

Biodiscovery and Other Legislation Amendment Bill 2019

- Submission by Griffith University -

Attention:
The Innovation, Tourism Development and Environment Committee
Queensland Parliament
Parliament House
Brisbane, QLD 4000
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Contents

Introduction

Response to the proposed Biodiscovery and Other Legislation Amendment Bill 2019

Definitions

New definition of "native biological materials"

Definition of Traditional Knowledge

Traditional Knowledge

Traditional Knowledge Code of Practice

Definition of Traditional Knowledge

Challenges

Benefit Sharing Agreements relating to Traditional Knowledge

Biodiscovery Plan

International Food and Agriculture Treaty

Contact

We kindly ask the Department to contact the Acting Deputy Vice Chancellor (Research) of Griffith University, Professor Andrea Bishop, for any questions relating to Griffith University's submission.

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Introduction

Griffith University contributed to the ongoing review of the Biodiscovery Act 2004 (Queensland), with written submissions and participation in the respective face-to-face feedback sessions.

Since the *Biodiscovery Act 2004* (Qld) has been implemented, Griffith University also has entered into a Benefit Sharing Agreement with the Queensland Government, that replaced the historic Benefit Sharing Agreements between Griffith University and the Queensland Museum and the Queensland Herbarium.

Griffith University – though its Griffith Institute for Drug Discovery (GRIDD; formerly named the “Eskitis Institute for Drug Discovery”) – is a worldwide recognised leader in biodiscovery and commercialisation of natural compounds. The heart of GRIDD’s Biodiscovery activities is Nature Bank, a globally unique megadiverse collection of over 45,000 biota samples derived from plants, marine and terrestrial invertebrates and microorganisms. Nature Bank includes 30,000 biota samples collected in Queensland under appropriate collection permits and Benefit Sharing Agreements with the Queensland Museum and Queensland Herbarium. As a major extension of Nature Bank, The Australian Institute of Marine Science (AIMS) has transferred custodianship of AIMS’ Bioresources Library to GRIDD, including several hundred samples collected in Queensland.

Under the leadership of Professor Ron Quinn, AO, GRIDD has collaborated with AstraZeneca in the field of biodiscovery and attracted more than AUD 110 million in research funding to Queensland. Since the end of the collaboration with AstraZeneca, GRIDD has conducted Biodiscovery utilising Nature Bank samples with a number of partners from industry (e.g. Pfizer, Actelion), and research on private-public partnerships and philanthropic organisations (e.g. Bill & Melinda Gates Foundation, Medicines for Malaria Venture, the Drugs for Neglected Diseases Initiative), and academic organisations world-wide.

Griffith University is fully committed to the spirit and application of the *Convention on Biological Diversity* (the “CBD”) and the *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity* (the “Nagoya Protocol”), and proud to be recognised as one of the world leaders in the ethical commercialisation of biodiversity.

There is a great opportunity for the Act to be an instrument that encourages First Nations people to grant access to native biological resources on land under their custodianship and to share their Traditional Knowledge.

This submission is in response to the Biodiscovery and Other Legislation Amendment Bill 2019 (Qld) (the “Bill”).

Griffith University wishes to contribute to shape this legislation to become an effective enabler for accessing and utilising Queensland’s biodiversity for the benefit of Queensland and the world. With this submission, Griffith University would like to provide some comments and suggestions, with a focus on commercialisation of natural products and historic large-scale collections of biota samples.

In addition to this submission, we have attached as Appendix A and B Griffith’s submissions:

- “Submission by Griffith University - Pathways to reform: Biodiscovery Act 2004 Options Paper” (January 2019); and
- “Notes by Griffith University - Biodiscovery Act 2004 Review Combined Traditional Knowledge Roundtable and Biodiscovery Entities Workshop (III)” (August 2019).

Which add further context and highlight key topics of concern for Griffith University.



Prof Andrea Bishop

Acting Deputy Vice Chancellor (Research)

Griffith University

Response to the proposed Biodiscovery and Other Legislation Amendment Bill 2019

Definitions

New definition of "native biological materials"

There are significant differences between "State biological resources" and "native biological resources", the latter being significantly broader in scope than the former. However, neither of these definitions are new to the Act. We also note that the caveat of "from, on or in, State land or Queensland waters" is used in relation to collection authorities and benefit sharing agreements, so in these instances there are a geographical connection to Queensland State land or waters.

However, this same caveat is not used in terms of the new Traditional Knowledge provisions (Part 2A). With respect to traditional knowledge the taking and use of native biological material is not limited to State land or Queensland waters - therefore the new Part 2A provisions will extend to traditional knowledge held anywhere within the State, including but not limited to native title holders, freehold and other non-crown related land holdings and any other third party. There may be no nexus between the collection site and the custodians of the Traditional Knowledge – please refer to our suggestions re "Custodians of Traditional Knowledge" discussed later in this submission.

Definition of Traditional Knowledge

The Bill utilises the definition provided by Schedule 1 of the *Acts Interpretation Act 1954* (Qld):

"Aboriginal tradition" means the body of traditions, observances, customs and beliefs of Aboriginal people generally or of a particular community or group of Aboriginal people, and includes any such traditions, observances, customs and beliefs relating to particular persons, areas, objects or relationships.

"Island custom", known in the Torres Strait as Ailan Kastom, means the body of customs, traditions, observances and beliefs of Torres Strait Islanders generally or of a particular community or group of Torres Strait Islanders, and includes any such customs, traditions, observances and beliefs relating to particular persons, areas, objects or relationships.

We note that the Traditional Knowledge of local communities (e.g. Farmer's Rights) is not recognised in the current proposed definition – however, the Nagoya Protocol includes “local communities”, which are not per se Indigenous Peoples.

Clause 10 is worded in a way that may have broader consequences, as it seems to extend the Traditional knowledge obligation to the use of digital sequence information and other information used separately from the physical materials. This is because Part 2A applies to taking and using native biological material for biodiscovery (s.9A), which is consistent with the Act's provisions on collection authorities and material Benefit Sharing Agreements, but the Traditional Knowledge obligation applies only to a person, who ‘accesses’ Traditional knowledge when engaging or preparing to engage in biodiscovery (s.9B). While the 2016 of the Biodiscovery Act 2004 review concluded the definition of Native Biological Material does not include digital sequence information, the proposed definition of biodiscovery includes such information:

“biodiscovery” means “biodiscovery research” and “biodiscovery research” means “the analysis of molecular, biochemical or genetic information about native biological material for the purpose of commercialising the material”. Schedule 2.

By not restricting the Traditional knowledge obligation to using “native biological material for biodiscovery” but instead applying it to the broader definition of biodiscovery, a user of genetic information alone (e.g. a DNA sequence), which is “about native biological material” (sourced wherever because the amended definition no longer has a geographical nexus and including substances from native biological resources or soil containing them) may need to negotiate a Benefit Sharing Agreement for access to Traditional Knowledge. This may render the provision unworkable. As an example, a company, which accesses digital genetic sequence data, may have unintended access to Traditional Knowledge from Queensland, as almost all sequence data are heavily annotated, and such annotation may include information gained from Traditional Knowledge from Queensland that may be in the public domain (e.g. originating from a scientific publication).

Griffith suggest considering that such consequences are contrary to the spirit of CBD (and Nagoya Protocol), which promotes information sharing about genetic resources. While these amendments do not address the issue of digital sequence information, they may have inadvertently increased its scope through the Traditional Knowledge amendments.

Traditional Knowledge

Griffith unequivocally welcomes the State's commitment to include Traditional Knowledge into the Biodiscovery legal framework.

As an institution, Griffith promotes reconciliation, respect, education and engagement. Griffith has the largest Indigenous-student population of any Queensland university, and the second largest number of Aboriginal and Torres Strait Islander academic staff in Australia. Led by Griffith's Pro Vice Chancellor (Indigenous) and guided by our Council of Elders, we continue to develop Aboriginal and Torres Strait Islander engagement strategies and partnerships for community empowerment, as well as a curriculum informed by respect for the knowledge systems of our First Peoples. Our Indigenous research development also aims to further the aspirations of Aboriginal and Torres Strait Islander communities.

Aligning Queensland legal framework closer with the CBD and Nagoya Protocol ensures that Biodiscovery Entities in Queensland can successfully commercialise native biological materials from Queensland, by providing legal certainty to industry partners.

Traditional Knowledge Code of Practice

Griffith supports the concept of a 'Traditional Knowledge Code of Practice' to guide custodians of Traditional Knowledge and biodiscovery entities. We welcome the consultation process to develop this Code. Griffith is fully committed to contribute to these consultations.

For Griffith and any other Biodiscovery Entity, the Code will be critical. We suggest that the State allocates a substantial amount of time for the respective consultations.

We also would recommend that the process also include stakeholders from a broad cross-section of the biodiscovery community, including actual or potential Subsequent Users in Biodiscovery, including the pharmaceutical, agriculture, nutraceutical, food and cosmeceutical industries, in Queensland, Australia and overseas. This will ensure that the

Code is an instrument that enables easy commercial engagement between custodians of Traditional Knowledge, Biodiscovery entities and industry partners.

Therefore, we propose to amend proposed section 9D accordingly:

In preparing the traditional knowledge code of practice, the Minister must consult with—

(a) Aboriginal and Torres Strait Islander groups in Queensland;

(b) biodiscovery entities; and

(c) stakeholders from biodiscovery industries, including the pharmaceutical, agriculture, nutraceutical, food and cosmeceutical industries.

Challenges

We note that the Bill does not address two of the three main concerns raised in Griffith's response to the "Pathways to reform: Biodiscovery Act 2004 Options Paper": (attached as Appendix A):

- Traditional Knowledge held by multiple indigenous groups; and,
- Traditional Knowledge in the Public Domain.

It is our understanding that these issues will be addressed in the proposed Traditional Knowledge Code of Practice (the "Code"). It will be important that these issues be addressed to provide sufficient legal security to Biodiscovery Entities and their partners (Subsequent Users) in dealing with Traditional Knowledge relating to Biodiscovery. We reiterate Griffith's proposed approach:

Traditional Knowledge held by multiple Indigenous Groups, including those outside of the State of Queensland

Complex issues arise where Traditional Knowledge is held by multiple indigenous groups, but the Biodiscovery entity engages only with one of them. Many questions arise, including:

- Should then all Traditional Knowledge holders be entitled to sharing the benefits?
- If so, how could a Biodiscovery entity find out, who else may hold similar Traditional Knowledge?

Griffith suggests that a single agreement with the actual discloser of the Traditional Knowledge be sufficient under the Act (or Code) and that no third party can make claims against the Biodiscovery Entity.

Traditional Knowledge in the Public Domain

There is an ongoing discussion world-wide, whether Traditional Knowledge that is in the public domain still should be treated like secret Traditional Knowledge. This issue is a vexing topic. So far, there is no solution.

