

# Nagoya Protocol on Access and Benefit Sharing - Technical Brief

The Nagoya Protocol on access and benefit sharing is a landmark in the international governance of biodiversity. The Convention on Biological Diversity (CBD) had already established the fair and equitable sharing of benefits as one of its main objectives, and also outlined basic principles such as prior informed consent and mutually agreed terms. Yet these principles remained largely unimplemented, with a range of difficulties and different views on ways of overcoming them. With the Nagoya Protocol, the fair and equitable sharing of benefits has been reaffirmed as a fundamental component of biodiversity strategies. In addition, a set of rules has been agreed upon to facilitate, promote and ensure its effective implementation.

For business, particularly companies using biodiversity as the source and inspiration for innovative ingredients for food and personal care products, the Nagoya Protocol will mean growing calls for measures to consider and put in practice fair and equitable benefit sharing. The Nagoya Protocol now clearly encompasses research and development to identify new bioactive compounds and natural ingredients for food, supplement and cosmetics products. The Nagoya Protocol also foresees mechanisms that will facilitate and control the implementation of access and benefit sharing principles along the supply chain. As a result, the Nagoya Protocol reasserts the need for companies to monitor, understand and comply with access and benefit sharing requirements. In addition, by providing a clearer and more level playing field, it also opens up opportunities for companies already working towards ethical practices in their sourcing of biodiversity.

The objective of this note is to provide a brief overview of the Nagoya Protocol. In particular, this note focuses on the provisions that may have a bearing on companies working with biodiversity-based ingredients in the food and personal care sectors, and explains their relevance and rationale. It should be kept in mind, however, that the Nagoya Protocol is only a starting point. A lot of the meaning and practical consequences of its provisions will depend on its further development in the context of the CBD, as well as its implementation at the national level.

## What is the Nagoya Protocol on access and benefit sharing?

The “Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization” (Nagoya Protocol) is an international instrument adopted in October 2010 under the CBD (see box 1). Its objective is the fair and equitable sharing of the benefits arising from the utilization of genetic resources, thereby contributing to the conservation and sustainable use of biodiversity. To advance fair and equitable benefit sharing, the Nagoya Protocol also addresses appropriate access to genetic resources and transfer of relevant technologies.

### Box 1. The Nagoya Protocol and the Convention on Biological Diversity (CBD)

The Nagoya Protocol was adopted under the auspices of the Convention on Biological Diversity (CBD). As a protocol to the CBD, the Nagoya Protocol is the instrument for the implementation of the access and benefit sharing provisions of the CBD. In this regard, the CBD provides the substantive, institutional and procedural basis for the Nagoya Protocol. For example, the scope of the Nagoya Protocol is defined by the scope of access and benefit sharing provisions of the CBD. Moreover, institutional arrangements such as dispute settlement mechanisms and secretariat services for the Nagoya Protocol will also be those already established under the CBD.

Nevertheless, the Nagoya Protocol is a new and separate international instrument. Countries need to sign and ratify the Nagoya Protocol for it to enter into force. The Nagoya Protocol will only be legally binding for the countries that do sign and ratify it. In addition, only countries that have signed and ratified the CBD are able to sign the Nagoya Protocol. In other words, countries such as the United States, which has not ratified the CBD, cannot sign or ratify the Nagoya Protocol. Countries that have signed and ratified the CBD, say Armenia or Finland, can choose to sign and ratify or not - in this latter case, countries would remain bound only by the overarching CBD provisions on access and benefit sharing. Finally, countries that sign and ratify the Nagoya Protocol will need to implement it through national legislation.

The Nagoya Protocol will open for signatures on 1 February 2011, for one year, and enter into force 90 days after the 50th ratification.

# Nagoya Protocol on Access and Benefit Sharing

## Technical Brief

### The main provisions of the Nagoya Protocol include:

- ✓ A definition of the objective, use of terms, scope and relationship with other international instruments of the Nagoya Protocol;
- ✓ Elaboration on the principles and main requirements on the fair and equitable sharing of benefits and access to genetic resources and traditional knowledge;
- ✓ Several possible mechanisms for implementation, including a multilateral benefit sharing mechanism and an access and benefit-sharing clearinghouse;
- ✓ Measures to promote compliance with legal and regulatory requirements, as well as with mutually agreed terms; and
- ✓ Measures to promote tools and awareness raising, capacity building and transfer of technology activities on access and benefit sharing.

### What activities are covered under its access and benefit sharing requirements?

Access and benefit sharing requirements of the Nagoya Protocol apply to “genetic resources” and the benefits derived from the “utilization of genetic resources.” This is also the scope of access and benefit sharing as established in the CBD. The Nagoya Protocol, however, through a definition of “utilization of genetic resources,” now provides an expansive interpretation of the scope of access and benefit sharing. In particular, the interpretation of “utilization of genetic resources” clearly covers research and development linked to the biochemical composition of plants and other components of biodiversity.

