EUROPEAN COMMISSION

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Dear President,

The Commission would like to thank the Senato della Repubblica for its Reasoned Opinion 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 {COM (2012) 576 final}, and apologises for the delay in replying.

The Reasoned Opinion of the Senato della Repubblica indicates that the draft Regulation is not in line with the principle of subsidiarity and proportionality as laid down in Protocol No. 2 of the Treaty on the Functioning of the European Union (TFEU). It also contains several other observations.

The Commission takes note of the concerns of the Senato della Repubblica in relation to the respect of the subsidiarity principle as well as the principle of proportionality. However, the reasons given by the Senato della Repubblica do not, in the Commission's view, refute the arguments laid down in the legal elements of the proposal's explanatory memorandum. As correctly highlighted by the Senato della Repubblica, different stakeholders throughout the EU use genetic resources; this, in the Commission's opinion, justifies a uniform approach at EU level. There is a need for the EU to streamline user compliance rules in order to maximize R&D opportunities inside the Union. The Commission is convinced that this can be best achieved in the form of an EU regulation. The explanatory memorandum also explains why, in the Commission's opinion, Article 192 paragraph 1 is the correct legal basis for the proposed Regulation.

The Senato della Repubblica also addresses the need for clarifications concerning collections. The provisions concerning collections are being reviewed in the course of the dialogue with the Member States and the Commission believes that this would clarify the open questions raised by the Senato della Repubblica concerning collections.

Nonetheless, the Commission would like to stress that the possibility for collections to become trusted collections in accordance with Article 5 of the proposed Regulation does not create an obligation for such collections in the respective Member State. Article 5 would offer to those collections that have the intention and the capacity to meet the requirements established in the Regulation to become certified and to offer their services to users. The requirements are very generic and the Commission does not see the need for trusted collections to be subdivided into different categories, e.g. with regard to

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agriculture and in situ *and* ex situ. *The concept is to leave the scope of Article 5 broad enough for it to be applicable to all types of collections concerned.*

As for the observations of the Senato della Repubblica on traditional knowledge it has to be stressed that "traditional knowledge associated to genetic resources" is defined in Article 3(8). In terms of this definition, traditional knowledge associated with genetic resources is what is described as such in benefit-sharing agreements and the draft Regulation therefore does not cover the issue of "access" to such genetic resources and traditional knowledge associated with genetic resources. The Regulation only provides for a clarification to what extent they actually are covered by the provisions concerning user compliance, which are designed to ensure compliance with Articles 14 through 17 of the Nagoya Protocol.

It has to be noted that - so far - neither the Nagoya Protocol nor the Convention on Biological Diversity nor other international or EU legislation contain a suitable definition of "traditional knowledge associated to genetic resources". It was important that the EU proposal defines this term in a suitable manner in order to facilitate the compliance with users' obligations deriving from the Nagoya Protocol when using a genetic resource together with an associated traditional knowledge.

There seems to be a need for clarification concerning the parties involved in the "mutually agreed terms". In accordance with the Nagoya Protocol, the terms of benefit sharing will have to be negotiated between the provider and the user in a private law contract. Therefore the European Union will not be involved in the benefit sharing aspect.

As Article 6, paragraph 1, 1st sentence of the proposed Regulation states, it would be up to each Member State to designate one or more competent authorities, so that Member States are free to decide how to organise their competent authorities, e.g. by choosing a sectoral approach.

With regard to the international duties to ratify and implement the Nagoya Protocol the Commission and the Member States are working closely together with the aim of producing a comprehensive set of implementing provisions that reduces to a minimum the need for additional legislative measures in the Member States and allows for a timely ratification of the Protocol.

The Commission hopes that these clarifications address the comments and concerns raised by the Senato della Repubblica and looks forward to continuing our political dialogue in the future.

Yours faithfully,

Maroš Šefčovič
Vice-President