REGULATION IMPACT STATEMENT FOR AUSTRALIA'S SIGNATURE OF 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

2011

Introduction

Australia became a Party to the Convention on Biological Diversity (CBD) on 18 June 1993. Article 1 of the CBD provides that the three objectives of the CBD are:

(i) the conservation of biological diversity,
(ii) the sustainable use of its components and
(iii) the fair and equitable sharing of the benefits arising out of the utilization of genetic resources[1].

Article 15 sets out the principles and obligations of Parties related to the third of these objectives, which is referred to as "access and benefit-sharing" or "ABS". Article 8(j) of the CBD also requires the Parties, subject to their national legislation, to encourage the equitable sharing of benefits arising from the utilisation of the knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity. In the context of the Nagoya Protocol, this is referred to as 'traditional knowledge associated with genetic resources'.

What is access and benefit-sharing under the Convention on Biological Diversity?

Until the implementation of the CBD, genetic resources were commonly considered the 'common heritage of mankind' and their utilisation for new products was largely undertaken without regard for the communities from which the source material was drawn. Major discoveries based on genetic resources (sometimes involving the use of traditional knowledge of Indigenous and local communities) generated no benefits for the country or community providing the material.[2]

Article 15(1) of the CBD recognises the sovereign right of States over their natural resources, including genetic resources, and that the authority to determine access to these resources rests with the State, subject to their national legislation. Parties are required to 'endeavour to create conditions to facilitate' access by other Parties to the CBD, but are free to determine whether to regulate access to some, all or none of their genetic resources.[3] When access is regulated, users must obtain the informed consent of the Party providing the resource before accessing the genetic resource. Under Article 15(4), where access is granted, it must be provided on the basis of mutually agreed terms (i.e. a contract). The mutually agreed terms set out how benefits arising from the use of the genetic resource are to be shared.

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[1] A "genetic resource" is defined in Article 2 of the CBD as and is any material of plant, microbial or other origin containing functional units of heredity which is of actual or potential value". An example of a use of a genetic resource is the antibiotic Erythromycin, which was ultimately derived from a Philippine soil sample.

[2] An example is Cyclosporin A, an anti-rejection drug developed from a soil sample taken from a nature reserve Norway. Annual sales for Cyclosporin A in 1997 amounted to US$1.2 billion. None of this revenue went to Norway. See *Understanding Australia's Nationally Consistent Approach* at http://www.environment.gov.au/biodiversity/publications/nca/index.html.

[3] In Australia, each government manages access to biological resources in its jurisdiction under its own laws, with each jurisdiction determining which, if any, genetic resources are regulated.

Benefits derived from genetic resources may include the results of research and development carried out on genetic resources, the transfer of technologies which makes use of those resources, participation in biotechnological research activities, or monetary benefits arising from the commercialisation of products based on genetic resources.

Article 8(j) requires Parties to the CBD, subject to their domestic legislation, to respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity. It also requires the Parties to promote the approval and involvement of the holders of such knowledge, innovations and practices, and to encourage the equitable sharing of the benefits arising from the utilisation of such knowledge.

The Nagoya Protocol

In October 2010 the Conference of Parties (CoP10) to the Convention on Biological Diversity adopted the 'Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization'. The CoP10 decision and the text of the Protocol can be found at: cbd.int/decision/cop/?id=12267

The Protocol establishes a legally-binding framework for access to genetic resources for biotechnology research and development and other research activities. It also establishes a framework to ensure compliance with the legislation of provider countries to promote the sharing the benefits from utilising genetic resources or associated traditional knowledge.

When implemented, the Nagoya Protocol promises more transparent and predictable implementation of Articles 8(j) and 15 of the Convention to meet its third objective: 'the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources'.

Developing a practical way to achieve the third objective of the CBD has been of particular concern to biodiversity-rich developing nations seeking to benefit from advances in biotechnology.

