



BACKGROUND

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THIS PAPER
WAS MADE IN
COOPERATION
WITH



THE NAGOYA PROTOCOL ON ACCESS AND BENEFIT SHARING (ABS) UNDER THE CONVENTION ON BIOLOGICAL DIVERSITY (CBD)

For a quick read

This background information covers the core provisions on the Nagoya Protocol that was adopted in 2010, and the building of effective national ABS systems. The Protocol puts the third objective of the CBD into practice and should prevent further biopiracy.

1) The Nagoya Protocol covers genetic resources as defined in Art. 2 of the CBD

- Meaning any material of biological origin containing functional hereditary material
- a) When used in research and development (but not for trade or food purposes)
 - Working on the genetic or biochemical composition of the material, including development of products and processes through biotechnology
- b) While Parties to the Protocol have to ensure that a benefit sharing does not only cover the benefits arising from research and development but also from commercialisation
- c) Parties to the Protocol may require a PIC (Prior Informed Consent) on access:
 - For genetic resources from areas under national jurisdiction
 - In case they are countries of origin
 - Including such genetic resources in ex-situ collections
(Parties are free to determine otherwise)
- d) Parties to the Protocol need to ensure that access to genetic resources of Indigenous Peoples and Local Communities is based on PIC (Prior Informed Consent) and benefit sharing will take place, but only covering benefits from research and development, not commercialisation;
 - On the condition that these groups have been granted the right to determine access to their genetic resources

2) The Nagoya Protocol covers traditional knowledge associated with genetic resources held by Indigenous Peoples and Local Communities

- a) Parties to the Protocol need to ensure that access to associated traditional knowledge is based on PIC and benefit sharing will take place (without defining traditional knowledge and its utilisation)

3) The Nagoya Protocol establishes a compliance system for genetic resources and associated knowledge

- a) Parties need to ensure that genetic resources and associated traditional knowledge utilized in the area under national jurisdiction have been accessed based on PIC (Prior Informed Consent) and MAT (Mutually Agreed Terms) as required by the provider country
- b) Supportive measures with regard to the utilisation of genetic resources include (associated traditional knowledge is not covered by these international requirements):
 - One or more effective checkpoints relevant to the entire product chain
 - The transformation of the national access permit – providing information on PIC (Prior Informed Consent), MAT (Mutually Agreed Terms), etc. – into an internationally recognised certificate of compliance through publication in the ABS Clearing House
- c) Parties need to support the fulfilment of MAT (Mutually Agreed Terms) through the possibility of legal recourses and access to justice for the foreign contract party



Devil's claw (*Harpagophytum procumbens*) is a traditional medicinal plant from South Africa and widely used in Europe to ease e. g. rheumatism

1. Introduction - A brief history

When the Convention on Biological Diversity (CBD) came into force in December 1993, it really was a newcomer in the arena of multilateral agreements. This was particularly true for the provisions of its Art. 15 establishing a set of principles and procedures to govern access to genetic resources and the fair and equitable sharing of the benefits arising from their utilisation (ABS). Art. 15 created three new international principles:

- » Recognition of the state's sovereignty over its genetic resources and thus of its right to determine the access to such resources,
- » Application of the concept of „Prior Informed Consent“ (PIC) as an access condition,
- » Bilateral negotiations between „providers“ and „users“ on „Mutually Agreed Terms“ (MAT) to determine conditions for utilisation, third party transfer and benefit sharing.

These provisions were created in a time period of competing visions and interests on how to use best genetic resources and traditional knowledge in combination with “modern, Western” technology and knowledge to support the protection and sustainable use of biodiversity.

Many experts in the 1980s propagated the use of national biodiversity and related traditional knowledge of Indigenous Peoples and Local Communities in developing countries as an abundant and cheap resource to foster the creation of domestic industries to make the country more independent of, for example, imports of expensive drugs from the North. Others created the model of a market-based transfer mechanism that would facilitate the exchange of genetic resources from developing countries with technologies from developed countries. The latter model was predominantly used during the negotiations of the CBD, because of its promise of a quick and easy path to development and industrialisation and the increasing popularity of market-based policy approached at that time. The narrative of the genetic resources from jungles that are transformed into „green gold“ by pharmaceutical companies illustrates the situation when the CBD was adopted in 1992 at the UN Conference on Environment and Development (UNCED).

