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Questions and answers on access and benefit-sharing

What is ABS?

Biodiversity, the variety of life on Earth, is protected by an international convention, the Convention on Biological Diversity (the CBD). The EU and its Member States are Parties to this Convention. One of its basic principles recognizes that States have sovereign rights over the genetic resources found within their national jurisdiction, and that they can set conditions for access to such resources. In line with Article 15 of the CBD, the signatories should do their best to facilitate access to their genetic resources "for environmentally sound uses".

The CBD introduced also a concept of benefit-sharing, hence "access and benefit sharing", or ABS. Any benefits that arise from conducting research and development on genetic resources falling under the scope, including R&D which leads to commercial use of the developed product, are to be shared fairly and equitably with the Party providing these resources.

What is the Nagoya Protocol and why was it needed?

The "Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity", is a legally binding treaty negotiated and adopted under the auspices of the CBD in Nagoya, Japan in 2010. This Protocol develops the general concepts contained in Article 15 of the Convention (i.e. the ABS provisions) into a fully-fledged operational regime.

The entry into force of the CBD did not create sufficient legal certainty. Some provider countries started to act upon the text of Article 15 of CBD and established national access legislation, which in some cases was so strict that users no longer had access to access genetic resources from those states anymore. Many other Parties, such as the Member States of the European Union, while recognizing the general principles of Article 15 of the CBD, did not consider it sufficiently clear to be implemented into national law. This need for a more specific agreement led to the opening of negotiations of an international agreement on the subject. This agreement – the Nagoya Protocol – was finalized and adopted in October 2010 in Nagoya, Japan.

The Nagoya Protocol provides specific framework conditions for procedures that govern how users of genetic resources and traditional knowledge associated with genetic resources may obtain access to such resources and traditional knowledge. In particular, it details information that needs to be included in the prior informed consent (PIC) given by the provider country. It also contains a general obligation on the establishment of a benefit sharing agreement to be established through mutually agreed terms between the provider and the user. The Protocol obliges states to ensure that users operating under their jurisdiction respect the legislative or regulatory requirements of states that provide genetic resources and traditional knowledge.

In practice a majority of the agreements concerning the access to genetic resources are expected to be signed between biodiversity-rich (and often developing) countries, and companies using the genetic resources, typically in more advanced countries.

Why do we need the ABS Regulation?

The EU ABS regulation brings EU law into line with the international obligations agreed at Nagoya.

As of when will the new rules apply?

The date for the entry into force for the Union of the Nagoya Protocol is 12 October 2014, i.e. the 90th day after deposit of the 50th instrument of ratification, acceptance, approval or accession by the Parties.

This is also the date for the entry into application of EU ABS Regulation 511/2014. The rules cover all genetic resources and traditional knowledge associated with genetic resources accessed as of the entry into force of the Protocol for the Union. Some of the key obligations applicable within the EU will only enter into application one year after that date.

In which cases do the ABS rules of apply?

The ABS rules apply to the utilization of genetic resources and traditional knowledge associated with genetic resources. Utilization means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology.

Genetic resources are being used in research and development for many different purposes. These are some examples:

- Identifying active compounds for medicine development: In April 2012, the Danish company LEO obtained FDA-approval for a topical gel against a precursor to skin cancer. The main active ingredient of this gel is derived from the *Euphorbia peplus* plant found in Australia, after an extraction, purification and crystallization process of about five months. LEO will now seek market approval in other major markets.

- Genetic resources also play a major role in developing nature-based renewable energy to face the energy challenges of a growing world population while ensuring biodiversity and environmental protection and make the transition to a post-petroleum economy.

- Polyurethane-eating fungi discovered in Amazonian rainforest. Researchers have identified plant fungi in the Ecuadorian rainforest that can digest plastic. The discovery hints that there may be a wide range of effective waste-consuming microbes in existence, according to the study, which found that several different fungi, including one called *Pestalotiopsis microspora*, can break down the widely used plastic, polyurethane.

What will the EU ABS regulation mean in practice for EU users?