However, very few countries have implemented a transparent access system that enables and encourages research. The lack of a coherent international standard has resulted in a high level of distrust and the creation of obstacles to biodiversity research and its potentially valuable outcomes.

The Nagoya Protocol aims for a workable balance between the rights of countries to provide access to their genetic resources only with their prior informed consent and on mutually agreed terms, and the need for transparent and workable rules that encourage research.

A global database will provide detailed information on the requirements of each country in respect to accessing their genetic resources. Such requirements will need to meet the minimum standards set out in the Protocol, including clarity, transparency and legal certainty.

In return, where access requirements are in line with Protocol standards, countries are also obliged to ensure that genetic resources used in their country have been obtained according to the requirements of the providing country.

The Protocol will come into force 90 days after its ratification in at least 50 countries.

A Regulatory Impact Statement on the mandate to negotiate was prepared by the Department of Foreign Affairs and Trade in 2010.

Australia's participation in the negotiation was conducted within the negotiating parameters agreed by relevant Ministers, and the text of the Protocol is considered by relevant agencies to be within those parameters.

The Nagoya Protocol is open for signature from 2 February 2011 to 1 February 2012.

This Regulatory Impact Statement (RIS) has been prepared to inform the decision making process on whether Australia should sign the Protocol. It is not intended to inform the later decision on whether to proceed to ratification. Nor does it address questions of implementation. Definite proposals for implementation have not yet been developed.

Australia's implementation of the CBD's ABS provisions

Each government within Australia is responsible for the genetic resources within their jurisdiction. In October 2002 ministers from Commonwealth, State and Territory governments constituting the Natural Resource Management Ministerial Council endorsed the *Nationally Consistent Approach for Access to and the Utilisation of Australia's Native Genetic and Biochemical Resources* (the "NCA"). The NCA underpins action by all Australian governments when developing, or reviewing, legislative, administrative or policy measures on access and benefit-sharing. The NCA implements the *Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Benefit-sharing of the Benefits Arising out of their Utilization*, adopted by the Parties to the CBD at the 6th Conference of the parties at The Hague to guide Parties in the development of domestic ABS measures.

Commonwealth implementation

The Commonwealth's ABS regime[4] governs access to native biological resources (which include genetic resources, organisms, parts of organisms, populations and any other biotic component of an ecosystem with actual or potential use of value for humanity[5]) for the purpose of research and development on the genetic or biochemical makeup of the resource.

[4] As set out in Part 8A of the *Environment Protection and Biodiversity Conservation Regulations 2000* ("EPBC Regulations') made under the *Environment Protection and Biodiversity Conservation Act 1999* ('EPBC Act')

[5] EPBC Act, s528. This definition is drawn directly from the Convention on Biological Diversity.

Anyone who wishes to access biological resources in Commonwealth areas[6] for such research or development must apply to the Competent National Authority in the Department of Sustainability, Environment, Water, Population and Communities (DSEWPaC) for a permit. Permits are granted under Part 8A of the *Environment Protection and Biodiversity Conservation Regulations 2000* (the EPBC Regulations) which entered into force in December 2005. There are penalties for accessing a genetic resource without a permit.

Anyone can apply for a permit to access biological resources in Commonwealth areas, but there are different requirements for research that is undertaken for non-commercial purposes and research that is undertaken for commercial purposes or which may have commercial potential. If the research is for non-commercial purposes, the permit applicant must sign a statutory declaration undertaking to negotiate a benefit-sharing agreement with the Commonwealth Government if the intended use of the resource becomes commercial, as well as the sharing of scientific data, samples and research results. If the research is for commercial or potentially commercial research purposes, the permit applicant must negotiate a benefit-sharing agreement (i.e. a contract to define the nature of benefits to be shared) before a permit can be issued.

A permit is evidence of prior informed consent granted by the Commonwealth Government for access to genetic resources within its jurisdiction, and evidence that mutually agreed terms have been established. All permit applications must demonstrate the proposed access is ecologically sustainable and consistent with the conservation of Australia's biodiversity. The permit system ensures there is sustainable use and equitable sharing of benefits resulting from the research and provides legal certainty for investment if there is commercialisation of research results. Samples cannot be provided by the permit holder to third party without obtaining permission from the Commonwealth Government.