But these technological promises were also met with reservations by developing countries because they were intrinsically linked with demands of northern countries to strengthen intellectual property rights (IPR) referring to genetic resources, genetic technologies and associated traditional knowledge. Despite some resistance of developing countries, a strong and global IPR system also covering the fields of agriculture and medicines was adopted in 1994: the TRIPS-Agreement of the World Trade Organization focussing on Trade Related Aspects of Intellectual Property Rights. Important elements connected with the use of genetic resources, and thus the protection and sustainable use of biodiversity, ultimately left the environment arena and from that time on were integrated in a regulatory framework following the free trade agenda. The proponents of this free trade agenda predominantly pushed the argument of mutual supportiveness between the CBD and the TRIPS-Agreement. It was in the same year, in 1994, when the expression „biopiracy“ was coined in an UNDP report written by the U.S.-Canadian NGO RAFI as response to the develop-

ment of several „bioprospecting“ models by experts from the USA that had just declined to ratify the CBD. But, as history shows, it can be a long and hard path from recognising the problems associated with biopiracy and agreeing on solutions to solve these problems.

What does biopiracy and benefit sharing mean?

Based on the CBD provisions, biopiracy is the utilisation of genetic resources and associated traditional knowledge without the prior informed consent of the provider, who may be Indigenous Peoples or governmental authorities. With respect to the rights of Indigenous Peoples, it is argued that biopiracy also comprises cases in which genetic resources and associated knowledge are accessed and utilised by others when the traditional users and custodians do not have the legal ownership over their resources and when governmental access rules do not recognize their right to determine on access. In a legally adequate language, biopiracy is called “misappropriation” in cases when an action takes place without prior informed consent, and “misuse”, when a user does not comply with the mutually agreed terms. Benefit sharing in the context of ABS rules needs to go beyond paying the market price for goods or services, it is not paying wages for harvesting or collecting plants. Benefit sharing must be based on mutually agreed terms and should award and support Indigenous Peoples, Local Communities and governmental authorities to protect and sustainably use biodiversity.

The 1991 agreement between the U.S. pharmaceutical company Merck and the Costa Rican para-statal institution InBIO brought both technologies for institutional development and some money for governmental conservation tasks, and for many years served as a flagship project in the northern political discussion on access and benefit sharing. While InBIO - also due to the several bioprospection contracts it has concluded - developed into a leading scientific institution in its region, the failure in terms of bringing larger amounts of money for biodiversity conservation is part of the general picture. A series of bioprospecting projects brought only limited amounts of monetary and non-monetary benefits to the provider communities and countries, mainly due to the lack of commercialised products or poor contractual control over the full chain of utilisation and commercialisation. It is without doubt that very large amounts of money are made with the commercialisation of industrial products based on the utilisation of genetic resources and associated traditional knowledge. It seems that the many projects and the existing national ABS-legislations in provider countries concentrate too much on access rules covering the initial research and development phases of realising the optional values of genetic resources instead of tapping the benefits from the current use of genetic resources, showing the actual value of commercialised genetic resources. What is lacking also, almost 20 years after the adoption of the CBD, is ABS-legislation in user countries that concentrates on end-of-pipe user measures guaranteeing the benefit sharing from successfully commercialised genetic resources.

2. The Nagoya Protocol on ABS – Some General Remarks

Dichotomy of „provider“ and „user“ countries

During the negotiation of the Nagoya Protocol on ABS the strict dichotomy of „provider“ and „user“ countries as well as the strict adherence to the North-South exchange model were loosened with regard to the fact that

many countries are providers and users at the same time and can benefit internally from a fair system that also governs domestic ABS situations. In the course of negotiations, especially emerging economies became aware of the fact that keeping a mere provider perspective could not match their present or future interests. Furthermore, it is obvious that any ABS system had to capture two categories of economic value of genetic resources and associated traditional knowledge:

- » Optional economic value: new access and utilisation have to come with ABS agreements
- » Realised economic value: ongoing utilisation based on earlier unregulated access has to come under a benefit-sharing agreement

Different products out of genetic resources

Several sectors are typical users of genetic resources and associated traditional knowledge in research and development as well as in commercialisation. One group of products is based on the utilisation of the biochemical compounds contained in the genetic resource and the creation of added values, i.e. by providing for specific health benefits and medical cures:

- » Phytopharmaceuticals, based on complex plant extracts
- » Pharmaceuticals, based on single active ingredients
- » Cosmetics, based on natural extracts or using specific natural compounds
- » Nutraceuticals, based on natural extracts or using specific natural compounds

A second group of products is based on the utilisation of the genes contained in genetic resources or their proteins, developed through biotechnology, and often also through the application of genetic engineering, i.e.:

- » Enzymes for industrial, processing or household utilisation, produced by optimised or genetically engineered micro-organisms, using specific genes from natural sources
- » Organisms under the scope of the CBD and their genes used for breeding purposes

