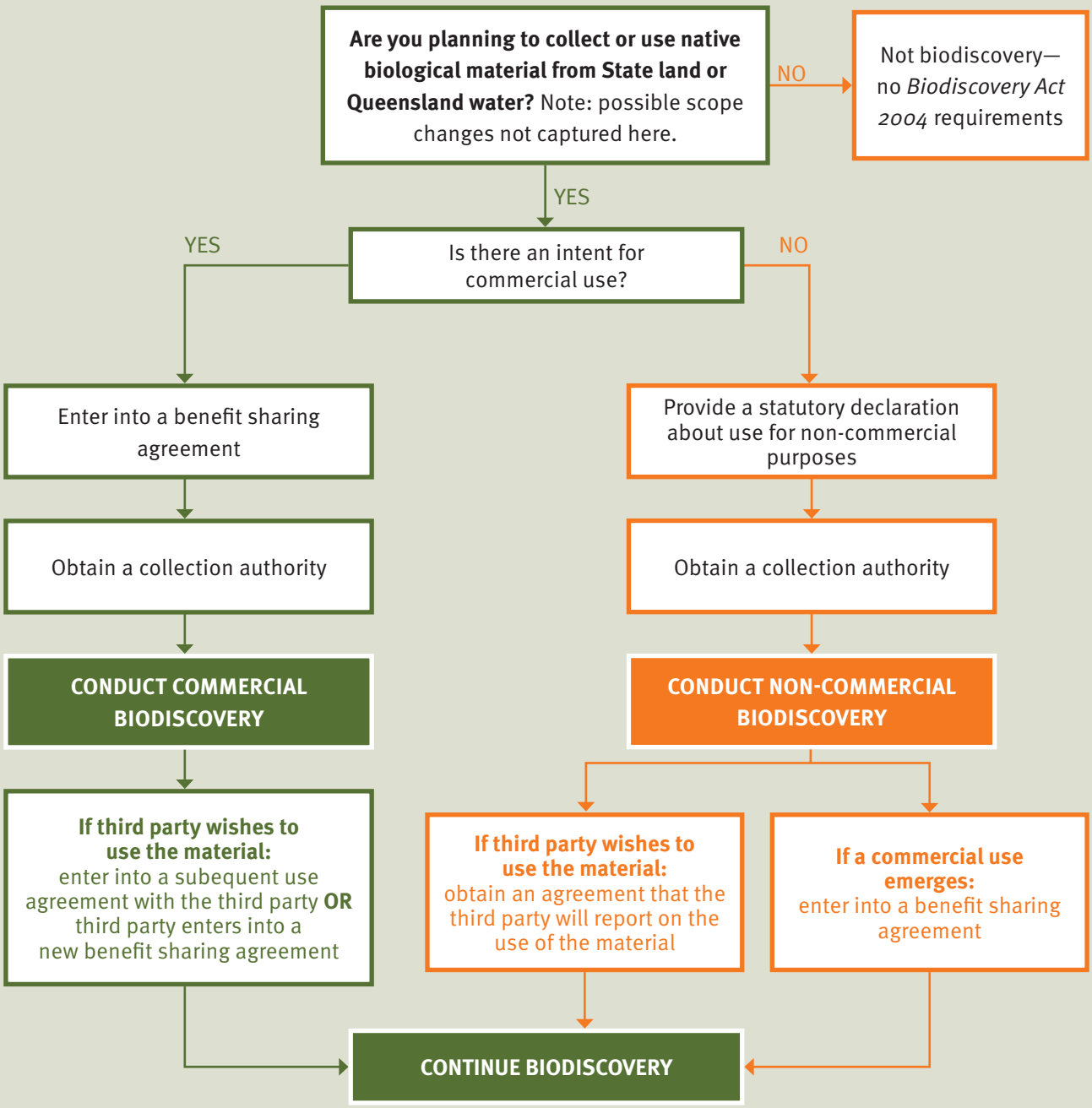
- enter into a benefit sharing agreement with the State as a precondition to obtaining a collection authority
- obtain a collection authority
- report regularly (possibly through a biodiscovery register).

If the recommendations about access to Aboriginal and Torres Strait Islander peoples' resources and traditional knowledge are adopted, the collection authority would be conditional on receipt of prior informed consent (including on mutually agreed terms) from the relevant Aboriginal and Torres Strait Islander peoples.