The “utilization of genetic resources” was not defined by the CBD. Experts and national legislations offered different interpretations on the types of activities covered by the term. There was no argument that activities such as the use of enzymes, genes or small molecules for the development of pharmaceutical, industrial and agricultural products fell under the scope of access and benefit sharing. Yet there were questions as to the degree that research and development based on naturally occurring biochemical compounds - rather than on genetic material itself - was also subject to access and benefit sharing requirements.

Achieving a meaningful sharing of the benefits of biodiversity, however, demanded addressing research on biochemical compounds. These compounds are the basis for a wide range of products, from drugs to food and cosmetic ingredients. Flavonoids, for example, are among the biochemical compounds found to have unique skin care properties and now widely used in cosmetic formulations. Alkaloids, such as those found in the seeds of coffee, cola and guaraná, are another biochemical compound broadly used, for instance in functional foods and beverages.

The Nagoya Protocol now defines “utilization of genetic resources” as “to conduct research and development on the genetic and/or biochemical composition of genetic material.” It also includes a definition of “derivatives” of genetic resources that also refers to biochemical compounds (see box 2). Research on the properties of extracts and molecules from plants, for example, and their development and commercialization as ingredients in pharmaceuticals, cosmetics or nutraceuticals would thus now be distinctly subject access and benefit sharing requirements. It is not yet clear how these requirements are implemented along the supply chain - will prior informed consent, for example, need to be sought only by the companies accessing the plants or also by the companies accessing the extract? What is clear is that all companies will now need to make sure that themselves or their providers comply will all relevant legislation.

#### Box 2. Derivatives

The issue of derivatives was often raised in negotiations on scope as an attempt to expressly expand the applicability of access and benefit sharing principles to activities linked to naturally occurring compounds, such as antibodies, vitamins, enzymes, active compounds and metabolites.

The Nagoya Protocol contains a definition of derivatives, as “a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources.” The access and benefit sharing requirements in the Nagoya Protocol do not expressly refer to the term “derivatives,” but the concept could be seen to complement the definition of “utilization of genetic resources.”

# Nagoya Protocol on Access and Benefit Sharing

## Technical Brief

### Will the Nagoya Protocol apply to new uses or all uses of genetic resources?

During negotiations of the Nagoya Protocol, there were different positions on when benefit-sharing requirements become applicable. Should benefit sharing apply solely in relation to plant material accessed after the entry of force of the new rules (for example, medicinal plants to be collected during a screening program in late 2012)? Or should these requirements extend to all new uses of genetic resources, even if access took place before the Nagoya Protocol (though after the adoption of the CBD)? Such would be the case, for instance, in the identification and development as a cosmetic ingredient of a type of fruit seed oil previously known only for its properties as a dietary supplement.

This issue, referred to as “temporal scope,” was not expressly resolved in the Nagoya Protocol. According to international law, provisions of an international instrument are not binding to any act that took place before or any situation that ceased to exist at the date of entry into force of the treaty. New uses of genetic resources entail new instances of access that would thus be covered. New benefits arising from prior or ongoing uses may also be considered as new situations for benefit-sharing requirements - but access requirements would not apply retroactively. Access that has already taken place and benefits that have already been accrued would not be covered by the new requirements.

In addition, the Nagoya Protocol, as a way to bridge the different positions on temporal scope, refers to a Global Multilateral Benefit Sharing Mechanism. This is still merely an idea - countries will need to decide on the need and modalities for such a fund (see box 3). Nevertheless, the aim would be for the Global Multilateral Benefit Sharing Mechanism to provide an answer to the practical difficulties of sharing of benefits derived from the utilization of genetic resources and traditional knowledge “for which it is not possible to grant or obtain prior informed consent.” Given the background of the provision, it is likely that such a benefit-sharing fund will seek to address cases such as new benefits or new uses of previously accessed resources insofar the origin or source of the genetic resources or traditional knowledge cannot be determined.

#### Box 3. A Global Multilateral Benefit Sharing Mechanism

The Nagoya Protocol calls on countries to consider the need for and modalities of a global multilateral benefit-sharing mechanism. This fund would facilitate fair and equitable sharing of benefits in transboundary situations or other cases in which it is not possible to grant or obtain prior informed consent. Such cases could include the use of resources coming from ex situ collections, unknown countries or areas beyond national jurisdiction. It could address situations of widely disseminated or publicly available traditional knowledge. The funds obtained through this mechanism must be used to support the conservation and sustainable use of biodiversity.

