EUROPEAN COMMISSION
Impact Assessment Board

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Opinion

Title **DG ENV - Impact Assessment on a proposal for a Regulation of the European Parliament and of the Council Implementing the Nagoya Protocol in the European Union**

(draft version of 21 June 2012)*

(A) Context

Access to genetic resources and equitable sharing of the benefits derived from their use are key objectives of the Convention on Biological Diversity (CBD), to which the EU and its Member States are Parties to. However, the Convention does not provide detail on how access and benefit-sharing (ABS) for the use of genetic resources and associated traditional knowledge should be carried out in practice. 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", adopted on 29 October 2012 by the 193 Parties to the CBD, concretises the rights and obligations in relation to access and benefit sharing of genetic resources. This impact assessment sets out policy options for implementing the Nagoya Protocol in the EU and its Member States and examines the value-added of EU action in the form of coordinating and setting common rules, so as to enable the EU to ratify and comply with the Protocol.

(B) Overall assessment

While the report presents the case in a structured and largely accessible form, it should be improved in a number of respects. Firstly, it should more clearly situate the EU commitment to ratify and implement the Protocol within the international policy context and better explain the bottlenecks in current practices of accessing and sharing genetic resources in the EU. On this basis, it should better demonstrate and substantiate with further qualitative and anecdotal evidence that the unilateral implementation of the Protocol by Member States risks disrupting the functioning of the internal market. Secondly, the report should clarify the legal basis to be used to implement the Protocol at the EU level, and should present objectives that would better correspond to the key implementation challenges. Thirdly, it should better justify the choice of policy options and explain how exactly they would be implemented, monitored and enforced. Fourthly, the report should more fully assess and substantiate the impacts of options, particularly in terms of benefiting SMEs, lowering transactions costs, ensuring the efficient use of public funds or preserving sector competitiveness. Finally, the report should more transparently present the views of key stakeholder groups.

* Note that this opinion concerns a draft impact assessment report which may differ from the one adopted

(C) Main recommendations for improvements

(1) Strengthen the problem definition and the baseline scenario. The report should explain upfront the EU commitment to ratify and implement the Protocol and describe where the EU stands in relation to other major international players in terms of progress with implementation and the level of ambition. It should then describe in more detail the current approaches to access and benefit-sharing for the use of genetic resources in the EU and more clearly identify the existing bottlenecks. On this basis, the report should explain and substantiate problems related to the internal market (e.g. business disruptions) as well as to the relationship with third country providers of genetic resources (e.g. retaliation) and clarify whether these problems already exist or are likely to develop only in the future. In particular, the report should better demonstrate that the unilateral implementation of the Protocol by Member States will disrupt the functioning of the internal market and create difficulties for the relevant research and business sectors. In the absence of data on the use and exchange of genetic resources in the EU, this should be based on: (i) anecdotal evidence or case studies illustrating the costs of fragmentation for EU researchers and economic actors operating across EU borders and (ii) a clear overview of the range of possibilities that exist for implementing the Protocol at national level.

2) Clarify the legal basis and define more specific objectives. The report should clarify if the environment-related legal basis is to be used and which one concretely. It should explain whether it is within the EU competence to set binding rules on access to genetic resources and discuss in more depth the advantages of a collective approach over unilateral initiatives by Member States. This should include assessing to what extent the access legislations already developed by Spain and Bulgaria are likely to infringe on the free movement of researchers and goods. The report should then present objectives in more specific and operational terms, which better correspond to the identified implementation choices of the Protocol at EU level. Finally, the report should provide a more elaborated set of monitoring indicators which are more clearly linked to the objectives.

3) Better present and explain the content of the options. The report should explain the rationale behind the design of the policy options and describe how exactly they would be implemented, monitored and enforced. In particular, it should describe in more detail how compliance with the 'due diligence' provisions will be ensured in practice, and which concrete reporting obligations will be imposed on the users of genetic resources. The report should provide more information on the development of the foreseen guidance and its content. Furthermore, the report should clarify which kind of sanctions are envisaged and explain why a Regulation was considered to be the most appropriate legal instrument. Finally, the report should clarify which concrete problem(s) are addressed by the introduction of 'trusted sources' and if this approach is in line with creating the EU level playing field for all users of genetic resources.

4) Improve the assessment and comparison of the options. The main report should more fully and in greater detail assess the impacts of the considered policy options. It should provide further qualitative and anecdotal evidence to support the claim that the proposed measures would have positive impacts in terms of creating a level playing field, benefiting SMEs or lowering transaction costs, ensuring the efficient use of public funds, and preserving sector competitiveness. Furthermore, the report should assess in detail and quantify, where significant, the administrative burden for both users of genetic resources as well as national authorities (particularly in comparison to the unilateral implementation by Member States). It should better explain which users and Member

States would be most affected by the proposed measures and in what respect. The report should also assess the overall impact upon third country providers. Finally, it should provide a clearer comparison of each of the options against a more developed baseline scenario and better demonstrate their effectiveness as well as efficiency and coherence.

Some more technical comments have been transmitted directly to the author DG and are expected to be incorporated in the final version of the impact assessment report

(D) Procedure and presentation

The report should in a more differentiated manner present the different views of stakeholder groups, particularly on the problem definition and the policy options. Duplications in the annexes should be avoided, particularly in the sector description. Finally, the executive summary should be presented separately from the main report and revised according to the standards set out in the IA guidelines.

(E) IAB scrutiny process	
Reference number	2012/ENV/002
External expertise used	No
Date of IAB meeting	18 July 2012