Link between the ABS system, natural resource management (NRM) and conservation

When implementing the Nagoya Protocol and building effective national ABS systems, strong linkages will need to be created between the ABS system, natural resource management (NRM), and conservation policies. It is already now that the strong interlinkage of ABS rules and land rights is stressed by Indigenous Peoples living in protected areas who in many cases see the activities of governmental or private institutions ruling over access to genetic resources in these areas as a threat to their traditional rights. Such linkages and integrations responding to the rights of Indigenous Peoples will not only lead to a more holistic implementation of the CBD but also to a better balance between the needs and interests of Indigenous Peoples and Local Communities vis-à-vis the aims of conservation and sustainable use policies. In the end they might create additional financial means for the conservation of biological diversity. ABS and NRM can, in many cases, be combined in a synergistic way, for example for all of those genetic resources that are collected/harvested on an annual basis and are utilised in high-value adding production chains. In this context, the creation of ABS certification schemes involving the (private) partners in the production chain in analogy to the „fair trade“ schemes may create a promising opportunity – provided the benefit sharing part is strictly separated from other areas where money is transferred, be it e.g. wages or harvesting technology. Moreover, in the context of conservation and sustainable use policies, the recipients of benefits out of ABS agreements can be many and others who are directly connected with collecting, cultivating or harvesting. For example, following the CBD bilateral approach benefiting the original provider, apart from collecting, cultivating and harvesting there can be linkages with Indigenous Peoples or Local Communities with authorities or initiatives conducting measures for the conservation of biological diversity and its sustainable use. Or, especially in cases where it is not possible to identify a specific provider, the benefit sharing will be to arrange with public funds managed by competent authorities.

3. The Nagoya Protocol - Core provisions

Any analysis of the Nagoya Protocol has to deal with the fact that only some of its operational provisions were agreed upon by all Parties during the usual, transparent, and inclusive negotiation process of the CBD.

Many of the core operational provisions could only be finalised in closed-door meetings between a few countries on the last day of COP10 in October 2010 in Nagoya. As a consequence, the text of the protocol lacks coherence and leaves considerable space for interpretation. In this context, it is important to take note of the fact that in many parts, the Nagoya Protocol sets minimum standards that do not hinder either parties or non-parties to opt for more effective rules and measures. At the end of the day, the question will be: "Is there still biopiracy or not?"

OBJECTIVE

Art. 1 The objective of this Protocol is the fair and equitable sharing of the benefits arising from the utilization of genetic resources, including appropriate access to genetic resources and appropriate transfer of relevant technologies, taking into account all rights over those resources and technologies, and by appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components.

The objective of the Nagoya Protocol was one of the few articles drafted with final wording before the last day of the ABS-negotiations. Four issues were debated intensively:

- » If and how to reflect the wording of CBD Article 15 2. „facilitate access“ for „environmentally sound uses“
- » If and how to reflect issues of compliance with international and national rules
- » If and how to reflect the prevention of misappropriation and misuse of genetic resources and associated traditional knowledge
- » If and how to reflect the topics associated with traditional knowledge, role and rights of Indigenous Peoples and Local Communities and specifically the UN Declaration on the Rights of Indigenous Peoples (UNDRIP).

During the negotiations, it was decided to drop the notion that the Nagoya Protocol needs to create conditions to „facilitate“ access mainly because the underlying CBD Art. 15 2. refers to national access legislation. Negotiators resorted to the wording of CBD Art. 1 that prescribes „appropriate“ access as requirement under international law. This decision was a breakthrough for a central demand of developing countries, because the expression “facilitating” access was always connected with the notion of lowest possible standards and paving the way for multinational companies. As a kind of compensation, the deal was that the task given by Art. 15 to ensure „environmentally sound uses“ of the accessed genetic resources was also kept out of the Nagoya Protocol. A draft paragraph on linking Environmental Impact Assessments with ABS issues that had been inserted by The African Group was deleted in the final closed-door meetings.

This early decision also included that the article dealing with the objective of the protocol did not tackle the controversial discussion on international compliance and the prevention of biopiracy - in legal wording, „misappropriation and misuse“. Surprisingly, any reference to associated traditional knowledge and the UN Declaration on the Rights of Indigenous Peoples UNDRIP was deleted, despite the fact that the Kuala Lumpur mandate to negotiate the ABS Protocol explicitly included associated traditional knowledge and, in fulfilling this task, that the negotiators had already developed a basic understanding on how to reflect the UNDRIP in the objectives.