As discussed above, European ideals about intellectual property struggle with addressing and protecting Traditional Knowledge. However, in some jurisdictions patent law provides protection – if Traditional Knowledge has been accessed and is used in a patent application, the applicant needs to show that they have an agreement with the owners of the Traditional Knowledge for the use of the respective intellectual property, or that the Traditional Knowledge is in the public domain. The European Patent System is on the forefront of this.

Copyright protects the particular expression of how Traditional Knowledge is disclosed (e.g. a song, dance, book or a video), but not the Traditional Knowledge as such – for example you are not allowed to reproduce and sell a cook book, but you can use a recipe in a cook book and sell the dish in your restaurant. However, applying this principle to Traditional Knowledge is contested by many indigenous groups world-wide.

A further concern is that when the intellectual property claims exhaust or expire (e.g. at the end of the patent (20 years) or copyright term life of the author plus 70 years), the formerly protected invention, expression, and so on, becomes available for use without any restrictions (into the public domain). Many indigenous groups world-wide contest this principle.

There is the risk that inclusion of public domain Traditional Knowledge will deter any commercial activity, as this would pose high legal and commercial risk – higher transaction cost, unforeseeable timelines to negotiate and gain access, the potential to be sued under the Act and reputational risk.

At this point in time, given the protection provided in the Australian context through oral promulgation and oral disclosure of Aboriginal and Torres Strait Islander people's Traditional Knowledge, there is some protection for such Traditional Knowledge.

We recommend that the topic of Traditional Knowledge that is in the public domain should be a major topic of the consultations for the Traditional Knowledge Code of Practice.

Progress in the international system for the protection of Traditional Knowledge (and Genetic Resources and Traditional Cultural Expressions) may help to address this in the future. We also recommend that the State continues to monitor the international developments around the protection and use of Traditional Knowledge and address these issues in developing the proposed Code.

Access to Traditional Knowledge when Preparing to Engage in Biodiscovery

S.9B(1) make reference to a person, who accesses Traditional Knowledge when “*preparing to engage in biodiscovery*”. It will be very important that the Traditional Knowledge Code of Practice clearly articulates what this may entail. Often there is significant research and passage of time between initial biodiscovery research and commercialisation. What constitutes access to Traditional Knowledge when preparing to engage in biodiscovery may vary considerably from project to project. Griffith suggests that this activity will be clearly articulated within the Code.

Custodians of Traditional Knowledge

S.9B(2) states that a person must take all reasonable and practical measures to ensure the person does not use any Traditional Knowledge for biodiscovery other than under an agreement with the custodians of the knowledge. This drafting does indicate that a Biodiscovery Entity will be required to enter into an agreement with all custodians of any Traditional Knowledge, which Griffith may intend to use in biodiscovery. The drafts have chosen to use "Custodians" as a plural, presumably because there may be instances where there is more than one custodian and potentially numerous custodians. It will be required to enter into an agreement with all custodians (and presumably also benefit sharing with all custodians). It will be critical that the Traditional Knowledge Code of Practice clearly articulates what are reasonable and practical measures, in terms of trying to identify all custodians of the relevant Traditional Knowledge. This also relates to the challenge “Traditional Knowledge in the Public Domain” discussed earlier in this submission. How does a Biodiscovery Entity deal with situations where the Traditional Knowledge crosses jurisdictional boundaries? e.g. Griffith sources the biological sample outside of Queensland and Traditional Knowledge outside of Queensland, but there are indigenous groups within Queensland that hold similar or identical Traditional Knowledge?

Benefit Sharing Agreements relating to Traditional Knowledge

Griffith is concerned about some potential practical difficulties with the proposed benefit sharing provisions.

First, the State is not party to Benefit Sharing Agreements relating to Traditional Knowledge, creating complexity and confusion for users of native biological material, who will require two separate agreements for the same transaction – one for the use of the materials from the State and one for the use of the Traditional Knowledge from the custodians. From the providers' perspectives, the state would not know what is in the Benefit Sharing Agreements relating to Traditional Knowledge and how it affects the Benefit Sharing Agreement relating to the materials and vice versa for the custodians of Traditional Knowledge, creating inconsistencies, potential issues and certainly higher cost for negotiation, drafting and execution of the respective agreements.

Secondly, the system does not offer certainty for international commercialisation of native biological material from Queensland when used in countries with Due Diligence obligations such as the European Union. The explanatory notes to the Bill explain that there is no need to demonstrate compliance with the Traditional Knowledge obligation before a collection authority is issued (EN p.4) – because a Benefit Sharing Agreement is required prior to actual collection of materials (s.17(1)). Unlike the Compliance Code or Collection Protocol with which compliance is a condition of the collection authority (s.17(3)), compliance with provisions under the Traditional Knowledge Code of Practice do not become a condition of authority under these amendments. The state requires confirmation that the Traditional Knowledge obligation is complied with when Traditional Knowledge has or will be used in Biodiscovery (clause 16). The Traditional Knowledge obligation only requires a person to take reasonable measures to ensure Traditional Knowledge is not used without a Benefit Sharing Agreement, but not that they comply with the Traditional Knowledge Code that will set out requirements for prior informed consent and mutually agreed terms. Both are essential under the European Union's Due Diligence obligations and are required to be proven before the materials and associated knowledge can be used in the European Union.

In addition, there is no requirement to provide confirmation of satisfying the Traditional Knowledge obligation to government for Biodiscovery using Traditional Knowledge from non-state land (EN p. 4) and for non-commercial purposes of materials from State lands and waters. This further limits the scope of demonstrating compliance for due diligence purposes.

The issue of Internationally Recognised Certificate of Compliance under the Nagoya Protocol has not been resolved, because the Commonwealth has not (yet) ratified the Nagoya Protocol and so the proposed Nagoya Protocol system has not been fully implemented. This means that Queensland needs to implement an equivalent and consistent scheme that provides formal certificates confirming State government approval. A similar arrangement is also necessary for orphaned materials (materials collected before these laws were in place).

The Nagoya Protocol provides for Internationally Recognised Certificate of Compliance that confirm free, prior and informed consent and equitable benefit sharing agreements, including appropriate dealings with Traditional Knowledge associated with materials from State lands and waters. The proposed legislation is silent on these matters. These need to be addressed so that those accessing Queensland materials can comply with the Nagoya Protocol obligations and countries that require these standards (e.g. European Union). A further concern are the orphaned materials (materials collected before these laws were in place) and that these need to be provided with an appropriate instrument consistent with an Internationally Recognised Certificate of Compliance. These matters will also need to be addressed in the proposed Code.

Not providing an instrument equivalent to an Internationally Recognised Certificate of Compliance could potentially deter companies engaging with custodians of Traditional Knowledge in Queensland and to utilise native biologic material from Queensland.

Thirdly, non-involvement of government in Benefit Sharing Agreements relating to Traditional Knowledge can exacerbate an imbalance of power between custodians of Traditional Knowledge and Biodiscovery Entities. Deterrents under Part 7 Div 2 regarding Benefit Sharing Agreements do not seem to apply (e.g. making false and misleading statements). There is no requirement for record keeping of Benefit Sharing Agreements relating to Traditional Knowledge under s.43 as with the Benefit Sharing Agreements relating to Native Biologic Material. While the State has the benefit of these and other compliance provisions for their Benefit Sharing Agreements for materials, custodians of Traditional Knowledge will have limited bargaining powers, if any, through the Traditional Knowledge Code as providers of Traditional Knowledge. While the Traditional Knowledge Code takes effect when it is approved by regulation, it is unclear what level of mandatory compliance or enforcement this legislation will have.

Biodiscovery plan

Griffith welcomes the abolition of the requirement of a Biodiscovery Plan. This will remove administrative burden from the process, for both, the State and the Biodiscovery Entity. Especially for Biodiscovery Entities with large collections, e.g. Griffith University, it is challenging to provide a sensible Biodiscovery Plan, due to the magnitude, heterogeneity and complexity of Biodiscovery activities.

International Food and Agriculture Treaty

Griffith welcomes that the Bill's exclusion of the plants listed in the International Treaty on Plant Genetic Resources for Food and Agriculture Treaty (the "Plant Treaty"), Annex 1 used for a food or agriculture purpose in a way that is consistent with the Plant Treaty.

However, the current scope of the Plant Treaty is currently determined by the plant and other materials that are available through the Multilateral System rather than limited to those plants listed in Annex 1. The proposed s.7A(1)(a) might be changed to reflect this using words, such as, "the materials available for facilitated access from the Multilateral System under the International food and agriculture treaty".

There is also an inconsistency between the explanatory notes and the Bill: The EN p.4 and p.12 indicates the amendments exempt plant materials when their use involves the use of materials for Biodiscovery (including the use of Traditional Knowledge for biodiscovery), whereas in the Bill s.8, the exemption appears to only apply when materials and Traditional Knowledge are used together. The latter seems restrictive and is not consistent with the Plant Treaty.

Pathways to reform:
Biodiscovery Act 2004
Options Paper

- Submission by Griffith University -

Attention:
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BE REMARKABLE

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Contents

Introduction

The Nagoya Protocol and Biodiscovery in Queensland

Response to Questions

Appendix 1

Contact

We kindly ask the Department to contact the Senior Deputy Vice Chancellor of Griffith University, Professor Ned Pankhurst, for any questions relating to Griffith University's submission.

Prof Ned Pankhurst
Senior Deputy Vice Chancellor

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www.griffith.edu.au

Introduction

Since 2015, Griffith University ("Griffith") actively contributed to the State's re-shaping of the *Biodiscovery Act 2004* (Queensland) with multiple written submissions, participation in face-to-face feedback sessions and by negotiating a Biological Benefit Sharing Agreement with the State that was signed in 2018.

Griffith University ("Griffith") – through its Griffith Institute for Drug Discovery ("GRIDD"; formerly named the "Eskitis Institute"), – is a worldwide recognised leader in biodiscovery and commercialisation of natural compounds. The heart of GRIDD's biodiscovery activities is 'NatureBank', a globally unique megadiverse collection of biota samples derived from plants, marine and terrestrial invertebrates and microorganisms. As a major extension of NatureBank, the Australian Institute of Marine Science (AIMS) is in the process of transferring its 'Bioresources Library' to Griffith.

Under the leadership of Professor Ron Quinn, AM, and now Associate Professor Rohan Davis, GRIDD has collaborated with AstraZeneca in the field of biodiscovery and attracted more than AUD 100 million in research funding to Queensland. Since the end of the collaboration with AstraZeneca, GRIDD has conducted biodiscovery utilising NatureBank samples with a number of partners from industry (e.g. Pfizer, Actelion), and research on private-public partnerships and philanthropic organisations (e.g. Bill & Melinda Gates Foundation, Medicines for Malaria Venture, the Drugs for Neglected Diseases Initiative), and academic organisations world-wide.

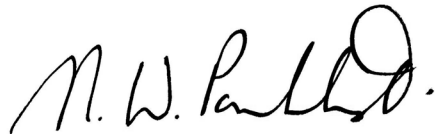
Griffith University is fully committed to the spirit and application of the *Convention on Biological Diversity* and the *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity* (the "Nagoya Protocol"), and proud to be recognised as one of the world leaders in the ethical commercialisation of biodiversity.

