Access and benefit sharing (ABS)

A primer for companies in the pharmaceutical sector

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for the German Federal Agency for Nature Conservation

Federal Agency for Nature Conservation

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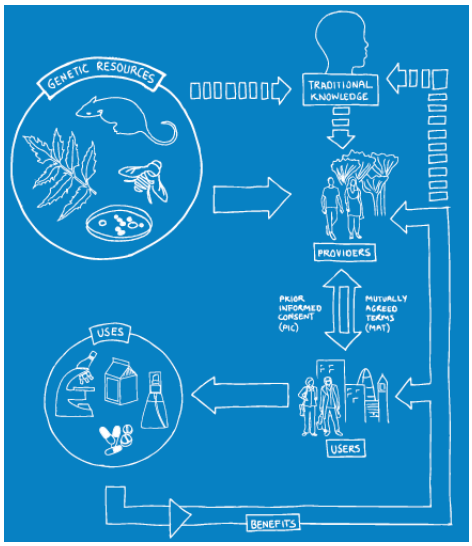

Figure 1. Basic ABS flowchart
(Source: CBD Secretariat, ABS Information Kit)

ABS is an acronym for “access to genetic resources and the fair and equitable sharing of benefits derived from their utilisation.” Or “access and benefit sharing” for short.

Biodiversity supports innovation in diverse sectors, including agriculture, pharmaceuticals, biotechnology, and cosmetics. Rules and practices on ABS seek to ensure that the use of biodiversity in research and development respects the rights of countries and communities over natural resources, and contributes to conservation, sustainable use and local development.

ABS requires companies, research institutes and other organisations seeking access to biodiversity for research and product development to secure adequate authorisation. Such authorisation, usually granted through a permit, is based on prior informed consent or PIC from the provider of plant or other biological samples and compounds. In addition, the provider and the user must negotiate an agreement – known as mutually agreed terms or MAT – to share the resulting benefits equitably (see Figure 1).

How is ABS relevant to companies in pharmaceutical sector?

ABS rules and practices are becoming increasingly important for companies working with biological material in the pharmaceutical sector, whether sourcing natural ingredients for phytopharmaceuticals or using plant, animal or microbial parts or compounds in the drug development process. Key trends include:

- Since the 2010 adoption of the Nagoya Protocol, there is growing interest and scrutiny on how companies access and use biological material, particularly for research and development (R&D).
- Countries around the world are developing, revising and putting in practice national laws and regulations on how biological material is acquired and used for research, development and commercialisation.
- Claims of non-compliance with ABS legal and ethical requirements are a source of reputational risk. The term ‘biopiracy’ is widely used in the media to describe cases of unauthorised use of genetic resources and associated traditional knowledge.
- ABS principles entail traceability, transparency and respect among actors, which have positive implications for how supply chains operate.

- ABS is emerging as a fundamental element of using biodiversity as a source of innovation and distinguishing brands and products on the basis of ethical sourcing.

Where does ABS come from?

ABS rules and principles have been agreed upon through international agreements. In 1992, the Convention on Biological Diversity (CBD) established a set of principles and requirements governing ownership, access and use of genetic resources and associated traditional knowledge. In 2010, the Nagoya Protocol on ABS was adopted to further clarify and develop these principles and requirements. The Nagoya Protocol recognises specialised agreements on ABS, such as the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA).

Countries implement ABS principles and requirements through national laws and regulations. It is these national rules that establish the specific obligations and procedures for access and use of genetic resources and associated traditional knowledge. Over 80 countries around the world now make reference to ABS in their regulatory framework.

Additionally, different groups of companies, research institutions, civil society organisations and indigenous peoples and local communities have developed various guidelines, codes of conduct, templates and other tools defining best practices on ABS.

What activities are affected by ABS?

The CBD and the Nagoya Protocol refer to “genetic resources.” The term can be explained because, at the time the CBD was adopted, countries focused on the impact that biotechnology might have on how the value of biodiversity was captured and shared. Nevertheless, the Nagoya Protocol clarified that the “utilisation of genetic resources”, which triggers ABS requirements, covers a broader range of activities. Utilisation of genetic resources is defined as R&D on the genetic and/or biochemical composition of genetic resources.