SCOPE

Article 2 The terms defined in Article 2 of the Convention shall apply to this Protocol. In addition, for the purposes of this Protocol: [...] (c) "Utilization of genetic resources" means 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.

The scope of the Nagoya Protocol could only be agreed upon in the final closed-door meetings. The consensus focuses on CBD provisions and the Kuala Lumpur mandate, while six of the seven major scope controversies listed below were shifted to other articles:

- » Geographic scope: if and how to deal with ABS issues related to genetic resources accessed in areas beyond national jurisdiction
- » Temporal scope I: if and how the benefit sharing provisions apply to the ongoing and new utilisation of genetic resources and associated traditional knowledge accessed between the entry into force of the CBD in 1993 and the entry into force of the Nagoya Protocol
- » Temporal scope II: if and how to address the utilisation of genetic resources and associated traditional knowledge accessed before the entry into force of the CBD
- » Physical scope: if the term "utilisation of genetic resources" would only cover the use of genes („functional units of heredity“) contained in the genetic resources, or if the rules would also apply in cases where the biochemical components, (which the genetic resource may also contain,) would be used
- » Political scope I: if and how to deal with genetic resources that are meant to be traded and used as commodities when they are accessed for research and development purposes (e.g. Roibos tea imported for consumption, but used for research purposes)
- » Political scope II: if and to cover how ex-situ collections (e.g. botanical gardens)
- » Political scope III: if and how to allow for sectoral approaches that may establish separate international ABS rules in specific fora as the FAO (e.g. animal genetic resources for food and agriculture) or WHO (e.g. pathogenic genetic resources for vaccine development).

Regarding the geographical scope, Art. 3 stipulates that the Nagoya Protocol applies to genetic resources within the scope of CBD Art. 15. This decision clarifies the geographic scope because CBD Art. 15 covers the area under national jurisdiction of the Parties, thus reflecting the position of developed countries. The alternative, CBD Art. 4(b), also covering areas beyond national jurisdiction, was supported by developing countries.

While it was accepted that access cannot be regulated retrospectively, developing countries insisted that according to the Vienna Convention on the Law of Treaties Art. 28 the continued use of genetic resources and associated traditional knowledge accessed between 1993 and the entry into force of the Nagoya Protocol is covered by its benefit sharing provisions. All issues related to temporal scope are dealt with indirectly in Art. 5 and 6, finally aiming at rejecting the positions of developing countries. Developed countries have a clear understanding that the provisions of the Nagoya Protocol only apply to future activities, i.e. after its entry into force. But, nevertheless, there is a discussion in developing countries that favours a more flexible interpretation of the Nagoya Protocol.

Art. 6.1 In the exercise of sovereign rights over natural resources, and subject to domestic access and benefit-sharing legislation or regulatory requirements, access to genetic resources for their utilization shall be subject to the prior informed consent of the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention, unless otherwise determined by that Party.

2. In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that the prior informed consent or approval and involvement of indigenous and local communities is obtained for access to genetic resources where they have the established right to grant access to such resources.

Art. 7 In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that traditional knowledge associated with genetic resources that is held by indigenous and local communities is accessed with the prior and informed consent or approval and involvement of these indigenous and local communities, and that mutually agreed terms have been established.

The physical scope was solved through the definition of „utilisation of genetic resources“ (i.e. “conduct research and development”) that makes the ABS rules applicable for the utilisation of the genes as well as the biochemicals contained in the genetic resource. This provision secures that the main source of benefits - the utilisation of biochemical compounds for e.g. drugs or cosmetics - is covered by the ABS protocol. Art. 2 also indirectly clarifies the issue of commodities and ABS rules. The Nagoya Protocol applies to research and development activities using genetic resources, which includes commodities if they are genetic resources and are used for research and development. Any utilisation of genetic resources in terms of research and development, including commodities, in the understanding of the Protocol without a PIC of the country of origin would contravene the treaty. The successful implementation of this provision depends on the effectiveness of the tracking and monitoring system. The issue on the inclusion of ex-situ collections is indirectly and partly addressed in Art. 5.1 when using the wording that benefit sharing shall take place with the „Party providing such resources“. According to CBD Art. 2, these resources can be „taken from ex-situ sources, which may or may not have originated in that country“. Even when Art. 5.1 of the Nagoya Protocol restricts its application to resources from ex-situ collections that occur in-situ in the country, it also notes the right of Parties to determine otherwise.

Art. 4.1 and 8 provide for the possibility of creating international (e.g. the WHO Pandemic Influenza Preparedness (PIP) Framework adopted in 2011) or national (e.g. simplified measures on access for non-commercial research) sectoral approaches, being one of the major demands of developed countries.