All users will have to exercise 'due diligence' to ascertain that the genetic resources and the associated traditional knowledge they use have been accessed in accordance with applicable legal requirements and to ensure that, where relevant, benefits are shared.

Users will also be obliged to declare at specific check points that the correct procedure has been followed.

The due diligence obligation should ensure that the information relevant to ABS is available throughout the whole genetic resources value chain. This will enable all users to know of and respect related rights and obligations. At the same time, the due diligence approach does not prescribe details of the measures to be taken by users, but leaves

users some flexibility to take measures that work best for their respective context, and also to develop sectoral best practices.

How will the "due diligence" concept work?

Users need to seek, keep and transfer to subsequent users' information on:

- the date and place of access to genetic resources or traditional knowledge associated with genetic resources;
- the description of the genetic resources or traditional knowledge associated with the genetic resources utilized;
- the source from which the genetic resources or traditional knowledge associated with genetic resources were directly obtained, as well as subsequent users of genetic resources or traditional knowledge associated with genetic resources;
- the presence or absence of rights and obligations relating to access and benefit sharing including rights and obligations regarding subsequent applications and commercialization;
- access permits, where applicable;
- mutually agreed terms, including benefit-sharing arrangements, where applicable.

In addition, a user needs to analyze if the information in his possession is sufficient and be certain that he or she complies with applicable legal requirements in the provider country. Otherwise, users must either obtain the missing information or discontinue utilizing the genetic resources and/or the traditional knowledge associated with genetic resources.

Users will be obliged to retain any information relevant for access and benefit-sharing for a 20-year period after the end of the period of use.

The EU ABS Regulation foresees that specific choices taken by users on the tools and measures applied for exercising due diligence should be supported through the recognition of best practices as well as complementary measures in support of sectoral codes of conduct, model contractual clauses, and guidelines with a view to increasing legal certainty and reducing costs.

Does the EU ABS Regulation contain all ABS measures applicable in the EU?

The EU ABS Regulation establishes the rules for the compliance measures, mandatory under the Nagoya Protocol within the EU. However, the Regulation will need to be read in conjunction with the secondary legislation concerning Articles 5, 7 and 8 of the regulation, which is under development, as well as with the further measures that the EU Member States have to take as mandated by the EU ABS Regulation, notably on penalties. Also, Member States' administrative law will contain all the possible measures that competent authorities can take in cases of non-compliance with the EU ABS regulation.

Are there additional costs and burdens for users?

Professional associations (and users) will be best placed to identify the most cost-effective ways of implementing the due diligence obligation. The flexibility of the due diligence concept should allow users to tailor due diligence measures to existing best practices, thereby lowering costs. Monitoring costs for users are limited, and declarations will only be made at points where users are already obliged to summarize and evaluate relevant information. Costs should be minimal, as:

- Declarations in the context of research funding are already standard practice;
- Users already prepare a dossier describing the product for which a permit is sought for product approval or commercialization.

Real costs may of course arise in cases where users have not been diligent, and have failed to seek relevant information on ABS when acquiring a genetic resource. The fact that the necessary information will be available throughout the research and development process should help them avoid that risk.

Does the Protocol (and thereby the EU ABS Regulation) apply to genetic resources collected before it enters into force?

No, the Protocol only applies to genetic resources accessed after it enters into force.

What is the advantage of acquiring samples of genetic resources via a registered collection?

Users who acquire a genetic resource from a collection included in the Union register will be considered to have exercised 'due diligence' as regards the seeking of all necessary information. This system of registered collections should substantially lower the risk of non-compliance. This should be particularly advantageous to academic researchers and SMEs.

Could a collection located outside the Union become a registered collection?

For legal reasons, the register will only contain collections established within the Union. This is linked inter alia with the need for Member States' competent authorities to assess whether these collections fulfil the criteria for being put into the register.

However, the EU remains open to look into enlarging this concept in the future, e.g. via bilateral agreements with other Parties to the Protocol. For the time being, however, the concept will be implemented firstly in the EU in order to gain the necessary experience.

What are the benefits in having a best practice recognized?

