

An explanation of the Nagoya Protocol by article

An overview of the Articles of the Nagoya Protocol is presented to better understand its scope and applicability. **An explanatory guide to the Nagoya Protocol on Access and Benefit-sharing prepared by IUCN has been a major source for this overview.**

Preamble

The preamble of an international agreement forms an integral part of the agreement. The purpose of the preamble is to provide assistance in the interpretation of terms, and help in resolving conflicting interpretations of provisions. It also gives insight into why the agreement was negotiated and adopted. Sometimes the preamble serves as a section to place text on issues that cannot be resolved in the operational articles of the instrument. The Preamble of the Nagoya Protocol, amongst other, refers to the importance of providing legal certainty with respect to access and benefit-sharing, to the special nature of agricultural biodiversity, and to the fundamental role of the International Treaty on Plant Genetic Resources for Food and Agriculture, and the interrelationship between genetic resources and traditional knowledge.

Article 1. Objective

The protocol has as its objective the fair and equitable sharing of benefits resulting from the utilization of genetic resources. This objective can only be reached upon access to genetic resources by users. Unlike the CBD itself, this Protocol links benefit-sharing directly and explicitly to conservation of biological diversity. Benefits are supposed to be used for the sake of conservation.

Article 2. Use of terms (Definitions)

In this article three very important terms have been defined, i.e. utilization of genetic resources, biotechnology and derivative. Utilization of genetic resources means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the use of biotechnology. Biotechnology means any technological application that uses biological systems, living organisms, or naturally occurring compounds resulting from the expression or metabolism of biological or genetic resources, even in the absence of functional units of heredity (DNA/genes). A derivative has been defined as 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. The definition of utilization of genetic resources is thus wide, but excludes direct use of genetic resources for production purposes. The Nagoya Protocol does not apply to direct use. However, no DNA has to be present in a product for the Nagoya Protocol to apply, as long as such derivative has been obtained by making use of genetic or biological resources.

Article 3. Scope

The Protocol applies to genetic resources and to traditional knowledge associated with genetic resources. Naturally occurring biochemical compounds accessed independently of genetic resources fall outside the scope of the Protocol.

Article 4. Relationship with other agreements

This article recognizes that relevant ABS provisions also exist in a range of international instruments and processes outside the CBD. It comes from the notion that "one size does not fit all". Countries may negotiate and implement any new international instrument as long as such instrument is supportive of the CBD and this Protocol. The Protocol will not operate in situations where a specialized instrument applies that is consistent with the CBD and this Protocol.

Article 5. Fair and equitable benefit-sharing

Benefit-sharing is a separate set of requirements which may or may not be connected to access procedures. Utilization of genetic resources may take place long after having acquired these genetic resources, and benefit-sharing requirements would still apply. Negotiations towards MAT may take place along the PIC process, or may be negotiated later in time. The separate rights of indigenous and local communities are explicitly recognized. Rights on traditional knowledge rest with the communities holding such knowledge. This article expressly recognizes also that benefits may be monetary and non-monetary. Such options are presented in more detail in the Annex to the Protocol. Traditional knowledge does not have to be old to qualify as traditional. The term traditional refers to the context in which the knowledge was generated.

Article 6. Access to genetic resources

This article stipulates the rights and obligations of providers in regulating access to genetic resources. It reaffirms the sovereign rights of states over their natural resources. In comparison with the CBD, this article is much more concrete as to what providing countries are supposed to undertake in offering access procedures. This includes clarity about the manner, extent and procedure by which PIC should be obtained and how to agree on MAT. A Party should be prepared to provide written evidence of PIC to the user. Parties to the Protocol are not obliged to require PIC. However, users should assume that PIC is required unless expressly stated otherwise. Access to a natural resource for use of a commodity does not come under the Protocol.

The provider country is to be either the country of origin or the country that acquired the genetic resources in accordance with the CBD. Where species have become part of new ecosystems and habitats and have developed new distinctive properties, away from their original *in situ* conditions, the new country would be regarded as the country of origin.