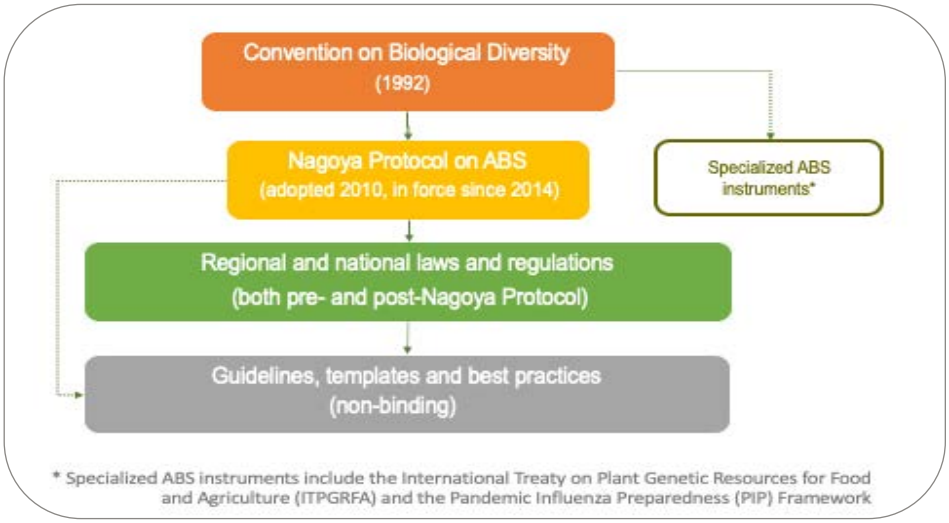

Figure 2. ABS framework
Source: UEBT

There is no further clarification on the type of R&D covered. Nevertheless, the rationale of ABS implies a focus on research into the properties of genetic and biochemical compounds and using these properties to develop new products. For example, in the phytopharmaceutical sector, research into secondary metabolites in an extract of aerial parts of a plant to identify potential antiviral and antibacterial effects for use would trigger ABS requirements. Similarly, ABS may be

relevant for companies screening biochemical compounds or extracts against therapeutic targets or using biological material as the basis for synthesising new chemical entities in the drug development process.

What are access requirements?

Traditional knowledge and ABS

In the context of ABS, the knowledge and practices of indigenous peoples and local communities are seen as a source of information for R&D on properties and uses of biological resources. Consequently, access to traditional knowledge associated with genetic resources is subject to prior informed consent and mutually agreed terms.

In practice, difficulties arise in putting in practice ABS requirements for traditional knowledge:

- *There are different views on what type of traditional knowledge should qualify for ABS protection, depending, for example, on its degree of dissemination.*
- *What is the utilisation of traditional knowledge? It is unclear whether ABS requirements should be triggered by the active consideration of traditional knowledge in R&D or merely by the existence of traditional knowledge related to R&D activities.*
- *Questions often arise on who is authorised to grant prior informed consent and through which process. The Nagoya Protocol introduces community protocols as a potential tool to address these questions.*

Ex-situ collections

ABS requirements also apply to genetic resources accessed through ex-situ collections of biological material. That is, companies undertaking R&D on samples from botanical gardens, gene banks, and other collections of biological material must ensure that these samples are:

- *Obtained with prior informed consent, if required, from the provider country, and*
- *Used according to the terms agreed upon with original providers.*

Many ex-situ collections, including the International Plant Exchange Network (IPEN) and the Global Catalogue of Microorganisms, have developed voluntary guidelines or best practices on traceability and compliance with ABS requirements.

At the international level, there is no definition of “access” to genetic resources. Nevertheless, the term can be understood as the acquisition of biological material for R&D into its genetic or biochemical components. That is, access requirements are triggered if there are two elements: acquisition of biological material and the intent of using it for R&D.

Countries have the right to regulate access to genetic resources, which they may do by requiring prior informed consent (PIC). PIC requires that access to genetic resources is granted with full awareness and explicit agreement to the foreseen utilisation, before any transfer or use of material takes place.

National laws and regulations define the relevant actors and procedures for PIC. In practice, PIC involves an administrative or a consultative process with government agencies, indigenous peoples, local communities, land owners and other actors with established rights over genetic resources.

What are benefit sharing requirements?

International rules on ABS establish that benefits arising from the utilisation of genetic resources, as well as subsequent applications and commercialisation, should be shared in a fair and

equitable way with the provider country. Such sharing should be upon mutually agreed terms (MAT). MAT is the agreement between the providers and users of genetic resources on the terms and conditions of access and use of the resources, including on the benefits to be shared. What is fair and equitable depends on the particular circumstances and is generally defined by the parties to the agreement.

