

# Access to Genetic Resources

## Article 6 of the Nagoya Protocol on Access and Benefit-sharing

### Introduction

One of the basic elements of the access and benefit-sharing (ABS) concept is the term “access” which is not defined within the Convention on Biological Diversity (CBD). For many, access is understood as obtaining samples, or having the right to obtain samples. Access to genetic resources more concretely, can be understood as obtaining samples of biological or other material containing genetic material from within a country’s borders for purposes of research, conservation, commercial or industrial application.<sup>i</sup> This understanding mirrors the time when the Convention was being negotiated, when developing countries agreed to facilitate access to researchers to sites and to take samples, legally, in exchange for developed countries’ acceptance of inclusion of the concept “equitable benefit-sharing” within the CBD’s text.<sup>ii</sup>

Article 6 of the Nagoya Protocol is the key provision addressing access to genetic resources in the Nagoya Protocol. It stipulates the rights and obligations of providers in regulating access to genetic resources. The provision mainly builds on the various elements of Article 15 of the CBD (under Paragraphs 1, 2, 3 and 5) which deal with the status of genetic resources and conditions/requirements for access. It is important to note in this context that prior to the CBD, genetic resources were often regarded as freely accessible without the users’ obligation to share benefits with provider countries. The CBD changed that understanding by confirming that genetic resources lay under the territorial sovereignty of individual countries where they are found (Preamble and Articles 3 and 15(1) of the CBD). This means that States have the right to determine the rules and conditions of access to genetic resources according to their national laws including, if existent, ABS legislations.

However, the authority of a State to determine access to genetic resources is qualified by Article 15(2) of the CBD which requires the Parties to endeavor to create conditions that facilitate access to their genetic resources for environmentally sound uses by other Parties, and do not impose restrictions that run counter to the objectives of the CBD. Determining when a use is environmentally sound is left to the discretion of the Party providing genetic resources. Furthermore, facilitating access and eliminating or minimizing restrictions implies that potential users of genetic resources should be supported in acquiring access to these resources. This is based on the understanding that fair and equitable sharing of benefits can only be realized after access to genetic resources has been actually granted.

Furthermore, access to genetic resources is made subject to the prior informed consent (PIC) of the Party providing the genetic resources, unless otherwise determined by that Party (Article 15(5) of the CBD); and where access is granted, it is conditional upon reaching mutually agreed terms (MAT) between the Party providing the genetic resources and the potential user (Article 15(4) of the CBD). PIC and MAT are thus the primary means to:

- Authorize access to genetic resources;
- Control their subsequent use; and
- Establish the fair and equitable sharing of benefits from their subsequent use.

The concept of PIC is based on the principle that prior to getting access those affected and those authorized to make decisions should be informed about the potential uses in order to be able to make a fully educated decision. In the context of ABS, PIC requires that:

- The provider gives his/her consent through an affirmative act;
- This decision (affirmative act/consent) is based on information provided by the potential user; and
- The information is provided prior to the actual decision (affirmative act/consent) granting access.

MAT implies a negotiation between the Party granting access to genetic resources and an entity aiming to use genetic resources, such as an individual, a company, or an institution. In the case of a successful negotiation, this will lead to an access agreement (sometimes called material transfer agreement, research agreement or contract).

## Understanding Article 6

Article 6(1) reaffirms the sovereign right of States over their natural resources and consequently, the authority to regulate access to genetic resources according to domestic ABS legislations and regulatory requirements and subject to the PIC of the Party providing such resources. It must not be forgotten that it is also within the sovereign rights of each State over its natural resources to



determine that PIC for access is not required and thus access is granted freely. According to Article 6(1), if the ABS measures of a provider country do not mention PIC requirements, this does not automatically mean that the Party does not require PIC. The fact that the provision expressly says “unless otherwise determined by that Party” suggests that PIC is actually the norm and that it must be said otherwise. Countries that do not require PIC, including those that traditionally do not regulate access to genetic resources, should therefore give a clear declaration to that effect.

In Paragraph 2, a new scenario is introduced, which did not exist in the international law of access before the Nagoya Protocol: the right of indigenous and local communities (ILCs) to determine access to genetic resources, where they have the established right to grant access to such resources. This provision needs to be distinguished from Articles 7 and 12 of the Nagoya Protocol which regulate access to traditional knowledge associated with genetic resources.

