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NOTE

from: General Secretariat

to: Delegations

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Subject: 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
- Information from the Commission

Delegations will find in Annex an information note from the Commission on the above-mentioned subject, which will be dealt with under "other business" at the Council (Environment) meeting on 25 October 2012.

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

- Information from the Commission -

In December 2010 the Council acknowledged the importance of the Nagoya Protocol on ABS and urged the Commission to work towards early EU ratification. After conducting the necessary public consultation and developing a comprehensive Impact Assessment, the Commission transmitted a legislative proposal to the Council and the European Parliament in early October 2012.

The Commission's proposal for an EU Regulation sets out obligations for users of genetic resources and traditional knowledge associated with genetic resources in the Union. It would oblige all persons conducting research and development on genetic resources to exercise due diligence to ascertain that genetic resources and traditional knowledge associated with genetic resources used were accessed in accordance with applicable legal requirements and that, where relevant, benefits are fairly and equitably shared upon mutually agreed terms. To that end, all users would need to seek, keep and transfer to subsequent users certain information relevant for access and benefit-sharing. The proposal sets out minimum features of due diligence measures.

Users would be able to build on existing ABS codes of conduct developed for the academic sector and for different industries. Associations of users may request the Commission to recognise a specific combination of procedures, tools or mechanisms overseen by an association as best practice. Competent authorities of the Member States would be obliged to consider that the implementation of a recognised best practice by a user reduces that user's risk of non-compliance and justifies a reduction in compliance checks.

Collections play a critical role in managing ABS-related information at the beginning of the EU user chain. Most users of genetic resources in the EU acquire their samples and related information from collections (gene banks, microorganism collections, botanical gardens). And almost all collecting activities in the wild are done by staff of collections or by university-based researchers that will place sample of collected material in a reference collection. The proposal foresees establishing a system of Union trusted collections to substantially lower the risk that illegally acquired genetic resources are supplied to EU users. Collections that wish to be included in the register of Union trusted collection would commit to supply only fully documented samples of genetic resources to third persons for their use. The competent authorities of the Member States would verify that a collection meets the requirements for being recognised as Union trusted collection. Users acquiring a genetic resource from a collection included in the Union register would be considered to have exercised due diligence as regards the seeking of all necessary information. The proposed system of Union trusted collections would be particularly beneficial for academic researchers as well as for small and medium sized enterprises.

Users would be obliged to declare at identified points that they complied with their due diligence obligation. Competent authorities of Member States would furthermore check on a risk-based approach whether users comply with their obligations under the proposed Regulation. Member States would also ensure that breaches of the Regulation by users are sanctioned by effective, proportionate and dissuasive penalties.

Taking into account the transnational character of access and benefit-sharing transactions, the proposed Regulation foresees that competent authorities of the Member States should cooperate between themselves, with the Commission, and with authorities of third countries in implementing the proposed Regulation.

As required by the Nagoya Protocol, and to lower costs and enhance legal certainty for users, the Regulation also foresees that the Commission and the Member States would take appropriate complementary measures to raise awareness, to support the development of codes of conduct and best practices, or to deploy advanced communication tools for monitoring and tracking genetic resources flow.

The proposed EU Regulation would comprehensively implement the user-compliance pillar of the Nagoya Protocol and enable ratification of the Nagoya Protocol by the Union and its Member States. Member States would retain full discretion whether or not to require prior informed consent and benefit-sharing for genetic resources that belong to them. Their decisions on this would not be a precondition for Union ratification of the Nagoya Protocol.