There must also be reasonable benefit-sharing arrangements where traditional knowledge has been used. Before a permit can be issued for access to resources in Commonwealth areas, the person seeking access must declare whether traditional knowledge has been used and, if so, the Government needs to be satisfied that mutually agreed terms have been reached with the providers of that knowledge.

If access is sought to genetic resources on Indigenous peoples' land[7] then the terms of that access are negotiated between the Indigenous owners and the person seeking access. Any benefits that come from the subsequent use go to the Indigenous community according to the terms of the mutually agreed terms. The Government's role is limited to verifying that the benefit-sharing agreement addresses certain issues and meets certain standards, that negotiations are fair, and that the consent of the access provider is informed. The relevant Commonwealth

[6] Defined at s525 of the EPBC Act

[7] Defined at subsection 363(3) of the EPBC Act

legislative provisions and regulations are at Attachment A – Relevant provisions in the EPBC Act and Attachment B – Part 8A of the EPBC Regulations.

State and Territory measures

Queensland and the Northern Territory have also enacted ABS legislation, namely the *Biodiscovery Act 2004* (Qld) and the *Biological Resources Act 2006* (NT).

The Queensland Act regulates native resources sought from State land or Queensland waters for commercial purposes. The Queensland legislation is supplemented by Queensland Biotechnology Code of Ethics which provides, among other things, for benefit-sharing from the use of traditional knowledge.

The Northern Territory legislation governs 'the taking of samples of biological resources, existing *in situ* or maintained in an *ex situ* collection of such resources, for research in relation to any genetic resources, or biochemical compounds, comprising or contained in the biological resources'.

In addition, non-legislative measures have been implemented at state level, namely: 'Biodiscovery in Victoria – a framework for managing access to and use of our native biological resources' and 'Biovision Tasmania 2007-2015: Tasmania's Biotechnology Strategy'.

The importance of an international regime on ABS and Australia's objectives in the negotiations

With around ten per cent of the world's biodiversity, 80 per cent of which is endemic to Australia, a growing biotechnology industry[8], and a rich and diverse indigenous culture, Australia stands to gain economic, social and environmental benefits from increased research and investment in biodiversity.

Australia's key objective in the ABS negotiation process was a workable, predictable and cost-effective international regime, consistent with Australia's national interests, aimed at improving and supporting the national implementation of Articles 8(j) and 15 of the CBD and its three objectives, and continuing to enable the realisation of value in Australian biodiversity. The overall outcome was to be an international regime that provides certainty and benefits to users and providers of genetic resources and associated traditional knowledge.

Other objectives included providing a basis for increased investment in research and development into Australia's genetic resources, leading to an increased understanding of Australia's unique biodiversity and potential revenue from the use of these resources; and avoiding unreasonable costs to Australian stakeholders, for example, by providing compliance measures that are sufficient to support and

[8] Australia's listed biotech companies were estimated to be worth $25.1 billion at the end of the first quarter of 2010. See www.innovation.gov.au/biotech_indicators.

enforce an effective and transparent ABS regime, while not imposing requirements and costs that would be a disincentive to commercial investment.

The protection of Australia's international standing as a constructive and engaged negotiating Party, seeking best possible outcomes for not only itself but also for the protection and conservation of the world's biodiversity as expressed in the CBD, remains an important priority.

It was noted in the Regulatory Impact Statement prepared in relation to the mandate to negotiate this Protocol that the negotiating text at that stage contained many red-line issues that were unacceptable to Australia. The draft Protocol developed in Nagoya satisfied all of Australia's concerns, and was duly supported for adoption on the basis of the negotiating parameters and Ministerial instruction.

What does signature of the Protocol mean?

