

ROADMAP	
TITLE OF THE INITIATIVE	Communication on the EU strategy for implementation of the international regime on access to genetic resources and benefit-sharing (Nagoya Protocol)
TYPE OF INITIATIVE	<input checked="" type="checkbox"/> CWP <input type="checkbox"/> Non-CWP <input type="checkbox"/> Implementing act/Delegated act
LEAD DG – RESPONSIBLE UNIT	ENV.E.2
EXPECTED DATE OF ADOPTION	second semester 2012
VERSION OF ROADMAP	No: 3 Last modification: July 2011

This indicative roadmap is provided for information purposes only and is subject to change.

It does not prejudice the final decision of the Commission on whether this initiative will be pursued or on its final content and structure.

A. Context, problem definition
<p>(i) What is the political context of the initiative? (ii) How does it relate to past and possible future initiatives, and to other EU policies? (iii) What ex-post analysis of the existing policy has been carried out and what results are relevant for this initiative?</p>
<p>((i)+(ii) At the 10th Conference of the Parties (COP) in Nagoya in October 2010, the 193 Parties to the Convention on Biological Diversity (CBD) adopted a new Protocol to the CBD. The Nagoya Protocol (NP) is a legally binding agreement that addresses in a horizontal manner two issues:</p> <ul style="list-style-type: none"> - How will states provide access to genetic resources and/ or associated traditional knowledge under their jurisdiction, and - What measures shall states take to ensure that benefits arising from the use of such resources or knowledge are shared with provider countries, including indigenous and local communities that have rights to traditional knowledge associated with such resources? <p>The EU Council authorised the signature of the NP by the European Union and the Protocol has been signed on June 23rd 2011 by the EU and 12 of its MS. More signatures from MS are expected for September 2012 during the UN General Assembly. The Commission has started preparations for the implementation of the Protocol in the Union. In parallel and in accordance with Article 218.6 lit. a) TFEU, the Commission is preparing its Proposal to the Council for a decision on early ratification of the ABS Protocol by the Union in order to participate successfully to the NP CoP/MoP I in October 2012 in Hyderabad, India.</p> <p>The NP will have an impact on activities and related stakeholders in both the public and private sector in Europe. It will affect a series of activities, from researchers undertaking biodiversity-related work to gene banks and private companies that hold or use genetic material acquired in a third country. It will touch upon a range of areas under Union competence and may affect existing Union legislation; in addition and as the Union has not adopted specific legislation on access to genetic resources and benefit-sharing, new Union legislation will most likely be needed to fulfil the Union's obligations as a Party to the NP.</p> <p>Implementation of the Nagoya Protocol is therefore likely to add ABS-specific nuances to a range of areas under Union competence and provide an opportunity to introducing into those areas broader EU policy objectives on biodiversity.</p> <p>DG ENV has started an Impact Assessment in order to have a clear picture of the situation, but it is already clear that a specific number of issues will come up.</p> <p>Such an assessment would lead to the initiation of an ordinary legislative procedure, which takes between 18-30 months. Full EU legislation will then be in force in late 2014/ early 2015. This would be within the Nagoya commitment to have the Nagoya Protocol fully functional by 2015¹.</p> <p>The Commission has asked an external contractor to make an impact study to assist with the analysis of the legal and economic aspects of implementing the Nagoya Protocol in the EU. The final report of this study will be delivered in January 2012.</p>

¹ See CBD-UNEP "Strategic Plan for Biodiversity 2011-2020 and the Aichi Targets" target n° 16

In October 2011, on the basis of the interim report of the impact study, the Commission will launch a public consultation of interested stakeholders.

Based on the results of the study and taking into account the results of the public consultation, the Commission will, in early 2012, develop the IA to the Commission Communication.

The IA could be submitted to the IA-Board in March 2012. The Communication will also be finalised at that same time. If things run smoothly in ISC, the Communication could be adopted by the College in June 2012. From that moment we could begin the drafting of legislative proposals.

(iii) not applicable

What are the main problems which this initiative will address?

Access to genetic resources and equitable sharing of the benefits derived from their use is the third objective of the CBD. Article 15 and Article 8j of the Convention on Biological Diversity establish a very general framework of obligations of states as regards access to and sharing of the benefits derived from the use of genetic resources and/ or traditional knowledge associated with genetic resources. The complexity of the subject matter and the lack of detail in Articles 15 and 8(j) of the Convention contributed to a low level of domestic implementation by Contracting Parties. To date, only few of the 193 CBD Parties have adopted specific domestic legislation on access and benefit sharing. EU stakeholders currently face strong political concerns about "biopiracy" while existing ABS frameworks do not provide for legal certainty, clarity and transparency of applicable rules.