### Are there any changes to existing access and benefit sharing requirements?

The Nagoya Protocol maintains the CBD approach to access and benefit sharing, based on the principles of prior informed consent and mutually agreed terms<sup>1</sup>. Notwithstanding, in developing these principles, the Nagoya Protocol contains significant innovations. In the CBD, the fair and equitable sharing of benefits is already a self-standing obligation. Nevertheless, access and benefit sharing seems to be presented as a step-by-step process. Access is based on prior informed consent and mutually agreed terms. These terms thus ensure the subsequent sharing of benefits in a fair and equitable manner. In the Nagoya Protocol, the need to share the benefits derived from the use of genetic resources appears to have been detached from access to these resources. Fair and equitable sharing of benefits must still take place on the basis of mutually agreed terms, but it is not clear that benefit sharing requires, or only takes place ensuing, access procedures. For example, the proposed Global Multilateral Benefit Sharing Mechanism may allow or require the sharing of benefits derived from the utilization of genetic resources even when the origin of such resources cannot be determined or when access took place prior to the entry into force of the Nagoya Protocol. The link between access and benefit sharing will also depend on national legislation (see box 4).

Another new provision refers to the utilization of genetic resources held by indigenous and local communities. In the CBD, a role of indigenous and local communities is only expressly recognized in relation to traditional knowledge. The Nagoya Protocol, however, also states that the use of genetic resources should take place with the prior informed consent of indigenous and local communities, in cases where they have the right to grant access to such resources.

# Nagoya Protocol on Access and Benefit Sharing

## Technical Brief

Similarly, benefits resulting from the use of genetic resources rightfully held by indigenous and local communities should be shared with those communities. Such measures, already required by some national laws and standards such as that of the Union for Ethical BioTrade (UEBT), now clearly become part of best practices on access and benefit sharing.

As the CBD, the Nagoya Protocol also contains access and benefit sharing requirements for the utilization of traditional knowledge. There is no further definition on the type of use that falls under access and benefit sharing requirements. Nevertheless, the Nagoya Protocol reinforces access and benefit sharing linked to traditional knowledge by requiring countries to establish mechanisms to support the development of community protocols and other community-based procedures and tools. In addition, the Nagoya Protocol requires countries to preserve customary use and exchange of genetic resources and traditional knowledge amongst indigenous and local communities. Another important point is the reference, in the decision adopting the Nagoya Protocol, to the need to assess the implementation of provisions on traditional knowledge in light of the work of other relevant international organizations, including the World Intellectual Property Organization (WIPO), in the context of the first review of the Nagoya Protocol, four years after its entry in force.

### Box 4. National rules on access and benefit sharing

Recognizing the gaps and complexities in the national implementation of access and benefit sharing, the Nagoya Protocol requires countries to provide for legal certainty, clarity and transparency in their relevant legislation or regulatory requirements. In addition, countries should make information available on how to apply for prior informed consent and provide written, cost-effective and timely replies to requests for such consent. Finally, countries should provide, at the time of providing access, for the issuance of a permit or its equivalent as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms.

## Which countries are required to establish measures for access and benefit sharing?

Compliance measures, aimed at ensuring observation of prior informed consent and mutually agreed terms requirements across national borders, are at the core of the Nagoya Protocol. Access and benefit sharing provisions in the CBD already established obligations not only for countries providing access to genetic resources, but also for countries where biodiversity-based research, development and commercialization usually take place. Yet little progress was made on legislative, administrative or policy measures that would ensure international compliance with access and benefit sharing.

The Nagoya Protocol now requires all countries to establish “appropriate, effective and proportionate” measures to provide that genetic resources and traditional knowledge utilized within their jurisdiction have been accessed on the basis of prior informed consent and mutually agreed terms, as required by the country of origin. As a result, it would be not only Brazil or Malaysia, for example, which would need to establish mechanisms to regulate and control access to their biological resources. France or Japan, for instance, would also need to ensure that research, development and commercialization conducted within their countries utilizes genetic resources according to the requirements established by the countries of origin of these resources. According to the Nagoya Protocol, France or Japan - to continue using those examples - would also need to take appropriate, effective and proportionate measures in cases of non-compliance. They would also need to collaborate with Brazil or Malaysia and grant access to justice in cases of alleged violation of these countries’ national access and benefit sharing legislations.

In order to monitor and enhance transparency on the utilization of genetic resources, countries must designate one or more “checkpoints.” These checkpoints could be established at any stage of the value chain: research, development, innovation, pre-commercialization or commercialization. Applications for intellectual property protection or government funding for biodiversity-based research and development could be used as opportunities to examine compliance with access and benefit sharing requirements (see box 5). Another possibility would be to use market approval processes as checkpoints. Applications under the Novel Food Regulation of the European Union, for example, could be required to include proof of compliance with prior informed consent and mutually agreed terms in the relevant country of origin of the genetic resources.