The decision required at this stage is whether the Government should 'sign' the treaty. Signature does not constitute entering into the treaty – the treaty is not binding on Australia on signature, and Australia does not become a Party to the Protocol on signature. This would happen only after ratification.

A treaty is generally tabled in Parliament after it has been signed for Australia, but before any treaty action is taken that would bind Australia under international law.

Modern multilateral treaties typically do not provide that signature alone is sufficient to bind a country to the terms of a treaty. When the text of a multilateral treaty is finalised, the common practice is to have the treaty 'open for signature' for a specified period. Countries may sign the treaty within that period but are not legally bound by its provisions until ratification occurs. Where a country has not signed a multilateral treaty, it will nevertheless generally be able to become a party to it when it is ready to ratify. This is typically called an act of accession. This process would be available in the case of the Nagoya Protocol.

It should be noted that two kinds of signature are in use in the United Nations treaty system – 'simple' and 'definitive'[9]. 'Simple' signature has no legally binding effect on a country, whereas definitive signature does. In this case, the Protocol requires a 'simple' signature, with the 'consent to be bound' by ratification being a separate process. With some treaties, therefore, signature entails legal and therefore possibly regulatory consequences – signature of the Nagoya Protocol does not have such consequences.

The reason for seeking a decision of Executive Council at this stage is to allow the Australian Government to make that decision taking into account the broader national interest, rather than allowing the decision to be made by default when the opportunity lapses on 1 February, 2012. If Australia does not sign the protocol

[9] See *United Nations Treaty Handbook*, pp.5-6 (http://untreaty.un.org/English/TreatyHandbookEng.pdf)

before it closes, this action is likely to be perceived as diminishing Australia's commitment to meeting its obligations under the CBD

Options

Option A – Signing the Protocol

Signature in itself does not entail regulatory change. It does not bind Australia to relevant international law, and it does not change in any way the legal obligations under which stakeholders operate.

Nonetheless, signature is an indication that the Australian Government intends to pursue ratification, and that consequently there may be changes in the regulatory environment in the future that will impact on the way the users of genetic resources and traditional knowledge associated with genetic resources operate.

The detail of such changes cannot be specified at this stage, at risk of prejudice to consultations to be undertaken in good faith, and at risk of pre-empting parliamentary processes and future decisions related to ratification.

A decision to sign gives a clear indication to key stakeholders – the Australian biotech industry and research community – of the Government's intention to strengthen Australia's existing domestic regime for accessing genetic resources to meet the requirements of an international framework through taking administrative, policy or legislative measures.

While the Nagoya Protocol proved satisfactory to Australia's assessment and interests, other Parties were perhaps less satisfied with the outcome of negotiations, but nevertheless agreed to adopt the Protocol. From meetings subsequent to the CoP, it is clear that some Parties intend to continue pressing on particular issues by negotiating the Protocol's interpretation.

While there is nothing unusual about this, this situation requires Australia to remain vigilant in this forum to ensure a workable, effective and efficient implementation of the Protocol, to protect Australia's interests.

By agreeing to adopt the Protocol on the basis of its conformity with the negotiating mandate given by the Australian Government, Australia indicated it was comfortable with the arrangements articulated in the Protocol text. Signature of the Protocol would indicate to the international community, and more particularly to our negotiating partners, that we stand by positions already articulated in negotiations and in agreeing to the adoption of the Protocol.

Australia has been engaged in the ABS negotiations for a number of years and to withdraw from participation in the process now that there is an agreed Protocol may cast doubt over Australia's *bona fides* and suggest to other parties that Australia was

not negotiating in good faith. Signature of the Protocol would be a clear signal to the international community of Australia's commitment to developing an effective international framework in relation to access and benefit-sharing.

Similarly, signature would enable Australia to maintain its leadership role in shaping an international ABS regime that is compatible with our domestic ABS measures. An international framework that promotes compliance with our domestic regimes would be of significant benefit in meeting the policy objectives of Australia's domestic legislation – the Nagoya Protocol would do this if implemented appropriately.