This submission is in response to the "Pathways to reform: Biodiscovery Act 2004 - Options Paper" released by the State on 29th November 2018.

This submission provides specific responses to the 53 Questions asked in the Options Paper and also some broader comments to the particular topics discussed in the Options Paper.

Griffith also provides an executive summary ('The Nagoya Protocol and Biodiscovery in Queensland') expressing Griffith's suggestions about reform in this area.

Brisbane, 30th January 2019

A handwritten signature in black ink, appearing to read 'N. W. Pankhurst'.

Prof Ned Pankhurst

Senior Deputy Vice Chancellor

Griffith University

The Nagoya Protocol and Biodiscovery in Queensland

The State's "Pathways to reform: Biodiscovery Act 2004 - Options Paper" raises important questions for the ongoing reform of the Reform of the *Biodiscovery Act 2004* (Queensland) ("the Act"), aiming at furthering the ethical commercialisation of biodiversity in accordance with the Nagoya Protocol.

The key topics are:

- Commercial vs non-commercial biodiscovery;
- Inclusion of non-State land and land under native title;
- Enabling access to and utilisation of traditional knowledge for the benefits of the custodians of such traditional knowledge; and,
- Reform of the regulatory framework.

Griffith response addresses these topics in a holistic way. Accordingly, this submission needs to be read as a whole. For example, Griffith's proposed definitions for "commercial" and "Native biologic material" flow through to the considerations regarding the regulatory framework.

Griffith suggests including non-commercial biodiscovery in the Act, but to exclude such research from the requirement of a benefit sharing agreement. However, Griffith believe that appropriate permitting for collection and equivalent systems need to be in place and that the Act or the respective Compliance Code need to provide guidance on which

Griffith supports the inclusion of non-State land in the legislation. However, Griffith is concerned about unintended consequences, especially regarding equity. Therefore, Griffith suggests that the State retain responsibility and oversight for all Biodiscovery in Queensland land and waters that are regulated by any future amendments of the biodiscovery legislation, regardless of the type of landholding to ensure equity amongst potential beneficiaries. Griffith envisages a biodiscovery register, in which biodiscovery entities would be required to report all biodiscovery activities undertaken (with permission of the landholder to access and collect), but the benefit sharing component is not activated until royalties commence. At that point in time, the State would distribute the funds to the relevant landholders.

With respect to traditional knowledge, Griffith already has disclosure and benefit sharing agreements in place with the custodians of traditional knowledge. Although Griffith support the inclusion in the Act, Griffith is concerned about unintended consequences, and discusses in this submission particularly:

- Traditional knowledge held by multiple indigenous groups;
- Use of native biological material without knowledge of relating traditional knowledge and without using such traditional knowledge; and,
- Traditional knowledge in the public domain.

With respect to the reform of the regulatory framework, Griffith supports the separation of non-commercial and commercial biodiscovery, changes to permitting, abandoning a biodiscovery plan and the establishment of a State-run confidential biodiscovery register.

Response to Questions

The following section contains Griffith's responses to the questions asked in the Options Paper. It follows the structure of the Options Paper.

1. Areas of reform

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 currently 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 be regulated (if at all)?

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?

At this time, there are two significant tensions intrinsic to any reform to Queensland's Biodiscovery regulation framework with the Nagoya Protocol, being:

- that access to genetic resources and traditional knowledge is subject to informed consent from and fair benefit sharing arrangements with all legitimate stakeholders; and
- that the reform will not add significant hidden cost or complexity to Biodiscovery non-commercial research and commercialisation, which could result in extinguishing interest in research, development and investment in Biodiscovery utilising Native biological materials from Queensland.

Failure to balance these tensions in an appropriate way will result in a significant set-back to the development of Biodiscovery in Queensland.

Leaving aside reform option D (which is discussed below), Griffith does not see any of the reform options as a greater priority. Griffith rather recommends that any reform process should be undertaken in a single step, be based on strong, consistent and balanced policy and jurisprudence and a cognisance of the impact on basic research, industry and the imposed regulatory cost. Any reform undertaken needs also to accord with reforms in other jurisdictions, because imposing more or less regulation and compliance cost with cause Queensland's emerging Biodiscovery industry to be at a competitive disadvantage.

Griffith does not support option D and has a strong view that regulation of non-commercial activities unduly interferes with rights to conduct basic scientific research and adds cost and complexity to industry and the role of the regulator without any corresponding benefit.

4.1 Implementation of the Nagoya Protocol

4.1.1 Purposes of the Act

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?

Dependent on the extension of the scope of the Act to include Aboriginal and Torres Strait peoples' resources, traditional knowledge and private land, as discussed in the Options Paper, Sections 4.1.2. and 4.1.3., the amended scope needs to be considered in Section 3, Purposes of Act, Subsections (1) (a) and (c), (2) (a) (i) and (ii), and (2) (b).

4.1.2 Aboriginal and Torres Strait peoples' resources and traditional knowledge

Aboriginal and Torres Strait Islander peoples' resources

Question 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?

Griffith strongly supports the spirit of the Nagoya Protocol. Land tenures and/or native title rights should give rise to requirements for prior informed consent from, and benefit sharing with, Aboriginal and Torres Strait Islander peoples provided that some form of exclusive right to the subject material is derived by the relevant peoples through the underlying tenure.

Griffith would support an approach, which ensures that Queensland's biodiscovery legislation would conform with the Nagoya protocol, protect Aboriginal and Torres Strait Islander people's traditional knowledge and rights of landholders, and which enables commercial Biodiscovery.

Griffith suggests that the State retain responsibility and oversight for all Biodiscovery in Queensland land and waters that are regulated by any future amendments of the biodiscovery legislation, regardless of the type of landholding to ensure equity amongst potential beneficiaries. Griffith envisages a biodiscovery register, in which biodiscovery entities would be required to report all biodiscovery activities undertaken (with permission of the landholder to access and collect), but the BSA component is not activated until royalties commence. At that point in time, the State would distribute the funds to the relevant landholders.

The rationale is:

Extending the Act to cover all landholding types (including freehold, non-exclusive or exclusive use/access rights arrangements and native title rights) would create a number of challenges:

- The need for – potentially very prolonged - identification of interested parties or their representatives, to be able to negotiate access and

benefit sharing between Biodiscovery Entities and indigenous individuals, corporations and/or organisations;

- Aboriginal or Torres Strait Islander people individuals, corporations and/or organisations have varying knowledge, experience, capacity and resources regarding biodiscovery, the Biodiscovery value chain and contractual matters; and,
- The opportunity for a Biodiscovery Entity to shop around and obtaining access from Aboriginal or Torres Strait Islander people groups that do not have the capacity and resources to appropriately protect their rights.

there have been various attempts to including land under native title or managed by indigenous groups/corporations into legislation both in Australia and overseas. With exception of the Commonwealth, which has established a general right to ensure that access and benefit sharing arrangements are in place no matter, who the landholder is, so far, to our knowledge, none has been successful, despite the genuine engagement with Aboriginal and Torres Strait Islander people in Australia.

It is very challenging and, in many cases, impossible to determine, who the rightful holders of the rights and/or beneficiaries are, in terms of both access (who controls the rights to collect and use flora and fauna – that moves and is often not unique to one landholder) and benefit sharing. If traditional knowledge is also added to this equation - given the vast trading links and interconnectedness of Australian indigenous communities – this is often very difficult to isolate. Griffith has had first-hand experience of this with a R&D project with the Jarlmadangah Burru Aboriginal Community (Kimberleys, WA), aiming to develop traditional knowledge around the Mudjala plant's use for the treatment of pain.

Despite grant of rights to a certain Aboriginal or Torres Strait Islander people individuals or group for a certain region, it may still be difficult to isolate the or a group, who holds the rights to which biodiscovery entities needs to be granted access to. Biodiscovery entities may face the challenge of negotiating with a substantial number of individuals or groups, each with divergent views and expectations. It is challenging to envisage, how in such situation access and benefit sharing could be negotiated in an equitable and fair manner. It is a challenge for a Biodiscovery entity to engage and negotiate with communities or groups that have no corporate registration and little biodiscovery and commercial understanding (in addition to administrative and legal resources) to broker an equitable deal on behalf of all members or groups.

Griffith expects that inclusion of other landholders over and above State land into the biodiscovery legislation will result in Biodiscovery entities continuing to collect the majority of native biological material from State or freehold land, to avoid these challenges and the reduce long negotiations, uncertain timelines and very high transaction cost.

This will lead to a loss for everyone:

- Aboriginal and Torres Strait Islander people may not be able to benefit from Biodiscovery from native biological material on land or in water to which they have certain rights;
- The State would not receive the benefits of Biodiscovery from native biological material found outside of State land; and,
- People world-wide may miss the opportunity to benefit from new drugs, agrochemicals, nutraceuticals, food additives and cosmeceuticals based on native biological material found on land other than State or freehold.

Please note that Griffith has experienced that access to Traditional Knowledge is easier to negotiate, taking in to account and valuing the role of Elders in the upholding, protection, promulgation and culturally adequate disclosure of Traditional Knowledge.

Griffith emphasises that Griffith believes that at that point in time, it is not fair and equitable to require that Aboriginal and Torres Strait Islander individuals / groups / corporations / organisations need to negotiate benefit sharing agreements with Biodiscovery entities. This is due to the complexity of the field, the broad legal knowledge required to make informed decisions and the very low percentage of commercially viable products that enable sensible benchmarking.

Further, for those landholders with the resources, there are very few lawyers, who appropriately understand the Biodiscovery legislation, the Queensland Biodiscovery system, and who also have sufficient knowledge about varying landholder rights to support these parties in such negotiations. We estimate the cost for such support is approximately \$AUD 25,000 per case for the title holders, for legal advice and representation for negotiation of access and benefit sharing agreements. This is expensive and may not be affordable for a number of Aboriginal and Torres Strait Islander individuals, groups, corporations or organisations.

In addition, there is insufficient knowledge about the low success rate in the development and regulatory approval of drugs, agrochemicals, nutraceuticals, food additives and cosmeceuticals. Further, there is often a divergent expectation regarding the actual value of the commercialisation outcome to the landholder once the commercialisation chain gets to the initial parties.; this would require thorough information for all landholders to manage their expectations of the benefits from Biodiscovery, which in Griffith's opinion could be should be provided by the State.

The inclusion of all landholder types into the biodiscovery legislation could potentially result in an extensive, expensive (substantial higher transaction cost), largely fragmented, ad hoc, individual, inconsistent and potentially inequitable, case-by-case approach.

Therefore, Griffith would suggest the State should retain responsibility for access and centrally issuing collection permits, approving biodiscovery plans and enter into benefit sharing agreements. The State could share the benefits of biodiscovery with all identified beneficiaries no matter what type of landholding they have (provided they have rights over the collection and use of native biological material and traditional knowledge. The State would need to establish an appropriate biodiscovery register and when commercialisation returns commence, then the process of identify the respective traditional title holders is undertaken and commercial returns are distributed to all eligible parties upon an equitable basis

A centralised approach would make the Biodiscovery framework very clear, straight forward and easy to navigate and keep timelines and transaction cost reasonably enabling.