Article 7. Access to traditional knowledge

This article regulates that Parties ensure that traditional knowledge is accessed with prior informed consent of the indigenous and local communities involved and that mutually agreed terms have been established. Obviously, this Protocol and article only cover traditional knowledge associated with genetic resources and held by indigenous and local communities. The access requirements apply regardless of how long ago the knowledge was generated by such communities, and irrespective how long the knowledge has been publicly available. The issue of rights associated with traditional knowledge is currently the subject of negotiations under the World Intellectual Property Organization, aiming at the effective protection of traditional knowledge.

Article 8. Special Considerations

This article addresses (1) non-commercial research; (2) emergency cases related to human, animal or plant health; and (3) genetic resources for food and agriculture. These issues should get the particular attention of the Parties to the Nagoya Protocol. (1) A special regime for non-commercial research remains controversial, since non-commercial research may develop into commercial research over time, and the results of the non-commercial research can be used for commercial applications. Any special arrangement allowing non-commercial research under simplified procedures is likely to require renegotiation of PIC and MAT in case of a later commercial intent. (2) Expeditious access and expeditious benefit-sharing can be taken into consideration by countries in case of emergencies, but there is no hard obligation. (3) This article, in combination with Article 4(4) suggests that PGRFA are waived from the provisions of the Nagoya Protocol, as far as they are listed in Annex 1 of the International Treaty and are used for food/feed uses. On-going work under the FAO Commission on GRFA addresses the question if other GRFA would also require specific ABS instruments, which would result in further exemptions from the working of the Protocol.

Article 9. Contribution to conservation and use

This article provides for measures to be taken by Parties to ensure that benefits deriving from utilization flow to efforts linked to the conservation and use of biodiversity. This may seem obvious, but it is not. The CBD itself has no similar provision, and the flow of benefits to those responsible for conservation has so far only be assumed.

Article 10. Global Multilateral Benefit-Sharing mechanism

A multilateral solution is suggested for situations in which compliance with ABS requirements is too complex from a political or practical point of view. Such situations include transboundary situations where a specific genetic resource occurs in several countries, in cases in which it is not possible to trace the country of origin of *ex situ* held materials, and in any other situations where no legal benefit-sharing obligations with a providing party exist but users nevertheless wish to share benefits. The article calls for a discussion between Parties about the desirability and feasibility of such multilateral mechanism. It is expected that the development and implementation of such mechanism will take several years.

Article 11. Transboundary cooperation

Biodiversity follows natural boundaries and not political borders. Genetic resources may have several countries of origin, and the same traditional knowledge associated with genetic resources may be held by different indigenous and local communities. Acknowledging this fact, through this article cooperation among countries of origin (being Parties) is promoted in implementing the objective of this Protocol.

Article 12. Traditional knowledge associated with genetic resources

This article contains some issues dealing with traditional knowledge not included in articles 5 (benefit-sharing), 7 (access) and 16 (compliance). It regulates that Parties shall take into consideration customary law and community protocols, and that Parties shall inform potential users of traditional knowledge about their obligations. It also requires Parties to help communities in developing minimum requirements for Mutually Agreed Terms and model contractual clauses. Finally, the article holds the obligation for Parties to not restrict the use and exchange of genetic resources and the associated traditional knowledge between indigenous and local communities themselves.

Article 13. National Focal Points and Competent National Authorities

Each Party is obliged to nominate a national focal point (NFP) on ABS. It is up to the Party to decide which institution will fulfil that role. The NFP is responsible to make information on ABS in the country available. It informs potential users about the applying ABS procedures. Each Party is also obliged to designate at least one competent national authority (CNA) on ABS. These functions may be combined. The NFP is to serve as a helpdesk or information hub in relation to applicants seeking access to genetic resources or to traditional knowledge, and to provide information on the CNA(s) and relevant indigenous and local communities. The NFP liaises with the CBD/Nagoya Protocol secretariat. The CNA is responsible for granting access and issuing written evidence thereof, and for advising applicants on how to fulfil PIC and MAT requirements. Contact details of NFPs and CNAs should be communicated with the CBD secretariat.

Article 14. The ABS Clearing House

The Access and Benefit-Sharing Clearing House is established as part of the CBD Clearing House Mechanism. It will involve a database on ABS information communicated by Parties to the CBD Secretariat. In particular, access information should allow providers and users to ascertain their rights and obligations before entering into any agreement or other relationship regarding the use of genetic resources and/or traditional knowledge associated to these. Information classified as confidential will not be communicated to the Clearing House.