Australia's domestic ABS system is held in high regard internationally as a singular example of an efficient and effective ABS regulatory regime. Australia's implied reluctance to continue in the process of establishing an effective international regime may entail the loss of the ability to advocate this approach through a compatible international framework that promotes research and innovation.

Australia's negotiating parameters were developed through an extensive and ongoing consultation process elaborated over the last decade. Stakeholders have contributed their views on numerous occasions and those views have been instrumental in shaping Australia's approach both to domestic regulation and international negotiating positions. Signature would provide a signal for those stakeholders that the Australian Government considers the Nagoya Protocol to address concerns raised by stakeholders.

Option B - Not signing the Protocol

The Australian Government can choose not to sign the Protocol at this stage. This decision, like a decision to sign, would have no direct regulatory effect.

If Australia does not sign the Nagoya Protocol, it would still be possible to accede to the Protocol. If Australia decides to consider accession rather than to sign and ratify, Australia would still need to decide on whether to implement the Protocol - the difference between the two processes is the subject of this RIS. In both processes, questions related to the national interest and regulatory impact of implementation would be addressed in the future, in the same way – through consultation, possible development of regulatory instruments and parliamentary scrutiny.

A decision not to sign the Protocol within the year available would certainly raise questions about Australia's *bona fides* internationally. This could impact on Australia's ability to shape negotiations in other multilateral contexts.

A decision not to sign would also raise questions about Australia's continued commitment to the positions it espoused in negotiations, and whether its policy indeed remains the same. This would be a false message. There has been no suggestion made by relevant agencies or other stakeholders that Australia's concerns have changed, or that existing concerns were not met by the adopted Protocol.

Similarly, a decision not to sign could be interpreted by stakeholders as indicating the Australian Government has concerns with the Protocol as negotiated. This is not the case.

Finally, stakeholders may well interpret a decision not to sign as a signal that there is no need to assess their activities in relation to the Protocol. The Protocol can be implemented in other countries, regardless of our decision on signature. The Protocol can also enter into effect at international law if 50 other countries decide to ratify it – again, irrespective of our decision to sign or not. Australian stakeholders would still find themselves subject to the requirements of the Protocol in foreign countries.

Impact Analysis

Developing a practical way to achieve the third objective of the CBD (the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources) has been of particular concern to biodiversity-rich developing nations seeking to benefit from advances in biotechnology. However, very few countries have implemented a transparent access system that enables and encourages research. The lack of a coherent international standard has resulted in a high level of distrust and the creation of obstacles to biodiversity research and its potentially valuable outcomes.

The Nagoya Protocol aims for a workable balance between the rights of countries to provide access to their genetic resources only with their prior informed consent and on mutually agreed terms, and the need for transparent and workable rules that encourage research. A global database will provide detailed information on the requirements of each country in respect to accessing their genetic resources.

Obligations under the Nagoya Protocol can be divided into the two parts: criteria for access requirements in provider countries; and compliance measures to be taken in the countries where such genetic resources and associated traditional knowledge are used for scientific research.

As a provider country, Australia has well established legislative regimes in place that already meet the obligations on access requirements. Existing legislative regimes are described on pages 3-5 of this document, under the heading **Australia's implementation of the CBD's ABS provisions.**

As a user country, further measures would be required for ratification. Should the Nagoya Protocol enter into force, all Parties would be obliged:

- to designate a competent national authority;
- to implement measures to ensure that genetic resources and traditional knowledge associated with genetic resources used in scientific research and development have been accessed in accordance with the domestic requirements of the provider country; and

- to establish a checkpoint to monitor the use of genetic resources in their jurisdiction and provide information to the provider country about their use.

