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NOTE

from: General Secretariat

to: Delegations

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- COM(2012) 576 final + COR 1

Subject: Current legislative files

- 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 Presidency
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Delegations will find in Annex an information note from the Presidency on the above-mentioned subject, which will be dealt with under "other business" at the Council (Environment) meeting on 18 June 2013.

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 Presidency -

Background

The Commission adopted the abovementioned proposal on 5 October 2012 and presented it to the Council on 25 October. Its main objective is to implement in the EU the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity and to enable its ratification by the EU. The Working Party on the Environment (WPE) started its examination in the past semester and held meetings in January, February, April and June in 2013, discussing Presidency's compromise texts and recently considering the draft amendments by the European Parliament (the ENVI vote is expected for 4 July 2013). The Council held an orientation debate at its meeting on 21 March.

The proposed Regulation would oblige users (feed and food industry, biotechnology sector, pharmaceutical and cosmetics industry, universities, collections of genetic resources and museums, researchers) to check and declare that genetic resources and associated traditional knowledge have been accessed in accordance with the applicable legal requirements in the country of origin ("due diligence obligation"), and that the benefits are fairly and equitably shared upon mutually agreed terms. Users found in breach of the Regulation would be sanctioned.

Sectoral best practices will play an important role, and associations of users may request formal recognition of best practices on access and benefit-sharing. An EU-register of trusted collections such as seed banks and botanical gardens would be established, identifying collections committed to supplying only fully documented samples of genetic resources. Users acquiring their material from a trusted collection would be considered to have complied with the due diligence obligation.

The Regulation would only apply to genetic resources and traditional knowledge that were acquired and utilised after the entry into force of the Nagoya Protocol for the EU.

State of play

Regarding the proposed obligations of users of genetic resources and their monitoring by the competent authorities of the Member States, the following points emerged from the discussions within Council:

- an overriding aim remains to keep burden and costs for users or authorities at a reasonable, proportional level. Legal certainty for users is a key issue. However, any new Union legislation should be comprehensive enough to cover the provisions of the Nagoya Protocol;
- due diligence obligation of users should be accompanied by their monitoring by authorities in order to ensure compliance with the Nagoya Protocol. While some Member States are generally satisfied with the approach proposed by the Commission others want to see monitoring of and checks on user compliance strengthened and increased user obligations although there are also some views supporting to have less detail on enforcement by authorities and allow Member States to devise systems as they see fit.

Other aspects of the regulation that have been discussed in detail are:

- the internationally recognised certificate of compliance as a tool to prove "due diligence";
- the links with other international instruments relating to the use of genetic resources;
- the use of genetic resources for Research and development (commercial and non-commercial);
- the role of trusted collections and recognised best practices to ensure compliance with the Nagoya Protocol;
- the Union platform on access.

The issue of prohibition on the use of illegally accessed genetic resources has been also mentioned during the preparatory work.

Work will continue during the next months. The timely adoption of this Regulation will allow the EU and its Member States to ratify the Nagoya Protocol before the First Meeting of the Conference of the Parties serving as the Meeting of the Parties to the Nagoya Protocol (tentatively planned 6-17 October 2014 in Pyeongchang, Korea).

It is to be mentioned in this context that the WPE has also advanced substantially consideration of the proposal for a Council decision on the conclusion, on behalf of the Union, of the Nagoya Protocol at its meeting in February. This proposal is subject to the consent by the European Parliament (TFEU Article 218.6(a)) before adoption by the Council.