Landholders would need to be consulted for prior informed consent access to their land, which should not be unreasonably withheld. This could be done by the Biodiscovery Entity or the entity collecting the Native biological material.

Question 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)?

There are no other types of rights Griffith considers should give rise to notification or consultation processes.

Traditional knowledge

In the Australian context, almost all Aboriginal and Torres Strait Islander people's traditional knowledge ("TK") is kept secret and only perpetuated in oral form. It usually is disclosed through oral communication. Typically, only a well-defined group of people has access to the TK, e.g. a certain Aboriginal community. So far, there is no collection of Aboriginal and Torres Strait Islander people's TK that is either private (secret with strict access conditions) or in the public domain and there is currently no register of such rights.

World-wide there are substantial discussions and consultations about the scope of TK, the resulting "intellectual property-like" rights and issues such as culturally adequate disclosure, protection, use, public domain knowledge, and access.

Griffith suggests following a pragmatic approach that:

- applies the Nagoya Protocol;
- provides a framework within which Aboriginal and Torres Strait Islander people's TK is protected, and which also acknowledges the important role of Aboriginal and Torres Strait Islander people in utilising their TK;
- is fair and equitable to Aboriginal and Torres Strait Islander people; and,
- enables commercial Biodiscovery based on such TK.

There is a great opportunity for the Act to be an instrument that encourages Aboriginal and Torres Strait Islander holders of TK to disclose their knowledge in a manner, which ensures that they are entitled to share in resultant benefits. The TK then could potentially create immense benefits for the people of Queensland, Australia and overseas, e.g. through the development of new pharmaceuticals, agrochemicals, food additives, nutraceuticals and cosmeceuticals.

The process is straightforward where holders of TK approach a Biodiscovery entity, offering their TK for the development of new products. An example is the relationship between the Jarlmadangah Burru Aboriginal Community (Kimberleys, WA) and Griffith University to develop TK around the Mudjala plant's use for the treatment of pain.

In a second scenario, a Biodiscovery Entity approaches holders of TK and formally seeks access to their TK. Examples include a pharma company asking

a Torres Strait Islander community whether they have and are willing to share their TK about the use of plants in treating dementia.

In these scenarios, the holders of TK and the Biodiscovery Entity naturally would enter into access and benefit sharing agreements, which also include appropriate confidentiality provisions.

However, there are very complex challenges around TK which any reform needs to take into account. These are exemplified in the following 3 scenarios:

1. TK held by multiple indigenous groups

More complex issues arise where TK is held by multiple indigenous groups, but the Biodiscovery entity engages only with one of them.

Many questions arise, including:

- Should then all TK holders be entitled to sharing the benefits?
- If so, how could a Biodiscovery entity find out, who else may hold similar TK?

Griffith suggests that a single agreement with the actual discloser of the TK should be sufficient under the Act and that no third party can make claims against the Biodiscovery Entity.

2. Use of Native biological material without knowledge of relating TK and without using such TK

A Biodiscovery Entity should be entitled to use Native biological material in circumstances, where a discovery is made without accessing any TK, without the need for any agreement with holders of such TK. An example is where a high throughput approach, with mass screening based on discovery assays for particular uses has independently discovered something known in TK. However, the respective TK was not disclosed to the relevant investigator before the discovery.

This scenario raises the underlying and fundamental question of how TK should be protected within the underlying jurisprudence. There are two possibilities being either:

1. TK is recognised and treated as confidential information unless it is protected by a valid patent which has been granted within the context of the existing patent application and grant processes; or
2. TK is recognised as a separate and new type of intellectual property and a system for registering, recording and prioritising such rights (such as a register in the nature of the patent register or the trademarks register is created to support the creation of the new right).

Alternative two seems impractical. Leaving aside the cost of establishing such a framework, there are no apparent means by which competing claims to the same or alike knowledge could be resolved, and there no means by which ambit or bogus claims could be tested and dismissed.

Griffith suggests that TK should be recognised, treated and protected as a specific subset of confidential information and, as such benefit sharing would only be appropriate where TK had been disclosed.

3. TK in the Public Domain

There is an ongoing discussion world-wide, whether TK that is in the public domain still should be treated like secret TK. This issue is a vexing topic. So far, there is no solution.

As discussed above, Western intellectual property rights struggle with addressing and protecting TK. However, in many jurisdictions patent law provides protection – if TK has been accessed and is used in a patent application, the applicant needs to show that they have an agreement with the owners of the TK for the use of that IP, or that the IP is in the public domain. The European Patent System is on the forefront of this.

Copyright protects the particular expression how TK is disclosed (e.g. a song, dance, book or a video), but not the TK as such – for example you are not allowed to reproduce and sell a cook book, but you can use a recipe in a cook book and sell the dish in your restaurant. However, applying this principle to TK that is in the public domain, is contested by many indigenous groups world-wide. There is the risk that inclusion of public domain TK will deter any commercial activity, as this would pose high commercial risk - higher transaction cost, unforeseeable timelines to negotiate and gain access and the potential to be sued under the Act.

At this point in time, given the protection provided in Australian context through oral promulgation and oral disclosure of Aboriginal and Torres Strait Islander people's TK, Griffith suggests that TK that is in the public domain should not be included in the Act.

This ensures that Aboriginal and Torres Strait Islander people's TK will be utilised, and benefits will be gained.

Progress in the international system for protection of TK may help to change this in the future. We recommend that the State continues to monitor the international developments around the protection and use of TK.

Please also refer to Griffith's response to Question 52.

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.

Question 5

Which option or combination of options do you prefer? Why?

Griffith would endorse Option 2 and offer the following as an alternative.

If you treat TK as confidential information, then equitable concepts of confidentiality will impose consent obligations on the recipient of the information and also provide injunctive remedies and rights to damages which equate somewhat to benefit sharing. We note *Foster and Others v Mountford and Rigby Ltd* (1976) 14 ALR 71, which is an important Australian case in the context of extension of concepts of confidentiality to protect cultural heritage.

We suggest that an appropriate option would be to amend the Act to acknowledge the protection of TK as confidential information. The control of the TK is vested in a group so that disclosure by one individual and consent by one individual does not constitute disclosure or consent by all and does not extinguish the underlying right to claim an equitable benefit from use of the confidential information.

This seems to create a viable and durable TK right without upsetting the existing intellectual property conceptual framework, and without creating an undue administrative burden for any of the stakeholders or increasing complexity.

Question 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?

Our suggestion in response to Question 5 propounds a viable and durable TK right without the need to enter into benefit sharing agreements or demonstrate consent.

Question 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?

Griffith has experience of obtaining prior informed consent and agreeing to share commercialisation returns with TK holders (see the Mudjala project, as mentioned above). The process is expensive, time-consuming and could act as a significant brake on commercial Biodiscovery, particularly, if it were voiced in complex or unduly prescriptive manner.

Our suggestion in response to Question 5 propounds a viable and durable TK right without the need to negotiate these types of arrangements, until a commercial discovery was made. At this timepoint, the Biodiscovery entity must negotiate with the provider of the confidential information (sic the TK) to provide a fair share of benefits for the provider of the confidential information.

Definition of traditional knowledge

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.

Question 8

Which options or combination of options do you prefer? Why?

None of these.

Griffith prefers a definition of "traditional knowledge" that

- is clear and unambiguous
- relates to the context of TK as confidential information.

Griffith's concern is that a traditional definition of 'traditional knowledge' and the CBD definition are not specifically related to Biodiscovery and problems could arise with implementation of a very general and broad definition into a scientific specific concept such as Biodiscovery.

Question 9

Are there other definitions that could be used as the basis for a definition in the Act or guidance?

Griffith proposes a tailored definition for the purpose of the Act, acknowledging that there is no generally accepted definition of “TK”. However, for the implementation of the Act, a definition is required to provide legal clarity for Biodiscovery.

Griffith suggests:

“The knowledge, innovations and practices of Indigenous communities relevant for the use of Native Biological Material for Biodiscovery.”

Alternatively, the IP Australia Discussion Paper “Indigenous Knowledge: Issues for protection and management”, 2018, utilises the following definition:

“Traditional Knowledge (TK) refers to the knowledge resulting from intellectual activity in a traditional context, and includes know-how, practices, skills and innovations. Traditional knowledge can be found in a wide variety of contexts, including: agricultural knowledge; scientific knowledge; technical knowledge; ecological knowledge; medicinal knowledge, including related medicines and remedies; cosmology; and biodiversity-related knowledge. This includes knowledge about genetic resources.”

The world Intellectual Property Organisation suggests:

“Traditional knowledge (TK) is knowledge, know-how, skills and practices that are developed, sustained and passed on from generation to generation within a community, often forming part of its cultural or spiritual identity.”

The WIPO provides some explanations:

TK in a general sense embraces the content of knowledge itself as well as traditional cultural expressions, including distinctive signs and symbols associated with TK.

TK in the narrow sense refers to knowledge as such, in particular the knowledge resulting from intellectual activity in a

traditional context, and includes know-how, practices, skills, and innovations.

Traditional knowledge can be found in a wide variety of contexts, including: agricultural, scientific, technical, ecological and medicinal knowledge as well as biodiversity-related knowledge.

The definition of TK needs to also reference its protection as confidential information.

Question 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?

Griffith's view is that the cultural heritage legislation stakeholder identification processes are too complex for application in the TK context. Our response to question 5 removes the need to have a mandated process for a specific identification process.

Question 11

For option 3, what do you think are the key principles that should be included?

As discussed above, consideration of option 3 is unnecessary, given our response to question 5.

Definitions of Aboriginal and Torres Strait Islander people and their 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'.

Question 12

Which options or combination of options do you prefer? Why?

Griffith suggests Option 3, with consideration of Griffith's response to Question 3.

Question 13

What, if any, other examples of relevant definitions could be used?

What are the benefits of these definitions?

-

Activities in exercise of native title rights

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.

Question 14

Which options or combination of options do you prefer? Why?

Griffith prefers Option 1. Activities carried out pursuant to native title rights, provided they are for the purpose of satisfying personal, domestic or non-commercial communal needs (which they ought to be, in any event, given the nature of native title), should not be within the scope of the Act.

Question 15

For option 1, do you have suggestions on the specific scope of an exemption?

Griffith suggests following the scope of the *Native Title Act 1993* (Cwth):

...the activity is the exercise of native title rights and is for the purpose of satisfying personal, domestic or non-commercial communal needs.

However, as discussed in Griffith's response to Question 4, what are the implications of a Native Title holder conducting Biodiscovery with Native biological material collected on the land under the Native Title?

Question 16

Are there any other measures that would be required to support biodiscovery activities undertaken by native title holders?

Griffith is concerned that biodiscovery activities undertaken by native title holders must be similar to those imposed upon biodiscovery entities. Otherwise, native title holders may invest resources and capital on biodiscovery activity only to find that commercial third parties are not willing to engage with them because they cannot demonstrate compliance or need to incur further administrative costs to inform about specific exemptions (prior informed consent, collection permits, biodiscovery research, commercialisation).