The proposed changes would also impact the downstream subsequent use of material, depending on whether the use is commercial or not. For commercial use, a subsequent use agreement could be utilised. For non-commercial use, the biodiscovery entity would be under an obligation not to pass on the material unless the third party agrees to report on the use of the material. This could be achieved through conditions on a material transfer agreement or similar permit.

A flow chart of option 2 is shown in Figure 2.

Figure 2. Flow chart for Option 2: The Review's recommended approach



PROS:

- Maximum consistency with Commonwealth
- Some streamlining of regulatory framework; biodiscovery plan removed
- Simplified process for conversion from non-commercial to commercial biodiscovery

CONS:

- Requirement to determine up-front whether biodiscovery is commercial
- Process for non-commercial biodiscovery retains some administrative complexity

Option 3: As with option 2, this option would remove the biodiscovery plan and incorporate these requirements into other parts of the regulatory framework, to streamline the operation of the Act. In addition, it would further reduce regulatory burden by use existing NCA permits to regulate collection of native biological material for biodiscovery. The department understands research institutions often better understand the NCA permit process than the Act's collection authority process. Therefore, utilising the NCA permits may simplify processes for biodiscovery entities and increase compliance with the Act.

The NCA permits most likely to be relevant include: scientific or educational purposes permits; permits to take, use, keep or interfere with cultural or natural resources; and protected plant licences. Utilising these permits for biodiscovery may require minor amendments, such as to require compliance with the Compliance Code and, if adopted, demonstration of prior informed consent regarding access to Aboriginal and Torres Strait Islander peoples' land and traditional knowledge.

Under this approach, the biodiscovery entity is not required to nominate whether its biodiscovery is commercial or non-commercial in nature until later in the approvals process. This is intended to realistically reflect the way that research is conducted, whereby the possible commercial uses of native biological material are often unknown at the outset of the research. It therefore allows biodiscovery to continue, in compliance with the Act, using a simplified process until a commercial use is established.

However, the NCA may not provide for the appropriate permits for all collection circumstances covered by the Act (e.g. microbes). Where this occurs, options to allow for collection of native biological material may include:

(a) **Collection authorities:** A simplified process (such as an online system that automatically creates a permit where conditions are met) could be utilised to generate permits.

(b) **Statutory declarations:** The biodiscovery entity would not be required to obtain any permit or collection authority, but must provide the Department a statutory declaration. The declaration would require proof of prior informed consent and assurance that commercialisation would not begin until the party has entered into a benefit sharing agreement with the State.

(c) **A self-assessable code:** The biodiscovery entity would not be required to provide any evidence to the State, but would be required to comply with a code. The code would outline requirements regarding prior informed consent and the need to enter into a benefit sharing agreement should the use become commercial.

Only one of permit options (a)-(c) would be reflected in the regulatory framework as part of this option. It is not proposed to allow biodiscovery entities to choose from those permit options in individual instances.

Where a permit under (a) or (b) was used, reporting requirements could be similar to the framework under option 2. Alternatively, a lighter monitoring approach could be used (and is likely to be required if option (c) is adopted), requiring the biodiscovery entity to retain evidence of compliance with the prior informed consent and benefit sharing requirements. This compliance could be checked through audits, requirements associated with applying for grants of State funding, and any ICC process. This would be complemented by the existing offence relating to using native biological material without a benefit sharing agreement.[40]

Although options (b) and (c) would appear to provide the most streamlined approaches, it would be necessary to consider ways of aligning with the Nagoya Protocol's requirement that the biodiscovery framework should 'provide for the issuance at the time of access of a permit or its equivalent as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms'.[41] The reporting approach would also need to be reconciled with the Nagoya Protocol's requirement for checkpoints to collect or receive information related to prior informed consent, the source of the genetic resource, establishment of mutually agreed terms, and the utilisation of genetic resources.[42]

A benefit sharing agreement would be required once a commercial use is identified, before the commercial use could commence. Reporting requirements as per option 2 may be included.

Use of the material by a third party could be managed through a subsequent use agreement for commercial biodiscovery. For non-commercial biodiscovery, a material transfer agreement or other legal arrangement between the biodiscovery entity and third party would be required to limit the use to non-commercial purposes unless a benefit sharing agreement is entered into. Guidance could outline the elements for material transfer agreements, similar to the Standard Material Transfer Agreement under the International Treaty on Plant Genetic Resources for Food and Agriculture[43] or the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization.[44]

A flow chart of option 3 is shown in Figure 3. Although this option appears complex in the flow chart, it may be the most streamlined option as it allows biodiscovery to continue under NCA permits (where possible) until a commercial use is found, and only then applies more stringent requirements.

