

Frequently Asked Questions on the Nagoya Protocol on ABS

What is the Nagoya Protocol?

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation (ABS) is an agreement under international law, entered into by over 70 countries around the world. It operates in the context of the Convention on Biological Diversity (CBD), aiming to implement one of its central objectives: the fair and equitable sharing of benefits derived from the utilisation of genetic resources.

"Utilisation of genetic resources" is understood as research and development into the genetic and biochemical composition of plants, animals or microorganisms. The Nagoya Protocol focuses on activities aiming to explore the properties and possible uses of genetic material or biochemical compounds. For example, companies can use genetic resources to develop specialty enzymes, enhanced genes, or small molecules. These can be used in crop protection, new plant varieties, drug development and the production of specialised chemicals.

The Nagoya Protocol outlines how countries may regulate access to biological resources for biodiversity-based innovation and the sharing of resulting benefits, as well as how countries must support compliance with ABS requirements and contracts. It also establishes several tools and mechanisms to facilitate the implementation of these measures, including the creation of an ABS Clearing-House. The Nagoya Protocol entered into force in October 2014. Over the course of 2016, it is expected to reach over 100 Parties – that is, countries committed to implementing its provisions.

How are countries implementing the Nagoya Protocol?

Countries implement the Nagoya Protocol through laws and regulations, which establish the ABS requirements and procedures that persons, companies and other organisations will need to follow to access and utilise genetic resources in their jurisdiction. For example, European Regulation 511/2014 focuses on the compliance measures outlined in the Nagoya Protocol. It requires companies and other organizations engaged in biodiversity-based research and development in Europe to ensure these activities respect ABS requirements in other countries.

National implementation is generally a complex process: it may take months or years for countries to adopt and operationalise their national rules on ABS. Many countries, including China, Mexico, Morocco, Namibia and Vietnam, are still in the process of elaborating rules for how biodiversity is accessed for research and development and how resulting benefits must be shared. Nevertheless, a number of countries, including Brazil, India and South Africa, already have ABS laws and regulations in place, based on the CBD provisions. In the ABS Clearing-House, over 20 countries have provided information on more than 60 legislative, administrative or policy measures on ABS.

ABS Clearing-House

The Nagoya Protocol established a platform for exchanging information on ABS, called the ABS Clearing-House. Countries provide the ABS Clearing-House with information on legislative, administrative and policy measures; the national focal point and competent national authorities; internationally recognized permits; and ABS checkpoints. Additionally, the ABS Clearing-House contains reference material, including model contractual clauses, community protocols, capacity-building resources and other publications.

The ABS Clearing-House can be accessed at absch.cbd.int/.

What is the relationship between the Nagoya Protocol and national rules on ABS?

National laws and regulations implementing the Nagoya Protocol must meet certain minimum standards. For example, countries are required to take measures to ensure the prior informed consent of indigenous peoples and local communities for access to genetic resources or associated traditional knowledge over which they have established rights.

However, national implementation may go beyond these minimum standards. For example, countries may require authorization to access not only to genetic resources but also its derivatives or, more broadly, biological resources. This is the case in countries such as Peru, India and South Africa. National laws or regulations may also define benefit sharing, rather than leaving it up to negotiations. For example, in Brazil, the ABS legislation adopted in 2015 establishes that a certain percentage of profits from products resulting from biodiversity-based R&D must be shared.

As a result, ABS requirements and procedures may differ from the Nagoya Protocol, as well as vary from country to country, depending on their approaches and aims.

What are the kinds of activities covered by the Nagoya Protocol?

For companies working with natural ingredients, research into the beneficial properties of biochemical compounds for new ingredients and products would be considered to fit within the definition of 'utilisation of genetic resources' in the Nagoya Protocol.

In the cosmetics sector, for example, research on plant extracts, oils and molecules to develop new ingredients with moisturizing, firming, anti-ageing or other properties would fall within the realm of ABS. Similarly, ABS would be relevant for companies analysing plant samples to inspire new molecules and synthetic material to include in fragrances. In the food sector, the development of a new natural colorant derived from

fruit pulp for use in food products. Similarly, ABS would be relevant for companies looking to scientifically prove the antioxidants in a traditional medicinal plant and developing a health beverage boasting these properties.