Article 15 and 16. Compliance with domestic regulations or regulatory requirements

These innovative articles (15 on genetic resources and 16 on associated traditional knowledge) require that Parties take measures to provide that genetic resources utilized within their jurisdiction have been accessed in accordance with PIC and MAT requirements of the providing country, and if applicable the indigenous and local communities involved. Only cases of utilization within the jurisdiction of the Party are covered by this Article. When a user does not observe such providing country obligation, the Party where utilization takes place should take "appropriate, effective and proportionate" measures. In cases of alleged violation, Parties are supposed to co-operate.

Article 17. Monitoring utilization

Like 15 and 16, this article requires another active role of countries where genetic resources are used. It introduces two new elements, i.e. checkpoints and certificates of compliance. A Party must nominate at least one entity that is responsible for monitoring the (importation) and utilization of genetic resources. Such checkpoints would collect or receive relevant information regarding PIC, the source of a genetic resource, the establishment of MAT and the utilization of a specific genetic resource. Users would be obliged to provide such information, including the permit showing PIC from the providing country. Appropriate entities in the providing country would be informed. A permit in accordance with Article 6 (Access) and communicated to the Clearing House (Article 14) constitutes an internationally recognized certificate of compliance. A common format does not exist but may be developed in the future. International exchange of genetic resources listed in Annex 1 of the Treaty takes place under the Standard Material Transfer Agreement that in such cases is equivalent with a certificate of compliance. This article also states that the certificate of compliance should at least contain the following information: issuing authority, date of issuance, provider, unique certificate identifier, user to whom PIC was granted, subject matter, proof of MAT and PIC obtained and intended commercial and/or non-commercial use.

Article 18. Compliance with MAT

This article completes the set of provisions covering "user country measures". Mutually Agreed Terms normally take the form of a civil law contract. These are usually not dealt with through a public international law instrument such as the Nagoya Protocol. This article therefore encourages the contract parties agreeing on MAT to include provisions in MAT for dispute resolution, e.g. on applicable jurisdiction, applicable law, and alternative dispute resolution options.

Article 19 and 20. Model contractual clauses. Codes of conduct, guidelines and best practices and/or standards

Through promoting the use of model clauses, Article 19 aims to bring consistency in the way that access and use of genetic resources is being negotiated. Such consistency would help to bring more legal certainty to providers and users alike and would reduce transaction costs. Model clauses are supposed to be optional. The text of article 20 mirrors article 19, but adds the option that the Conference of the Parties may consider adoption of specific codes of conduct, guidelines and best practices and/or standards. Codes of conduct set out the rules for the members of an organization, such as the International Plant Exchange Network IPEN in which botanical gardens have been organized. Guidelines generally aim to promote particular approaches. Standards set out rules, guidelines or characteristics for products or related processes. For example, the Ethical BioTrade standard includes ABS requirements for companies working with natural ingredients.

Article 21 and 22. Awareness raising. Capacity building

Article 21 provides for a range of outreach measures to promote awareness of the core objectives of the Protocol. Such measures may involve promotion of the Protocol, capacity building of providers, including indigenous and local communities, and users, promotion of experiences and promotion of tools as mentioned in articles 19 and 20. Article 22 addresses capacity building in developing country Parties. Lack of capacity on the ABS issue has been a continuous concern for Parties and many stakeholders. Capacity building may concern a large number of aspects, including legal and institutional development, training to negotiate mutually agreed terms, development and use of valuation methods, bioprospecting studies.

Article 23. Technology Transfer, collaboration and cooperation

This article requires Parties to the Protocol to cooperate in technical and scientific research and development, including through technology transfer. It stresses implicitly the importance and value of non-monetary forms of benefit-sharing that may also be part of MAT between two private parties.

Articles 24 to 36. Articles overseeing the functioning of the Protocol

This set of articles regulates how the Protocol will be operationalized. The articles deal with non-parties, finance, decision-making, subsidiary bodies, secretariat, monitoring, compliance to the Protocol, review, signature, entry into force, reservations, withdrawal and authentic texts (read languages) of the Protocol. The Protocol will enter into force after the fiftieth ratification.

Annex

The Protocol contains an annex with non-exhaustive examples of monetary and non-monetary benefits.