



EUROPEAN COMMISSION

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Dear President,

The Commission would like to thank the Riksdag for its Reasoned Opinion on the Commission 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 {COM (2012) 576 final}.

Although the Opinion of the Riksdag is generally positive, it raises a point on the application of the principle of subsidiarity and proportionality. It in particular considers the EU proposal for the establishment of a Union platform on access to genetic resources disproportionate and in breach of the subsidiarity principle (art.13 of the proposal).

The Riksdag argues that the proposal as it stands does not exclude transfer of national competences to the EU in the field of access to genetic resources. It considers that the creation of a Union platform on access designed to discuss national access legislation is an unnecessary measure with no advantages and that this would represent an initial step for an EU harmonized access law in an area where the legislative competence should remain with the Member States.

The Commission takes note of these concerns. It would however like to stress that the proposal for establishing a platform for discussion is non-binding; it does not create obligations for the Member States nor in any way imply a transfer of sovereignty to the Union. The Commission clearly indicated in its proposal that it did not intend to legislate in the area of access, which remains under Member States sovereignty.

In the Commission's view there is no need for harmonized EU rules on access nor is there the intention to transfer national competences to the Union. The establishment of an EU platform on access to genetic resources is proposed as a flexible way for discussing access practices between EU Access and Benefit Sharing (ABS) focal points, competent national authorities, and EU stakeholders. Deliberations would not be legally binding on participants and could include: access to genetic resources in Member States requiring Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT); simplified access for non-commercial research; access practices of EU ex-situ collections; access of EU stakeholders in non-EU countries; and the sharing of best practices.

The Commission believes the proposal is justified by the fact that in the area of access to genetic resources no legislation exists at present: only 2 Member States have minimum access rules in place. Therefore there is a strong potential for Member States to learn

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from each other in the development and implementation of policies on ABS. The platform would contribute to collective learning and thus help Member States to make choices on issues such as specialised ABS systems, access requests by researchers or companies from non-Parties. In fact the Nagoya Protocol, especially in its Article 8, obliges Parties to establish special rules for access in order to encourage non-commercial research, to deal with present or imminent emergencies threatening human, animal or plant health and to tackle the issue of genetic resources for food and agriculture.

Since R&D activities in the EU are not confined to national boundaries, companies and researchers establish transnational collaborations and there is a need for Member States to streamline their access rules in order to maximize R&D opportunities inside the Union. The platform would help to showcase best practices, allowing mutual learning between Member States but also assist potential users to identify the most suitable access frameworks for their purposes. Both aspects could positively contribute to research and development opportunities in the EU.

The Commission hopes that these clarifications address the comments and concerns raised in the Reasoned Opinion submitted by the Riksdag and looks forward to continuing our constructive political dialogue in the future.

Yours faithfully,

Maroš Šefčovič
Vice-President