ACCESS

The access provisions of Art. 6 and 7 of the Nagoya Protocol cover three cases:

- » Access to genetic resources
- » Access to genetic resources of indigenous and Local Communities
- » Associated traditional knowledge held by indigenous and Local Communities

Art. 6.1 refers to the provisions of CBD Art. 15.3 with the effect that genetic resources can only be accessed in those Parties which are also the country of origin of this resource or which have acquired the genetic resource in accordance with the CBD. Access to a genetic resource in a country to which it has been brought (maybe also illegally) from its country of origin would be in contradiction to the Nagoya Protocol. Art. 6.1 finally leaves it to the Parties to adopt national access legislation that rules otherwise, recognising the stated intention of some European countries to allow access without PIC.

Art. 6.3 contains a set of international access standards. These standards were introduced by developed countries and strongly objected by developing countries as „CBD-plus“ conditions interfering with the sovereign rights of states to determine access legislation. Finally, negotiators agreed that these standards should be regarded as „tools to encourage compliance“. Negotiators agreed on most of the provisions before the final session but the issue of whether the Nagoya Protocol should adopt „WTO-language“ and call for „non-discriminatory“ access rules or if it should use general legal language stating that the rules must be „non-arbitrary“. The latter provision was chosen in the last closed-door session and reflects the position of developing countries.

BENEFIT SHARING

Art. 5.1 In accordance with Article 15, paragraphs 3 and 7 of the Convention, benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization shall be shared in a fair and equitable way with the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention. Such sharing shall be upon mutually agreed terms.

2. Each Party shall take legislative, administrative or policy measures, as appropriate, with the aim of ensuring that benefits arising from the utilization of genetic resources that are held by indigenous and local communities, in accordance with domestic legislation regarding the established rights of these indigenous and local communities over these genetic resources, are shared in a fair and equitable way with the communities concerned, based on mutually agreed terms. [...]

5. Each Party shall take legislative, administrative or policy measures as appropriate, in order that the benefits arising from the utilization of traditional knowledge associated with genetic resources are shared in a fair and equitable way with indigenous and local communities holding such knowledge. Such sharing shall be upon mutually agreed terms.

The benefit sharing provisions of the Nagoya Protocol cover three cases:

- » Utilisation of genetic resources as well as subsequent applications and commercialisation
- » Utilisation of genetic resources held by Indigenous Peoples and Local Communities
- » Utilisation of associated traditional knowledge held by Indigenous Peoples and Local Communities

Art. 5.1 prescribes that the benefits to be shared are not only arising from the research and development phase (defined as „utilisation“) but also from „subsequent applications and commercialization“ This provision guarantees that the main phase of the creation of benefits based on the utilisation of genetic resources, the commercialisation phase, can be covered by ABS agreements. In connection with Art. 2, the benefits arising from the utilisation of the biochemical compounds derived from the accessed genetic resource will also fall under ABS agreements. This provision reflects the demands of developing countries. A matter of concern is that the obligation of Art. 5.1 to share the benefits arising from commercialisation as the most lucrative phase in the product development chain is lacking in Art. 5.2 dealing with genetic resources of Indigenous Peoples and Local Communities. This obvious discrimination could be a result of the low level consolidation of the legal text and needs to be rectified in national ABS legislation.

In contrast to these new and broad provisions, the temporal scope as defined in Art. 5.1 mainly reflects the position of developed countries arguing for a scope of the Nagoya Protocol to be as narrow as possible. The obligation to share benefits arising from the utilisation of genetic resources only seems to apply when the resources were accessed in a Party to the Protocol, meaning after the entry into force of the Protocol. Developed countries dispute that benefits arising from the continued use of resources that have been accessed before the entry into force of the Protocol are covered by the international rules. However, in connection with Art. 4 4., which says that the Nagoya Protocol is the instrument for the implementation of the ABS provisions of the Convention, this position seems not to be too strong. In this regard, it should be remembered that the trigger for benefit sharing is not access to the genetic resource itself, but its utilisation (by research and development) and commercialisation.

It is important to note that the Nagoya Protocol through its provisions in Art. 5.2 and 5.5 sets new international standards and opens a window for the implementation of UNDRIP. While the CBD aims at integrating global environmental and sustainability objectives, the Nagoya Protocol adds a linkage to justice and human rights objectives. While it is the UNDRIP that recognises the rights of Indigenous Peoples over their genetic resources and traditional knowledge as international standards, the Nagoya Protocol obliges its Parties to ensure through national regulation that PIC is sought by users and benefits are shared. One condition is that the ownership rights over their genetic resources have been granted to Indigenous Peoples and Local Communities before, otherwise it would be still the role of the State to determine on access according to the CBD.

