

Discussion: a proposal for measures to implement the Nagoya Protocol in Australia

Many obligations of the Nagoya Protocol are already met by existing Australian legislation and policy. However, ratification of the Protocol will require Australia to meet specific obligations that are currently not addressed by existing law, administrative procedure or policy. These are:

- to ensure that genetic resources and traditional knowledge associated with internationally sourced genetic resources used in scientific research and development within Australia have been accessed in accordance with the domestic law of the provider country (Art 15 and 16); and
- to monitor the use of genetic resources (Art 17).

It is the intention of the Australian Government to implement these obligations in a way that minimises administrative burden, that supports effective pathways to commercialisation and that provides legal certainty for all stakeholders, including the industry and research sectors.

Several jurisdictions within Australia already have legislation that regulates access to their genetic resources, and all jurisdictions have agreed to a nationally consistent approach to access to and utilisation of Australia's native genetic and biochemical resources. The Nagoya Protocol does not require countries to regulate access, but sets standards if they choose to do so. Existing Australian legislation meets these access standards.

In this paper, certain terms have the following meanings:

access – acquisition of genetic resources/associated traditional knowledge in accordance with applicable regulatory requirements

associated traditional knowledge – knowledge obtained from Indigenous people relevant to the use of genetic resources

clearing house mechanism – the international information-sharing portal established by the Protocol and managed by its Secretariat.

genetic resources – genetic material of actual or potential value

use of genetic resources – to conduct R&D on the genetic or biochemical composition of genetic resources

user of genetic resources – natural or legal person using genetic resources/associated traditional knowledge.

Monitoring the use of genetic resources

Under the Protocol, Australia will be obliged to establish one or more information checkpoints requiring disclosure of the source and legal status of genetic resources/associated traditional knowledge used in research.

It is important to realise that this information checkpoint will not veto or invalidate R&D activities. It is a transparency measure that will provide information and permits to the international clearing house mechanism, enabling researchers to demonstrate legal compliance.

1. The Australian Government proposes to monitor use of genetic resources/associated traditional knowledge by:

- requiring through relevant Australian Government public funding specific to biodiscovery research, the disclosure of information on source, prior informed consent of the provider country, and the establishment of mutually agreed terms;
- requiring users of genetic resources/associated traditional knowledge to provide such information on request, including where the user of genetic resources/associated traditional knowledge is not a recipient of public funding; and
- authorising the Department of Sustainability, Environment, Water, Population and Communities operating as the information checkpoint to pass on such information to the Clearing House Mechanism.

Ensure that genetic resources/associated traditional knowledge associated with genetic resources have been accessed with in accordance with the domestic law of the provider country.

The Nagoya Protocol will be a new international standard for R&D using genetic resources/ associated traditional knowledge. It will be important for Australian research and international researchers using Australian genetic resources to be able to demonstrate compliance with Australian law, and therefore, compliance with the Protocol. The ability to demonstrate compliance will facilitate potential commercialisation of Australian research internationally with clear legal provenance established early in the process, with minimum administrative impact.

The Protocol makes provision for an internationally recognised certificate – this is a permit that has been issued by a Competent National Authority and registered on the Clearing House Mechanism. Presentation of an internationally recognised certificate would demonstrate legal acquisition. Likewise, documentation of transfers of genetic resources/associated traditional knowledge that link back to such a certificate would also be a clear demonstration of legal acquisition.

However, the absence of a certificate may not indicate illegal acquisition, for a variety of legitimate reasons. In such cases, the Competent National Authority would certify that a permit is not required in the relevant jurisdiction.

The clearest and most flexible way to implement the compliance obligations in Articles 15 and 16 would be with an offence provision in the *Environment Protection and Biodiversity Conservation Act 1999*. Any legislative provisions would be carefully drafted to specifically target the situation where the genetic resource/associate traditional knowledge concerned was acquired in contravention of the law in the country where it was obtained.

Any legislative provision would also make clear the conditions for legitimate use of genetic resources/associated traditional knowledge. Such conditions should be set with a view to enabling Australian R&D and resources to be usable in other countries implementing the Nagoya Protocol.

2. The Australian Government proposes to allow use of genetic resources/associated traditional knowledge only where that resource has been legally acquired, through the development of a legislative provision that prohibits the use of genetic resources/associated traditional knowledge that has been acquired:

- a. in a country which has measures regulating access to their genetic resources or traditional knowledge of Indigenous people within their jurisdiction, where the requirements of those measures have been made publically available on the Access and Benefit-sharing clearing house mechanism; and
- b. in contravention of those measures.

The legislation should also provide opportunity for users of genetic resources/associated traditional knowledge to take remedial action to enable continued use of genetic resources/associated traditional knowledge that was not acquired legally.

3. The Australian Government proposes to develop conditions for demonstrating legitimate use of genetic resources/associated traditional knowledge, including but not limited to reference to the internationally recognised certificate under the Nagoya Protocol. These would be elaborated in further consultation with interested stakeholders.

4. The Australian Government proposes to exempt from additional permitting requirements genetic resources for which access and benefit-sharing is governed by a specialised international instrument to which Australia is a Party – for example, the International Treaty on Plant Genetic Resources for Food and Agriculture.

5. The Australian Government proposes:

- to assist researchers and bio-based industry by ensuring that permits issued in Australia are recognised internationally;
- to maintain effective communication with counterpart Competent National Authorities; and
- to provide written assurance, if required, for foreign checkpoints and authorities if genetic resources/associated traditional knowledge do not require permits under Australian law.

6. The Australian Government proposes to consult further on the ways and means to

communicate new standards and measures relating to the use of genetic resources/associated traditional knowledge to all relevant stakeholders.

7. The Australian Government proposes that the Department of Sustainability, Environment, Water, Population and Communities be designated as the National Focal Point and Competent National Authority for Commonwealth areas.

8. The Australian Government proposes that any new measures would apply only to those genetic resources/associated traditional knowledge accessed on or after the date those measures come into effect.

The Protocol has specific obligations in relation to access to traditional knowledge associated with genetic resources, that are independent of access to the genetic resources themselves. For example, traditional knowledge may provide a new lead for the scientific discovery of properties of a genetic resource that has been held in a collection for many years, properties previously unknown to science. Under the protocol, this knowledge should be obtained with the prior informed consent of the knowledge holders, and on mutually agreed terms.

9. The Australian Government proposes that, to enable Indigenous people to share knowledge with researchers with their prior informed consent and on agreed terms, the Competent National Authority be authorised to certify that Associated Traditional Knowledge has been obtained in accordance with the Nagoya Protocol. Such certification would be on presentation of evidence of the prior informed consent of the Indigenous people who provided knowledge used in R&D and that mutually agreed terms for fair and equitable benefit-sharing have been established with them. The elements of such benefit-sharing agreements and prior informed consent would be developed through further consideration with Indigenous organisations and groups.

Consistent, streamlined rules for access to genetic resources in each Australian jurisdiction continues to be a priority for the research and industry sectors. The *Nationally Consistent Approach to Access and Utilisation of Australia's Native Genetic and Biochemical Resources*, an intergovernmental agreement established in 2002, continues to provide best-practice principles for implementing Australia's international access obligations.

10. The Australian Government proposes to continue working with counterpart agencies in State and Territory Governments towards achieving the aspiration of a nationally consistent approach to access.

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