The NP concretises the rights and obligations of states under Articles 15 and 8j CBD. The Protocol addresses in a horizontal manner how states shall in the future provide access to genetic resources and/ or associated traditional knowledge under their jurisdiction and the measures to support the sharing of benefits arising from the use of such resources or knowledge.

This initiative indicates how the Commission would work to implement the Nagoya Protocol within the Union through legislative and other measures.

The adoption of the Commission's Communication would be the result of a political level decision to override eventual concerns of lawyers and ABS stakeholders due to the early ratification of the NP i.e. before implementing legislation is adopted. It will also contain certain minimum elements needed to preserve the EU acquis and EU's leading role in this area. Those elements are:

- A political commitment by the Council that despite the Protocol's early ratification, the full EU legislative process will continue through the ordinary legislative procedure;
- An advanced state of preparation for draft legislative proposals;
- Certain minimum rules in place within MS to avoid non-compliance procedures against the EU and its MS at an early stage of the Protocol's life.

Who will be affected by it?

EU stakeholders (research, industry, collections, museums, and gene-banks) will be affected. They now have a keen interest in the entry into force of the NP as it will provide them with improved access to genetic resources, legal certainty about uses of material as well as a level playing field vis-à-vis competitors from other jurisdictions.

The extent of the impact on specific stakeholders affected by EU implementation of the NP depends on policy-choices that will be made by Parties to the NP, which will impact on the choices for implementing the NP in the Union. It could include:

- EU researchers undertaking biodiversity-related research in third countries or at home based on genetic material acquired in a third country as well as foreign researchers undertaking biodiversity-related research in the EU;
- EU funders of biodiversity-related research;
- Industry using genetic resources for research and development (e.g., animal and plant breeding, food industry, biotechnology and pharmaceutical products, cosmetics, natural products and health-care);
- Non-commercial users and institutions such as universities and research centres, museums, botanical gardens, public and private collections of genetic resources as well as institutions hosting gene-banks in the EU.

- (i) Is EU action justified on grounds of subsidiarity?
- (ii) Why can Member States not achieve the objectives of the proposed action sufficiently by themselves? (Necessity Test)
- (iii) Can the EU achieve the objectives better? (Test of EU Value Added)

The provisions of the NP are relevant to a range of areas where the Community has competence to act, such as environment, public health, common commercial policy, customs cooperation, internal market, other policies related to the free movement of persons, agriculture, approximation of laws, development cooperation, research and technological development, judicial cooperation in civil matters etc. Furthermore, the NP could impact on a broad range of existing EC legislation in those areas and in particular in the internal market area; finally the NP may also affect a number of existing obligations with third Parties.

Having in mind the above elements it is clear that Member States alone cannot achieve the objectives established in the Protocol and therefore EU action can achieve them better. However, the specific balance between Union and Member State actions to implement the Nagoya Protocol in the Union and its Member States can only be assessed after the finalisation of an Impact Assessment initiated by the Commission.

B. Objectives of the initiative

What are the main policy objectives?

The Communication would set out policy options for implementing the Nagoya Protocol in the Union and its Member States in the international context as described above and in a way that creates legal certainty, clarity and transparency about applicable rules for all stakeholders. It will also address the appropriateness and choice of legal instruments to do so.

Do the objectives imply developing EU policy in new areas?

Implementation of the NP is likely to add ABS-specific nuances to a range of areas under Union competence where non-ABS specific legislation already exists. This provides an opportunity to introducing into those areas broader EU policy objectives on biodiversity, ecosystem services, green economy and the integration of environmental considerations into EU and international markets.

C. Options

- (i) What are the policy options being considered?
- (ii) What legislative or 'soft law' instruments could be considered?
- (iii) How do the options respect the proportionality principle?

Legislative and non-legislative options will be under consideration. Soft law instruments alone will not be sufficient to ensure compliance with the binding provisions of the Protocol. Full implementation of the Protocol may need either change on existing legislation or, as required, adoption of new EU legislation. These aspects can only be fully assessed in more detail after successful finalisation of an Impact Assessment already initiated by the Commission.

D. Initial assessment of impacts

What are the benefits and costs of each of the policy options?

