

Submission by the EU and its Member States in reply to notification 2012-106 on the progress towards ratification and implementation of the Nagoya Protocol additional issues that may need to be addressed in preparation for the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol

Progress towards ratification and implementation of the Nagoya Protocol

The EU and its Member States are pleased to have the opportunity that will be provided during the eleventh meeting of the Conference of the Parties to take stock of progress made by Parties towards ratification and implementation of the Nagoya Protocol, to exchange experiences and to discuss challenges with a view to overcoming obstacles and to find constructive approaches to implementation.

The EU and 25 of its Member States have signed the Nagoya Protocol while it was open for signature.

As the Nagoya Protocol touches both on matters of EU and Member States competence, it will have to be ratified and implemented both by the EU and its 27 Member States.

The EU and its Member States are committed to the timely ratification and effective implementation of the Nagoya Protocol, at the earliest possible time before CBD COP 12.

Below, we provide information from the EU and its Member States on what steps have been taken towards ratification and implementation of the Nagoya Protocol and what are the challenges encountered in doing so.

Information with respect to steps taken towards ratification and implementation of the Nagoya Protocol at European Union level

The European Commission held a web-based public consultation from 24 October to 30 December 2011 to seek feedback on a list of questions that addressed key aspects of Nagoya Protocol implementation. 43 replies were received that represented a much broader number of respondents, since the majority of replies came from European or international associations with hundreds or thousands of members each. The respondents covered most sectors potentially affected by implementing measures under the Nagoya Protocol.

All respondents (except one neutral reply) pleaded for a EU-harmonised approach to user-compliance measures, with a clear majority considering an EU-Regulation as the most appropriate instrument for achieving harmonised implementation. The majority of respondents considered that implementing measures could have positive effects on competitiveness and on administrative burden, but stressed that such effects depend on the specific implementing measures chosen.

Industrial users (e.g. pharmaceutical, biotechnology, seeds, health&beauty) stressed their lengthy supply chains and that information about prior informed consent and benefit-sharing arrangements is currently not available at points in the chain where it may be needed.

Research institutions stressed the importance of clear, simple and transparent rules and the need for clarifying ABS-related issues at the time of access to avoid difficulties later on.

The list of questions together with the results of the web-based public consultation have been published under the following link:

http://ec.europa.eu/environment/consultations/abs_en.htm

The results of the public consultation, research undertaken by an external consultant team as well as information gathered through many formal and informal meetings with stakeholders helped the Commission's Environment Directorate-General to undertake, in close collaboration with other Commission services, a comprehensive assessment of the economic, social and environmental effects of different options for implementing the Nagoya Protocol in the EU. On the basis of this assessment, DG Environment developed a draft legislative proposal for Union-level measures that is currently (August 2012) in formal consultation between the services of the Commission.

Depending on the outcome of this formal consultation, the Commission will present a formal legislative proposal for implementing the Nagoya Protocol in the Union still before the eleventh conference of the parties to the CBD in October 2012. Such proposal would be forwarded to the Parliament and the Council of the EU, the Economic and Social Committee and the Council of the Regions for their consideration

All relevant documents drawn up in the course of developing the Commission proposal would be made public after its presentation (ie. proposal, impact assessment, documents from the public consultation, eventual expert study).

Steps taken at Member State level

Belgium

I. Steps taken

Belgium has decided that a timely ratification of the Nagoya Protocol is a high political priority. To this effect, a joint external impact assessment study on possible options for the implementation of the Nagoya Protocol, involving stakeholders, was commissioned. The study is on-going and its final recommendations are expected by the end of 2012. The political discussions on the implementation and ratification process could start then.

Apart from some exceptions, Belgium does not have specific ABS legislation and measures in place. Therefore, existing legal instruments would need to evolve and additional instruments would need to be adopted in order to fulfil the obligations of the Nagoya Protocol.

Relevant options for implementation in view of their potential application in Belgium, have been identified for further analysis, *inter alia* through a stakeholder workshop which was held on 29 May 2012. The identified options focus on the following core implementation obligations:

92
93 1. Access and Benefit Sharing

94 It was recommended to establish the following general legal principle(s): only Benefit
95 Sharing (BS) (option 1) or BS and Prior Informed Consent (PIC) (option 2).
96 Operationalization of these principles would take place in a phased, subsidiary and
97 flexible fashion.

98 Under the second option, three different sub-options were identified on the further
99 operationalization of PIC. All three sub-options take existing legislation (notably
100 legislation on protected areas and protected species) and expertise (*inter alia* the *ex situ*
101 collections) as a starting point, and aim *inter alia* at increasing data collection and
102 improving legal certainty, while keeping administrative burden as low as possible for all
103 parties involved.

