**Linnean Society Taxonomy & Systematics Committee**

**Summary Briefing Document on the Nagoya Protocol (Access and Benefit-Sharing)**

**Edited by Dr Chris Lyal,** *NHM (London) and CETAF Legislation and Regulation Working Group*

*And* **China Williams,** *Science Policy, Science Directorate, Royal Botanic Gardens, Kew*

## Scope and Purpose:

By providing an overview of the **Nagoya Protocol (NP),** together with links to more detailed information, this document seeks to enhance awareness and understanding of this international agreement. This document will be updated as needed.

## Access and Benefit-Sharing

The "*fair and equitable sharing of benefits arising from the use of genetic resources and traditional knowledge*" is one of the three objectives of the Convention on Biological Diversity (CBD). The concept is usually considered as a two-part process: '**Access**' (to genetic resources, including collecting organisms *in situ*) and **Benefit-Sharing**, hence 'Access and Benefit-Sharing' or ABS (CBD Article 15). Legislation covering Access has been around as long as the CBD (indeed, before that since countries have had sovereign rights over their natural resources since 1962 – this was agreed at the UN, so all countries already acknowledge this). Not all countries have legislation governing access, but for those that do there are requirements for anyone wishing to collect genetic resources.

- If an individual intends to access genetic material or traditional knowledge, they must first discover whether the country requires permission to be sought for access. If so, they must seek prior informed consent (PIC) from the appropriate government department(s) and any other bodies required (for example come countries require separate permission to be granted by indigenous peoples for research on their lands and access to Traditional Knowledge), mutually agree the terms on which access will take place (MAT).
- Researchers and collection managers should be aware that ABS agreements entered into at the time of access may govern what they do with material, even if they were not part of that original agreement.
- All Parties and stakeholders need to agree on appropriate benefits to be shared. In practice many benefits are set out in the permits obtained and can be delivered close to the time of access (e.g. fieldwork with local counterparts).
- Benefits may be monetary or non-monetary, such as royalties or the sharing of R&D results, education & training to build in-country capacity, technology transfer, etc. See Bonn Guidelines for further information: https://www.cbd.int/abs/bonn/ .

**Overview of the Nagoya Protocol**

The Nagoya Protocol on Access and Benefit Sharing is a supplementary agreement to the CBD. It aims to add clarity to the ABS regime and sets out that Parties must introduce compliance measures to ensure that any genetic resources utilised have been accessed with PIC and MAT. The NP terms this '*Utilization of genetic resources*' which is defined as "*to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention*.

Parties to the Protocol are not required to develop and implement Access legislation; many are doing so but others (the UK for example) are not.

Countries become Party to the Protocol by a process of ratification, with which they accept its legally-binding commitments. The NP does not apply in countries which are not Party to it. However, anyone working in such countries, or accessing genetic resources from them, are subject to their laws on legal collection and any bilateral agreements such as permits which set out terms of access and benefit-sharing.

- By helping to ensure benefit-sharing, the Nagoya Protocol creates incentives to conserve and sustainably use genetic resources, and therefore enhances the contribution of biodiversity to economic development and human well-being
- The Nagoya Protocol also establishes a compliance regime that means penalties will be imposed if genetic resources are utilised illegally
- More information on traditional knowledge as considered under the NP can be found here Traditional Knowledge

- The Nagoya Protocol entered into force on 12th October 2014 (following its adoption in 2010). As of March 2017, 93 countries are party to the Nagoya Protocol. This ABS Clearing House (ABSCH - https://absch.cbd.int/) provides up to date information on Parties and their ABS legislation and is a key tool for facilitating implementation of the Nagoya Protocol.
- The EU became a Party to the Protocol on 12th October 2014, and introduced Regulations governing compliance which apply to all Member States. The UK became a Party to the Protocol in May 2016. UK Regulatory Delivery (RD), part of the Department for Business, Energy & Industrial Strategy (BEIS) is the Competent Authority for enforcing compliance with the relevant legislation (see 'The Nagoya Protocol in the UK' below).

