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) - 12/09/2013 - Text adopted by Parliament, partial vote at 1st reading/single reading

The European Parliament adopted **amendments** to 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 the competent committee. **The vote on the legislative resolution was set back to a later session**.

The main amendments adopted by Parliament concerned the following points:

Objective : Members 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 amendments also stated that the Regulation :

- lays down obligations for users of genetic resources and traditional knowledge associated with genetic resources;

- includes provisions encouraging activities by relevant actors to raise awareness of the importance of genetic resources and traditional knowledge associated with genetic resources and related access and benefit-sharing issues, as well as activities contributing to capacity-building in developing countries, in line with the Nagoya Protocol's provisions.

User obligations: Members called for the utilisation of illegally acquired genetic resources to be prohibited in the Union. "Illegally acquired genetic resources" means genetic resources and traditional knowledge associated with genetic resources acquired in contravention of the applicable international and national law on access and benefit-sharing in the country of origin. The amendments make the following points:

With a view to **improving the chain of custody of genetic resources** and the associated traditional knowledge, users must exercise due diligence to ascertain that access to genetic resources was obtained with prior informed consent and based on mutually agreed terms.

Genetic resources should only be transferred to other users if in accordance with the internationally recognised **certificate of compliance** and mutually agreed terms.

If **subsequent users** envisage utilising such genetic resources or traditional knowledge under conditions that were not included in the prior terms, those users shall be required to seek mutually agreed terms from the country of origin.

Users, when negotiating mutually agreed terms with providers of genetic resources or of traditional knowledge associated with genetic resources, should seek to ensure that such terms contribute to the conservation of biological diversity

Union trusted collections: Parliament proposed **deleting** Article 5 as regards Union trusted collections. In a recital, it recalled that most collections are the most accessible suppliers of genetic resources and traditional knowledge associated with genetic resources utilised in the Union. As suppliers they could play an important role in helping other users in the chain of custody to comply with their obligations. In order to do so, Members suggested that a **system of Union registered collections** should be set in place which would substantially lower the risk that illegally acquired genetic resources are utilised in the Union. Union registered collections should adhere to the objective of the Nagoya Protocol.

Competent authorities and potential users: the competent authorities and the focal point on access and benefit-sharing shall provide **advice to the public and potential users** seeking information on the implementation of the Regulation and of the relevant provisions of the Convention and the Nagoya Protocol in the Union.

Monitoring user compliance: amendments provided that the users shall declare to the competent authorities that they have fulfilled the obligations and shall submit the related information on the occasion of establishing prior informed consent and mutually agreed terms; applying for patents or for new plant variety rights at relevant national, regional or international institutions; or requesting market approval for a product developed on the basis of genetic resources.

Competent authorities shall **verify the information** and transmit to the Access and Benefit Sharing Clearing House Mechanism, to the Commission and if appropriate to the competent authorities of the State concerned. The Commission shall within three months summarise the information received and make it public in an easily accessible open, internet-based, format.

Montoring of compliance with the rules : the amendments provided that users must declare to the competent authorities that they have fulfilled the obligations and **submit the related information** on the occasion of: (i) establishing prior informed consent and mutually agreed terms; (ii) receiving research funding involving utilisation of genetic resources and traditional knowledge associated with genetic resources; (iii) applying for patents or for new plant variety rights covering, inter alia, the genetic resources accessed.

Competent authorities shall **verify the information** provided and transmit to the Access and Benefit Sharing Clearing House Mechanism, to the Commission and if appropriate to the competent authorities of the State concerned. The Commission shall summarise the information received and **make it public in an internet-based format**.

Penalties: Parliament called for fines to be proportional to the value of the use activities related to the genetic resources concerned and that at least effectively deprived those responsible of the economic benefits derived from the infringement.

Cooperation : Members considered that the Commission should seek arrangements with the European Patent Office and with the World Intellectual Property Organization to ensure that references to genetic resources and their origin are included in patent registrations.

Union platform on the access and benefit-sharing: the Union platform must contribute to the streamlining of access conditions at Union level by discussing related issues, including the design and performances of access regimes established in Member States, the promotion of research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries.

Any advice, guidance or opinions provided shall have **due regard for the requirement to involve the relevant indigenous and local communities** concerned.

Additional measures: the Commission and the Member States should also, if necessary:

- take measures to support, including through existing research programmes, collections that contribute to the conservation of biological diversity and cultural diversity but have insufficient means, to register their collections in the Union register;
- ensure that, in the event of illicit use, providers who are competent to grant access to genetic resources and sign mutually agreed terms are entitled to bring an action to prevent or stop such utilisation, including through injunctions, and to seek compensation for any damages resulting thereof;
- encourage users and providers to direct benefits arising from the utilisation or subsequent commercialisation of genetic resources towards the conservation of biological diversity;
- support regional cooperation on benefit-sharing regarding transboundary genetic resources;
- support research and development of genetic catalogues both within the Union and in third countries.

Consultation Forum: Members considered that Member States experts as well as stakeholder organisations should have an opportunity to participate and contribute to the implementation of the Regulation. To this end, they proposed the creation of a Consultation Forum based on the model in the Eco-Design Directive 2009/125/EC.