ASSOCIATED TRADITIONAL KNOWLEDGE

The Nagoya Protocol provides for new obligations towards Indigenous Peoples and Local Communities to determine over access to their genetic resources and associated traditional knowledge and negotiate terms of benefit sharing. The finally successful creation of a tandem approach - adopting specific provisions as well as enlarging the applicability of the CBD principles of PIC and MAT - was based on three factors:

- » The 2004 Kuala Lumpur mandate
- » The 2007 UNDRIP
- » The continuous and strong participation of representatives of ILC through the recognition of the International Indigenous Forum on Biodiversity as an advisory body to the CBD and the allowance of contributions on the text under negotiation, if supported by a Party

Up until the last rounds of negotiations, negotiators debated whether the ILC-related provisions of the Nagoya Protocol should be subjected to national law, meaning that governments have full description in applying them or not, or if the provisions actually pose obligations on the Parties. Parties in the end agreed that the provisions related to Indigenous Peoples and Local Communities should have a certain degree of autonomy but need to be „in accordance with domestic legislation“. While Art. 5, 6, and 7 prescribe certain ABS-standards, the legal capacity of Indigenous Peoples and Local Communities to make use of them depends on domestic legislation that gives them (back) the ownership rights over their genetic resources and associated traditional knowledge. Those developed countries opposing this step forward with regard to CBD Art. 8j could only agree when the corresponding compliance provisions were dropped from the text.

Art. 12 specifically deals with associated traditional knowledge. This article was deemed necessary to suggest tools and mechanisms important for the national implementation of the provisions related to Indigenous Peoples and Local Communities. The Nagoya Protocol does not give any explanations or definition what traditional knowledge means. This task is in the hands of national governments and Indigenous Peoples and Local Communities, additionally there are negotiations for an international understanding on the nature of traditional knowledge in the context of the World Intellectual Property Organisation (WIPO).

The Nagoya Protocol also applies its bilateral approach to issues related to Indigenous Peoples and Local Communities. PIC and benefit sharing through MAT is always coupled with those Indigenous Peoples and Local Communities which are the rightful holder of the genetic resource or associated traditional knowledge. This approach and the possible implications on Intellectual Property Rights was the reason for developed countries to categorically reject the demand of India and China to bring associated traditional knowledge under the Nagoya Protocol that is publically available, but can no longer be tracked back to certain Indigenous Peoples and Local Communities. The quoted examples were the Indian ayurvedic and the Chinese traditional medicine whose body of knowledge is publicly available and used by many domestic and foreign commercial users. With the deletion of this proposal from the Protocol text the implications on the application of ABS rules regarding the publishing of information on genetic resources and associated traditional knowledge in scientific journals or patent applications have been avoided.

COMPLIANCE

Art. 18.2 Each Party shall ensure that an opportunity to seek recourse is available under their legal systems, consistent with applicable jurisdictional requirements, in cases of disputes arising from mutually agreed terms.

3. Each Party shall take effective measures, as appropriate, regarding:
(a) Access to justice; and
(b) The utilization of mechanisms regarding mutual recognition and enforcement of foreign judgments and arbitral awards.

Each Party to the Nagoya Protocol is, in accordance with Art. 15 and 16, required to take „appropriate, effective and proportionate legislative, administrative or policy measures“ to ensure compliance of providers and users with its national ABS system. If Parties were to fail, the case could be brought to the compliance mechanism of the Nagoya Protocol according to Art. 30. The 1st meeting of the Parties shall „consider and approve cooperative procedures and institutional mechanisms“ in this regard. Art. 18 also obliges Parties to ensure that disputes arising on the basis of private ABS agreements between users and providers can be brought to the national judicial system.

While these three articles focus on compliance with national ABS systems, the issue of international compliance rules was regarded by observers and developing countries as the major issue for the ABS negotiations, not least because the CBD Art. 15 does not provide for such rules. Cross-border compliance standards are of crucial importance in any multilateral agreement. In the case of ABS it is especially important because countries have the capacity to adopt, implement and monitor ABS rules and prosecute breaches in their own country, but have no control over compliance of foreign users when the genetic resource or the traditional knowledge have left the providing country. Art. 18 contains provisions that support the solution of cross-border disputes between the contracting parties.

