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COVER NOTE

from:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	4 October 2012
to:	Mr Uwe CORSEPIUS, Secretary-General of the Council of the European Union
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Subject:	Commission staff working document Executive summary of the Impact Assessment *accompanying the document* 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

Delegations will find attached Commission document SWD(2012) 291 final.

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COMMISSION STAFF WORKING DOCUMENT

EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT

Accompanying the document

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}
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COMMISSION STAFF WORKING DOCUMENT

EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT

Accompanying the document

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

Executive summary

This impact assessment (IA) accompanies the Commission proposal for an EU Regulation on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the European Union.

The presentation of the proposal responds to political commitments for an early EU implementation and ratification of the Nagoya Protocol made by the European Parliament, by the Council of the European Union, and by the Commission. It is the next step after the Union formally signed the Nagoya Protocol in June 2011.

For preparing this IA, DG Environment contracted an external consultant team to undertake a comprehensive study. It also conducted a public consultation with stakeholders. Commission officials further held numerous meetings with experts from stakeholders and Member States, and also consulted with several international partners. The findings of this work are summarized in this document.

The Convention on Biological Diversity (CBD) obliges all Parties to facilitate access to genetic resources over which they hold sovereign rights. It also obliges all Parties to share in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Party providing these resources. The CBD also addresses the rights of indigenous and local communities that hold traditional knowledge associated with genetic resources, and which may provide important lead information for the scientific discovery of interesting genetic or biochemical properties.

However, the CBD provides little detail on how access and benefit-sharing (ABS) for the use of genetic resources and associated traditional knowledge should be done in practice. Particularly industrialized country Parties have been reluctant to adopt measures supporting effective benefit-sharing of their researchers and companies. As one consequence, some provider countries have established increasingly restrictive conditions for access to genetic resources or associated traditional knowledge. At the same time and in the absence of clear rules, European researchers and companies have been accused of 'biopiracy' by countries claiming a violation of their sovereign rights. These problems have seriously undermined global progress to conserve and sustainably use biological diversity; not least since states that are considered as 'biodiversity-hotspots' stand to gain the most from an effective ABS framework.

The Nagoya Protocol is a new international treaty adopted on 29 October 2010 by the 193 Parties to the CBD by consensus. It is a treaty with legally binding force that significantly expands the general ABS framework of the CBD. The Nagoya Protocol is expected to enter into force in 2014. Once operational, it will generate significant benefits for biodiversity conservation in states that make available the genetic resources over which they hold sovereign rights. It will in particular:

– Establish more predictable conditions for access to genetic resources.

– Ensure benefit-sharing between users and providers of genetic resources.

– Ensure that only legally acquired genetic resources are used.

The Nagoya Protocol will need to be ratified by the Union and all of its Member States. The Union and each of its Member States must be able to demonstrate compliance with all Protocol obligations. How this is achieved is an entirely internal matter to the EU and its Member States. The concrete approach chosen rests on legal and practical considerations: any EU-level intervention presupposes the existence of Union competence and the demonstration of added value that will not be achieved through implementing measures under the sole responsibility of Member States.

A broad set of options was considered in the course of the IA. All options were analyzed against a "business as usual"-baseline without implementing measures at EU or Member State level.

Options on access analyzed were "no EU-level action" (A-1) and the "establishment of an EU platform for discussing access and sharing best practices" (A-2).

Options on user-compliance analyzed were "Open method of coordination" (UC-1), "Self-standing general due diligence obligation on EU users" (UC-2), "General due diligence obligation on EU users complemented with a system to identify collections as 'trusted sources' of genetic resources" (UC-3), "Prohibition to utilise illegally acquired genetic resources or associated traditional knowledge with a 'downstream' monitoring system (UC-4).

The IA also analyzed two options for the temporal application of EU-level measures. These were the possibility of applying EU-level measures only to genetic resources or associated traditional knowledge acquired in the future (T-1) and the application of such measures as of the entry into force of the CBD in 1993 (T-2).

Complementary measures analyzed related to: Bilateral agreements between EU and major provider countries or regions (C-1); Sectoral codes of conduct and contractual model clauses (C-2); Technical tools for tracking and monitoring (C-3); and Awareness raising and training activities (C-4).

The specific criteria for analysing and comparing the options addressed issues specific to the Nagoya Protocol as well as economic, social and environmental impacts.

The best performing set of EU-level implementing measures identified in this IA are:

– the establishment of an EU platform where Member States, the Commission, and stakeholders will discuss access to genetic resources and the sharing of best practices (A-2).

– an obligation on EU users to take steps to the best of their ability to ensure that genetic resources and associated traditional knowledge utilized were acquired in line with access laws of provider countries and that resulting benefits are shared (UC-3).

– a system for identifying collections (botanical gardens, microorganism collections, gene banks etc) with control measures to assure that only well documented samples of genetic resources are made available for utilization (UC-3).

– complementary measures to enhance the effectiveness of the EU-level intervention (C-1, C-2, C-3, C-4).

The EU Regulation would only apply to genetic resources and traditional knowledge that were acquired and utilized after the entry into force of the Nagoya Protocol for the Union (T-1).

The EU platform for discussing access and sharing best practices has some potential to streamline access conditions applied by Member States that require prior informed consent. This would not result in an EU-level playing field on access. Nevertheless any narrowing of differences between Member State access frameworks would lower transaction costs and be particularly beneficial for SMEs and recipients of public funds. The EU platform would also showcase best practices on access. This would help Member States to learn from each other. It would also help users to identify the Member State with the best functioning access frameworks. Both aspects would positively contribute to research and development opportunities in the EU.

The due diligence obligation on EU users complemented by a system to identify collections as "trusted sources" would provide an EU-harmonised approach to implementing the user-compliance pillar of the Protocol. It would establish a level playing field for all actors in the EU genetic resources value chain, provide legal certainty, minimise their risks of operation and maximise research and development opportunities. It would also prevent differences in user-compliance obligations between different Member States that would result in costs and barriers for researchers and companies active in more than one Member State. Notably, stakeholders unanimously supported an EU harmonised approach to user-compliance in the consultation.

The system of EU measures for implementing the Nagoya Protocol could be based on the Union's environment competence. The creation of an EU-wide system of user-compliance measures could also be based on the Union's competence for the internal market. An EU-level intervention on user-compliance is also justified as it avoids negative effects on the internal market in nature-based products and services that would result from a fragmentation of user-compliance systems in the Member States and also has the best performance as regards the creation of an enabling context for research and development on genetic resources with benefits for the conservation and sustainable use of biological diversity worldwide.

The totality of measures taken at EU-level would allow Union ratification and achieve full EU compliance with Nagoya Protocol. Member States would have 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.