104
105 2. Competent National Authority

106 Flowing from the division of competence on environment and nature protection in
107 Belgium, it was recommended to establish four Competent National Authorities (CNA),
108 to represent the three regions and the federal government, either with separate entry
109 points per CNA (option 1) or with a single point of contact (option 2).

110
111 3. Compliance

112 Although there are relevant provisions in existing Belgian legislation, these are
113 considered not to be sufficient to fulfil the obligations of articles 15 and 16 NP. Therefore
114 the possibility for a general criminal provision in Belgian legislation that refers back to
115 certain (depending on the option) aspects of the legislation of the provider country
116 regarding compliance with PIC and/or MAT is being examined.

117
118 4. Monitoring/checkpoints

119 In order to respect the political commitment for timely ratification only two options are
120 being explored at this point in time: 1) upgrading the existing patent disclosure obligation
121 and 2) PIC as a checkpoint. In a subsequent phase, once more experience has been
122 gained, it might be required to consider more effective checkpoints to monitor the
123 utilization of genetic resources. Moreover, it is expected that other possible checkpoints
124 will be presented in the proposal for draft EU legislation.

125
126 5. National ABS Clearing House (CH) component

127 Taking into consideration the two distinct tasks of a Belgian CH-component (i.e. general
128 information sharing on the NP, supporting awareness, capacity building, technological
129 transfer etc. on the one hand and specific, technical needs for the ABS CH on the other
130 hand), different options for the execution of the different tasks are being examined,
131 including with the following authorities/institutes: 1) the current Belgian CBD CHM, 2) a
132 research office hosting several collections and their databases (BELSPO), and 3) the
133 current Belgian BCH.

134
135 6. National Focal Point

136 Options for the National Focal Point to the Nagoya Protocol will depend on the choices
137 for the other implementation measures.

Further information (in English) on the Belgian Impact Assessment Study is available on the Belgian CHM (<http://www.biodiv.be/implementation/cross-cutting-issues/abs>).

II. Challenges encountered

Belgium is a member state of the EU and implementation and ratification will therefore need to take place in loyal cooperation with the steps taken at European level. Moreover, as a federal state Belgium encounters further challenges in multilevel coordination and cooperation in the implementation and ratification of the Nagoya Protocol.

Further difficulties encountered in the current stage of preparation of implementation of the Nagoya Protocol are:

- Difficulties in getting everyone understand certain concepts of the Nagoya Protocol (e.g. Benefit Sharing, Prior Informed Consent) and how they relate to existing national concepts (e.g. the distinction between national property right versus access rights in the sense of the Nagoya Protocol);
- The lack of information on the current access to and use of genetic resources in Belgium;
- The lack of awareness on ABS and the NP with stakeholders and administrations;
- The need to build on existing procedures and mechanisms in order to avoid adding unnecessary burden.

Bulgaria

I. What steps have been taken in ratification and implementation of the Nagoya Protocol?

Is prepared a draft Act, amending the Act on Biodiversity, which regulates the terms and conditions for access to genetic resources and the responsibilities of the provider and user:

- Has been designated a National Focal Point;
- Have been nominated six competent national institutions;
- Has been regulated genetic resources's monitoring, the competent authorities may require additional information from the user;

II. What are the challenges encountered in doing so?

- Has still not an National ABS Clearing House (CH) mechanism and certain checkpoints.

The Czech Republic

There is no specific ABS legislation in place at this point in time, however, several legal acts cover the access and utilisation of genetic resources in the agriculture sector, mainly in the area of research. Therefore, the Ministry of the Environment as the current administration authority accountable for the ABS issues commissioned a more complex study in August 2012. It should be finished by 2012 or early in 2013 and is focused on 1) the assessment of the utilisation of

genetic resources across sectors and stakeholders at the national level, 2) the impact of the Nagoya Protocol on existing Czech legislation, 3) options regarding PIC, monitoring of utilisation of genetic resources and related checkpoints, 4) cost analysis of different options, and 5) analysis of the EU impact assessment. The Ministry of the Environment has already designated the National ABS Focal Point and cooperates closely with the national Patent Office. As the EU Member State, we will seek to ratify and implement the Nagoya Protocol in close coordination and cooperation with other EU countries and EU institutions.

Denmark

A draft bill of law has been published in September 2012 with the aim of passing legislation before the summer of 2013. The content of the draft legislation concentrates on user country measures introducing prohibition of utilisation of genetic resources that have been obtained in violation of access-legislation in the countries in which the resources were accessed or utilisation of genetic resources, where such utilisation is dependent on traditional knowledge that were obtained in violation of regulatory requirements in the countries where the knowledge were accessed.