Major controversies remained until the end of the negotiations on the question of which mechanisms should be built up to enable the governments and privately contracted parties to monitor the fate of the utilisation of specific genetic resources and how to be able to detect possible breaches of legal and contract provisions. While developing countries favoured a concrete list of institutions, including intellectual property (IP) offices, as checkpoints controlling the compliance with the provisions of the protocol regarding PIC and MAT, developed countries strictly opposed such detailed obligations. Especially the naming of IP offices was rejected categorically because, according to the argument, the Nagoya Protocol would not be in a position to intervene in the rules and proceedings governing the system of Intellectual Property Rights. The negotiators could finally agree on the provision in Art. 17.1(a) (iv) that „checkpoints must be effective and should have functions relevant to implementation of this subparagraph (a). They should be relevant to the utilisation of genetic resources, or to the collection of relevant information at, inter alia, any stage of research, development, innovation, pre-commercialization or commercialization.“ Art. 17 also establishes the „internationally recognized certificate of compliance“ to show that a genetic resource has been accessed with PIC and following the national requirements on MAT. Developing countries demanded that checkpoints and certificates were meant as an instrument dedicated to control the use of genetic resources and associated traditional knowledge. Due to the pressure of developed countries, their role was limited to monitoring and enhancing transparency of the utilisation of genetic resources. Moreover, regarding the certificate, Art. 17 4. contains a list of nine minimum information items that ironically can all be kept confidential, even including the name of the issuing authority or the unique identifier of the certificate. In the end, the Nagoya Protocol only obliges its Party to announce the mere fact that an access permit had been issued without revealing any further information.

Apart from these obvious deficits in the effectiveness of the international system which should support the monitoring of the utilisation of genetic resources, its major shortcoming is that it does not cover associated traditional knowledge of Indigenous Peoples and Local Communities. The attempt to at least partially rectify these deficits remains to be a major challenge in the creation of national ABS systems.

Art. 8 In the development and implementation of its access and benefit-sharing legislation or regulatory requirements, each Party shall:
(a) Create conditions to promote and encourage research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries, including through simplified measures on access for non-commercial research purposes, taking into account the need to address a change of intent for such research

Art. 9 The Parties shall encourage users and providers to direct benefits arising from the utilization of genetic resources towards the conservation of biological diversity and the sustainable use of its components.

NON-COMMERCIAL RESEARCH

Simplified access rules for non-commercial research were first debated in the context of „facilitated“ access under scope. While there was agreement on the importance of non-commercial research for reaching the CBD objectives, developing countries were concerned that through such „facilitated“ access genetic resources could be introduced into commercial research and applications without appropriate ABS-agreements and notification of the first provider. After having agreed that the scope of the Protocol is on „appropriate“ access and reconfirming in Art. 6.1 that legislation on access to genetic resources stays a matter of national sovereignty, negotiators could agree on a provision that requires Parties to include „simplified access measures“ for non-commercial research in their national ABS legislation. National legislation should also include provisions that deal with a „change of intent“ for such research, meaning the transformation of non-commercial into commercial research.

CONTRIBUTION TO CONSERVATION AND SUSTAINABLE USE

The issue of using the benefits for financing measures to protect and sustain biological diversity is one of the central themes of the CBD itself. While Article 9 deals with this central linkage of the three CBD-aims, the language is rather weak. Art. 9 does not oblige Parties to secure the realisation of this linkage but to encourage the negotiating partners of each ABS agreement to include such provisions in their private contract.



Ginger (*Amomum elephatorum*) is used in traditional Chinese medicine

4. More work to do!

The entry into force of the Protocol is foreseen for 2015. Already this brief overview about the Nagoya Protocol shows that all its Parties need to work intensely in the

next years to implement its provisions and to build appropriate national ABS-systems. A first major task for developing countries is to either develop new or adapt existing ABS legislation that serves the interests of the country and the holders of rights over genetic resources and traditional knowledge. The interests of many stakeholders from research and industry will also play an important role in that process. Almost all provisions of the Nagoya Protocol leave the door open for flexibility - or inactivity - in that legislative process: terms as “as appropriate” can be found throughout the whole document, many articles only set up principles or call for certain actions but the text had been left silent deliberately with regard to procedures or actual content.

Developing countries should not limit their sovereign rights over their genetic resources, i.e. implement the CBD provision linking the decision on granting access to the environmentally sound use of the genetic resource. The provisions on access in Art. 6 are mostly procedural but not about substantive issues at the national level. Parties should specifically deal with the provisions of Art. 8 when develop their national ABS systems, advising on issues as biodiversity-related research, health emergency situations and food security. Art. 8 does not eliminated the need for PIC and MAT, any access should be linked to a clear commitment and obligation for benefit sharing.

