

# Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (Nagoya Protocol 2010): compliance measures for users in the Union

2012/0278(COD) - 04/10/2012 - Legislative proposal

**OBJECTIVE:** to implement the Nagoya Protocol in the Union and to allow the ratification of this Union Treaty with a view to creating new opportunities for nature-based research, and contribute to the development of a bio-based economy.

**PROPOSED:** Regulation of the European Parliament and of the Council.

**CONTEXT:** **genetic resources** - the gene pool in both natural and cultivated stocks - play a **significant and growing role in many economic sectors**: 26% of all new approved drugs over the last 30 years are either natural products or have been derived from a natural product.

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, some also use traditional knowledge associated with genetic resources.

The main international instrument governing access to and use of genetic resources is the **Convention on Biological Diversity (CBD)** approved by Council Decision 93/626/EEC. However, the CBD currently provides little detail on how access and benefit-sharing (ABS) for the use of genetic resources and associated traditional knowledge should be done in practice. In the absence of clear rules or with very burdensome rules in most provider countries, European researchers and companies have repeatedly been accused of “biopiracy” by countries claiming a violation of their sovereign rights.

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 new international treaty adopted on 29 October 2010 by the consensus of the Parties to the CBD. It is expected to enter into force in 2014. Once operational, the Nagoya Protocol will generate significant benefits for biodiversity conservation in States that make available the genetic resources over which they hold sovereign rights. It will in particular:

- establish more predictable conditions for access to genetic resources;
- ensure benefit-sharing between users and providers of genetic resources;
- ensure that only legally acquired genetic resources are used.

The Commission proposes from then on to **set out a clear and sound framework for implementing the Nagoya Protocol** that should enhance opportunities available for nature-based research and development activities in the Union.

**IMPACT ASSESSMENT:** in particular, the Commission analysed in-depth **two options for access measures and four options for user-compliance measures**. All options were analysed against a business as usual baseline without implementing measures at EU or Member State level. It also analysed two options on the temporal application of EU-level measures as well as a range of complementary measures.

The analysis identified:

- 1) the preferable option on access as the establishment of an EU platform for discussing access to genetic resources and sharing best practices;
- 2) the identified preferable option on user-compliance as a due diligence obligation on EU users complemented by a system to identify collections as “trusted sources” of genetic resources.

LEGAL BASIS: Article 192(1) of the Treaty on the Functioning of the European Union.

CONTENT: the proposal sets out obligations for users of genetic resources and traditional knowledge associated with genetic resources in the Union.

The proposal sets out obligations for users of genetic resources and traditional knowledge associated with genetic resources in the Union. It would oblige all users to exercise due diligence to ascertain that genetic resources and traditional knowledge associated with genetic resources used were accessed in accordance with applicable legal requirements and that, where relevant, benefits are fairly and equitably shared upon mutually agreed terms. To that end, all users would need to seek, keep and transfer to subsequent users certain information relevant for access and benefit-sharing. The proposal sets out minimum features of due diligence measures.

**Obligations of users:** The proposal obliges all users to exercise **due diligence** to ascertain that genetic resources and traditional knowledge associated with genetic resources used were accessed in accordance with applicable legal requirements and that, where relevant, benefits are fairly and equitably shared upon mutually agreed terms. To that end, all users would need to seek, keep and transfer to subsequent users certain information relevant for access and benefit-sharing. The proposal sets out minimum features of due diligence measures.

**Good practice:** to comply, users could build on existing ABS **codes of conduct** developed for the academic sector and different industries.

Associations of users may request the Commission to recognise a specific combination of procedures, tools or mechanisms overseen by an association as best practice. Competent authorities of the Member States would be obliged to consider that the implementation of a recognised best practice by a user reduces that user's risk of non-compliance and justifies a reduction in compliance checks.

**Union trusted collections:** this proposal also foresees a system of Union trusted collections that would substantially lower the risk that illegally acquired genetic resources are used in the Union. Collections that wish to be included in the register of Union trusted collection would commit to supply only fully documented samples of genetic resources to third persons for their use.

The competent authorities of the Member States will have to verify if a collection meets the requirements for recognition as Union trusted collection. Users acquiring a genetic resource from a collection included in the Union register would be considered to have exercised due diligence as regards the seeking of all necessary information.

**Checks on user compliance:** users would be obliged to declare at identified points that they complied with their due diligence obligation.

Competent authorities of Member States should check on a risk-based approach whether users comply with their obligations under this Regulation. Member States should also ensure that infringements of this Regulation by users are sanctioned by effective, proportionate and dissuasive **penalties**.

Lastly, the proposed Regulation also foresees the **creation of a Union platform on access**.

**BUDGETARY IMPLICATION:** the proposal does not entail any significant financial implications for the Community budget.