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40 s.54 *Biodiscovery Act 2004*

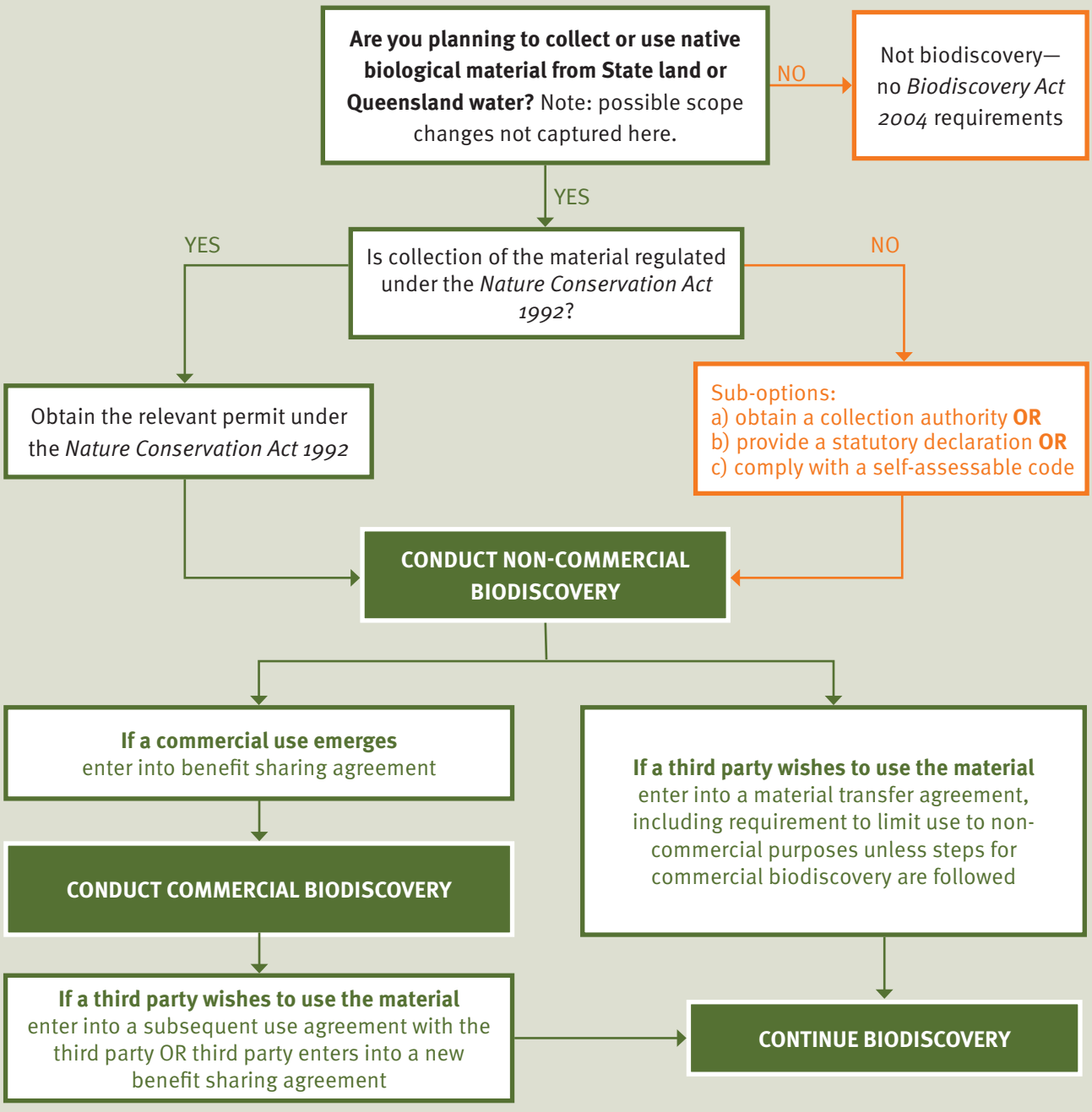
41 Nagoya Protocol article 6(3)(e)