**The Nagoya Protocol does not replace or negate existing laws, regulations, or agreements on legal collection, access or benefit sharing that many countries already have in place.** These may include legal collecting permits, permissions from landowners, CITES and other export permits, local legislation, rules on working with indigenous communities, permissions to collect endangered or threatened plants, plant health regulations etc. The conditions on permits and similar documents include elements such as training, sharing information, joint publication, and return of specimens. One still needs to comply with all of these, as well as any additional legislation a country has to implement the Nagoya Protocol.

**The Nagoya Protocol in the UK**

The UK's responsibility under the Nagoya Protocol is to put in place a system to manage compliance with regulations in provider countries by users in the UK.

The UK legislation addressing the Nagoya Protocol in the UK is the UK Statutory Instrument [ http://www.legislation.gov.uk/uksi/2015/821/pdfs/uksi_20150821_en.pdf ]. This implements the EU Regulation on compliance measures [ http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R0511&from=EN ] and the EU Implementing Regulation [ http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOL_2015_275_R_0003&from=FR ]. Background on the EU Regulation can be found here [ http://ec.europa.eu/environment/nature/biodiversity/international/abs/index_en.htm ].

An easily-navigable version of the UK Statutory Instrument can be found here. http://www.legislation.gov.uk/uksi/2015/821/contents/made

The EU regulations apply only to Genetic Resources and associated Traditional Knowledge accessed from a Party to the Nagoya Protocol since 12 October 2014. It is a 'due diligence' approach meaning that anyone utilizing genetic resources from a country that is Party to the Protocol needs to show due diligence in seeking information on how to legally acquire them and then to carry out these requirements. This might involve obtaining *Prior Informed Consent* from the Competent Authority in the country, and assenting to *Mutually Agreed Terms*. Due diligence must be exercised by all users of genetic resources in the EU to ensure the Genetic Resources were accessed legitimately and they are aware of relevant conditions regarding their use and benefit sharing. Users of genetic resources in the EU will be asked submit declarations of due diligence to their competent authorities (Regulatory Delivery in the case of the UK) at two points:

- At the point of receiving funding for a project involving utilization of genetic resources or associated traditional knowledge
- At the stage of final development of a product developed through utilization of genetic resources or associated traditional knowledge

  It is important for researchers and collection holders to understand fully their legal responsibilities. Details are beyond the scope of this website but further information may be found here [ https://www.gov.uk/guidance/abs ].

**Information and tools to help ABS compliance**

**The Plenary meeting of the Linnean Society's Taxonomy & Systematics Committee, held 22nd September 2016, entitled *Understanding and implementing current environmental legislation: biology, borders and ownership,*** considered the Nagoya Protocol and video podcasts of the talks can be found here: https://www.linnean.org/meetings-and-events/events/understanding-and-implementing-current-environmental-legislation-biology-borders-and-ownership

The **ABS Capacity Development Initiative** has produced a short film explaining ABS. It can be found here: https://tinyurl.com/l6fkl5n

***Available Codes of Conduct for Best Practice***

A number of organisations relevant to Linnean Society members have been developing Best Practices, Codes of Conduct and other tools to manage ABS compliance. A helpful explanation of best practices and their implementation at Royal Botanic Gardens Kew is given in a presentation by China Williams [https://www.cbd.int/doc/meetings/abs/icnp-03/presentations/icnp3-Kew.pdf]

Relevant Best Practices include:

- The Consortium of European Taxonomic Facilities (CETAF): (https://tinyurl.com/hmon7ff) or http://cetaf.org/sites/default/files/final_cetaf_abs_coc.pdf (2016 version - some modification has been made since and there may be more, depending on discussions with the European Commission.
- the Microbial Resource Research Infrastructure (MIRRI) **Best Practice Manual on Access and Benefit Sharing**) 25pp. **May 2016** https://tinyurl.com/ht5rx9g)
- World Federation of Culture Collections TRUST - TRansparent User-friendly System of Transfer, **implementing the Nagoya Protocol in microbiology**. 43pp **March 2016** (http://bccm.belspo.be/projects/trust).
- the Global Genome Biodiversity Network (GGBN) **Best Practice for Access and Benefit-Sharing** (16pp., **June 2015**) and Code of Conduct for ABS (7pp., **Jan 2015**) (https://tinyurl.com/jzudwwv and https://tinyurl.com/hq8gct3)
- Botanic Gardens Conservation International (BGCI) Results of the Pilot Project for Botanic Gardens 83pp. **2001** (http://www.bgci.org/files/ABS/Principles_on_ABS.pdf)

