

# A Model for Implementing the Nagoya Protocol in Australia



## What is the Nagoya Protocol?

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (the Protocol) is a global agreement that implements the access and benefit-sharing obligations of the Convention on Biological Diversity (CBD). It was adopted in October 2010 and will come into force when ratified by 50 countries.

## The Challenge

Genetic resources from plants, animals and microorganisms are increasingly valuable in the development of specialty enzymes, enhanced genes, or small molecules. These products can be used in many areas, including crop protection, drug development, production of specialised chemicals, biotech innovation and industrial processing.

The Protocol aims to ensure the fair and equitable sharing of benefits arising from the use of genetic resources. Finding a practical way to do this has been challenging and few countries, other than Australia, have implemented an access system that welcomes and encourages research. Lack of a coherent global standard has also resulted in a high level of uncertainty, creating obstacles to biodiversity research.

## The Protocol's Benefits

The Protocol establishes a legally-binding framework that helps biotechnology and other researchers access genetic resources in return for a fair share of any benefits from their use. This

provides the R&D sector with the legal certainty they need to invest in biodiversity-based research.

Indigenous and local communities may also benefit through the Protocol's requirement of prior informed consent for the use of their traditional knowledge associated with genetic resources.

## A Workable, Cost Effective System

Proper implementation of the Nagoya Protocol will maximise benefits from research based on genetic resources and associated traditional knowledge.

The Government aims to develop a workable, ethical and cost-effective way to implement the Protocol in Australia. The aim is to increase certainty for both users and providers of genetic resources and associated traditional knowledge.

When implemented, the Nagoya Protocol will affect the operations of those who use genetic resources and associated traditional knowledge.

- The principal effect will be to enhance transparency in the use of genetic resources and associated traditional knowledge, enabling users to demonstrate that these resources are sourced legally.
- International standards in access and certification will enable users of these resources to be satisfied that the resources they use were legally acquired.
- User countries will be obliged to take measures on compliance and the use of these resources in their country, while provider countries will need to meet new standards in providing access.



**Australian Government**

**Department of the Environment**

## Certainty for Users and Providers of Genetic Resources

All countries have the right to determine access to their genetic resources, and many countries already regulate their collection and use. Parties to the Protocol must ensure that genetic resources and associated traditional knowledge used in their country are acquired legally in the country from which they were sourced.

The Nagoya Protocol makes it easier to find out how to access genetic resources, and to provide evidence demonstrating their legal acquisition. This increases legal certainty and confidence in the use of genetic resources by users and providers.

Under the Protocol, regulations for access to genetic resources will need to meet new standards of transparency, timeliness and legal certainty. Regulations must be published on the Protocol's website, and be clear on how permission to access genetic resources can be obtained.

Australian legislation that requires a permit for the collection and use of genetic resources meets the standards required by the Protocol. Users of genetic resources from Australia will need to be able to demonstrate that they have obtained that permit. Users of associated traditional knowledge will need to be able to demonstrate that it was obtained with prior informed consent and on mutually agreed terms, and in accordance with applicable laws.

## Implementing the Protocol Internationally

An Access and Benefit-sharing (ABS) Clearing House website will be established to publish access legislation and associated permits. Other countries implementing the Protocol will recognise published access permits as International Certificates of Compliance (ICC). ICCs will play an important part role in establishing provenance of genetic resources and associated traditional knowledge.

- Australia proposes to recognise ICCs as evidence of legal acquisition of genetic resources and associated traditional knowledge

Parties need to monitor the use of genetic resources at one or more checkpoints and establish appropriate measures to effectively deal with non-compliance. Australia's implementation of the Protocol will give provider countries the assurance of compliance they need, which will assist researchers in accessing resources in those countries.

## Implementing the Protocol in Australia

### *Scope of the Protocol*

- Australia proposes to implement compliance measures only in relation to genetic resources and associated traditional knowledge acquired after the Protocol comes into effect in Australia

For some ex-situ collections, such as existing bio-resource libraries, this means that they would not have to provide provenance details for material acquired before the Protocol comes into effect. However, to maximise the usefulness of their collections for research, such collections may prefer to administer their whole collection to meet Protocol's standards.