4.1.3 Scope of the Act

Non-commercial activities

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.

Question 17

Which option or combination of options do you prefer? Why?

Griffith prefers Option 1.

Griffith is concerned that extending the scope of the legislation to non-commercial activities is a potential fetter on basic scientific research. However, this risk can be mitigated by:

- amending the Act clearly define 'commercial' vs 'non-commercial' activities;
- provision of guidance for trigger points for the transition from non-commercial to commercial biodiscovery activities;
- exempting non-commercial activities from the requirement of a Benefit Sharing Agreement, e.g. by implementing the regulatory framework of Option 3 in Question 34 (Section 4.3.1.);
- enabling transfer of Native biological materials for non-commercial research under appropriate material transfer agreements, that contain

a set of minimum prescribed terms to ensure that the recipient does not conduct commercial biodiscovery with the material; and,

- amending the regulatory framework of Option 3 in Question 34 (Section 4.3.1.) to include multiple options that allow collection of Native biological material.

Question 18

What are the likely impacts for your organisation if non-commercial activities were included (and quantify where possible)?

To what extent would it change the administrative burden of complying with the Act?

Including non-commercial activities under similar conditions as commercial activities, would create an immense burden. This is particularly the case for entities, which have large collections of Native biological material, e.g. Griffith University (NatureBank).

Griffith regularly share samples with academic research partners domestically and overseas for non-commercial biodiscovery purposes, mainly the discovery of new compounds and their biological function, publication and use as research tools.

Such sharing is done under appropriate Material Transfer Agreements, which prohibit the commercial use of any Native biological material or information derived from them (broad scope of Griffith's proposed definition) and include information about the requirements of the Qld Biodiscovery legislation.

If a collaborator finds a compound that may have commercial potential, the collaborator must come back to Griffith to enter into a Subsequent Use Agreement ("SUA"; trigger point).

If each academic collaboration would require a SUA, the transaction cost for Griffith and our collaborators would be high and many collaborators would prefer to use compounds/collections, which do not require a SUA. Usually, processing an MTA requires about 1 work day and 1-2 weeks communication with the recipient or provider; negotiating an SUA would require at least 10 work days over 6-9 months.

Therefore, enabling non-commercial Biodiscovery is key to enable broad utilisation of Qld's Native biological material for the general advancement of science.

Land tenures

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.

Question 19

Which option or combination of options do you prefer? Why?

Extending the Act to cover private land would create the need to negotiate access and benefit sharing agreements between Biodiscovery Entities and individuals, corporations or organisations with varying knowledge, experience and capacity about biodiscovery, the value chain and contractual matters.

As mentioned in Griffith's response to Question 3, there is not a large number of lawyers who appropriately understand the Biodiscovery legislation and the Queensland Biodiscovery system. We estimate the cost for such support >>AUD 15,000 per case for the land owners, for legal advice and representation for negotiation of access and benefit sharing agreements. This is expensive and may not be affordable for a number of land owners.

In addition, there is insufficient knowledge about the low success rate in the development and regulatory approval of drugs, agrochemicals, and to an extent of nutraceuticals, food additives and cosmeceuticals, and the fact that the actual value at the time of transaction is low; this would require thorough information for land owners to manage their expectations of the benefits from Biodiscovery, which should be provided by the State.

This potentially would increase the transaction cost for Biodiscovery, for engagement and negotiation with the owners.

Griffith suggests Option 3. Owners of private land have rights to control what occurs on their land (for example, through laws relating to trespass) whether or not the Act is amended. Investing effort in guidance, particularly for landholders, enhances the likelihood of landholders sharing in the benefits of biodiscovery without adding to legislative complexity or compliance costs.

Question 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)?

To what extent would it change the administrative burden of complying with the Act?

Extension to private land (and native title) would create the need to negotiate access and benefit sharing with individuals and organisations with varying knowledge about biodiscovery, the value chain and contractual matters. That would put a large administrative and financial burden on Griffith University. Please also refer to Griffith's response to Question 19.

Implications

Similar to holders of Native Title, how would the Act address the case, where a land owner conducts Biodiscovery with Native biological material collected on their land?

It is our understanding that under the current Act, such activities are not regulated. The owner conducting such activities is not a Biodiscovery entity and not required to seek permits for collection of Native biological materials on their land, or to enter into benefit sharing agreements with the State.

If a private owner would then downstream in the Biodiscovery process partner and commercialise the outcomes of their Biodiscovery activities with a third party, e.g. an agrochemical company, would such activity then fall under the Act? In this scenario, would the private owner become a Biodiscovery entity? Or the 3rd party?

4.1.4 Demonstrating provenance and prior informed consent on mutually agreed terms

Applications for Queensland Government funding

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?

It is in the interest of a Biodiscovery entity to be able to demonstrate compliance with all applicable biodiscovery legislation to be able to attract industry partners to commercialise the outcomes of Biodiscovery. Demonstrating underlying freedom to operate is an essential component of any commercial drug development process.

Therefore, if non-State land is included in the legislation, and the regulatory framework would be amended as proposed by Option 3 in Question 34 (Section 4.3.1.) to exempt non-commercial biodiscovery activities, the requirement would be no additional burden.

International Certificates of Compliance

Question 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?

Griffith's view is that Queensland's regulatory activities in this sphere should be developed in step with and consistently with those of the Commonwealth and the other States, to the maximum extent possible. Griffith's point of view has consistently been that the Act was unduly prescriptive, drafted without reference to underlying realities and has been a major impediment to the conduct of drug discovery in this jurisdiction. Against this backdrop, any initiatives that do not conform with developments elsewhere should be discouraged.

Question 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?

Griffith believes that such counterparties to a drug development transaction are likely to conduct extensive due diligence on freedom to operate regardless of whether or not a collection authority has issued an ICC (which is likely to be heavily conditioned in any event). In this context, Griffith's point of view is that Queensland-based Biodiscovery entities are unlikely to benefit from ICCs.

Biodiscovery register

Question 24

What are the key considerations you think are important in the development of a biodiscovery register? Why?

The register would enable the Queensland Government to monitor the progress of biodiscovery activities, both commercial and non-commercial, provide a platform for simpler reporting under benefit sharing agreements, and help biodiscovery entities to meet international obligations (if it would be the basis for issue of ICCs by the State).

The register also would enable the State, based on the location of collection, to identify and share the benefits of Biodiscovery with Aboriginal and Torres Strait Islander people having -rights to the native biological material which has been collected and used.

The key consideration is that the register not be structured in a way that reveals commercially valuable information to the public (either by being searchable by the public or through an RTI process). Getting this balance wrong so that the conduct of commercially valuable biodiscovery in Queensland involves potential disclosure to competitors could ensure that no commercial biodiscovery occurs in this jurisdiction.

Question 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

Griffith suggests that the following information is sufficient to enable the State to monitor progress of and benefits received from Biodiscovery activities:

- Description of native biological material (e.g. coral);

- Taxonomic information (e.g. following the Atlas of Living Australia, www.ala.org.au: kingdom Animalia, phylum Bryozoa, class Gymnolaemata, order Cheilostoma, suborder Ascophorina, infraorder, Lepraliomorpha, superfamily Celleporoidae, family Phildoloporidae, genus *Triphyllozoon*, species *Triphyllozoon moniliferum*);
- Collection Permit(s);
- Collection information (where, GPS coordinates; when; who; quantity; re-collected);
- Traditional Knowledge transferred with collection? If yes, describe the traditional knowledge;
- Benefit Sharing Agreement(s) – which information should not be publicly accessible;
- Genetic information (sequences) derived from native biological material; as this data could be confidential, it is not possible to require to post these data to international sequence database such as the National Centre for Biological Information (NCBI; www.ncbi.nlm.nih.gov; USA). This part of a register should not be accessible by the public;
- Native biological material shared with
 - o non-commercial biodiscovery – entity, project leader, purpose
 - o commercial biodiscovery – entity, project leader, purpose, benefits of biodiscovery and when the benefits are to be provided, royalty rates and milestone fees (may be commercial in confidence); and,
- Benefits of biodiscovery obtained for the State) – all of which information should not be publicly accessible.

The biodiscovery entity should be required to annually update its activities in the register.

As discussed above, large parts of the database need to be confidential, with restricted access for provider and the State only, due to the inclusion of information about secret and/or culturally-sensitive Traditional Knowledge, potentially un-disclosed non-commercial research activities, and commercial in confidence terms for commercial biodiscovery partnerships.

The State needs to consider that such register would have immense scope and would hold a large amount of data, in combination with complex access rights. As such, it would be an expensive undertaking that requires constant maintenance and updating. However, Griffith believes that the benefits outweigh the cost.

Trusted institutions

Question 26

Should the Queensland Government wait to develop a trusted institution framework that is consistent with the Commonwealth or should it develop its own system independently?

Griffith suggests that the State takes leadership and develops a trusted institutions framework. It should be based significantly upon the European Union's system of registered collections.

Question 27

What do you consider to be key requirements of a framework that accredits trusted institutions?

A clear relationship between the State and the trusted institution is essential because that helps biodiscovery entities assess whether to engage with the State and/or a trusted institution for access to native biological material.

There also should not be different benefit sharing conditions for access (e.g. royalty rates), so that biodiscovery entities have no commercial pressure in deciding which resource they wish to access.

Any framework needs to be similar to other like frameworks and support a very streamlined process to limit the number of repeated interactions between the State and the Trusted Institution

Question 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?

For Griffith, this would not have impact for our current collection, NatureBank.

4.2 Definitions

4.2.1 Native biological material

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).

Question 29

Which option or combination of options do you prefer? Why?

Option 2, to provide clear guidance, what material and information is included under the Act.

We emphasise that “man-made materials” (Option 2 g)), should not be excluded, as they could be based on information gained from native biological material (see below “Structural Homologues and Functional Analogues”) and thus constitute a use of the native biological material.

To clearly define the scope of “native biological material” in the context of biodiscovery, Griffith suggests that the State may consider utilising the concept and definitions typical utilised in the context of a Material Transfer Agreement (MTA), e.g. of the UBMTA (The UBMTA Project, Association of University Technology Managers (AUTM), 111 Deer Lake Rd, Suite 100, Deerfield, IL 60015),

Both, concepts and definitions, are widely understood, accepted and utilised in academia and industry, when dealing with R&D materials and relating information in all industry sectors relevant for Biodiscovery. The intended scope of the definition of Native biological material is similar to the term ‘Original Material’ in such MTAs and is scoped through inclusion of a number of further well-defined terms, such as “progeny”, “unmodified derivatives” and “modifications”. While this would introduce more definitions in the Act, it would provide immense clarity.

Griffith proposes the State to consider drafting the definition around the following ‘MTA-like’ definitions.

Native biological material means

a) a native biological resource;

b) a substance sourced, whether naturally or artificially, from a native biological resource;

c) any progeny, unmodified derivatives, modifications;

d) any structural homologues, functional analogues; or

e) any information derived from or created using native biological resource.