42 Nagoya Protocol article 17(1)

43 www.fao.org/3/a-bc083e.pdf

44 Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization, Appendix 1 www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf

Figure 3. Flow chart for Option 3: Remove biodiscovery plan and use other permits to the extent possible



PROS:

- Maximum streamlining of regulatory framework; no biodiscovery plan and use of existing NCA permits
- Simplified regulation of non-commercial biodiscovery
- Simplified process for converting from non-commercial to commercial biodiscovery
- Requirement to decide whether biodiscovery is commercial is deferred

CONS:

- For sub-options b) and c), lack of permit as evidence of compliance with Nagoya Protocol
- Framework less consistent with existing Commonwealth approach

Overview of options

Table 1 is intended to facilitate easy comparison of the options outlined in this section and indicates how non-commercial activities would be regulated if they were within scope of the Act.

Table 1. Overview of options for regulatory framework

	Option 1 Existing framework expanded to non-commercial activities	**Option 2** Review recommendations	**Option 3** Utilise NCA permits
When commercial vs non-commercial is determined	After benefit sharing agreement negotiated	Prior to collection of native biological material	After collection, before commercialisation begins
Documentation for commercial biodiscovery	• Biodiscovery plan • Collection authority • Benefit sharing agreement	• Collection authority • Benefit sharing agreement	• NCA permit or collection authority under the Act • Benefit sharing agreement
Documentation for non-commercial biodiscovery	• Biodiscovery plan • Collection authority • Benefit sharing agreement	• Collection authority • Statutory declaration	• NCA permit or collection authority under the Act
Third party use (commercial)	• Subsequent use agreement or benefit sharing agreement • Biodiscovery plan	Subsequent use agreement or benefit sharing agreement	Subsequent use agreement or benefit sharing agreement
Third party use (non-commercial)	Subsequent use agreement or benefit sharing agreement	Agreement to report on the use of the material	Material transfer agreement limiting use to non-commercial

If the Act is not amended to include non-commercial activities, these activities would continue as per current arrangements (i.e. unregulated or regulated under any other relevant legislation, such as the NCA). If a commercial use emerged at a later time, the biodiscovery entity would be required to:

- under **option 1**, submit a biodiscovery plan, obtain a collection authority, and enter into a benefit sharing agreement.
- under **option 2**, obtain a collection authority and enter into a benefit sharing agreement.
- under **option 3**:
  - if an NCA permit had been obtained, enter into a benefit sharing agreement
  - if an NCA permit had not been obtained, obtain a collection authority and enter into a benefit sharing agreement.

QUESTIONS

34. Which option or combination of options do you prefer? Why?
35. For option 3, do you prefer permit option (a), (b) or (c) to authorise the collection of native material that would not be covered by a permit under the NCA? Why?
36. Do you consider that retaining both collection authorities and the permits under the NCA is necessary for regulating collection of native biological material for commercial and/or non-commercial purposes? Why?
37. What do you think would be the most effective and efficient way to regulate non-commercial activities to ensure that commercialisation is not undertaken prior to a benefit sharing agreement?
38. What, if any, opportunities do you think there are to simplify and/or automate the permitting process?

4.3.2 Compliance Code and Code of Ethics

Biodiscovery entities are currently contractually required to comply with the Code of Ethics through a requirement in the benefit sharing agreement. The Code of Ethics currently contains a section regarding biodiscovery that states:

- We will comply with the *Biodiscovery Act 2004*.
- We will collect native biological material from State land and Queensland waters only with the prior informed consent of the State.
- Before collecting samples from privately owned land, we 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.
- 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 traditional knowledge from Indigenous persons, we will negotiate reasonable benefit sharing arrangements with these persons or communities.
- In the course of biodiscovery activities we will comply with the *Native Title Act 1993* (Cwth).
- We will not commit acts of biopiracy and will not assist a third party to commit such acts.[45]

The Compliance Code is a statutory instrument under the Act,[46] and must be complied with as a condition of all collection authorities.[47] The Compliance Code includes minimum standards for taking State native biological material to ensure that collection is undertaken sustainably and with minimum impact.[48]

The Review recommended that consideration be given to incorporating the biodiscovery-related sections of the Code of Ethics into the Compliance Code (recommendation 3). The review outlines that this approach may reduce administrative burden and simplify the regulatory structure for users. In addition, it would give the relevant parts of the Code of Ethics regulatory force under the Act.

