Implications of the Nagoya Protocol for animal genetic resource exploitation and collections

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Under the Convention on Biological Diversity (CBD): "States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources." i.e. biodiversity of a country belongs to that country, and non-nationals have no rights to it.

Permission to collect or sample genetic resources can only be granted by the country that has sovereign right over those resources (i.e. the provider).

In October 2010 the CBD agreed **"International Regime on Access and Benefit-Sharing"** ('Nagoya Protocol'). So far 92 countries (including the UK) have signed the Protocol and more than 50 have ratified it. It is therefore a legally binding agreement covering the usage of genetic resources.

Definitions and terms used in the Nagoya Protocol

Access and Benefit-sharing' (ABS): "the fair and equitable sharing of the benefits arising out of the utilization of genetic resources"

Genetic resources; Genetic material of actual or potential value.

Genetic material; Any material of plant, animal, microbial or other origin containing functional units of heredity.

Derivative: A naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity.

These definitions provide legal certainty and ensure a fair relationship between users and providers. They also give confidence to providers that users will respect proper procedures for access and share benefits fairly.

Utilization of genetic resources; Research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology.

Biotechnology; Any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.

Benefits arising from the use of genetic resources may be monetary or non-monetary.

Monetary When research and development leads to a commercial product, royalties, milestone payments, licensing fees, etc

Non-monetary. Identifications, biological inventories, technology transfer, training, sharing research results, research partnerships, access to scientific information relevant to conservation and sustainable use of biological diversity, etc

Prior Informed Consent (PIC). The permission given by the competent national authority of a provider 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.

Mutually Agreed Terms (MAT). An agreement reached between the providers of genetic resources and users on the conditions of access and use and the benefits to be shared between both parties.

Traditional Knowledge (TK) associated with genetic resources is also covered.

The MAT may apply to specimens in perpetuity. This also applies to third parties (i.e. if someone receives material acquired by someone else) and also to "borrowers" of materials.

If a 'new' use is contemplated, the PIC and MAT may have to be renegotiated.

EU regulations, the Nagoya Protocol and some doubts

The scope of the EU regulations applies to genetic resources and associated traditional knowledge "that are accessed after the entry into force of the Nagoya Protocol for the Union". This essentially means that EU members, subject to their national legislation, may not need to consider the need for prior informed consent and benefit sharing for new R&D on millions of previously accessed and collected genetic resources – and traditional knowledge associated with it – that already exists in gene banks, botanic gardens, herbariums, university and private collections.

The EU move raises important questions around the potential effectiveness of the Protocol, suggesting it could depend entirely on national implementation policies. Furthermore, the implications of having inconsistent approaches to access and utilisation in different countries and regions could fuel concerns among biodiverse developing countries and indigenous and local communities around the instrument's ability to ensure meaningful benefit sharing.

The current draft Regulation puts a strong emphasis on the role of ex situ collections, proposing a system of 'Union Trusted Collections'. A "register" of such trusted collections will be kept by the European Commission, and to be considered as a trusted collection, a collection will need to:

(a) apply standardised procedures for exchange;

(b) only supply material and related information with documents providing evidence that they were accessed legally, with PIC and MAT as appropriate;

(c) keep records of all samples and information supplied to third parties;

(d) use unique identifiers for samples supplied; and

(e) use appropriate tracking and monitoring tools for exchanging samples with other collections.

When users acquire material from 'trusted collections', they will be considered to have exercised due diligence with respect to ABS. The draft Regulation's preamble notes that collecting of genetic resources in the wild is mostly undertaken for non-commercial purposes, and that in the majority of cases and across user sectors, access to newly-collected resources is gained via intermediaries, collections or other agents. In effect, the draft Regulation positions EU collections firmly between providers and users. Consequently *ex situ* collections in all sectors are in the process of determining whether, and how, they will need to change their practices to account for a possible increase in demand from commercially-orientated users, and whether the costs (of implementing comprehensive monitoring mechanisms, and of negotiating with providers terms might need to extend to later commercialisation) involved in being a 'trusted collection' outweigh the benefits.

Once the Regulation is adopted each members state will need to decide on what changes are needed at the national level. The Regulation provides no prescription as to exactly how collections should implement ABS, as long as those that are registered as 'trusted' can fulfil the legal and tracking requirements, and (like the NP) suggests complementary measures, such as the development of sectoral codes of conduct, model contractual clauses, guidelines and best practices. Hence ABS measures will likely continue to be developed and implemented on a voluntary sector-specific basis.

In the UK, compliance with the provisions will be assessed by DEFRA at two key points:

- Receipt of research funding; and
- Commercialisation of a product (including applying for market approval in the EU).

The regulation indicates that the provisions will not be retroactive and will only apply to genetic resources accessed after 12 October 2014.

