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

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The Committee on the Environment, Public Health and Food Safety adopted the report by Sandrine BÉLIER (Greens/EFA, FR) 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 committee recommends that the European Parliament's position at first reading, following the ordinary legislative procedure, should amend the Commission's proposal as follows:

Objective: Members specify that the objective of this 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 aim to:

- lay down obligations for users of genetic resources and traditional knowledge associated with genetic resources;
- include 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.

User obligations: Members call for the utilisation of illegally acquired genetic resources to be prohibited in the Union. "Illegally acquired genetic resources" shall mean 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.

With a view to **improving the chain of custody of genetic resources** and the associated traditional knowledge, users shall exercise due diligence to ascertain that genetic resources and traditional knowledge associated with genetic resources used were accessed in accordance with applicable access and benefit-sharing legislation or regulatory requirements, after obtainment of **prior informed consent** when so required and with full respect of existing duties regarding fair and equitable benefit sharing upon **mutually agreed terms**.

Genetic resources shall only be transferred to other users if in accordance with the internationally recognised **certificate of compliance** and mutually agreed terms, or prior informed consent and mutually agreed terms.

In the absence of mutually agreed terms or if **subsequent users** envisage utilising such genetic resources or traditional knowledge under conditions that are 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, shall seek to ensure that such terms **contribute to the conservation of biological diversity** and the sustainable use of its components and to technology transfer to developing countries.

Union trusted collections: Members **deleted** Article 5 as regards Union trusted collections. Most collections are the most accessible suppliers of genetic resources and traditional knowledge associated with genetic resources utilised in the Union. As suppliers they can play an important role in helping other users in the chain of custody to comply with their obligations. In order to do so 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 this Regulation and of the relevant provisions of the Convention and the Nagoya Protocol in the Union.

Monitoring user compliance: amendments provide 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.

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

Union platform on the access and benefit-sharing: the Union platform shall 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 such 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 situations where genetic resources and associated traditional knowledge are utilised illegally, or not in compliance with prior informed consent or mutually agreed terms, 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;
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encourage users and providers to direct benefits arising from the utilisation or subsequent commercialisation of genetic resources towards the conservation of biological diversity and the sustainable use of its components;

- support, including through capacity-building, upon request, regional cooperation on benefit-sharing regarding transboundary genetic resources and associated traditional knowledge;
- support research and development of genetic catalogues both within the Union and in third countries.

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