National laws and regulations define the relevant actors and procedures for MAT. MAT are often contracts signed with indigenous peoples, local communities, land owners and other actors with established rights over genetic resources. In some legislations, government approval of the MAT is also required.

Once requirements linked to access and benefit sharing have been fulfilled, countries issue a permit or its equivalent as evidence of PIC and MAT. They may notify the Access and Benefit-sharing Clearing-House, an international platform for information exchange.

How are ABS requirements monitored?

In the context of ABS, most attention has focused on requirements for access to genetic resources. Yet equally important are measures to ensure that the utilisation of genetic resources, which often takes place in other countries, complies with these requirements.

The Nagoya Protocol requires that countries take measures to ensure that genetic resources utilised within their jurisdiction have been accessed in accordance with PIC and MAT, as required by the laws and regulations of the provider country (see Figure 3).

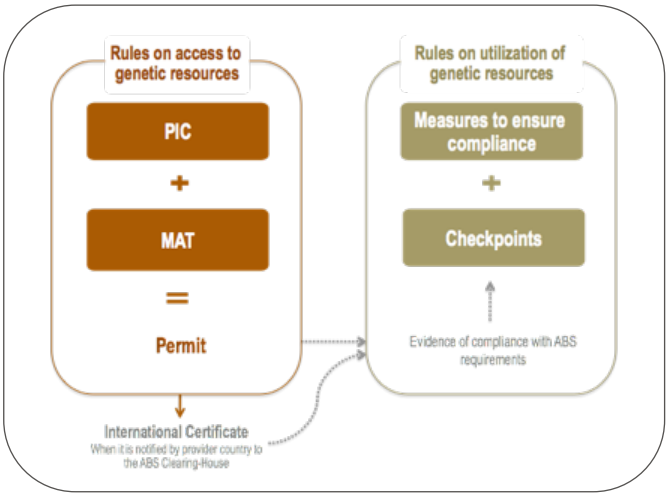

Figure 3. Interaction between ABS rules (Source: CBD Secretariat)

Such measures include the designation of one or more checkpoints along the value chain (e.g. during research, development or commercialisation activities) where information is collected on the origin of the genetic resources used in R&D and applicability and compliance with any relevant ABS requirement in the provider country.

EU regulation on ABS: Key concepts and requirements

Overview

EU regulation No 511/2014 implements the Nagoya Protocol in the European Union, focusing on provisions to monitor and ensure compliance with ABS requirements. Whether or not to adopt requirements for access to genetic resources for their utilisation and sharing of resulting benefits is left up to EU Member States. The EU regulation on ABS, which entered into force in June 2014 and became fully applicable in October 2015, requires that companies and other organisations conducting biodiversity-based R&D in the European Union ascertain whether access and use of these resources is in line with legal requirements in the country where the biological material is sourced from. That is, at the core of EU rules on ABS is a requirement of “due diligence.”

Other elements of EU rules on ABS include:

- Competent authorities in EU Member States implement EU rules on ABS
- Compliance is monitored by requiring users of genetic resources to declare due diligence in specific situations
- Competent authorities also check user compliance
- A register of collections and the recognition of best practices support implementation and are further developed through an Implementing Regulation adopted in 2015

In Germany, the competent authority for implementing EU rules on ABS is the German Federal Agency for Nature Conservation (Bundesamt für Naturschutz, BfN). The German Implementing Act was adopted in November 2015 and entered into force in July 2016.

Scope of application

EU rules on ABS apply to genetic resources accessed from countries that are part of the Nagoya Protocol and have ABS requirements in place, if such access took place after the entry of force of the Nagoya Protocol in the European Union - on 12 October 2014. That is, there is no retroactive application for samples that were collected, for instance, in 2008 and used to develop herbal medicines or food supplements that were put in the market in 2012.

Additionally, EU rules only apply to companies involved in the “utilisation of genetic resources”. This term comes from the Nagoya Protocol and means to conduct R&D on the genetic and/or biochemical composition of genetic resources. A guidance document on the scope of EU ABS requirements was adopted in 2016.

