

Nagoya Protocol

Individual academics and researchers at Harper Adams University have a legal obligation to comply with the [Nagoya Protocol on Access and Benefit-sharing](#).

[Regulation \(EU\) No. 511/2014](#) of The European Parliament and of The Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union is part of UK law under [The Nagoya Protocol \(Compliance\) Regulations 2015](#).

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (the 'ABS' Protocol) is an international agreement that implements the access and benefit-sharing obligations of the Convention on Biological Diversity (CBD).

Genetic resources in this context include any material of plant, animal, microbial or other origin containing functional units of heredity which is of actual or potential value, or derivatives.

Researchers who source or use such material are required to 'exercise diligence' to ensure that genetic resources and traditional knowledge associated with those resources have been accessed in accordance with applicable access and benefit sharing laws implemented by the source country.

Traditional knowledge refers to knowledge, know-how and practice of indigenous and local communities relevant for the utilisation of the genetic resources accessed under the protocol.

The protocol does **not** apply to:

- human genetic resources
- genetic resources covered by specialised ABS treaties that are supportive of the CBD (for instance, the [International Treaty on Plant Genetic Resources for Food and Agriculture](#)).

The ABS framework

Kew Gardens' lead on the CBD, China Williams, has summarised the ABS framework as:

- follow national laws
- get prior informed consent from the provider
- mutually agree terms with the provider
- share benefits fairly and equitably.

This aim is to provide the incentive for conservation and sustainable use.

Steps to follow

If you are **accessing material** that is subject to the Nagoya Protocol, you must:

1. Use the [Access and Benefit-Sharing Clearing-House](#) (ABSCH) to identify the relevant national laws, procedures and contact points in the country(ies) from which you wish to source the material
2. Make all reasonable efforts to gain prior, explicit informed consent and agree the terms and conditions of access. This should deal with the dissemination of research results, the publication or other sharing of research data, and any potential exploitation
3. Keep records related to (1) and (2) for 20 years. These records may be inspected by the regulator.

If you are **providing access** to material that is subject to the Nagoya Protocol, you must:

1. Ensure such action is consistent with the original access and benefits-sharing arrangements
2. Keep records of such sharing/access for 20 years. These records may be inspected by the regulator.

Records that must be kept for 20 years

Users of genetic resources accessed under the Nagoya Protocol are required to seek, keep, and transfer to subsequent users, information about the following:

- the date and place the genetic resources and associated traditional knowledge were acquired
- a description of the items acquired, using unique identifiers where they are available
- the source from which the items were obtained
- whether the items are subject to rights and obligations regarding access and benefit sharing
- any decision made regarding the access, as well as the mutually agreed terms of access.

Users are:

- required to maintain such information for a period of **20 years** following the end of the period of use
- mandated to declare at identified points that they have complied with their due diligence obligations
- subject to audit/inspection by the regulatory authorities.

The Nagoya Protocol and the research life cycle

There are several likely touch points where researchers will come into contact with questions or requirements related to the Nagoya Protocol on access and benefits-sharing (ABS). These include:

- applying for a research grant (e.g. you may be asked to describe ABS considerations or have agreements in place)
- being awarded a research grant (e.g. you may be required to demonstrate ABS approvals compliance at the outset or within a specified period)
- seeking departmental project approval

- going to obtain or purchase genetic resources
- seeking to lodge material in collections (or museums, laboratories, libraries, gardens or herbaria in other locations) (e.g. you will almost certainly be asked to show ABS compliance and records)
- seeking to provide or give access to genetic resources to/from other researchers, universities, or other third parties
- seeking to patent certain discoveries (where it is suspected that genetic resources from another country have been used)
As the [RHS noted](#), for these patents to progress applicants will need to prove that agreements relating to the collection and use of the genetic resources are in place with the host country. Alternatively, they will need to show that they have carried out 'due diligence' to check that the material falls outside of the scope of the legislation)
- seeking to sell or in other ways commercialise resources or products based on genetic resources. **This is a particular focus under the protocol to ensure that providers of material and local knowledge (including indigenous and local communities) receive a fair and equitable share of benefits.**

UK implementation to date

The Nagoya Protocol was adopted by European legislation and entered into force in the UK on 22 May 2016. The responsible UK agency, Defra, focused initially on working with industry, especially pharmaceuticals, beauty, food and beverage, seed and plant biotechnology.

Defra and the Regulator, the [Office for Product Safety and Standards](#) (based in the [Department for Business, Energy & Industrial Strategy](#) (BEIS)) are planning to develop information and education material for academic researchers.

There is no UK-mandated 'legal template' for the informed consent and access agreements under the Nagoya Protocol. Defra anticipates that researchers in universities and other public bodies will act in good faith and keep records of relevant discussions and agreements.

The University does not wish to proscribe a single form for such records.

Sanctions for breaches of the Protocol

The regulator in the UK, the [Office for Product Safety and Standards](#) will carry out checks on user compliance.

The checks will be conducted through a risk-based approach. Additional checks will be conducted when a competent authority is in possession of relevant information concerning a user's non-compliance.

Where a user has judged genetic resources (or associated traditional knowledge) to be out of scope and therefore not requiring compliance, the authorities will ask for justification of why it is thought to be out of scope.

Regulatory Delivery will have the power to impose compliance notices and variable monetary penalties. Non-compliance will normally be dealt with through civil sanctions, although Regulatory Delivery will be able to pursue criminal sanctions in serious cases.

Further information and contacts

- Requests for advice regarding the Nagoya protocol can be made to Professor Peter Mills, Deputy Vice-Chancellor: petermills@harper-adams.ac.uk or Dr Kreseda Smith, Research Grants Administrator: ksmith@harper-adams.ac.uk
- [United Kingdom of Great Britain and Northern Ireland - National Focal Points on the Conservation of Biological Diversity](#)
- [Guidance on compliance measures for users \(European Commission\)](#)

Quick links

- [Nagoya Protocol on Access and Benefit-sharing](#)
- [Regulation \(EU\) No. 511/2014](#) of The European Parliament and of The Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union
- [The Nagoya Protocol \(Compliance\) Regulations 2015](#)
- [International Treaty on Plant Genetic Resources for Food and Agriculture](#)
- [Access and Benefit-Sharing Clearing-House](#) (ABSCH)
- [Office for Product Safety and Standards](#)
- [Department for Business, Energy & Industrial Strategy](#) (BEIS)
- [United Kingdom of Great Britain and Northern Ireland - National Focal Points on the Conservation of Biological Diversity](#)
- [Guidance on compliance measures for users \(European Commission\)](#)