***Links to other useful ABS tools:***

- The **European Commission** has developed a horizontal guidance document to assist with understanding the **EU legislation** (**Aug 2016**), which is available at http://eur-lex.europa.eu/legal-content/AUTO/?uri=CELEX:52016XC0827(01)&qid=1472592469771&rid=1
- The United Nations University carried out a **Survey of Model Contractual Clauses, Codes of Conduct, Guidelines, Best Practices and Standards** 25pp. (Nov 2013) for the CBD. This provides some useful 'boilerplate' clauses for MTAs/MATs).
- http://ethicalbiotrade.org/dl/benefit-sharing/UEBT-ABS-Nagoya-Protocol.pdf This 5pp. **technical brief** (**2010**) makes reference to **'derivatives'** ("a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources.") and **patents & biodiversity** (although there is no reference to patents or other intellectual property rights in the Nagoya Protocol, there is building pressure for both patent rules and practices to take into account access and benefit sharing requirements.
- Most CBD parties (189 of 196, 96%) have developed their **National Biodiversity Strategies and Action Plans (NBSAPs**) https://www.cbd.int/nbsap the most recent (6th **March 2017**) being Liberia's second NBSAP for 2017-2025, and Rwanda's revised NBSAP on 6th Feb 2017. Anyone planning to work with a particular country should read the respective NBSAP, so as to understand that country's priorities and needs in terms of biodiversity information and biodiversity management.

- Model ABS agreements can be very useful. However, models need to be flexible to be used with other sectors and governments who may have their own models - capacity building is required to ensure terms are understood and can be renegotiated. The Swiss Academy of Sciences has produced a Toolbox for drafting Mutually Agreed Terms: Bourdon ABS 2016 (Agreement on Access and Benefit-sharing for Academic Research). This is available here [ http://www.naturalsciences.ch/organisations/biodiversity/abs/toolbox ]
- One form of model agreement is model Material Transfer Agreements (MTAs). Those produced by CETAF can be found here:
    - http://cetaf.org/sites/default/files/final_cetaf_mta_1-_provision_no_change_in_ownership.pdf
    - http://cetaf.org/sites/default/files/final_cetaf_mta_2-_provision_change_in_ownership_0.pdf
    - http://cetaf.org/sites/default/files/final_cetaf_mta_3-_receipt_change_in_ownership.pdf

***Further information on the Nagoya Protocol***

- The ABS Clearing House is a major source of information about national contacts and legislation, and of many different ABS developments and tools. It can be found here. [https://absch.cbd.int/]. Further information provided by the CBD is here [https://www.cbd.int/abs/default.shtml]
- The European Commission has a general information page on the Nagoya Protocol at http://ec.europa.eu/environment/nature/biodiversity/international/abs/index_en.htm
- Outcomes from the recent (**Dec 2016**, Mexico) **UN Biodiversity Conference** (CBD Conference of the Parties) can be found at https://www.cbd.int/conferences/2016/np-mop-2/documents provides, including a paper on ***Digital sequence information on genetic resources*** (CBD/NP/MOP/DEC/2/14).
- Further information is available on the **CBD website,** including these two fact-sheets at (https://www.cbd.int/abs/policy-brief/default.shtml/) 2pp. not dated https://www.cbd.int/abs/infokit/revised/web/factsheet-nagoya-en.pdf 5pp **2011**
- https://cmsdata.iucn.org/downloads/an_explanatory_guide_to_the_nagoya_protocol.pdf (**2012**) This **IUCN Environmental Policy and Law Paper** No. 83 provides a detailed 394pp guide to the NP, including **model contractual clauses**, and a useful schematic of a potential due diligence compliance and monitoring system (Figure 6, p. 313).
- **RHS update** https://www.rhs.org.uk/science/articles/nagoya-protocol-update-september-2015
- The Society for the Preservation of Natural History Collections (SPHNC) has developed a WIKI on Access and Benefit-Sharing (Nagoya Protocol and the CBD). This can be found here [ http://spnhc.biowikifarm.net/wiki/Access_and_Benefit-Sharing_(Nagoya_Protocol_and_the_CBD) ]. The SPHNC home page can be found here [ http://www.spnhc.org/ ]
- The Natural History Museum, Royal Botanic Gardens Kew and Royal Botanic Gardens Edinburgh have a site providing information for staff here [ http://nagoyaprotocol.myspecies.info/ ]