“Utilisation of genetic resources” in the pharmaceutical sector

In the pharmaceutical sector, R&D is the process of developing innovative drugs to prevent or treat disease and improving existing drugs and treatments. R&D processes for new medicines and vaccines involve screening for chemical and biological compounds that exhibit the potential for treating health conditions. Once promising compounds have been identified, companies test them to ensure efficacy and safety, a process that involves pre-clinical and clinical trials and may take 10 to 15 years.

Biodiversity is an important source of compounds for drug development, as shown in reviews of new drugs approved in recent decades. These studies show that natural products remain the most important basis for drug development, in spite of the reduced drug discovery programs in major pharmaceutical companies. However, not all R&D is conducted on “genetic resources.” Many compounds used in drug discovery fit within the definition of “derivatives”, which in the Nagoya Protocol are naturally-occurring compounds such as crude extracts, proteins and enzymes. In some cases, such derivatives may fall outside the scope of ABS requirements.

Similarly, not all research and development falls under the definition of “utilisation of genetic resources.” The use of different genetic resources may be required at different times for different purposes along the development pathway of a single product candidate, including for the development of diagnostic tests or R&D tools. Additionally, in the context of phytopharmaceuticals, one fo the major drivers of innovation is new formulations. This involves combining well-known ingredients and does not involve looking at the genetic or biochemical composition of biological material for new properties. However, companies in the

phytopharmaceutical sector do sometimes conduct research to identify new applications of well-known ingredients, which may fall within the notion of “utilisation of genetic resources.”

Due diligence

If their activities fall within the scope of EU Regulation 511/2014, companies and other users of genetic resources must exercise “due diligence”. Due diligence means that, companies must gather, keep and transfer to subsequent users information relevant to ensuring ABS compliance, including the date, place and source of the biological material or samples used for R&D and any ABS permits and agreements required in the provider country, including those recognised through the ABS Clearing House, an information exchange platform managed by the CBD.

Due diligence is meant to inform decision-making: That is, the information should help companies make sure that any biological material obtained and used for R&D meets applicable legal requirements on ABS in the country providing this material. If legal compliance on ABS cannot be verified or secured, EU rules on ABS require that the company stop its R&D.

Companies in the pharmaceutical sector that establish due diligence systems have found certain challenges, including complex R&D processes that often involve numerous samples and multiple actors. Responsibilities for ABS compliance may be hard to establish, particularly if the scope and approaches of ABS requirements in countries involved differ significantly. Limited awareness of ABS among suppliers is also a challenge and raises questions on the reliability of information on compliance.

Declaration requirements

EU rules on ABS require companies and other users of genetic resources, in certain situations, to make a declaration of due diligence to competent authorities in EU member states. Information provided through such declaration is shared with the European Commission and the ABS Clearing House. This allows other countries to monitor compliance with their national requirements on access and utilisation of genetic resources.

There are two “checkpoints” or situations in which companies must make a declaration of due diligence: when receiving research grants and when reaching the final stages of product development. The “final stages of product development” have been further clarified as involving the moment of notifying, securing authorisation or placing a product on the market. If the user does not reach these stages itself, the declaration must be made at the moment of transferring the results of R&D to another company for the purposes of commercialisation in the European Union or the outcomes of R&D for further utilisation or commercialisation outside the European Union. A due diligence declaration is required only once.

DECLARE is the EU-wide web-based tool through which users of genetic resources may submit the due diligence declarations to the relevant competent authorities. In Germany, the competent authority - BfN - is designated as the checkpoint on ABS. In fact, BfN acts as the ‘institutional’ checkpoint, collecting and receiving information from different sources, such as patent offices, sources of research funding, user assessments, which are seen as the ‘functional’ checkpoints.

Monitoring and compliance

Competent authorities in EU member states carry out checks to verify whether users comply with their due diligence and declaration obligations. Such checks follow a risk-based approach; for example, risks of non-compliance are seen to be lower in a company that is implementing best practices.

Setting up a due diligence system on ABS

Aim and approach of a due diligence system

As established by the EU rules on ABS, the aim of due diligence is to ascertain compliance with ABS requirements for the utilisation of genetic resources and associated traditional knowledge. That is, “due diligence” requires seeking, keeping and transferring information relevant to determine legal compliance on ABS. Its aim goes beyond simply ensuring relevant information or documentation exists or is put together - due diligence implies the need to assess the information and take measures to address any uncertainties or potential lack of compliance.