Progeny: Unmodified descendant from the native biological material, such as virus from virus, cell from cell, or organism from organism.

Unmodified derivatives: Substances created which constitute an unmodified functional subunit or product expressed by the native biological material. Some examples include: purified or fractionated subsets of the native biological material, e.g. compounds isolated from an organism or proteins expressed by DNA/RNA derived from a virus.

Modifications: Substances created which contain/incorporate the native biological material.

Information: Data, results, structures, genetic codes.

Structural homologues and functional analogues: Substances created utilising information gained from the native biological material, Progeny, Unmodified Derivatives and Modifications. Some examples include a synthetic compound with the same 3-dimensional structure, but different chemistry than a compound isolated from a coral (structural homologue); a compound with unrelated chemical structure synthesised to have similar function like a compound isolated from a fungi (functional analogue).

If the State would prefer to retain the current terminology of the Act, Griffith suggest following a similar approach to the MTA terminology to define the scope of native biological material"

'Native biological material means -

a) a native biological resource; or

b) a substance sourced, whether naturally or artificially, from a native biological resource; or

c) a substance created utilising a substance sourced from a native biological resource;

d) a substance created utilising genetic, structural or functional information derived from a native biological resource; or,

e) any information derived directly or indirectly from native biological material.

These examples would clarify the scope:

“a substance sourced“ includes any ex situ collection, extracts, chemical compounds etc.

“a substance created utilising a substance sourced” includes any modification or derivative of “a substance sourced”

“a substance created utilising genetic, structural or functional information derived from a native biological resource” includes any structural homologues and functional analogues of “a substance sourced” and “a substance created utilising a substance sourced”

“any information derived directly or indirectly from native biological material” includes any genetic, structural or functional information.

Griffith also would propose to amend the definition of “native biological resource”, to address the proposed changes discussed in sections 4.1.2 and 4.1.3.

Native biological resource means -

a) a non-human living organism or virus indigenous to Australia and sourced from land or waters within the territory of the State of Queensland;

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

Question 30

For option 2, which components of the amendments do you support?

Why?

Please see above.

Question 31

What would the implications of any of these changes be to your organisation (and quantify where possible)?

How would it change the administrative burden of complying with the Act?

The proposed changes would provide clarity of scope that greatly simplifies communication of the scope of the Act to industry partners.

It also would clarify reporting requirements.

4.2.2 Commercialisation

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 the 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.

Question 32

Which option do you prefer? Why

Griffith prefers none of the Options but proposes to amend the

The scope of the current definition can be further clarified, by either adding to the meaning of "gain" or adding exemptions, or both.

The following is modelled on language widely used in license agreements:

commercialisation, of native biological material -

- a) means to exploit the material or intellectual property relating to the material in any way to generate income, including:*
- b) manufacture, sell, hire or otherwise exploit a product or process that uses or incorporates material or intellectual property relating to the material;*
- c) provide a service that utilises or incorporates material or intellectual property relating to the material;*

- d) *grant a licence, sub-licence or enter into a joint venture or make any other similar arrangement with any third party to do any or all of the things referred to in (a) and (b) above; and*
- e) *assign or otherwise dispose of, whether partially or wholly, any or all rights in material or intellectual property relating to the material.*

commercialisation, of native biological material does not include -

- f) *using the material or to obtain financial assistance from a government e.g. through a grant from a State, the Commonwealth, Australian competitive grant scheme or any similar overseas granting scheme;*
- g) *using the material or to obtain financial assistance from a philanthropic entity;*
- h) *activities, where a third party wishes to test, whether extracts, or compounds derived from Native biologic material can be assessed in their screening and evaluation systems, without any rights to the material and outcomes; and,*
- i) *activities conducted solely for academic publication, e.g. collaboration between academic institutions under a simple material transfer agreement or collaboration agreement;*

if these activities f)ih) do not include any of a)-e) above.

Please note that the proposed definition is based on the proposed definitions of "Native biologic material" above.

The State should also provide guidance materials assisting in understanding any amended definition. For example, the Compliance Code could set out a number of examples to illustrate commercial vs non-commercial activities. Griffith has included some examples in Griffith's answer to Question 33 below ("trigger points").

Question 33

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

Griffith suggests the following as examples for triggers:

- Entering into any agreement with a third party that grant the right to develop and market a product or service from native biological material to the third party.
- Entering into any agreement with a third party that grant an option to license intellectual property relating to Native biological material (under Griffith's proposed broad definition, answer to Question 29), grant of a licence to such intellectual property, grant of the right to protect with intellectual property rights outcomes from R&D activities.
- An academic collaborator, who has access to Native biological material under an appropriate Material Transfer Agreement (which prohibit the commercial use of any Native biological material or information derived from them), finds a compound or use of a compound that may have commercial potential and wishes to commercialise, the collaborator must come back to the Biodiscovery entity to enter into a Subsequent Use Agreement (SUA).
- Within an Australian Research Council linkage project, an academic Biodiscovery entity grant to an industry partner the right to develop and market a product or service from native biological material, or an option to license intellectual property relating to Native biological material, a licence to such intellectual property, or the right to protect with intellectual property rights outcomes from R&D activities.

In contrast, the following activities should not be considered as trigger points:

- A company wishes to test, whether extracts, or compounds derived from Native biological material work in their screening and evaluation systems but does not receive any rights to materials and the outcomes.

- Filing for IP rights claiming native biological material or use of native biological material (under Griffith's proposed broad definition, answer to Question 29), as filing a patent does not mean that the patent will be exploited commercially.

The trigger point for commercialisation and the associated benefit sharing process should be abundantly clear in the regulations and Compliance Code.

4.3 Regulatory framework

4.3.1 Authorisation to collect and use native biological material

Question 34

Which option or combination of options do you prefer? Why?

Griffith prefers Option 3. It will allow especially academic institutions to commence collection and biodiscovery, without the need for a Biodiscovery Plan and a Benefit Sharing Agreement. These would be negotiated with the State or other land owners, when applicable trigger points are met (please also see Griffith's answer to Question 33). without having to wait interrupt the research component. This creates substantial value through shortened timelines.

The abolishment of a Biodiscovery Plan will remove administrative burden from the process, for both, the State and the Biodiscovery Entity. Especially for Biodiscovery Entities with large collections, it is challenging to provide a sensible Biodiscovery Plan, due to the magnitude, heterogeneity and complexity of Biodiscovery activities.

Question 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?

Griffith would prefer a number of mechanisms, including the options a-c, to facilitate easy access to Native biologic material for non-commercial biodiscovery.

Please note that the NCA covers only listed species, while many Biodiscovery approaches collect plants that are not listed. Appropriate NCA-like permits are required to enable such Biodiscovery activities.

Question 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?

If Option 3 is implemented, permits under the NCA or other approved mechanisms should be sufficient.

Question 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?

Griffith suggests that any Biodiscovery entity annually reports about their Biodiscovery activities and the use of any Native biological material, with the Act enabling the State to audit such reports. A Biodiscovery register would be a good tool for such reporting. Please refer also to Griffith's response to Question 24 and 42.

Question 38

What, if any, opportunities do you think there are to simplify and/or automate the permitting process?

From the University's perspective an online automated permit process could have substantial benefits. It would result in the collection of material becoming significantly easier (and the reality is that with larger more diverse collections may increase the chance of successful outcomes. Reducing the red-tape around collection and pure academic research would ensure larger collections and increased academic research opportunities. It would also give the State potentially more data which may prove useful regarding long-term management of these resources.

4.3.2 Compliance Code and Code of Ethics

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.

Question 39

Which option or combination of options do you prefer? Why?

Griffith prefers Option 1. This would provide most legal and regulatory clarity and make these highly visible by collating all obligations in one place.

Question 40

Which of the additions (if any) suggested by the Review do you think should be incorporated into the Compliance Code?

All. However, although a method of identification and storage of samples needs to be considered carefully, as it could become unnecessarily prescriptive and may preclude utilisation of technical advancements.

Question 41

Are there aspects of the Compliance Code you think could be better explained through guidance material (for example on the department's website)?

Griffith would prefer to add guidance in a document referred to in the Compliance Code, e.g. "Guidelines for Compliance Code".

4.3.3 Reporting requirements

Question 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?

Griffith proposes that the State establish a Biodiscovery register. Such register could be built in a way that enables Biodiscovery entities to directly report to the State through the register as and when needed, but with at least an annual report. This would replace any current reporting requirements. Please refer also to Griffith's answer to Question 25 and 37.

Question 43

If regular updates on non-commercial biodiscovery are required, what frequency do you consider more appropriate? Why?

As proposed in Griffith's answer to Question 25 and 37, the Biodiscovery entity should report for non-commercial activities through a new Biodiscovery register.

Question 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)?

The new scope of the Act, as proposed by Griffith in this response, would make the Act fully compliant with Nagoya Protocol and thus there should be no Biodiscovery activities outside of the scope of the Act.

4.4 Other Matters

4.4.1 Submission of samples

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 (such as the Compliance Code).

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

Question 45

Which option or combination of options do you prefer? Why?

Griffith would prefer Option 2. Both the Museum and the Herbarium are key caretakers for Queensland's biodiversity. Ensuring that the State's biodiversity is centrally collated, stored and preserved is a gift to future generations. Griffith believes that the benefits outweigh the cost.

Griffith University has worked with these institutions for more than two decades and highly values our partnership with the Museum and the Herbarium.

Question 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?

Griffith does not support Option 1.

Question 47

For option 2, what do you think the key required characteristics of samples should be?

The key requirement needs to be simplicity, as there would be a significant compliance cost in providing (and then for the Museum and Herbarium in curating) underlying data, information or sequences of native biological material.

4.4.2 Ministerial power to declare exemptions from the Act

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.

Question 48

Which option do you prefer? Why?

Griffith prefers Option 1.

Question 49

For option 1, what do you think the criteria should be for exercise of the ministerial discretion?

Griffith suggests that the criteria for the Minister's power to intervene should be voiced in terms of a matter of State significance and interest.

Question 50

For option 2, which treaties or other legislative processes do you think should be exempt?

Griffith does not support Option 2.

4.4.3 Compliance measures

Question 51

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

Griffith suggests that the State continues to provide education about the State's Biodiscovery framework to well inform entities, such as academic institutions and companies, which are interested in conducting Biodiscovery.

In addition, land owners and holders of traditional knowledge and/or native title would benefit from the State providing information and education regarding Biodiscovery.

Besides enabling entities and land owners and holders of traditional knowledge to comply with the Act, this also could lead to increased Biodiscovery activity, for the benefit of the land owners and holders of traditional knowledge, the State, all Queenslanders and Australians and people world-wide.

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

Question 52

What compliance measures do you think are most important to include?

Griffith suggests implementing the first two measures a provided by the State in Section 4.4.4:

- powers to audit in relation to prior informed consent and benefit sharing; and,
- the right to request further information in relation to the provision of prior informed consent and benefit sharing.