- http://plantnetwork.org/wordpress/wp-content/uploads/14664/the-nagoya-protocol-training-day-booklet.pdf This is the Plant Network's resource booklet (25pp.) used for a '**Nagoya Protocol and Plant Collection Responsibilities Training Day'** held **Feb 2015**

***Where can I get further guidance and keep up-to-date with evolving developments?***

- DEFRA has an open ABS stakeholder group, which has been running for many years and provides an opportunity to discuss issues with the relevant UK authorities and express views on the developing legislation (including the UK legislation post-BREXIT). Contact via Holly Kelley-Weil (Holly.Keller-Weil@defra.gsi.gov.uk) as the UK ABS National Focal Point, hosts the meetings. The NFP will act as a source of information for those looking to access genetic resources, traditional knowledge, and information held in that state.
- Currently, guidance documents for a number of sectors are being finalised (Animal breeding, Biocontrol and Biostimulants, Biotech, Cosmetics, Food and Feed, Pharmaceuticals, Plant Breeding). However, time for comment is very limited now, but if you wish to see the drafts circulated by the Commission, Chris Lyal can send them to you. Further sectoral guidance for Collections and Research will be developed over the next few months.
- The European Commission has instituted a stakeholder Consultative Forum, comprising representatives of sector organisations (including CETAF, BGCI etc). It held its second meeting on 6th March (27 stakeholders participated) – see report here (Additional Information tab) [ http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=3396 ]

**Other FAQs**

- ***What are 'PIC' and 'MAT'?***

PIC – Prior Informed Consent - and MAT – Mutually Agreed Terms – are key to ABS agreements. PIC is the permission given by the competent national authority of a providing country to a user prior to accessing genetic resources, in line with an appropriate national legal and institutional framework, i.e. what a user can and cannot do with the material. MAT is an agreement reached between the Providing Country of genetic resources and a user on the conditions of access and use and the benefits to be shared between both parties.

- ***Whose responsibility is it to seek Prior Informed Consent?***

Seeking consent is not a national responsibility, but rests with individual users. The UK does not have to seek consent from a provider country, this being the explicit responsibility of the individual user.

- ***What about the costs associated with developing any benefits?***

For example, isolating and characterising microbiological organisms introduces a downstream cost for those utilising genetic resources – can this cost be offset when 'sharing benefits'? Such costs should be addressed in the Mutually Agreed Terms and any subsequent benefit-sharing agreement between the provider and the user. There are several tools available to help draft contracts, for example from the Swiss Academy of Sciences [ http://www.naturalsciences.ch/organisations/biodiversity/abs/toolbox ] and the ABS Capacity Development Initiative [ http://www.abs-initiative.info/fileadmin/media/Knowledge_Center/Pulications/Introduction_to_Drafting_Successful_ABS_Agreements/Introduction_to_Drafting_Successful_ABS_contracts_-_ABS-I_FNI_-_201609.pdf ]

- ***It can be difficult obtaining information on access requirements of a country, and actually obtaining relevant permits; what should I do?***

An important source of information is the ABS Clearing House [https://absch.cbd.int/], which lists the National Focal Point, whose responsibility it is to provide information on ABS access requirements. Currently contact with the NFPs can be difficult – improving users' ability to discover relevant requirements is an important need.

- ***Is there help in ensuring conditions on the permits and any subsequent agreements (Mutually Agreed Terms) allow the utilization planned and are effective contracts regarding benefit-sharing?***

There are tools available to support this, for example the Swiss Guidelines at http://www.naturalsciences.ch/organisations/biodiversity/abs/toolbox and the CETAF Use of Materials statement (see Annex 1 of the CETAF Code of Conduct at http://cetaf.org/sites/default/files/final_cetaf_abs_coc.pdf; a slightly revised version will be published soon).