A due diligence system on ABS must be effective in ascertaining compliance with ABS requirements. However, users of genetic resources have the flexibility of defining how such an objective is best reached, in the context of their particular activities or structures. For example, users are left to determine how to gather and assess such information, and what follow-up steps are required to ensure compliance in each case. This means that, it is up to each company to define the structure and elements of its due diligence system and to define the steps to develop and implement such system.

Key elements

Based on legal requirements and sectoral characteristics, it is nevertheless possible to identify key elements for a due diligence system on ABS, as well as some supporting tools (see Figure 4). The starting point is committing to compliance with ABS requirements, which is done through corporate policies and procedures. As will be mentioned below, it is strategic to ensure that ABS-related procedures are mainstreamed within other procedures dealing with sourcing, R&D, and claims. Similarly, ABS-related policies should consider and advance the company’s broader business and sustainability strategies.

1. Committing to compliance with ABS requirements
   - Policy establishing commitment and describing approach to due diligence
   - Procedures that define scope, steps and responsibilities for due diligence
2. Gathering and managing information
   - Questionnaires to gather information from suppliers and other actors
   - Platforms for managing and sharing information along R&D processes
3. Assessing applicability and implications of ABS requirements
   - Checklist to determine applicability of ABS requirements
   - Decision tree to guide next steps in context of corporate strategies
4. Taking measures to ensure compliance
   - Projects to apply or support securing ABS permits and agreements

Figure 4. Key elements and tools - Due diligence system on ABS (Source: UEBT)

The other three elements are the steps of due diligence itself: gathering and managing information, assessing the applicability and implications of ABS requirements to the genetic resources at issue, and, finally, if relevant, taking measure to ensure compliance. As is described below, there are different tools and approaches that may be adopted within a company to support these processes.

Steps in setting up a due diligence system

In practice, setting up a due diligence system is not like a puzzle, where you have all pieces on the table and only have to find where they fit. Rather, there are questions that users of genetic resources must pose and decide upon to define the most effective approach and functioning for a due diligence system. Then, companies must decide how to formalise the system, establish responsibilities and procedures. Finally, when the system is being implemented, there should be continuous improvement based on monitoring and evaluation. These are the steps in setting up a due diligence system, as illustrated in Figure 5.

Defining the scope of due diligence procedures

The first step is defining the scope of due diligence. The questions here involve defining which of the ingredients sourced by the company and which of its functions and processes fall under the scope of EU rules on ABS - namely by constituting "utilisation of genetic resources." It is not sufficient to refer to the legal terms: each company must understand how these concepts relate to their own specific situation and translate them into definitions that will be clear to researchers and other staff charged with implementing the due diligence system. For example, for a particular company developing natural ingredients, genetic resources might translate as samples of plant, animal, fungi or microbial material and compounds entering the R&D process (this definition, strictly speaking, would be broader than "genetic resources" in the EU regulation, but might be a clearer cut-off point for initial assessments of whether ABS requirements apply).

Identifying control points on ABS

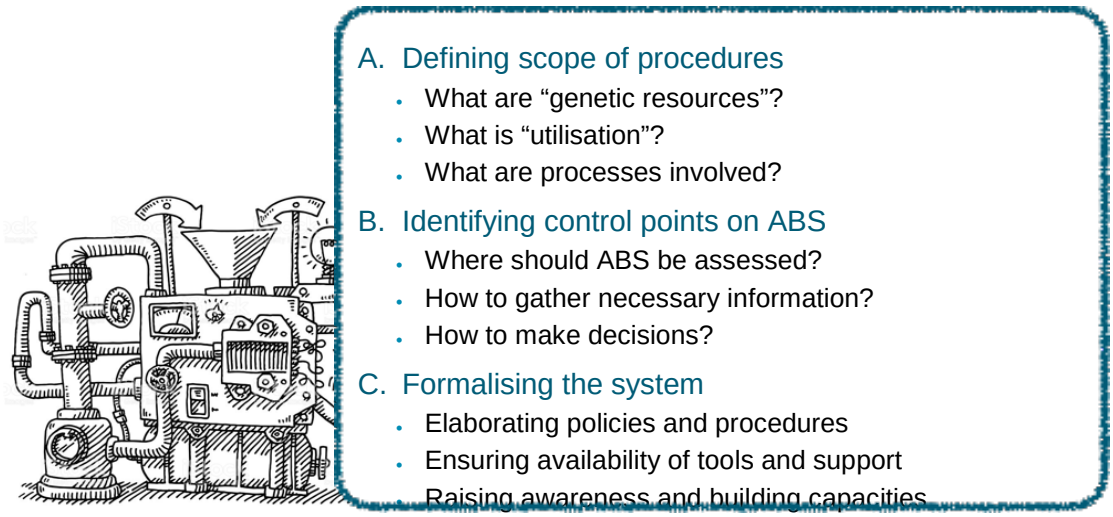

Figure 5. Steps in setting up a due diligence system on ABS

The second step is identifying control points on ABS. That is, the stages in which company activities could trigger obligations linked to access, utilisation or benefit sharing should be checked:

- The most significant checks are those at the entry point for genetic resources into the R&D pipeline. There may be several different ways in which samples enter the company - for example, through samples sent through suppliers, acquired in trade fairs or shared among departments within the company. All of these situations should be checked for ABS compliance.

- Additionally, a due diligence system must identify control points on ABS along the research, product development and pre-commercialisation stages. These control points are needed, for example, to ensure there is no change of use or other activities conducted beyond legal or contractual requirements. Moreover, these would be the control points that would ensure the company complies with any applicable declaration requirements and benefit sharing obligations.

Once control points are identified, the information to be gathered must be identified, as well as the way in which such information should be gathered, assessed and acted upon. The EU regulation on ABS includes a list of information to be secured, but it is important to "translate" these items into the types of information and documentation that the company would understand to gather from its suppliers and other sources.

Information may be obtained internally within the company, from suppliers, or through external sources or support. For example, the supplier may provide information on the country of origin of the sample, as well as a certificate of origin. However, given low levels of awareness on ABS, suppliers may not be the most reliable source on the existence or applicability of ABS requirements. Here, the ABS Clearing House, the competent authority in the EU member state or national focal point in the provider country may confirm the supplier's and company's understanding.

Supplier questionnaires

In most cases of access to genetic resources for their utilisation, the supplier is the main source of information on the applicability and implications of ABS requirements. This is the reason supplier questionnaires are increasingly used in the cosmetic and other sectors as an approach for due diligence. However, it is important to note that supplier questionnaires do not extinguish due diligence obligations for the user and should only be one of the tools used to gather and assess ABS-related information.

Formalising the due diligence system

Once the company understands the scope of due diligence within its activities and has identified the control points for ABS, this understanding must be turned into policies, procedures and tools. In this process, there are strategic questions. For example, how much is the company looking to engage in ABS agreements? Will it prioritise some countries over others as source of genetic resources? How will ABS engagement fit within broader business strategies, market positioning, and innovation targets? There are also procedural questions: should there be one single standard operating procedure on ABS? Or should changes be made to research, sourcing, regulatory and other procedures?

Implementing the due diligence system

Finally, a due diligence system on ABS needs to be not only set up, but also put to work. Users of genetic resources must ensure the system is operational and effective in reaching its objective of ascertaining compliance with ABS requirements. This is an ongoing process, which is why due diligence systems should include documentation, monitoring and evaluation processes.

For further information

ABS Clearing House Mechanism, available at http://absch.cbd.int

Bundesamt für Naturschutz (BfN), available at https://www.bfn.de/en/activities/nagoya-protocol-utilisation-of-genetic-resources.html

CBD ABS Information Kit, available at https://www.cbd.int/abs/information-kit-en/

CBD Policy brief on ABS and the pharmaceutical sector, available at https://www.cbd.int/abs/policy-brief/default.shtml/

European Commission, available at http://ec.europa.eu/environment/nature/biodiversity/international/abs/index_en.htm

IFPMA, Technical briefing on responsible use of biodiversity, available at https://www.ifpma.org/resource-centre/technical-briefing-on-biodiversity-responsible-use-of-biodiversity-industry-perspective-part-1/

International Chamber of Commerce, available at https://iccwbo.org/global-issues-trends/innovation-ip/genetic-resources-traditional-knowledge/

IUCN Explanatory Guide to the Nagoya Protocol, available at https://cmsdata.iucn.org/downloads/an_explanatory_guide_to_the_nagoya_protocol.pdf

UEBT FAQ on the Nagoya Protocol, available at https://www.ethicalbiotrade.org/resources/

UEBT Biodiversity-based innovation in the European Union, available at https://www.ethicalbiotrade.org/resources/

Prepared by the Union for Ethical BioTrade (UEBT) for the German Federal Agency for Nature Conservation (Bundesamt für Naturschutz, BfN)

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