Note that it is not proposed that the Code of Ethics be abandoned altogether, as it has wider implications than just the Act.

The Review also made a number of content recommendations if the Compliance Code were to be updated, including:

- guidelines for access and benefit sharing with freehold landowners or parties negotiating with them (including access and use of traditional knowledge and on mutually agreed terms) (recommendation 5)
- a detailed explanation of the revised permitting process, if significant changes are made (recommendation 17)
- updated requirements for the method of storage of samples (recommendation 19)
- explanation of the requirements for downstream arrangements (recommendation 22)
- clear examples of the activities and material which would be covered by the Act (recommendation 34).

Recommendations relating to the storage of samples are discussed further in section 4.4.1. In addition, legislative amendments relating to downstream arrangements (recommendations 21 and 23 in the Review) have already been enacted and are not canvassed in this paper. However, for both storage of samples and downstream use, this paper seeks feedback on the best way to provide guidance.

Implementation of these recommendations is dependent on retention of a collection authority for all biodiscovery covered by the Act, as discussed in section 4.3.1. Other mechanisms for incorporating requirements to comply with the Compliance Code will be developed should collection authorities not be retained.

A consequential change from this approach is that benefit sharing agreements would no longer require biodiscovery entities to comply with the Code of Ethics.

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45 Queensland Biotechnology Code of Ethics, para 10
46 Part 6 *Biodiscovery Act 2004*
47 s.17 *Biodiscovery Act 2004*
48 s.44 *Biodiscovery Act 2004*

Option 1: Incorporate the relevant parts of the Code of Ethics in the Compliance Code.

Option 2: Retain the current separation of the Compliance Code and the Code of Ethics, and update both documents as necessary to reflect any amendments to the Act.

QUESTIONS

39. Which option or combination of options do you prefer? Why?
40. Which of the additions (if any) suggested by the Review do you think should be incorporated into the Compliance Code?
41. Are there aspects of the Compliance Code you think could be better explained through guidance material (for example on the department's website)?

4.3.3 Reporting requirements

The Review set out a range of recommendations relating to reporting requirements, including that:

- the existing requirement to provide material disposal reports yearly should not change, although technological solutions to the method of reporting may be considered
- the existing requirement to provide a sample of the material to the relevant authority should be reconsidered in light of updated scientific technologies (recommendation 16)
- the existing requirement to report in relation to collection pursuant to the Compliance Code should not change, other than that it may apply to non-commercial activities if the relevant recommendations are accepted
- for non-commercial activities, a requirement to report regularly in relation to the use of the material should be added, potentially through the biodiscovery register (recommendation 13)
- for commercial activities, the existing requirement to report annually and on other reportable matters should not change, but may potentially be undertaken through the biodiscovery register
- for activities involving access to Aboriginal and Torres Strait Islander peoples' resources or traditional knowledge, a requirement to upload information around prior informed consent on mutually agreed terms should be uploaded into the biodiscovery register (recommendations 8 and 42). This requirement would relate only to evidence of prior informed consent and would not concern details of the biodiscovery being undertaken nor what traditional knowledge has been utilised. In this way, commercial-in-confidence and sensitive traditional knowledge would be protected from public disclosure.
- for activities out of scope of the Act, a voluntary option to upload information into the biodiscovery register should be provided to assist with provision of ICCs (recommendation 42).

All of the recommendations that propose a change to current reporting arrangements are discussed in other sections of this options paper. As such, the purpose of this section is to synthesise possible reporting obligations under a reformed Act, and further options have not been developed specifically in relation to reporting.

QUESTIONS

42. For reporting on biodiscovery activities, do you consider a single annual return report or itemised reporting based on individual activities undertaken to be more efficient?
43. If regular updates on non-commercial biodiscovery are required, what frequency do you consider more appropriate? Why?
44. Would the ability to voluntarily report on activities outside the scope of the Act aid access to international research markets (for example, by demonstrating prior informed consent)?

4.4 Other matters

4.4.1 Submission of samples

Section 30 of the Act currently requires the holder of a collection authority to give a sample of the material to the State as soon as practicable after collecting the native biological material for biodiscovery.

Animal's samples are provided to the Queensland Museum, plant/fungal samples to the Queensland Herbarium, and any other organisms are to be provided to an entity specified in the benefit sharing agreement. The current drafting of the provisions within the Act includes requirements for size, quality, labelling and preservation method of the sample and was originally intended to apply only to physical samples.