The draft legislation will not require Prior Informed Consent but provides for requirement of notification of sampling of genetic resources in Denmark to the competent authority in order to obtain information that can serve as an internationally recognized certificate.

Denmark has a checkpoint in relation to patent application and contemplates the establishment of other relevant checkpoints such as application for public funds for research.

Link to Danish legislation proposal in public consultation September 2012 is available at:
<https://bdkv2.borger.dk/Lovgivning/Hoeringsportalen/dl.aspx?hpid=33921>
(Danish version only)

Cover letter to the legislation proposal is available at:
<https://bdkv2.borger.dk/Lovgivning/Hoeringsportalen/dl.aspx?hpid=33922>
(Danish version only)

When the legislation has been passed Denmark will be ready to ratify the Protocol. Ratification may however be postponed to follow a joint European ratification.

Estonia

Although Estonia was not able to not sign Nagoya Protocol before 1st February 2012, it is committed to ratify it. In July 2012 new Nature Conservation Development Plan until 2020 was adopted by Estonian Government. This plan is equivalent to the NBSAP of Estonia. According to the plan, conservation of genetic resources is a priority and Nagoya Protocol will be ratified latest by 2015. Currently Estonia has some elements of regulation of genetic resources in place. These are mostly connected to Nature Conservation Law and protected species. Estonia is also

party of the International Treaty on Plant Genetic Resources for Food And Agriculture and following it, has adopted the Plan of Collection and Conservation of Genetic Resources of Agriculture Crops until 2007 to 2013 (will have follow up plan 2014 to 2020). National Focal Point of Nagoya Protocol is named from University of Tartu, however contact institution for the Protocol is Ministry of Environment's Nature Conservation Department. The CHM of ABS will most probably connected to the CHM of CBD. The ratification calendar of Protocol will depend of the joint EU ratification process.

Finland

What steps have been taken in ratification and implementation of the Nagoya Protocol?

Finland has concluded and published a national study on the implications of the Nagoya Protocol on access and utilization of genetic resources in June 2012. The study contains administrative and legislative proposals for the implementation and ratification of the Nagoya Protocol including proposals for amendments to existing legal acts as well as a proposal for a new ABS Act. The legislation and administrative measures needed for the ABS will be prepared by a separate working group starting its work in 2012 after the EU impact study has been launched. Finland has already designated a National ABS Focal Point and has an existing authority in relation to patent applications. Finland still needs to establish a National ABS Clearing House mechanism and checkpoints in line with the Protocol (e.g. research funding agencies). Finland aims for the joint European ratification and implementation of the Nagoya Protocol.

France

France plans to ratify the Nagoya Protocol by 2014, in line with the EU ratification calendar, after having adopted an ABS national legislation.

In France, there is currently no general ABS legislation. However, some overseas territories have adopted rules for regulating access and benefit-sharing on genetic resources: the South Province of New-Caledonia (Deliberation no. 06-2009 of 18 February 2009 on access and exploitation of biochemical and genetic resources ; articles 311-1 et s. of the environmental code of the South Province of New Caledonia) ; French Polynesia ("Loi du pays" no. 2012-5 of 23 January 2012 on access to biological resources and benefit sharing resulting from their use) ; and the National Park of French Guiana (Law no. 2006-436 of 14 April 2006 ; art. L. 331-15-6 of the environmental code).

Outside these territories and until an ABS legislation is adopted, the French Ministry of sustainable development is answering voluntary requests for access to genetic resources, through an application form. Based on information provided, the Ministry issues a letter on access conditions, informing about existing procedures often linked with ABS (e.g. protected species, sanitary procedures, etc.), as well as on voluntary benefit-sharing provisions benefiting to relevant stakeholders (e.g. *ex-situ* collection, national park, research centres, etc.).

An inter-service working group with all concerned ministries has been active since end of 2010 with the aim of developing options for implementing ABS in France. These options will then be proposed and discussed by stakeholders (researchers, industries, NGOs, etc.).

An online consultation was conducted between May and July 2012 to identify ABS current practices (use of GR and TK) and expectations of French actors concerning ABS, and to start analysing the impact of the future national ABS legislation on research and industry. The results will complete a study conducted in 2010 that explored options for implementing ABS in French territories overseas, contribute to the impact assessment of ABS in France and ensure that the future ABS legislation is operational.

Germany

By signing the protocol Germany has documented its commitment to the Nagoya Protocol. Germany is committed to implementing and ratifying the Nagoya Protocol at the earliest time before CBD COP 12. The implementation of the Protocol shall take place in a coordinated fashion with the EU and other member states.

