



Nagoya Protocol

“Many of the large [pharmaceutical] companies with active natural products programmes and associated bioprospecting efforts overseas have closed their programmes Today natural product discovery is found largely in smaller discovery companies, semi-governmental or governmental entities and universities around the world.”

LAIRD, WYNBERG, Bioscience at a Crossroads: Implementing the Nagoya Protocol on Access and Benefit Sharing in a Time of Scientific, Technological and Industry Change, published by the CBD, 2012.

What is the Convention on Biological Diversity?

The Convention on Biological Diversity was inspired by the world community’s growing commitment to sustainable development. The CBD was opened for signature in June 1992 and entered into force in December 1993. The Convention has 3 objectives:

- Conservation of biological diversity
- Sustainable use of its components
- Fair and equitable sharing of benefits arising from utilization of genetic resources

The CBD requires its members to facilitate access to their genetic resources (GR) and users of such resources to share in a fair and equitable way the results of research and development and the benefits arising from the commercial use of such resources.

EFPIA and IFPMA fully support the goals of the Convention on Biological Diversity (CBD) and stand ready to work with the EU to ensure the Protocol’s fair and balanced implementation across the EU.

What is the Nagoya Protocol?

The [Nagoya Protocol](#) is a supplementary agreement to the Convention on Biological Diversity (CBD), providing an international and transparent legal framework for the effective implementation of the third objective of the CBD. It was signed in October 2010, requiring signatories to take measures to ensure that only legally acquired genetic resources and associated traditional knowledge were utilized within their jurisdiction.

The Protocol rests on three main pillars:

- Access - Establish more predictable conditions for access to genetic resources.
- Benefit-sharing - Ensure benefit-sharing between users and providers of genetic resources.
- Compliance – Ensure that only legally acquired genetic resources are used.

The Nagoya Protocol entered into force on October 12th, 2014, as did partially EU Regulation no. 511/2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union.

Background information

Genetic resources can play a significant role in many economic sectors. A broad range of players in the Union, including academic researchers and companies from different sectors of industry use genetic resources for research

and development purposes. Within the pharmaceutical industry, lead compounds, vaccines, diagnostic materials, research tools and production processes may all be affected.

Actors at the beginning of the genetic resources value chain in the Union (mostly collections and academic researchers) pass on samples of genetic resources and first research results to other users that engage in basic or applied research. Actors situated at the end of the genetic resource value chain engage in often lengthy development activities that require significant investments with uncertain outcomes.

A clear framework of obligations for all users of genetic resources throughout what are often long and complex value chains is essential for creating an enabling context for facilitated access to quality samples of genetic resources with high legal certainty.

Implementation in the EU: EFPIA position on the Draft Regulation on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising from their Utilization.

The European Union and all of its 27 Member States are Parties to the CBD. Regulation 511/2014 implements the Nagoya Protocol within the European Union.

Its objectives are to protect the rights of countries and of indigenous and local communities that allow their genetic resources and associated traditional knowledge to be used, while also giving researchers in Europe improved, simple and reliable access to quality samples of genetic resources.

- o The proposed Regulation would oblige users to check that genetic resources and associated traditional knowledge have been accessed in accordance with the applicable legal requirements in the country of origin, and that the benefits are fairly and equitably shared. Users would also be obliged to declare that they have exercised the “due diligence” required by the Regulation (or will do so in future). Users found in breach of the Regulation would be exposed to sanctions.
- o The Regulation also aims to help researchers and industry comply with the rules. Sectoral best practices will play an important role, and associations of users may request formal recognition of best practices on access and benefit-sharing, building on existing access and benefit-sharing codes of conduct for the academic sector and for different industries.
- o An EU-register of trusted collections such as seed banks and botanical gardens would be established, identifying collections committed to supplying only fully documented samples of genetic resources. Users acquiring their research material from a trusted collection would be considered to have complied with most of the due diligence obligation. An EU platform would also be set up to streamline access conditions in Member States.

EFPIA-IFPMA Position Paper

Definitions: Genetic Material vs. Genetic Resources

Genetic material refers to any material of plant, animal, microbial or other origin containing functional units of heredity. Genetic resources refer to genetic material of actual or potential value.

Further readings

- Adoption of Regulation on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (Nagoya Protocol)
- Realising the potential of natural resources
- Attacking the Patent System for Pricing Issues Is a Non-Starter
- The Nagoya Protocol on Access to Genetic Resources – The Important Issues Behind a Big Name
- Nagoya Protocol Enters into Force: Challenges ahead