### Box 5. Patents and biodiversity

There is no reference to patents or other intellectual property rights in the Nagoya Protocol. Nevertheless, the work of the World Intellectual Property Organization on traditional knowledge, for example, is to be considered in the context of the Nagoya Protocol insofar it does not run counter to the objectives of the Protocol - language similar to the CBD reference to intellectual property.

The Nagoya Protocol also does not include a list of mandatory checkpoints, among which many biodiversity-rich developing countries had proposed patent offices be included. Nevertheless, it is clear that there is building pressure for both patent rules and practices to take into account access and benefit sharing requirements.

# Nagoya Protocol on Access and Benefit Sharing

## Technical Brief

### What does this mean for natural ingredients in food and personal care?

For companies working with biodiversity-based ingredients for food and personal care products, perhaps the most important development in the Nagoya Protocol is the clear incorporation of its activities into the scope of access and benefit sharing requirements. Research conducted on the biochemical composition of plants to determine beneficial properties, as well as the subsequent development and commercialization of bioactive compounds as ingredients is considered “utilization of genetic resources.” It must therefore take place with prior informed consent and fair and equitable sharing of benefits. Though some companies in the food and personal care sectors were already considering access and benefit sharing in the context of their ethical sourcing practices, such a clarification reaffirms the need for all companies working with biodiversity-based ingredients to review their relevant policies and practices.

In such a review, companies will now be able to refer to the more comprehensive and practical provisions on access and benefit sharing of the Nagoya Protocol. There are also new issues to consider, including how benefit sharing functions without a necessary link to access procedures, how the prior informed consent of indigenous and local communities is appropriately obtained, and how new mechanisms for access and benefit sharing, including certificates of compliance (see box 6) and the possible multilateral benefit sharing mechanism can be used and navigated.

It should be kept in mind that the Nagoya Protocol does not constitute an immediate or magical solution. It will open for signatures in February 2011 and only enter into force after the fiftieth ratification. Even then, it will take some time for policy-makers, experts and other stakeholders to determine what the Nagoya Protocol can and should mean in practice. As a negotiated text with intentional ambiguities, the Nagoya Protocol leaves a number of questions unresolved, and answers others only in part.

There is a range of mechanisms to be further defined, elaborated and put into effect. In many sense, the Nagoya Protocol is only a starting point.

The Nagoya Protocol is nevertheless a reaffirmation of the importance of access and benefit sharing and a renewed call for all stakeholders to take relevant principles into consideration in all their activities. Even as the Nagoya Protocol is further defined and put into effect, early adopters of access and benefit sharing practices in the food and personal care sectors will gain a competitive advantage. In addition, early adoption of access and benefit sharing practices will reduce the growing reputation and regulatory risks of non-compliance. For companies working with biodiversity-based ingredients for food and personal care products, therefore, addressing access and benefit sharing - including through membership in organizations such as the Union for Ethical BioTrade, which incorporate access and benefit sharing in its standard, tools and technical support - should be seen an opportunity to advance their engagement and commitment to ethical sourcing of biodiversity.

#### Box 6. Certificates of compliance

During negotiations, certificates of compliance were put forth as possible tool to monitor, facilitate and verify the use of genetic resources and traditional knowledge. It was suggested that these certificates could act as “passports” along the supply chain.

The Nagoya Protocol includes references to “internationally recognized certificates of compliance.” This does not imply an international system of certificates. Rather, a permit or equivalent document issued by national authorities as evidence of prior informed consent and mutually agreed terms - and made available to the CBD Access and Benefit-sharing Clearing-House - becomes an internationally recognized certificate of compliance. These certificates could then be required, for example, in checkpoints and verification of compliance with access and benefit sharing requirements.

### For more information

More information on access and benefit sharing and related work by the Union for Ethical BioTrade, as well as additional resources on access and benefit sharing, are available at [www.ethicalbiotrade.org](http://www.ethicalbiotrade.org).

Contact: Maria Julia Oliva  
Senior Adviser - Access and Benefit Sharing  
Union for Ethical BioTrade  
32, Rue de Berne, 1201, Geneva, Switzerland  
Phone: + 41 22 5661585  
Fax: + 41 22 7310340

<sup>1</sup> See, e.g., Union for Ethical BioTrade, “Access and Benefit Sharing: Basic Information Sheet,” available at [www.ethicalbiotrade.org/resources](http://www.ethicalbiotrade.org/resources).