Signature of the protocol is a decision to undertake development the measures to implement the protocol's obligations in preparation of ratification. Accordingly, the detail of these measures has not yet been developed. Such detail will be developed in close consultation with stakeholders. As part of consultation conducted this year, the Department mooted one possible means of implementation, as follows:

Competent National Authority/National Focal Point (Article 13)

Under the Protocol, a Party must designate a Competent National Authority and National Focal Point, to be the authorised point of contact to the Nagoya Protocol Secretariat, the ABS Clearing House Mechanism, and with counterparts in other countries. It would be required, for example, to authorise posting of permit details to the clearing house mechanism, to be used as an 'internationally recognised certificate'. This would be an important means for researchers to demonstrate compliance with access legislation in provider countries, including Australia.

The Protected Area Policy and Biodiscovery Section of the Australian Government's Department of Sustainability, Environment, Water, Population and Communities currently fulfils both functions, primarily through its role in providing permits to give access to biological resources in Commonwealth areas (Part 8A of the Environment Protection and Biodiversity Conservation regulations 2000). State and Territory authorities with their own 'access to genetic resources' legislation also act as Competent National Authorities in their own jurisdiction.

A possible approach to meeting the Nagoya Protocol obligations is for the for the Protected Area Policy and Biodiscovery Section to act as the National Competent Authority and National Focal Point liaising with the States and Territories. Alternative arrangements could be discussed and implemented administratively at any point.

Obligations to Ensure Compliance (Article 15 and 16)

One option to achieve the compliance objectives could be with an offence provision in the Environment Protection and Biodiversity Conservation Act 1999 which makes it an offence to 'use' in Australia either genetic resources or traditional knowledge obtained in contravention of domestic legislation of the country providing the resource. The impact of this measure would be that Australian researchers would be required to demonstrate their compliance with the legislation of the country in which they acquired

Establishment of a Checkpoint (Article 17)

A checkpoint, under the Nagoya Protocol, requires that information be provided on the use of genetic resources in Australia, for use by the Access and Benefit-sharing Clearing House or other relevant countries.

The Protocol does not envisage or require that the checkpoint would cancel or invalidate any R&D activities. Rather it is a way to enhance transparency and provide a strong incentive to comply with provider country legislation. A designated checkpoint would receive and collect information on the source and use of genetic resources, and on compliance with relevant legislation. This information would be sent via an Australian Competent National Authority to the provider country (without prejudice to confidential information). The direct provision of information to the National Competent Authority – and not via administrative measures within the checkpoint - would be strongly preferred to reduce administrative burden.

A checkpoint should ideally provide a strong incentive towards compliance, without adding substantially to existing regulatory and administrative burdens, not only for users of genetic resources and traditional knowledge associated with genetic resources, but also for the designated checkpoint which was established for other purposes.

Checkpoints may reveal cases of non-compliance – in which event, remedy for that non-compliance should be sought not in the checkpoint's process but either under the contract between the researcher and provider or other measures taken to implement Articles 15 and 16. Such measures would sit under the EPBC Act and be the administrative responsibility of the Minister responsible for that Act.

As most genetic resource R&D occurs in the universities and Publicly Funded Research Agencies, a possible approach which would integrate Nagoya Protocol implementation with existing processes and avoid additional layers of bureaucracy would be to align compliance with research funding arrangements and related codes of ethics.

This would assist in improving compliance with Australian access legislation , would provide a strong incentive to comply with existing standards in public funding agreements, and provide too a means by which compliance can be easily demonstrated.

<u>Impact of future measures</u>

The use of existing mechanisms would be the most effective way to reduce possible impact of the Nagoya Protocol on stakeholders.

The impact of there being a Competent National Authority would be positive in enabling researchers and innovators to more easily demonstrate compliance with Australian law, if required by foreign jurisdictions.

It is anticipated that the presentation of the permit issued under existing legislation will be sufficient to satisfy any new measures required under the Protocol. Third party users of research on genetic resources and associated traditional knowledge will need to ascertain the legal provenance of genetic resources and associated traditional knowledge they use, to demonstrate that they were legally acquired – again, the permit issued under existing legislation will be sufficient for this purpose.