Germany is currently investigating possible ways for the implementation of the Protocol and related effects on various user sectors. This includes a process of regular stakeholder consultations to raise awareness for and inform about the Protocol and to ensure appropriate stakeholder involvement.

Also the German Federal Ministry for the Environment, Nature Conservation and Nuclear Safety and the Federal Agency for Nature Conservation have established an ABS-Homepage (www.abs.bfn.de) which collects ABS-related information including a collection of SMTA, information on the international and national processes and a documentation of existing sectoral approaches to ABS in Germany and elsewhere.

Biodiversity and ABS are also key areas of the German Development Cooperation as we see ABS as an important tool to valorize genetic resources, enhance legal certainty for users and providers of genetic resources and to reduce poverty in our partner countries. We believe that tailor made solutions are necessary as we see a growing demand by our partner countries for support in implementing the Protocol.

Furthermore Germany is hosting the ABS Capacity Development Initiative since 2005 that is also supported by Denmark, Norway, the Institut de l'énergie et de l'environnement de la Francophonie, and the EU.

Hungary

Since the signing of the protocol consultations have started in Hungary about the implementation of the Nagoya Protocol with regard to the below elements,:

- Hungary plans to require prior informed consent in case someone accesses genetic resources in Hungary.
- The unit/institution currently providing the CBD and ICNP National Focal Points is planned to be designated as the National Focal Point for the Nagoya Protocol.
- The current system of the Hungarian nature conservation authorities is examined as potential competent authority/authorities for the Nagoya Protocol.
- The national CBD CHM (<http://www.biodiv.hu/>) is planned to be expanded to serve as the CHM for the Nagoya Protocol.
- Possible interrelations with the PGRFA are considered when developing the implementation measures for the Nagoya Protocol.
- Discussions have started about some potential checkpoints.
- No specific information is available yet about user country measures.

Italy

The preparatory work for the ratification of the Protocol, and for its inclusion into the national legal system, requires different administrative and legislative acts.

The official translation of the Protocol has already been carried out and it is published on the Ministry of the Environment website.

Consultations with other government bodies are ongoing.

Preliminary to the final ratification of the Nagoya Protocol the assessment, through comparison of the national legislation as a whole, is in process, in order to avoid possible regulatory conflicts due to the wide range of the topic.

The analysis of the regulatory framework and, consequently, the assessment of an internal regulatory intervention hypothesis are ongoing.

In particular, this analysis concerns the art.13-20 where the protocol establishes a set of specific requirements for compliance with the legislation or national regulations of the Contracting Party providing genetic resources as well as the contractual obligations, which are reflected in the terms mutually agreed upon.

Finally, Parliamentary procedures have to be undertaken in order to adopt the Law of ratification.

The Protocol implementation will be carried out in coordination with the European Union and the other Member States.

Romania

Has already designated a National ABS Focal Point but still needs to establish a National ABS Clearing House mechanism and checkpoints in line with the Protocol. Romania is in favor of the joint European ratification and implementation of the Nagoya Protocol.

Spain

After the signing the protocol Spain has initiated the legal procedures for its ratification. It has also produced a review of the obligations and implications of the Nagoya Protocol, and has looked into different administrative and legislative options for its implementation.

The legislative and administrative measures needed, at the national level, will be developed in the context of the revision of the current Spanish Biodiversity Act, which already foresees the possibility to regulate access to Spanish genetic resources. This revision will be launched in the coming months and will take into account the EU legislative proposal when presented

UK

The UK commissioned a study from September 2011 to April 2012 with the aim providing policy makers with an idea of the costs, timescales and delivery options required for the UK to be able to implement the obligations set out in Articles 15–18 of the Protocol covering compliance, monitoring and enforcement of the utilisation of genetic resources and associated traditional knowledge in the UK.

The study also undertook to consult with UK stakeholders regarding the UK's Protocol commitments and to consider how much the UK could be considered a provider of genetic resources. The UK intends to make the results of the study available ahead of CBD COP11.

In implementing the Protocol the UK does not intend to require PIC for genetic resources at this time and will focus on implementing the user requirements in order to be in a position to ratify the Protocol as soon as possible by COP12.

Additional issues that may need to be addressed in preparation for the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol

The EU and its Member States believe that full use should be made of all opportunities to exchange experiences on implementation of the Nagoya Protocol (NP). Moreover, we believe that also the items “Establishment of form and intervals of monitoring and reporting on implementation” (article 29 NP) and “Stock taking of the development and use of model contractual clauses, codes of conduct, guidelines and best practices and/or standards” (articles 19 and 20 NP) should be added as additional issues that need to be addressed in preparation of the first meeting of the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol to the ones enumerated in the draft provisional agenda proposed in document UNEP/CBD/ICNP/2/6.