Other research and development activities – including environment and toxicity studies for natural ingredients, improvements in plant extraction processes or new product formulations with known ingredients – would not fall under ABS as defined in the Nagoya Protocol. Neither would the ongoing sourcing of natural ingredients for cosmetics products. However, it is important to consider that national laws and regulations implementing the Nagoya Protocol may extend ABS requirements to a broader range of activities than the "utilisation of genetic resources".

What about commodities? Are they covered or impacted by the Nagoya Protocol?

In principle, buying and selling commodities and other plants, crops or biological material that is already traded does not fall under the Nagoya Protocol. However, this is only as long as the aim is only production or consumption and no research and development activities are undertaken. For example, buying seeds in a market to produce breakfast cereals is not considered 'utilisation of genetic resources.' However, if the seeds were analyzed for their genetic or nutritional properties, in order to develop an extract or conduct plant breeding, such activities would be considered within the realm of ABS.

It is important to note that a specialised ABS system exists for the utilisation of plant genetic resources for food and agriculture. The 2001 International Treaty on Plant Genetic Resources for Food and Agriculture establishes a multilateral system on ABS for 64 of the world's most important crops, including barley, rice and wheat. However, the utilisation of these plant genetic resources for uses other than research and breeding for food and agriculture, as well as the utilisation of crops not included in this multilateral system (e.g. soy, coffee, etc) still falls within the scope of the Nagoya Protocol.

What kind of use of traditional knowledge triggers ABS under the Nagoya Protocol?

The Nagoya Protocol also applies to traditional knowledge and to the benefits arising from the utilisation of such knowledge. The term 'traditional knowledge' refers to the knowledge, innovations and practices associated with genetic resources and held or owned by indigenous and local communities.

There is no definition of how traditional knowledge may be "accessed" or "utilised" in order to trigger ABS requirements. Nevertheless, given the definition of the "utilisation of genetic resources", the focus would be on gathering and using traditional knowledge in the process of

researching the beneficial properties of genetic material or biochemical compounds and using these properties to develop new products.

Will the Nagoya Protocol apply retroactively to prior research and development activities?

In line with international law, the Nagoya Protocol does not apply to activities that took place before its entry into force. Access and utilisation of genetic resources that have already taken place and benefits that have already been accrued would not be covered. For example, the cultivation of vanilla outside Central America, which took place in the nineteenth century, past research activities leading to the development of related fragrances and flavours, and ongoing trade in vanilla as a spice would not be included in the Nagoya Protocol.

However, it is still unclear how national laws and regulations will deal with the issue of new utilisation of previously accessed genetic resources. This would be the case, for example, of plant samples acquired prior to the Nagoya Protocol – but after the entry of force of the CBD – and utilized in new research and development projects or introduced in products resulting from such research and development.

What steps should companies take on ABS?

As a first step, it is fundamental for companies to increase their understanding of evolving international and national laws and best practices, as well as of the practical implications. Organisations like UEBT provide introductory material and capacity-building courses specifically designed for companies, both members and non-members.

Second, companies should gather information on ABS laws and regulations in countries in which sourcing activities take place. This is also a critical step in establishing a due diligence system under the European regulation on ABS. The ABS Clearing-House is an important source of information, which can be complemented with UEBT fact sheets, assessments and other ABS tools.

Third, it is essential for companies to realize ABS is not only about legal compliance. Claims of 'biopiracy' generally do not focus on cases that violate laws or regulations, but rather on situations that do not respect ABS principles. To address this, UEBT has developed a framework on factors of risk and responsibility linked to ABS, which includes species, type of research, intellectual property protection, and marketing claims.

Finally, companies should establish how ABS must be mainstreamed in their activities, including pinpointing control points in the purchasing, sustainability, research and innovation, product development, legal and marketing departments.

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