The Review recommends that the State consider whether the prescribed methods for sample storage require updating to reflect technological advancements. If updated, these could be reflected in the Compliance Code (or updated equivalent) (recommendation 16).

The Queensland Government agrees with the recommendation; the State needs to keep pace with technology and have a regulatory framework that avoids being unnecessarily prescriptive. It is also noted that, if implemented, extending the definition of native biological material to cover underlying data, information or sequences of native biological resources (see section 4.2.1) may have consequences for requirements around samples.

A less burdensome approach (for both the State and biodiscovery entity) may be to require a sample to be provided to the State in an appropriate form, only upon request. This would require the relevant institutions to be aware of what material is being collected, such as through a notification when collection authorities (or equivalent) are issued.

Guidance issued by the State could provide information regarding the form in which a sample must be provided, with the guidance able to keep pace with contemporary storage methods; and, this may include the format in which underlying data, information or sequences of native biological resources should be provided.

Option 1: Amend the Act to require that samples be provided only on request.

Option 2: Amend the Act to remove detailed requirements about the sample's characteristics, and put appropriate information into regulations or guidance material (suh as the Compliance Code).

Option 3: Do not amend the Act in relation to submission of samples.

QUESTIONS

45. Which option or combination of options do you prefer? Why?
46. For option 1, what do you think is the best way to notify collections that they may request samples?
    a. What benefits or concerns, if any, would you have with the department notifying the Queensland Museum or Queensland Herbarium when relevant permits are issued?
47. For option 2, what do you think the key required characteristics of samples should be?

4.4.2 Ministerial power to declare exemptions from the Act

The Review recommended that the State consider including a provision for the minister to declare that the Act (or part thereof) does not apply to specified native biological material or a specified collection of native biological material where use of the resources is controlled under an international agreement or treaty to which Australia is a party (recommendation 35).

For example, Australia is a signatory to the *International Treaty on Plant Genetic Resources for Food and Agriculture* (the Plant Genetic Resources Treaty), the objectives of which are the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their use. The Plant Genetic Resources Treaty is consistent with the CBD with respect to benefit sharing and provides for the protection of traditional knowledge, a major consideration in the current reform program.

The Review suggested this outcome be accomplished by utilising similar provisions to regulations 8A.03(3) and 8A.05 of the Environment Protection and Biodiversity Conservation Regulations 2000 (EPBC Regulations). These provisions have the effect of allowing the minister to declare that certain activities are exempt from the provisions of Part 8A of the EPBC Regulations that ordinarily apply to taking biological resources in Commonwealth areas for biodiscovery.

Regulation 8A.05 provides for the minister to declare that Part 8A does not apply to specified biological resources or a specified collection of biological resources (including future additions to the collection), if use of the resources is required to be controlled under any international agreement to which Australia is a party.

There are examples of Queensland legislation that provide for ministerial declarations. For example, the *State Development and Public Works Organisation Act 1971* provides for the minister to declare a project to be a 'prescribed project' or a 'critical infrastructure project', and this can affect the application of other State legislation to that project.[49]

The limited number of submissions received supported this recommendation.

An alternative may be to draft regulations that establish relevant exemptions from the Act. This could provide a higher degree of certainty as to which treaties and agreements are exempt, and the extent to which the Act applies (if at all) in each case. Development of regulations would be consistent with standard Queensland regulatory processes and allow for a clear, consistent and transparent process.

49 s.76E *State Development and Public Works Organisation Act 1971*

Option 1: Amend the Act or develop regulations to give the minister the ability to declare that the Act, or part of the Act, does not apply to specified native biological material where use of the resources is controlled under an international agreement or treaty to which Australia is a party.

Option 2: Develop regulations that exempt certain use cases of native biological material from the Act or part of the Act. For example, it may exempt uses controlled under an international agreement or treaty to which Australia is a party.

Option 3: Do not amend the Act or develop regulations on this issue.

QUESTIONS

48. Which option do you prefer? Why?
49. For option 1, what do you think the criteria should be for exercise of the ministerial discretion?
50. For option 2, which treaties or other legislative processes do you think should be exempt?

4.4.3 Compliance measures

The Review noted that the existing enforcement of compliance was effective and appropriate to the circumstances. It also noted that, in general terms the offence provisions under the Act are more substantial and carry greater penalties than the Northern Territory and the Commonwealth equivalents.