However, measures 3 and 4 are very problematic, and without further clarification, pose a major risk for any Biodiscovery entity:

- an offence for using traditional knowledge other than with prior informed consent and benefit sharing could be an egregious legislative impost if it did not specifically reference an aspect of wilfulness following explicit disclosure. Without these qualifications and remembering there is no definitive searchable register of TK and custodians of TK, the only manner in which researchers could definitively avoid prosecution would be by not conducting research;
- 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.

The key issues that must be considered include:

- *TK held by multiple indigenous groups* – If the Biodiscovery entity has an access and benefit sharing agreement with one indigenous group, no other group should be allowed to make a claim against this Biodiscovery entity.
- *Use of native biological material without knowledge of relating TK and without using such TK* - a written declaration of the Biodiscovery Entity,

or any measure required by the State, should satisfy evidence of non-access and non-use of TK.

- *TK in the Public Domain* - TK that is in the public domain should not be included as base for any offence at this point in time.

Please refer to Griffith's considerations in Section "Traditional knowledge" and answers to Questions 5 and 6.

Question 53

Are there any other measures that you think should be introduced?

Griffith suggests that the State continues to provide information and education about the State's Biodiscovery framework to holders of traditional knowledge.

Appendix 1 – Options and Figures for Section 4.3.1

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

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.

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.

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.

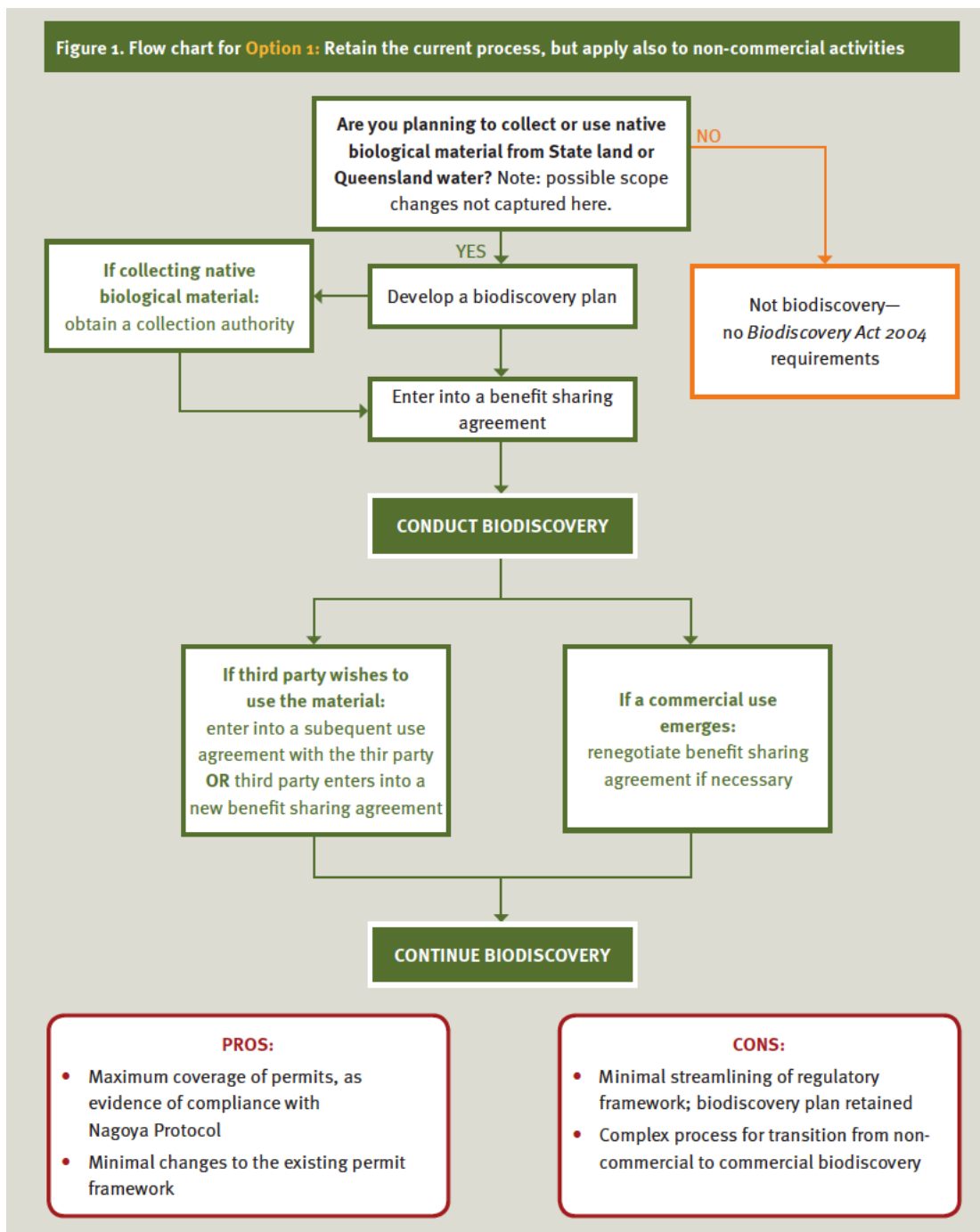
Where a permit under (a) or (b) was used, reporting requirements could be similar to the framework under option 2. Alternatively, a lighter monitoring approach could be used (and is likely to be required if option (c) is adopted), requiring the biodiscovery entity to retain evidence of compliance with 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

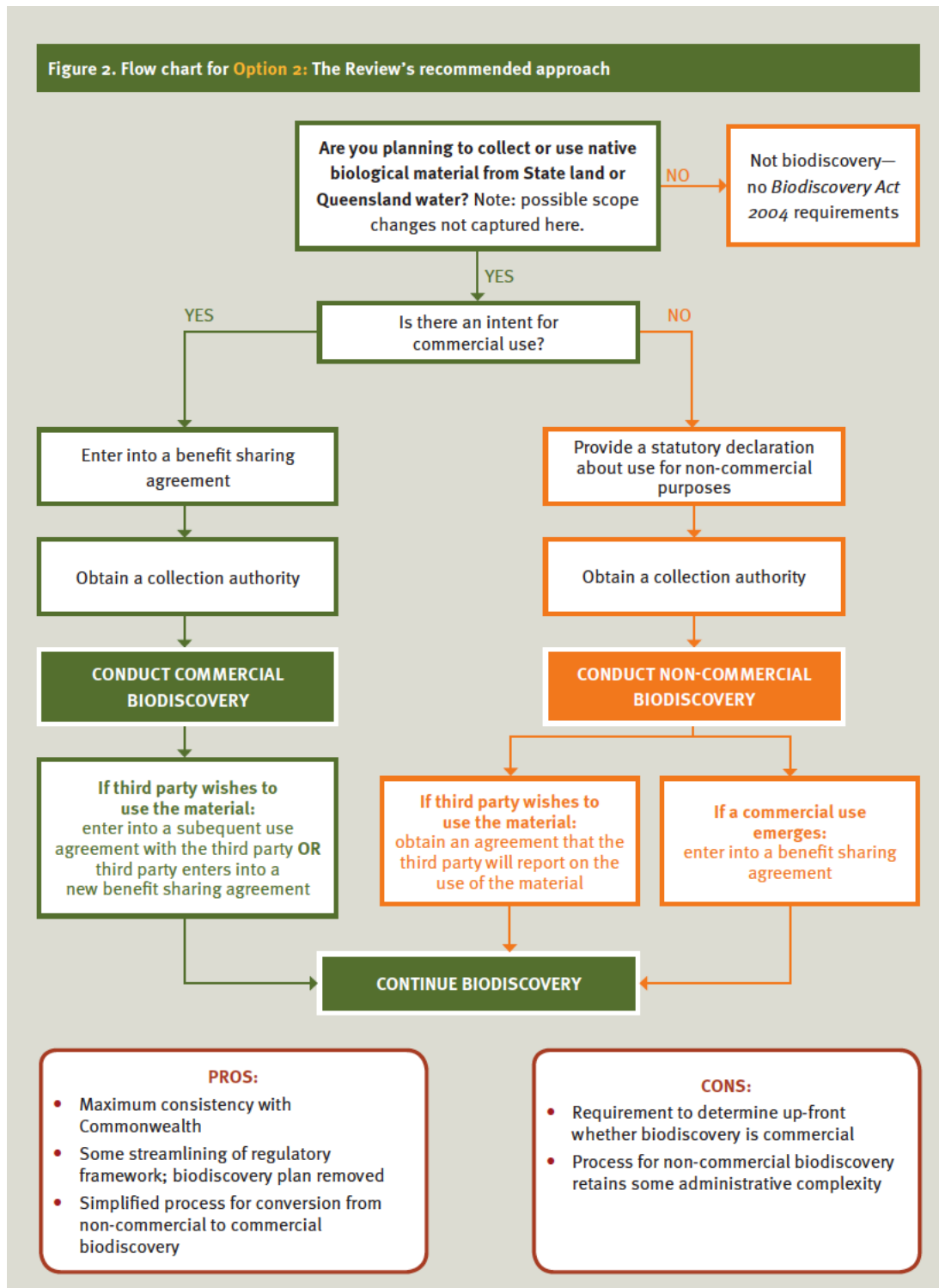
A benefit sharing agreement would be required once a commercial use is identified, before the commercial use could commence. Reporting requirements as per option 2 may be included.

