UNIVERSITY OF CAMBRIDGE

Nagoya Protocol: An Introduction

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Background

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 is a supplementary agreement to the Convention on Biological Diversity.

It is designed to provide a legal framework for users to **access and utilise genetic resources** and associated **traditional knowledge** while also ensuring the **fair and equitable sharing of benefits** arising out of the utilisation of said resources with the original provider.

Adopted by EU October 2014. Took effect in the UK in October 2015.

Scope 1

Applies to anyone who accesses or ‘utilises’:

- **Genetic Resources (GR)**: any material of plant, animal, microbial or other origin containing functional units of heredity (e.g. genes and DNA) which is of actual or potential value **(*excluding human genetic material*).**
- **Traditional Knowledge (TK)**: knowledge, know-how and practice of indigenous and local communities associated with said GR.
- Derivatives of RG (e.g. proteins, lipids, enzymes or RNA) when derived from genetic resources accessed under the Protocol.

Scope 2

Applies only to GR or TK for which all of the following apply:

- Accessed from the country of origin on or after 12 October 2014;
- Accessed from a state that has ratified the Protocol and established applicable access measures
- Accessed for the purposes of ‘utilisation’ - defined as conducting research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology. This includes basic and applied research.

Access under existing instruments that are consistent with the Protocol (e.g. International Treaty on Plant Genetic Resources for Food and Agriculture) is exempt.

What is required?: Due Diligence

Anyone who accessing GR or TK directly from the country of origin or from a third party for the purposes of research and development must determine whether the Protocol applies**.**

1. **Is the GR or TK in scope?**
2. **Has the country of origin issued relevant access measures?**
   a) **Check Access and Benefit Sharing Clearing House**
   b) **Contact National Focal Point**
3. **Keep a record of this decision making process**

What is required?: Direct access

If the Protocol applies the user must comply with relevant access measures, this is likely to include:

- An application for prior informed consent;
- Establishment of mutually agreed terms (which you must analyse and abide by).

The country of origin should issue an internationally recognised certificate of compliance.

The user must store the certificate for twenty years after the end of the period of utilisation and transfer it to any future users of the GR/TK.

Alternative due diligence information

If the country of origin does not issue an internationally recognised certificate of compliance, the user must instead store and transfer:

- the date and place of access to GR and TK;
- the description of GR or TK utilised, including unique identifiers where available;
- the source from which the GR or TK were directly obtained;
- the presence or absence of rights and obligations relating to access and benefit-sharing, including subsequent applications and commercialisation;
- access permits, where applicable;
- mutually agreed terms, where applicable.

What is required?: Indirect access

Anyone who receives GR or TK that fall under the Protocol from a third party must seek, keep and transfer to subsequent users either:

- The internationally recognised certificates of compliance as well as information on the content of the mutually agreed terms; or
- The alternative due diligence information.

The user must analyse the mutually agreed terms and abide by them. If the mutually agreed terms do not apply to the use to which it is intended to put the GR/TK, new terms must be sought with the provider country.

Anyone obtaining GR or TK from a collection registered with the EU will be provided with sufficient information to demonstrate due diligence. This will make compliance more straightforward.

What is required: Declarations of compliance

Regulatory Delivery (RD), a Director of BIS, is responsible for monitoring compliance with the Protocol in the UK.

RD will require declarations of due diligence for:

- Any funded research involving the utilisation of GR or TK subject to the Protocol – after the receipt of the first instalment of funding, but before the final report (or if no final report) the end of the project;
- At the final development stage of any product developed via the utilisation of GR or TK subject to the Protocol.

Template declaration forms will be provided by the Research Office.

University plans

- The Research Office is developing a website and guidance on the Nagoya Protocol.
- Departments will be asked to identify a contact to receive Protocol related guidance and lead on the development of local processes.
- Template forms for receiving and transferring due diligence information will be prepared centrally for optional use and adaption by Departments.
- Departments are likely to require:
  - A process and database for recording accession of material covered by the Protocol;
  - An approach to collecting and storing due diligence information;
  - Guidance for staff on local processes for compliance.
- The Research Office will help departments on the above and work with departments on an approach to due diligence declarations.