There are also supporting internal departmental documents, like the regulatory strategy and enforcement guidelines.

The Queensland Government is committed to increasing compliance with the Act and considers that an increased range of tools could assist to achieve this goal.

Maximum penalties for non compliance with the Act are not proposed to be increased. Instead, the Queensland Government proposes to consider additional measures with the aim of guiding entities and providing a graduated compliance pathway, such that penalties are rarely required. This may include measures such as caution notices, official warnings and/or the ability to suspend, revoke or cancel permits or approvals.

Continued education will also play an important role in increasing compliance.

QUESTION

51. Are there any measures you think are important to increase compliance with the Act?

4.4.4 Compliance regarding Aboriginal and Torres Strait Islander peoples' resources and traditional knowledge

The Review recommended that the Act's enforcement and monitoring provisions should be updated to ensure compliance with the broadening of the scope of the Act to cover traditional knowledge and access to Aboriginal and Torres Strait Islander peoples' land (recommendation 36). Specific examples provided were adding, specifically in relation to traditional knowledge and access to Aboriginal and Torres Strait Islander peoples' land:

- powers to audit in relation to prior informed consent and benefit sharing;
- the right to request further information in relation to the provision of prior informed consent and benefit sharing;
- an offence for using traditional knowledge and accessing Aboriginal and Torres Strait Islander peoples' land other than with prior informed consent and benefit sharing; and
- an offence for giving false and misleading information regarding prior informed consent and benefit sharing.

Submissions indicated in principle agreement with the recommendation to include powers to enforce compliance with provisions relating to access to Aboriginal and Torres Strait Islander peoples' land and traditional knowledge.

QUESTIONS

52. What compliance measures do you think are most important to include?
53. Are there any other measures that you think should be introduced?

Attachment A: Previous consultation

The Review was informed by consultation with a variety of organisations and bodies including government departments, industry representatives, private companies, research institutes, cultural groups and other interested parties.

The following organisations made submissions and/or participated in a face-to-face feedback sessions during the Review:

- Queensland Museum
- Griffith University
- James Cook University
- Great Barrier Reef Marine Park Authority
- David Claudie, Chuulangun Aboriginal Corporation, John Locke, BioCultural Consulting P/L and Leslie Shirreffs
- EcoBiotics Limited
- QIMR Berghofer
- Griffith University
- University of the Sunshine Coast
- University of Queensland (Queensland Alliance for Food and Agriculture Innovation).

Issues raised during consultation on the Review related to a broad range of topics including:

- the purpose and effectiveness of the Act
- the definitions of commercialisation, biodiscovery and native biological material
- extending the scope of Act to private land
- Native Title and traditional knowledge
- structure and effectiveness of benefit sharing agreements and collection authorities
- publicly funded institutions
- exclusions
- enforcement and compliance
- consistency with other domestic and international jurisdictions and agreements.

The Review and Government Response were published on the Queensland Government's *Get Involved* website from 26 April 2018 to 8 June 2018 (inclusive).

To coincide with their release, the Department of Environment and Science (the department) contacted approximately 200 individuals and organisations from state, interstate and Commonwealth government agencies, universities, research institutes, private companies, and Aboriginal and Torres Strait Islander representatives.

During the consultation period, the department met with representatives from the University of Queensland (UQ), Griffith University (GU), James Cook University (JCU), the Queensland University of Technology (QUT) and the Dugalunji Aboriginal Corporation.

Information sessions and a webinar were also held, and the department attended and/or presented at workshops and seminars convened by QUT, JCU and the UQ Law Society.

Valuable consultation has been undertaken with the Reef Catchments Traditional Owner Reference Group (TORG), which is made up of representatives from Yuwibara, Koinmerburra, Barada Barna, Wiri, Ngaro, and Gia and Juru within the boundaries of the Reef Catchments Mackay Whitsunday Isaac region.

The department also followed up with submitters to the Review including John Locke, David Claudie and access and benefit sharing experts including Dr Daniel Robinson and Dr Margaret Raven.

Eleven submissions were made in response to the Review and Government Response relating primarily to the scope of the Act, biodiscovery and commercialisation, the definition of native biological meeting, the Nagoya Protocol and traditional knowledge; and the licensing framework for benefit sharing.

The submissions are discussed in section 4 Areas of reform.

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