Developing countries should only ratify the Protocol when the main user countries themselves have done so to avoid situations of imbalance and asynchronicity. Developing countries could also use the opportunities given by PIC and MAT to accelerate the rate of implementation of the Nagoya Protocol in the countries of foreign users. Access could only be granted to users operating in Parties that have implemented strong and effective access and benefit sharing legislation. This includes access to justice of the user country in cases of misappropriation and misuse, a commitment of the use country to prevent new utilisation and commercialisation of genetic resources acquired without PIC, or the existence of an effective checkpoint system covering the entire product chain.

Effective user measures could also include awareness raising amongst users about issues of third party use, including the obligation to apply for a new PIC in cases of new uses of the genetic resource, meaning uses going beyond those agreed upon in the MAT. Developing countries could also consider, to amend export licences of raw materials by a commitment of the exporter to advise importers on the fact that utilisation (in the sense of research and development) of these materials would require PIC and MAT.

With regard to the rights of Indigenous Peoples and Local Communities to determine about access to their genetic resources and associated traditional knowledge it remains to be stated that an effective implementation of these aspects contained in the UNDRIP through the implementation of the Nagoya Protocol needs new or a change of existing national legislation. It needs to be assured in national law that Indigenous Peoples and Local Communities have the legal right to determine on ABS issues, especially on PIC and MAT. Resolving land tenure conflicts will be crucial for ABS issues, especially in regions where communal management systems prevail. In cases where the same resource or knowledge is hold by two or more groups, support for collaboration and, in case, dispute settlement, might be important.

Major international ABS-related provisions and decisions

1992 CBD Article 15. Access to Genetic Resources

1. Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.
2. Each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention.
3. For the purpose of this Convention, the genetic resources being provided by a Contracting Party, as referred to in this Article and Articles 16 and 19, are only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention.
4. Access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article.
5. Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.
6. Each Contracting Party shall endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties.
7. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 20 and 21 with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms.

1992 CBD Article 8. In-situ Conservation

Each Contracting Party shall, as far as possible and as appropriate: [...]

(j) Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices;

1992 CBD Article 2. Use of Terms

For the purposes of this Convention:

„Genetic material“ means any material of plant, animal, microbial or other origin containing functional units of heredity.

„Genetic resources“ means genetic material of actual or potential value.

1992 CBD Article 2. Use of Terms

„Country of origin of genetic resources“ means the country which possesses those genetic resources in in-situ conditions.

„In-situ conditions“ means conditions where genetic resources exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties.

„Habitat“ means the place or type of site where an organism or population naturally occurs.

„Country providing genetic resources“ means the country supplying genetic resources collected from in-situ sources, including populations of both wild and domesticated species, or taken from ex-situ sources, which may or may not have originated in that country.

2002 Plan of Implementation of the World Summit on Sustainable Development

44 [...] The Convention is the key instrument for the conservation and sustainable use of biological diversity and the fair and equitable sharing of benefits arising from use of genetic resources. A more efficient and coherent implementation of the three objectives of the Convention and the achievement by 2010 of a significant reduction in the current rate of loss of biological diversity will require the provision of new and additional financial and technical resources to developing countries, and includes actions at all levels to: [...]

(o) Negotiate within the framework of the Convention on Biological Diversity, bearing in mind the Bonn Guidelines, an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources;

2004 CBD COP 7 Decision VII/19

D. International regime on access to genetic resources and benefit-sharing

The Conference of the Parties, [...]

1. Decides to mandate the Ad Hoc Open-ended Working Group on Access and Benefit-sharing with the collaboration of the Ad Hoc Open ended Inter-Sessional Working Group on Article 8(j) and Related Provisions, ensuring the participation of indigenous and local communities, non-Governmental organizations, industry and scientific and academic institutions, as well as intergovernmental organizations, to elaborate and negotiate an international regime on access to genetic resources and benefit-sharing with the aim of adopting an instrument\instruments to effectively implement the provisions in Article 15 and Article 8(j) of the Convention and the three objectives of the Convention;

2007 United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP)

Art. 31 1. Indigenous peoples have the right to maintain, control, protect and develop their cultural heritage, traditional knowledge and traditional cultural expressions, as well as the manifestations of their sciences, technologies and cultures, including human and genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures, designs, sports and traditional games and visual and performing arts. They also have the right to maintain, control, protect and develop their intellectual property over such cultural heritage, traditional knowledge, and traditional cultural expressions.

2. In conjunction with indigenous peoples, States shall take effective measures to recognize and protect the exercise of these rights.

Visit the CBD website for more information: <http://www.cbd.int/abs/>

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