- ***What are the administrative requirements of making Declarations of Due Diligence under the UK implementation of the EU Regulations?***

Regulatory Delivery will give advice on this – information can be found here [ https://www.gov.uk/guidance/abs ]. The European Commission is currently developing tools to facilitate making declarations.

- ***Is downloaded digital DNA sequence data included under the Protocol?***

Not at present. CBD COP 13 / MOP2 in Mexico last December debated this and there will be a consultation globally starting later this year. DEFRA undoubtedly will be seeking views, and it will also be possible to make submissions directly. See https://tinyurl.com/j2mva8j and https://www.cbd.int/doc/notifications/2017/ntf-2017-018-abs-en.pdf

- ***What about biological reference collections, assembled before 2014, in museums and other institutions and exchanging material between them?***

**The Nagoya Protocol requirements do not apply retrospectively** so, with two caveats, the EU Regulation does not apply to material held in collections that was accessed prior to October 2014. However, if the material is held in an *ex situ* collection of the country where it was originally collected, and that country has access legislation, this legislation may apply to that material. In addition, whenever the material was collected the original permit conditions still apply and should be adhered to.

Future acquisitions for natural history collections will require greater levels of due diligence and more sophisticated digital data management systems than were previously required, and awareness of this is important for holders of collections. Much greater detail of what collection-holders should do is given in the Best Practices (see section [hyperlink]). The best practices extend beyond collection-holders. Best practices (and sometimes permit conditions) require users of collections to cite specimens appropriately in publications, including permit identifiers. This places a degree of responsibility on publishers, who should require full specimen citations to facilitate implementation of benefit sharing.

The Protocol does not apply to genetic resources covered by specialised access and benefit-sharing agreements such as the International Treaty on Plant Genetic Resources for Food and Agriculture, or the framework for pandemic preparedness of the World Health Organisation.

- ***What are the implications for horticulture and cultivated plant diversity?***

A long horticultural tradition in the UK has brought a rich diversity of plants to our gardens which has arisen from extensive collecting, exchanging and rising of new plants and has depended on the flow of new plants from other countries. The legality of plant collecting is not changed by Nagoya; as before, collectors should obtain the appropriate permits from the countries in which they are seeking plants. A provider country may set a date for compliance prior to 12 October 2014, and may consider privately owned material and/or cultivated (domesticated) plants as Genetic Resources within scope of national legislation. While provider country legislation should be adhered to, this does not change the requirements of the EU Regulation, which only covers material accessed after 12 October 2014 from a Party to the Nagoya Protocol that has access legislation.

Breeding programmes to create a new plant variety based on landraces or naturally occurring plants are in scope (EU Guidance Document, August 2016) and the breeder/registrant of Plant Variety Rights (PVR) will need to comply with any benefit sharing provisions, having previously done their due diligence on utilisation of genetic resources. However, once granted plants with PVR are no longer within scope of the EU Regulation and are available for use by other breeders, although the original breeder will continue to share benefits. Pathways of dissemination of plant material are complex, so there are concerns, especially regarding the traceability through multiple transfers of plants and through professional and amateur networks. To support due diligence requirements those distributing plant material, such as in seed lists, should seek assurances on the status of plant material they include and provide a statement for recipients. Further consideration of the EU Regulation for Plant Breeders are being addressed in a sectoral guidance document currently being finalised at the Commission.

- **What impact will BREXIT have?**

The CBD and associated Nagoya Protocol are international agreements outside EU. Because the UK is Party to the CBD and the Nagoya Protocol our **obligations under these agreements would be unaffected by BREXIT.** The legislation implementing the Nagoya Protocol in the UK (UK Statutory Instrument) relies on an EU Regulation and a Commission Implementing Act. Until there is notification from the UK Government this will continue to apply. DEFRA is currently considering what changes might be appropriate post-BREXIT.

- **Where can I find more information on CBD in general?**

For the younger reader, this is an excellent overview on the CBD: **'CBD in a Nutshell'** developed by the Global Youth Biodiversity Network and launched in Cancun. It's a great introduction to the CBD and its processes – for anyone really – but particularly aimed at young people. Here's the link: https://gybn.org/resources/guidebook/