# 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) - 11/03/2014 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 630 votes to 14 with 38 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union.

The matter had been referred back to committee during the plenary session of 12 September 2013.

Parliament adopted its position in first reading following the ordinary legislative procedure. The amendments adopted in plenary are the result of an agreement negotiated between Parliament and Council.

**Objective**: Parliament wanted to clarify that the objective of the Regulation is the fair and equitable sharing of the benefits arising from the utilisation of genetic resources, thereby contributing to the **conservation of biological diversity** and the sustainable use of its components, in accordance with the objectives of the Convention on Biological Diversity the ('Nagoya Protocol').

**Obligations of users**: the amended text stipulates that users shall exercise due diligence to ascertain that genetic resources and traditional knowledge associated with genetic resources which they utilise have been accessed in accordance with applicable access and benefit-sharing legislation or regulatory requirements. Genetic resources and traditional knowledge associated with genetic resources shall only be transferred and utilised in accordance with **mutually agreed terms** if they are required by applicable legislation or regulatory requirements.

Accordingly, businesses, private collectors and institutions who use genetic resources that come, for example, from plants and animals in developing countries must seek, keep and transfer to subsequent users:

**the internationally-recognised certificate of compliance**, as well as information on the content of the mutually agreed terms relevant for subsequent users; or where no internationally-recognised certificate of compliance is available, **information and relevant documents on**: (i) the date and place of access of genetic resources or of traditional knowledge associated with genetic resources; (ii) the source from which the genetic resources or traditional knowledge associated with genetic resources were directly obtained, as well as subsequent users; (iii) the presence or absence of rights and obligations relating to access and benefit-sharing including rights and obligations regarding subsequent applications and commercialisation; (iv) mutually agreed terms, including benefit-sharing arrangements, where applicable.

'Internationally recognised certificate of compliance' means a permit or its equivalent issued at the time of access as evidence that the genetic resource it covers has been accessed in accordance with the decision to grant prior informed consent, and that mutually agreed terms have been established for the user and the utilisation specified therein by a competent authority, that is made available to the Access and Benefit-sharing Clearing House established under the Nagoya Protocol.

Users acquiring **a genetic resource that is determined to be the causing pathogen of a present or imminent public health emergency** of international concern, or of a serious cross-border threat to health for the purpose of public health emergency preparedness in not yet affected countries and response in affected countries, shall fulfil the obligations listed the text: (i) one month after the imminent or present threat to public health is terminated, or (ii) three months after commencement of utilisation of the genetic resource, whichever is the earlier.

**Register of collections**: the Commission shall establish and maintain a register of collections within the Union. It shall ensure that the register is internet-based and is easily accessible to users. The register shall include the references of the collections of genetic resources, or of parts of those collections, identified as meeting the criteria set out in the regulation.

**Complementary measures**: the Commission and Member States shall, as appropriate:

- **promote and encourage information**, awareness-raising and training activities to help stakeholders and interested parties to understand their obligations arising from the implementation of this Regulation, and of the relevant provisions of the Convention and the Nagoya Protocol in the Union ;
- **encourage the development of sectoral codes of conduct**, model contractual clauses, guidelines and best practices, particularly where they would benefit academic, university and non-commercial researchers and small and medium-sized enterprises;
- encourage users and providers to direct benefits from the utilisation of genetic resources **towards the conservation of biological diversity** and the sustainable use of its components in accordance with the provisions of the Convention;
- promote measures in support of collections that contribute to the conservation of biological diversity and cultural diversity.

**Consultation forum**: the Commission shall ensure a balanced participation of representatives of the Member States and other interested parties in issues related to the implementation of this Regulation. They shall meet in a consultation forum.