It is anticipated that all of these measures would be subject to a full cost-benefit analysis and Regulatory Impact Statement, the normal legislative amendment process, as well as a National Interest Analysis, and the scrutiny of the Joint Standing Committee on Treaties.

The Australian Government is committed to an appropriate response to consultation feedback, to explore possible implementation measures that focus on ensuring clarity, simplicity and the minimum of red tape by aligning new requirements to existing processes. The Government foresees an intensive consultation process including road-show visits to industry and research locations, to develop tools and options to further enhance Australia's position of advantage in this field.

The development and implementation of these measures will occur during the process of ratification and would properly require the development of a further Regulatory Impact Statement. The impact of the decision that is the subject of this Regulatory Impact Statement would be less direct.

Option A - Signing the Protocol

In the event that signature of the Protocol is taken as a signal that such compliance measures will be seriously pursued, stakeholders may decide to prepare for such measures. This would involve ensuring that researchers are aware of possible future consequences - researchers obtaining genetic resources and traditional knowledge associated with genetic resources in a country that is a Party to the Protocol may need to be able to demonstrate their compliance with those requirements in order to use those resources in other countries party to the Protocol. To demonstrate compliance, it will be important for researchers to keep records of any permits issued by the provider country. This would include Australia, should Australia ratify the Protocol to become a Party. It should be noted that no country has ratified the Protocol at this stage.

The impact of developing such measures would be largely borne by the Australian Government. The impact to users of genetic resources and traditional knowledge associated with genetic resources would be in providing input into the regulatory development and consultation process. The consultation process for this stage period will continue as it has been conducted for some years – through established consultation panels, whole of government meetings and broader invitation to comment. Additional consultation will occur through the Joint Standing Committee on Treaties process, and the development of a National Interest Analysis.

Option B - Not signing the Protocol

The impact of a decision not to sign the Protocol would largely be as a consequence of the message that non-signature sends to different constituencies.

If Australia's influence in ongoing discussions on implementation of the Protocol is reduced, as outlined above, the cost would be a potentially reduced opportunity to represent and protect Australia's interests in the discussions. As the negotiations to date have already demonstrated, there are many Parties with views on ABS

implementation that are inconsistent with Australia's, and relinquishing our current leadership role would greatly increase the risk that these views would prevail to Australia's detriment. Moreover, this could impact on Australia's ability to shape negotiations in other multilateral contexts.

Australia's domestic ABS system is held in high regard internationally as a singular example of an efficient and effective ABS regulatory regime. A loss of influence would entail the loss of the ability to advocate this approach through a compatible international framework that promotes research and innovation.

If users of genetic resources and associated traditional knowledge decide that non-signature in Australia means that the Nagoya Protocol would have no effect on them, perhaps because of confusion between signature and ratification, then they are unlikely to be as vigilant in complying with requirements in foreign countries where the Protocol is implemented. This might happen in a similar way that researchers from the countries that are not party to the CBD might assume that laws implementing its provisions in Australia do not apply to their research. This situation would tend to undermine Australia's efforts to meet existing ABS obligations under the CBD.

Consultation statement

Since 1998, the Australian Government has been engaged in an extensive process of consultation to ensure that it identifies as many of the key stakeholders as possible and that it is aware of whose interests are likely to be impacted. In 2010 DFAT consulted widely on draft text prepared by the Access and Benefit Sharing Working Group, with a view to informing its negotiating parameters for the tenth meeting of the Conference of the Parties in October 2010. The RIS that DFAT prepared, including a summary of stakeholder views, is at Attachment C.

Following transfer of lead agency responsibilities from DFAT in May 2011, DSEWPaC has continued to consult broadly to inform its decision on signing, including by co-hosting with Flinders University the 2nd National Biodiscovery Forum in Adelaide, in August.

A range of stakeholders have an interest in the regulation of genetic resources and associated traditional knowledge:

- research institutes and universities;
- industry (for example, the pharmaceuticals, medical and cosmetics industries; agriculture and forestry; aquaculture and fisheries; horticulture and biotechnology);
- the Commonwealth and State and Territory governments;
- Indigenous people; and
- private individuals.