Associations of users and other interested parties may ask the Commission to recognize a specific combination of procedures, tools or mechanisms overseen by an association as best practice. Competent authorities of the Member States should consider that the implementation of a recognized best practice by a user reduces that user's risk of non-compliance and justifies a reduction in compliance checks. The same should apply to best practices adopted by the collective of the Parties to the Nagoya Protocol (art. 20 of the Protocol).

Why has ABS been problematic in the past?

Access and benefit sharing for the utilization of genetic resources was a controversial issue in the context of CBD discussions. The utilization of such resources is linked to the exercise of the sovereign right of states over their resources, the extent of rights of indigenous and local communities, and economic and technological development in provider countries. The convention includes a provision establishing a general principle calling for users to obtain the prior informed consent (PIC) of, and to share benefits with provider countries when their genetic resources are used for research and development.

In the absence of the Nagoya Protocol, there was no sufficient legal framework to ensure that the genetic resources were obtained in compliance with domestic law of the provider country. Companies and scientists often developed commercial products based on genetic

resources and, in many cases, filed patents using that material. In some situations this led to conflicts and accusations of "bio-piracy".

How will the Protocol help achieve broader conservation goals?

The Protocol encourages Parties to direct benefits arising from the access to and utilization of genetic resources towards the conservation of biological diversity and the sustainable use of its components. It is also hoped that these benefits may help vulnerable populations that depend on genetic resources to use them sustainably. It could also help to enhance the management and establishment of protected areas that are important to conserve biodiversity.

Is there an obligation for provider countries to adopt access rules?

No. Parties are free to decide whether they want to establish access legislation or not. If they don't, access to their genetic resources is considered to be free.

The Nagoya Protocol also foresees a role of indigenous and local communities in the context of granting access. So, if the country decides to provide for rules on access, they may need to also include specific requirements concerning prior approval to be obtained from indigenous and local communities.

What happens in cases of non-compliance with the Protocol?

The Protocol foresees the set-up of an ABS Clearing House, an international mechanism enabling the sharing of relevant information, such as national access measures applicable in provider countries, contact points as well as access permits issued by the authorities. This mechanism fosters compliance, but it also allows for identification of possible problems. In such a case, the country concerned will have the possibility to address a case to a court.

As regards the obligation of states adhering to the Nagoya Protocol, the Protocol foresees the adoption of specific compliance procedures and mechanisms, including dispute settlement procedures, that will help Parties to comply and that will address cases of non-compliance. These will be agreed at a later date.

Are any genetic resources excluded from the scope of the Protocol?

Human genetic resources are excluded from the scope of the Protocol. Further, genetic resources obtained from areas beyond national jurisdictions (e.g. the high seas) are also excluded from its scope.

To what extent does the Nagoya Protocol address indigenous and local communities' concerns?

The Nagoya Protocol recognizes the capacity of indigenous and local communities to grant prior informed consent with respect to their genetic resources and traditional knowledge associated with genetic resources. Provider states need to ensure that indigenous and local communities can exercise their rights granted under the Nagoya Protocol and the respective national law.

National rules on the rights of indigenous and local communities can sometimes entail challenging questions. This practical, political and image related factors should be considered in addition to the legal requirements.

Does the Nagoya Protocol create business opportunities?

Yes, by creating a transparent and clear legal framework for access and by obliging user countries to provide for user measures that ensure the provider countries that their genetic resources will only be used in accordance with the applicable legislation and regulatory requirements, the Protocol will open the way for more access deals. Improved access to quality samples of genetic resources with high legal certainty and at the lowest possible transaction costs will maximize research and development opportunities on genetic resources.

Why are there no dedicated provisions for non-commercial research?

The Protocol does not distinguish between non-commercial and commercial utilization. In line with the Protocol, the EU ABS Regulation does not do so either. However, the Nagoya Protocol foresees that countries, when developing their ABS laws, shall 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.

Simplified measures on access for non-commercial research will be found in the respective access measures of provider countries, not in the EU ABS regulation which covers only the measures for user compliance.