The benefits for the EU are mainly the creation of legal certainty for economic operators and research and development in the area of the use of genetic resources. Both legislative and non-legislative instruments are needed for ensuring easiness and security of operations implying use of genetic resources. EU stakeholders will be able to access and use genetic resources which will contribute to the competitiveness of European research and research based industries. The costs can only be assessed after finalisation of an Impact Assessment initiated by the Commission.

Could any or all of the options have significant impacts on (i) simplification, (ii) administrative burden and (iii) on relations with other countries, (iv) implementation arrangements? And (v) could any be difficult to transpose for certain Member States?

It is likely that the implementation will have an impact on all these elements, but the specific impacts can only be assessed after finalisation of the impact assessment i.e. in the beginning of 2012.

- (i) Will an IA be carried out for this initiative and/or possible follow-up initiatives? (ii) When will the IA work start?
- (iii) When will you set up the IA Steering Group and how often will it meet? (iv) What DGs will be invited?

(i) Yes.

(ii) Work on the impact assessment has started in June 2011. In a first phase an impact study will be conducted using the services of an external contractor as well as a technical workshop to evaluate results. Upon finalisation

of that study, the IA will be finalised.
(iii) The Impact Assessment Steering Group will be set up in September 2011.
(iv) It is planned to invite services that have followed the Nagoya Protocol negotiations and that have also been involved in various inter-service consultations on the Commission's negotiating mandate. This includes: AGRI, DEVCO, ENTR, JLS, MARE, MARKT, SANCO, RTD, TAXUD and TRADE. It is planned that the Impact Assessment Group will meet two or three times (to frame the exercise, at interim and/ or pre-final stages).
(i) Is any of options likely to have impacts on the EU budget above €5m?
(ii) If so, will this IA serve also as an ex-ante evaluation, as required by the Financial regulation? If not, provide information about the timing of the ex-ante evaluation.
(i) Unlikely.

E. Evidence base, planning of further work and consultation
(i) What information and data are already available? Will existing impact assessment and evaluation work be used?
(ii) What further information needs to be gathered, how will this be done (<i>e.g. internally or by an external contractor</i>), and by when?
(iii) What is the timing for the procurement process & the contract for any external contracts that you are planning (<i>e.g. for analytical studies, information gathering, etc.</i>)?
(iv) Is any particular communication or information activity foreseen? If so, what, and by when?
(i) A thorough analysis of the legal and economic impact of different options for implementing the Nagoya Protocol in the Union is needed. The Commission and some Member States have continually and informally consulted stakeholders from research and industry over the years of negotiation of the Nagoya Protocol. However, the results of these consultations are not systematic and often of informal status. On the other side, literature and studies, both legal and scientific, dealing with ABS issues are abundant but refer to the situation before the adoption of the NP. According to our knowledge very few studies or analyses exist covering the post-Nagoya period. We have no knowledge about previous impact assessments and evaluation works on this subject.
(ii) The Commission's impact assessment will be supported by a study carried out by an external contractor. Further information gathered for the impact assessment will include: information from a public consultation; information from expert workshops with representatives from Member States and stakeholders; information obtained through consultations with other Commission services to identify existing EU legislation and evaluate its role for implementing the ABS Protocol in the Union, information obtained through informal consultations with other Parties of the Nagoya Protocol.
(iii) The IA requires a detailed understanding of relevant existing policies and of the potential impacts <i>inter alia</i> on EU industries. As said, the IA will be supported by a preparatory study. The contractor's work begins in July 2011. The duration of this contract is seven months.
(iv) Focussed communication will accompany the public consultation exercise. As appropriate, further press releases, explanatory memorandum and Q&A documents will accompany the proposals for ratification as well as eventual legislative proposals after their adoption by the college.
Which stakeholders & experts have been or will be consulted, how, and at what stage?
Over the years of negotiation on the Nagoya Protocol the Commission has built up a network of stakeholders and experts that includes the following groups, with which we mostly liaise through Brussels-based representations: pharmaceutical companies, biotechnology companies (including SMEs); museums and public collections of plants and animals, plant and animal breeders; natural products and health-care companies; cosmetics companies; horticultural industry; research laboratories and foundations; individual researchers; horticulture; experts on intellectual property rights from patent offices, NGOs.
During the initial phase of the expert study (September 2011), DG ENV will carry out a technical workshop with EU MS and ABS stakeholders such as above as well as with NGOs and third countries. Feedback from this consultation should provide additional input for the finalisation of the study.
DG ENV will also conduct an internet-based public consultation inviting any interested party to submit comments and observations.