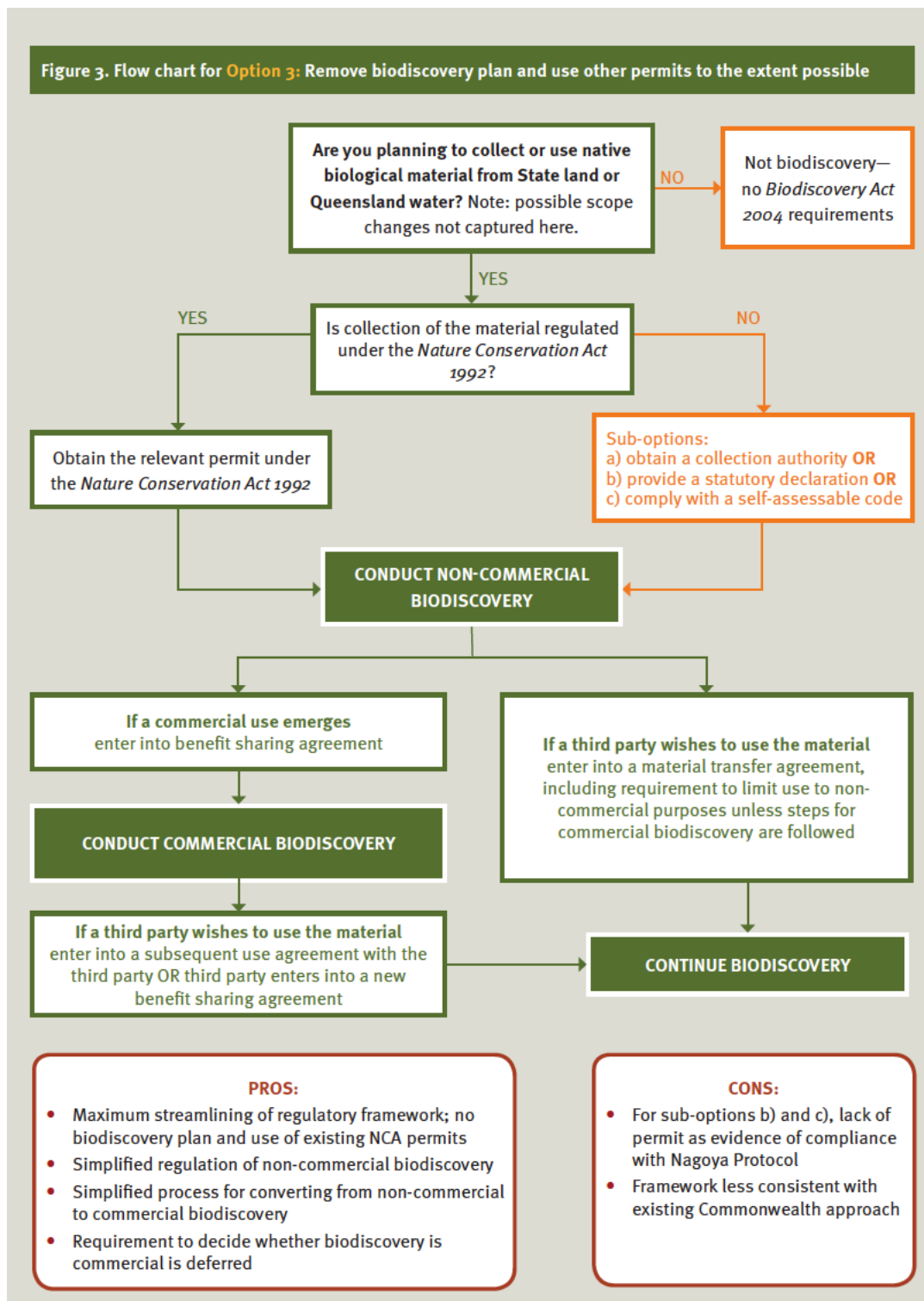
Use of the material by a third party could be managed through a subsequent use agreement for commercial biodiscovery. For non-commercial biodiscovery, a material transfer agreement or other legal arrangement between the biodiscovery entity and third party would be required to limit the use to non-commercial 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 Agriculture⁴³ 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.







Biodiscovery Act 2004 Review Combined Traditional Knowledge Roundtable and Biodiscovery Entities Workshop (III)

- Notes by Griffith University -

Attention:
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BE REMARKABLE

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Introduction

Griffith appreciates the opportunity to contribute to the State's re-shaping of the Biodiscovery Act 2004 (Queensland).

Griffith University is fully committed to the spirit and application of the Convention on Biological Diversity and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (the "Nagoya Protocol"), and proud to be recognised as one of the world leaders in the ethical commercialisation of biodiversity.

There is a great opportunity for the Act to be an instrument that encourages native title holders to grant access to native biological resources on land under their custodianship and to share their Traditional Knowledge.

Based on our extensive engagement with the pharmaceutical, agriculture, nutraceutical, food and cosmeceutical industries, we believe that Griffith can contribute to shape the Act in a way that it fully enables commercial and other biodiscovery to create immense benefits for the people of Queensland, Australia and overseas, e.g. through the development of new pharmaceuticals, agrochemicals, food additives, nutraceuticals and cosmeceuticals and through understanding nature and our natural world.

Large Collections vs (one-off) focussed Biodiscovery

Historical Collections

Griffith University, through its Griffith Institute for Drug Discovery (GRIDD), is applying a large-scale, industrial, high-throughput approach to identify compounds useful for the development of new drugs, agrochemicals, nutraceuticals, food additives and cosmeceuticals based on native biological material sourced from Queensland land and waters. Please note that Griffith is not using any Traditional Knowledge ("TK") for this biodiscovery activity, but follows an unbiased, discovery assay-based approach.

Based on collection permits and benefit sharing agreements with the Queensland Museum and the Queensland Herbarium, Griffith have collected ~30,000 biota samples (including different parts of a single plant), from Queensland land and waters between 1992-2005. Collection happened at approximately >1,000 different sites all over Queensland. The aim was to cover as many ecosystems as possible. Since then, further biota samples have been collected, e.g. from land owned by the Irwin family. The Herbarium estimates that the Griffith collection covers up to 80% of plants in Queensland. The samples, respective extracts, fractionated extracts and compounds are stored at Griffith (collectively: "NatureBank"). In addition, in 2018, the Australian Institute for Marine Sciences

has transferred custodianship of its large collection of biota to Griffith, including biota from Queensland waters.

In 2018, Griffith has entered into a new Biodiscovery Benefit Sharing Agreement with the State.

Griffith University also collects, holds and exchanges many biological materials through its global network of collaborative science, ranging from samples collected from waterways for immediate water quality testing to the permanent collection outlined above.

Upon the contemplated amendments of the Act in relation to Griffith University's existing collections – extending the Act to private owned land and land under or with the possibility of falling under native title in the future, and requiring a biodiscovery entity having access and benefit sharing agreements with the State or landowners or actual or potential native title holders, Griffith would need to

- Assess the ownership status of each location from which samples have been obtained (State, freehold, non-exclusive/exclusive native title, potential non-exclusive/exclusive native title);
- Identify the respective entity (private persons, corporations, trusts, lease holders, traditional owners);
- Identify the respective person(s) for negotiation of benefit sharing arrangements;
- Engage with the entities and persons, and negotiate and execute benefit sharing arrangements; and,
- Upgrade Griffith's database systems to record all these data, and then track and trace and update this information into the future.

We believe that this task would be monumental and require substantial resource commitment. If these resources were expected to come from within the University, Griffith's biodiscovery and other research activities utilising native biological material may well be rendered unviable.

Griffith also suggests considering the implications for the collections held at the Queensland Museum and Queensland Herbarium, and indeed all the other biological materials held *ex situ* and relating information stored *in silico* throughout Queensland. These will face even bigger challenges than Griffith, if they need to get access and benefit sharing agreements with all entities, who have rights or could have rights in the future to biota samples (all biological materials and relating data) in their collections.

Re-Collection

Less than 5% of the Griffith permanent collection has been re-collected. Despite the challenges mentioned above, the State could require access and benefit sharing agreements for re-collection of samples. That would narrow the scope and enable Griffith and others to manage the resource requirements, on a case by case basis.

Griffith suggests that the State considers grandfathering provisions protecting large collections such as Griffith's NatureBank, and these of the Museum and Herbarium and ensures that the resource can be utilised as is, without the requirement to retrofit access and benefit sharing agreements to reflect the current or future ownership and access right structure for the land or water the samples have been collected.

Griffith also suggests that the State would be best placed to provide support for any Biodiscovery entity in identifying traditional owners and decision makers in a clear, transparent and robust process.

Freedom of Research

During the consultation, University and Public Funded Research Institute biodiscovery entities raised their concern about the implications of the proposed amendment for their ability to use native biological materials for academic, non-commercial biodiscovery research. This also pertains to access, use, sharing and publications based on use of native biological materials.

This concern is heightened by the potential inclusion of information in the current Act

The current Act already includes "*biodiscovery research means the analysis of molecular, biochemical or genetic information about native biological material for the purpose of commercialising the material*" and states "*a substance sourced, whether naturally or artificially, from a native biological resource*", potentially extending the reach of the act to anything created based on molecular, biochemical and genetic information obtained through biodiscovery on native biological material.

We are concerned about unintended consequences, which may heavily restrict basic research, sharing of research resources, results, information and knowledge, including public domain knowledge.

In addition, this approach is also not in line with the Commonwealth's approach to biodiscovery and the Nagoya Protocol's current use of terminology (such as 'genetic resources' as functional units of heredity). The Protocol currently does not cover any synthetic compounds created utilising information gained from Biodiscovery: "*(e) "Derivative" means a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity.*".

Griffith proposes to have a dedicated workshop exploring these issues.

Definitions

Native biological resources

The proposed definition for “native biological resources” should be considered in the light of the above-discussed issues relating to freedom of research and non-commercial biodiscovery.

Indigenous to Australia

It would be beneficial to clearly define “indigenous”, e.g. through a cross reference to another applicable Act.

Traditional Knowledge

We reiterate the main concerns raised in Griffith’s response to the “Pathways to reform: Biodiscovery Act 2004 Options Paper”:

1. TK held by multiple indigenous groups;
2. Use of native biological material without knowledge of relating TK and without using such TK; and,
3. TK in the Public Domain.

TK should be carefully defined. It is unclear, whether the issue could be addressed through a definition or would require more extensive consideration in the drafting of the amendments for the Act.

We also note that the traditional knowledge of local communities (e.g. farmer's rights) is not recognised in the current proposal – the Nagoya Protocol includes “local communities”, which are not *per se* Indigenous Peoples.

Griffith proposes a workshop about definitions or engagement with a smaller specialised group to shape these and other key definitions.

FOA Treaty vs Biodiscovery

Concerns have been raised about the future interaction between the Food and Agriculture Organisations (“FAO”) Treaty and the Qld Biodiscovery Act.

The amended Act should clarify the relationship to FAO and which system ‘overrides’ the other. The ACT *Nature Conservation Act 2014* (ACT) s 208 perhaps provides a suitable model.

In addition, the consultation should consider potential unintended effects on a sustainable aquaculture sector (plant and animal) and consider an exclusion for grow out or selective breeding (but not aquaculture biotechnology).

Informed Consent

Seeking informed consent for access to land and knowledge is a key principle of the Nagoya Protocol that would be reflected in the amended Act.

However, if such informed consent could be withdrawn at any time at the sole discretion of the consent giving entity/person, that would jeopardise any research collaboration, the ability to publish and any commercial dealing with resources collected with such informed consent.

Griffith proposes that consent could be only withdrawn after a material breach by the biodiscovery entity or a subsequent user.

Subsequent User Agreements

Principle 5 should be clarified that Subsequent User Agreements (SUAs) also can provide access to resources, information and TK for Subsequent Users and no agreements are required between a Subsequent User and the initial entity/person providing access or TK. A set of minimum prescribed terms would be useful.

Certificate of Compliance Instruments

Certificate of compliance instruments need to be backed by some kind of formal governmental process - preferable empowered through legislation like a regulation. This ensures that such compliance certificates must reflect assessment that BSA etc. is meeting the Nagoya requirements – inclusive adequate benefit sharing – make the BSA non-contestable. These certificates are intended to establish uncontested legal provenance and that should be the aim of the Queensland laws.

Further Consultation

Griffith suggests that the further consultations should include potential Subsequent Users, e.g. a multi-national pharma, food, agriculture, nutraceutical or cosmeceutical companies. Through this, the amendment of the Act could benefit from feedback and a 'real-world check' provided by industry to ensure that the Act will be an enabling instrument that actively drives utilisation of Queensland's native biological materials for the benefit of Queenslanders and people world-wide.