- Australian measures would not apply to:
  - resources acquired in jurisdictions that do not meet the relevant provider standards;
  - resources acquired beyond national jurisdiction; and
  - resources acquired under another specialised international ABS system, such as the Multilateral System of the International Treaty on Plant Genetic Resources for Food and Agriculture

## Australia's Approach

In order to meet Protocol obligations as a user country, some changes are required to legislation. Australia proposes to:

- *Support and facilitate the development of Codes of Conduct* that are consistent with the Nagoya Protocol for different user sectors. Codes of Conduct would document reporting obligations as well as standards for, and the circumstances where, due diligence processes should be undertaken.
- *Require an agreement* between users of associated traditional knowledge and the Indigenous people providing that knowledge that is negotiated in accordance with a specific code of conduct—either a community protocol, the AIATSIS *Guidelines for the Conduct of Research in Indigenous Studies* or a *sui generis* Code developed in consultation with Aboriginal and Torres Strait Islander people. The Australian Government does not have jurisdiction over access to associated traditional knowledge, and would not be a party to mutually agreed terms for its use.
- *Recognise trusted institutions* which opt and qualify to be accredited to provide genetic resources. These institutions would be required to demonstrate a due diligence and administrative standard that provides a warranty for the legal acquisition and use of genetic resources.
- *Establish a checkpoint* that requires recipients of Commonwealth government funding for research using genetic resources and/or associated traditional knowledge to report on and provide evidence for the legal provenance of those resources. In the case of the use of associated traditional knowledge held by Australian Indigenous people, reports would include evidence of an agreement with the holders of that knowledge.
- *Create an offence* within the Environment Protection and Biodiversity Conservation Act to use illegally acquired genetic resources and/or associated traditional knowledge:
  - a. where use is reckless to the source; and
  - b. where genetic resources and/or associated traditional knowledge were obtained in contravention of provider measures (where such measures are available on the ABS Clearing House website and meet the standards required by the Protocol).

It would not be an offence if:

- a. due diligence was conducted in accordance with an agreed code of conduct, and
- b. on the available evidence, it is reasonable to believe that the genetic resources and/or associated traditional knowledge were legally obtained.

An International Certificate of Compliance or equivalent would be taken as evidence of legal acquisition, as would obtaining the resources from a 'trusted institution'.

- *Provide audit powers* to the Commonwealth to monitor, using a risk-based approach, the use of genetic resources and/or associated traditional knowledge for potential breaches of the above offence.

A person or institution in good standing with the relevant code of conduct would be regarded as being of low risk for audit purposes.

- *Provide an option for remedy* to allow a user of genetic resources to remedy the legal status of potentially illegally acquired resources with written permission of the source country, and on established mutually agreed terms. If this cannot be negotiated, it would remain an offence to continue to use the resource.

## Interaction with International ABS Schemes

The European Union is a major user of genetic resources and associated traditional knowledge. It intends to enact Union-wide legislation to implement the Protocol by July 2014.

Proposed European regulation would oblige users of genetic resources to check that genetic resources and associated traditional knowledge have been accessed in accordance with the applicable legal requirements in the source country.

Due diligence obligations on users would be monitored to ensure compliance with the Nagoya Protocol.

It is highly likely that the European model will set the standard for other industrialised users of genetic resources.

This will have implications for Australian researchers using genetic resources, whether native or exotic, in collaboration with EU researchers or where seeking to access European commercialisation pathways.

A primary objective in implementing the Nagoya Protocol in Australia is to ensure that Australian research, and research involving Australian genetic resources or associated traditional knowledge, continues to have access to international research, development and potential commercialisation opportunities.

## Glossary

**ABS** means access and benefit-sharing in relation to the use of genetic resources and associated traditional knowledge.

A **genetic resource** is any material of plant, microbial or other origin containing functional units of heredity which is of actual or potential value.

An **International Certificate of Compliance** is a permit or equivalent, issued in accordance with the standards of the Protocol, which is made available on the ABS Clearing House Mechanism website.

**Use/utilisation of genetic resources** means to conduct research and development on their genetic and/or biochemical composition.

**User countries** are countries where genetic resources and traditional knowledge are used for research and development activities.

**Provider countries** are countries where genetic resources are sourced.

## Further information

For further information on the Nagoya Protocol visit <http://www.cbd.int/abs/> or <http://www.environment.gov.au/biodiversity/science/access/biological-diversity.html>