Finally, Paragraph 3 obliges Parties providing genetic resources subject to PIC to take a number of access measures. It should be noted that under the CBD, no concrete measures were foreseen to facilitate access to genetic resources and to hinder the imposition of restrictions that run counter to its objectives as foreseen under Article 15(2) of the CBD. The measures described in seven subparagraphs under Article 6(3) of the

Nagoya Protocol could thus be seen as a concretization of Article 15(2) of the CBD. Accordingly, Parties shall

- Provide for legal certainty, clarity and transparency of domestic ABS legislation or regulatory requirements (Subparagraph (a)): Certainty means that ABS requirements may not suddenly change; clarity means that requirements are sufficiently precise and not contradictory; and transparency means that information to understand and monitor ABS laws and regulations is freely and easily accessible to all.
- Provide for fair and non-arbitrary access rules and procedures (Subparagraph (b)): Fairness means that equal treatment in access applications is accorded to similar domestic and foreign applicants; non-arbitrariness refers to non-dependence on individual or one-sided discretion.
- Provide information on PIC applications (Subparagraph (c)): This includes information on national authorities granting PIC, specific requirements to fulfil, specific procedures to follow, etc.
- Provide for clear, written and cost-effective PIC decisions within a reasonable period of time (Subparagraph (d)): The decision should therefore not be oral but written, readily understood and straightforward in order to avoid varying interpretations, minimize transaction costs as much as possible, and it should be taken without undue delay.
- Provide for the issuance of a permit or equivalent as evidence of PIC and MAT, and for notification of the ABS Clearing-House (Subparagraph (e)): An access permit must therefore reflect the terms mutually agreed between the applicant and the national authorities. Once the permit has been granted, the same is to be notified by the provider to the ABS Clearing-House established under Article 14 of the Nagoya Protocol, such notification constituting an internationally recognized certificate of compliance.
- Establish criteria and/or processes for obtaining PIC or approval and involvement of ILCs (Subparagraph (f)): However, not every Party providing genetic resources is obliged to do so, as the provision refers only to situations where this is applicable, and makes the establishment of criteria and/or processes subject to domestic legislation.
- Establish clear rules and procedures for establishing MAT (Subparagraph (g)): This refers to the obligation to establish grounds when MAT shall be required and to make clear how the terms shall be established. In addition, Subparagraph (g) provides an indicative list of terms that may be required or established between parties – dispute settlement clause; terms of benefit-sharing (including in relation to intellectual property rights); terms on subsequent third-party use; and terms on changes of intent.

It is important to note that Parties are flexible in their decision how to implement these measures, whether through legislative, administrative or policy instruments. Furthermore, it should be understood that Article 8 of the Nagoya Protocol requires a number of special considerations in the development and implementation of national ABS regimes. Accordingly, each Party is obliged to

- Promote and encourage scientific research that contributes to the conservation and sustainable use of biological diversity;
- Pay due regard to cases of present or imminent emergencies that threaten human, animal, or plant health; and
- Consider the importance of genetic resources for food and agriculture and their special role for food security.

**Possible elements for a PIC application as included in Costa Rican Decree 31514 of 2003**

- ✓ Aims of research, bioprospection, or economic exploitation;
- ✓ Site/sites where research or exploitation will be settled on;

- ✓ Number of researchers, bioprospectors or authorized persons who will enter the site and how they might be identified (if guidance by ILC members is required, these should be duly hired and paid for, if the parties so agree);
- ✓ Type of material of interest and approximate quantity;
- ✓ Potential destination of genetic or biochemical elements or resources and their subsequent destinations;
- ✓ Methods of collection or exploitation of material;
- ✓ Initial price of extracted sample, when applicable;
- ✓ Approximate time the whole process will last and how many times the access site will be entered;
- ✓ Formal commitment by the interested party to provide evidence of the origin of the resources and the related knowledge, in any publication, procedure, or their future use;
- ✓ Agreed terms regarding the exchange of knowledge related to characteristics, qualities, uses, procedures and tending over the genetic and biochemical elements and resources of biodiversity and how this knowledge will contribute to conservation of species and ecosystems;
- ✓ Agreed terms about any other condition that the practice or the result of the participatory process of the ILCs indicate as required;
- ✓ Express manifestation by intellectual property that the protection measures of the related knowledge, practices, and innovations of ILCs will be respected, as established in the national legal system on *sui generis* Comunitarian Intellectual Rights;
- ✓ Agreed terms on a possible study on cultural impacts of access if required;
- ✓ Agreed terms on the type and ways of transfer of technology or generation of information derived from research, bioprospection, or economic exploitation towards the national counterparts, ILCs and the provider of the resource;
- ✓ Agreed terms on the equitable distribution of environmental, economic, social, scientific, or spiritual benefits, including possible commercial profits at short, mid, and long term of any product or sub-product derived from the acquired material;
- ✓ Approximate terms for the distribution of benefits;
- ✓ Special emphasis should be made so that granting of PIC is carried out, as far as possible, with the equitable participation of both genders;
- ✓ Signature or fingerprint of the provider and applicant;
- ✓ Other terms agreed.

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<sup>i</sup> Sarah Laird and Rachel Wynberg (2003). *Biodiversity prospecting & access and benefit-sharing*. IUCN, Gland, Switzerland and Cambridge, UK. P.30.

<sup>ii</sup> Morten Walloe Tvedt and Tomme Young (2007). *Beyond Access: Exploring Implementation of the Fair and Equitable Sharing Commitment in the CBD*. ABS Series No. 2. IUCN Environmental Policy and Law Paper No. 67/2. IUCN, Fridtjof Nansens Institute. P.14.