In addition to discussions with key interested parties, DSEWPaC consults through the following means:

- meetings and teleconferences with stakeholders, both in Canberra and interstate, as well as with other Parties in the negotiations;
- briefing of State and Territory governments through the Standing Committee on Treaties (SCOT) contacts, with the most recent briefing on 17 May 2011;
- meetings with the Biodiscovery Working Group (which includes SCOT contacts) and the Biodiscovery Industry Panel;
- regular inter-departmental meetings to brief Australian Government stakeholders, including representatives from: the Department of the Prime Minister and Cabinet; the Department of Agriculture, Fisheries and Forestry; AusAID; Intellectual Property Australia; the Australian Institute of Aboriginal and Torres Strait Islander Studies; CSIRO; AIMS; the Attorney-General's Department; the Department of Health and Ageing; the Department of Families, Housing, Community Services and Indigenous Affairs; and the Department of Innovation, Industry, Science and Research;
- Letter/email invitations to comment to key stakeholders, including most recently in July 2011

Sectoral, industry and academic sectors were consulted in August 2011 through the 2nd National Biodiscovery Forum co-hosted by Flinders University and co-sponsored by DSEWPaC and DIISR. A workshop on the Nagoya Protocol was conducted as part of the program.

Indigenous consultation has been undertaken throughout the Nagoya Protocol negotiations, including through representation on the Australian delegation. Members of the DSEWPaC Indigenous Advisory Committee have also been briefed on the Protocol, and Indigenous groups are included on the list of stakeholders maintained by the Department.

DSEWPaC maintains information about the Nagoya Protocol on its website at **http://www.environment.gov.au/biodiversity/science/access/index.html** seeking feedback from interested parties via the grm@environment.gov.au mailbox.

Consultation conducted after the adoption of the Nagoya Protocol has been highly appreciative of Australia's successful negotiation effort, welcoming the Nagoya Protocol and in general, urging Australia's signature. Concerns raised focus on the practicalities of implementation post-ratification not only in Australia, but around the world, while noting the importance of Australia maintaining its leadership role in this area. While this is a reasonable concern where 'signature' has its ordinary meaning of full acceptance of obligations, as discussed above, signature of the Protocol does not entail commitment to any form of implementation.

The Australian Government is committed to an appropriate response to consultation feedback, to explore possible implementation measures that focus on ensuring clarity, simplicity and the minimum of red tape by aligning new requirements to

existing processes. The Government foresees an intensive consultation process including road-show visits to industry and research locations, to develop tools and options to further enhance Australia's position of advantage in this field.

A summary of comment from the most recent consultation is at Attachment D.

Conclusion

Signature would entail no regulatory action, and therefore no immediate or direct impact on the industry and research communities. A failure to sign risks a confused signal that could undermine Australia's implementation of existing CBD obligations, our leadership credentials in this area, and our standing in this and potentially other international fora.

In response to consultation, and a consideration of the costs and benefits related to the decision on whether or not to sign the Nagoya Protocol while it remains open for signature – bearing in mind the particular legal consequences of 'signature' in this case - **the preferred option is for Australia to sign the Nagoya Protocol before this opportunity lapses on 1 February 2012.** This recommendation will be made with the clear qualification that any regulatory action proposed to implement the obligations of the Nagoya Protocol pursuant to a ratification process will be subject to a Regulatory Impact Statement, National Interest Analysis, and comprehensive consultation on specific implementation measures.

Implementation and Review

As the simple signature of this treaty does not have binding legal consequence, it cannot be 'unsigned', in the same way that Australia's decision to support the adoption of the Protocol at the 10th Conference of Parties to the CBD cannot be changed. However, should the Nagoya Protocol enter into force for Australia in the future, there is provision within the treaty to withdraw by written notification. The Provision to review any future decision related to the Nagoya Protocol would be properly part of the ratification process and would be addressed in the Regulatory Impact Statement.