Informal comments on implementing the Nagoya Protocol

The approach taken by the **Centre for Genetic Resources (Netherlands)** is to refrain from claiming legal ownership of, or intellectual property rights on, the germplasm (and related information) in its gene bank, and to keep it as unrestrictedly available as possible, passing on these same obligations to future recipients. It uses Memoranda of Understanding to cover its collection missions, and the SMTA as a basis for collecting material

Zoos and Aquaria. A review of UK stakeholders indicated that the acquisition of animals from wild populations for the zoo sector is generally covered by written agreements following the guidelines of the UK Federation of Zoos and the World Zoo Conservation Strategy, which are not specifically ABS-related, but ban illegal and unethical trade. Draft guidelines on ABS were discussed by WAZA member organisations in 2006. The draft laid out core commitments covering PIC, MAT, benefit-sharing, conservation and sustainable use, traditional knowledge, community participation, and information and transparency, and incorporated the Principles on ABS. WAZA members would be expected to record the terms and conditions of acquisition, track and audit the use of those resources and benefits arising from use, record disposal to third parties, including terms, and should develop an institutional policy. However it is not clear whether these guidelines were further developed and released.

Institutions will need to:

- Update their current policies and processes for ABS and Fieldwork (probably incomplete, incorrect and not implemented at present in most institutions)
- Create a policy for Traditional Knowledge including how and when to collect it and how to protect it.
- Decide who, within an organization, should sign documentation with other institutions or countries (effectively a contract) and in what circumstances
- Decide what should happen to documents. Need copies and originals of permits and agreements and be able to find them in the future..
- Ensure that specimens are always legally obtained
- Provide guidance / requirements / support to staff
- Develop a mechanism to ensure staff do not collect samples without full permits
- Destroy ‘illegal’ specimens?
- The Protocol refers to Global Multilateral Benefit-Sharing Mechanisms
    - How can financial) benefits be shared if the country of origin cannot be identified

The Protocol is not retrospective but:

- Many model policies suggest we should act as if it is and indeed some countries (e.g. African countries) will not recognize that the Protocol is not retrospective.

- Many specimens collected since 1993 have not been documented
  This means retrospective work collecting data and permit details

Comments about Molecular studies

Worrying for some countries

- Are we legally able to extract, analyse and publish genetic information from all our specimens?
- What are the implications for depositing sequence data in public repositories that do not permit restrictions on use?
- Need to link molecular samples with record of processes carried out, voucher specimens and MAT
- Helpful to track specimens and their MATs internally and externally
- Requires linking specimen data, terms and treatments applied (e.g. sequences)

D Young & Co have a useful link about implementation of the Nagoya Protocol (The following is an extract)

http://www.dyoung.com/article-nagoyaeu

Compliance mechanism

An international body known as the Access and Benefits Sharing (ABS) Clearing House is to be set up to act as an intermediary to co-ordinate the implementation of the Nagoya Protocol. In principle the system should work as follows:

A provider country informs the clearing house of its national access and benefits sharing (ABS) information which the clearing house will keep up-to-date.

If a user wishes to access a genetic resource from provider country A, the user contacts the clearing house for details of how to agree mutually agreed terms with country A.

The user contacts the relevant government department in country A and obtains permission for either non-commercial or commercial use (the terms can be re-negotiated later if commercialisation appears likely).

Country A issues to the user a national permit and additionally country A files this at the clearing house.

The clearing house issues an internationally recognised certificate of compliance (IRCC) which is proof that the resource has been accessed in accordance with the Nagoya Protocol.

When a checkpoint is triggered (eg upon commercialisation) the IRCC will need to be presented.

The user communicates details back to the clearing house which in turn contacts provider country A to report on the progress in the R&D on their genetic resources. If necessary country A can use this as an opportunity to negotiate new terms (eg pertaining to a commercialisation agreement).

For point 3, it would appear that details of the use will need to be provided to the provider country. However, when submitting documentation to the ABS Clearing House it is planned that specific details can be made confidential and thus not open to inspection by third parties.

Consequently there are serious concerns about the confidentiality of information shared with government bodies of the provider countries and much care will need to be taken to determine the minimum level of disclosure required to comply with a provider country's requirements without giving away valuable commercial information.

Best practice

The regulation for implementing the Nagoya Protocol allows for the setting of 'best practices' to serve as a 'gold standard' for compliance. The intention is that if a researcher can show that they have carried out their due diligence as required by the best practice, any investigation as to their compliance when putting a product onto the market, for example in the EU, will be superficial.

Open issues

There is no detailed guidance as to the scope of the legislation.

There are still no specific details as to what constitutes an appropriate level of due diligence.

An Implementing Act will be published by the EU Commission (final draft expected October 2015 – the first month in which compliance with the Nagoya Protocol will be checked).