

**Submission by the EU and its Member States to CBD Notification 2019-025:
Submission of views and information further to decision NP-3/14
on Article 4, Paragraph 4, of the Nagoya Protocol**

Further to decision NP-3/14 the notification invites Parties to submit (a) information on how specialised international access and benefit sharing instruments are addressed in their domestic measures, and (b) views on the potential criteria contained in the study summarised in Annex to decision NP-3/14, taking into account Article 4, paragraphs 1 to 3, of the Protocol.

The EU and its Member States are pleased to share the following relevant information and views on the topic.

(a)

In reference to the first part of the notification on domestic measures addressing ABS specialised international instruments, the EU-wide ABS legislation, namely Regulation (EU) No 511/2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union, recognises two ABS specialised international instruments:

- The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) (preamble 12);
- The Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits (the 'PIP Framework') (preamble 16).

Since in line with Article 2(2) the Regulation does not apply to genetic resources covered by ABS specialised international instruments that are consistent with, and do not run counter the objectives of the Convention and the Nagoya Protocol, the Regulation does not apply to genetic resources falling under these two regimes. The EU Regulation does apply to genetic resources covered by ITPGRFA and WHO's PIP Framework, when these are accessed in a country that is not a Party to those agreements but is a Party to the Nagoya Protocol with enacted access legislation applicable to these genetic resources. The Regulation also applies where genetic resources covered by such specialised instruments are utilised for purposes other than those of the specialised instrument in question (e.g., if a food crop covered by the ITPGRFA is utilised for pharmaceutical purposes) (see also Commission Guidance 2016/C 313/01).

(b)

In reference to the second part of the notification concerning views on potential criteria contained in the study summarised in Annex to decision NP-3/14, taking into account Article 4, paragraphs 1 to 3, of the Protocol, the EU and its Member States welcome the suggested criteria for considering an international instrument to be a specialised ABS instrument, as specified in the study. We believe that they provide good reference points of elements that need to be considered when developing an international specialised ABS instrument but would benefit from some modifications to bring them in line with the provisions of the Nagoya Protocol.

At the outset, the EU and its Member States would like to stress that the objective is to explore the criteria that could be used to identify what constitutes a specialised international access and benefit sharing (ABS) instrument in the context of Article 4(4) of the Protocol. This analysis should be done thus taking into account the concept of *lex specialis* and the general principles of law.

In this context, we stress that any criteria should pay particular consideration that all potential specialised instruments are supportive of and do not run counter to the objectives of the Convention and the Protocol, in particular the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources, but that they should not be more stringent than elements provided in Article 4 of the Protocol.

Firstly, we believe that it is not always relevant for the instrument to be developed through an intergovernmental process, although we do agree it is important and appropriate that States or governments endorse or agree on such instrument.

It is important to develop agile criteria for such instruments to respond to potential new issues, and thus consider situations outside of the currently known SII context (i.e. ITPGRFA and PIP Framework).

The criteria set up under point 3 of the Annex to decision NP-3/14 are to be fulfilled (i.e. the instrument needs to be consistent with biodiversity conservation and sustainable use objectives, provide for fair and equity in the sharing of benefits, provide for legal certainty with respect to access to genetic resources or traditional knowledge associated with genetic resources and to benefit-sharing, and contribute to sustainable development, as reflected in internationally agreed goals, and finally be respectful of other general principles of law, including good faith, effectiveness, and legitimate expectations). The process leading to development of such instrument could however take various forms.

An international specialised instrument could result from a formal intergovernmental process leading to its adoption through a diplomatic conference, most typically in the form of a treaty. It could result from a formal process within a specific international organisation, and then be adopted in accordance with its rules and procedures. It is also possible that an ABS SII would develop as a result of existing practice, and then will be endorsed by an intergovernmental organisation in accordance with its rules and procedures. An international specialised instrument could also result from an informal cooperation, such as a regional cooperation initiative, where no intergovernmental organisation structure exists but where States nonetheless agree on an international specialised ABS instrument.

States that will become Parties to such an instrument take a sovereign decision whether they wish to be part of that instrument or whether they prefer that specific genetic resources (or specific uses of genetic resources) remain under the Nagoya Protocol and respective legislation implementing it. In other words, it will be a sovereign decision of a State not to apply their existing access legislation implementing the Nagoya Protocol and put certain types of genetic resources (or certain uses of genetic resources) under specialised agreement. This is why we believe that such instrument needs to be agreed or endorsed by States, as it is the decision of a State Party to Nagoya not to apply their access legislation implementing the Protocol.

We would like to stress that the criteria as set up under point 3 would need to be fulfilled irrespectively of how ABS specialised international instrument was developed (including provisions on fair and equitable sharing of benefits). Irrespectively also from the process of development of the instrument, such instrument would require endorsement from States or governments or an agreement between States or governments.

Furthermore, in our view it is not necessary that the conditions concerning applicability of the instrument to specific uses of genetic resources and/or traditional knowledge associated with genetic resources and to specific set of genetic resources need to be cumulative. In other words, a specialised international instrument could be developed for specific use of genetic resources (and apply to all genetic resources) or for specific group of genetic resources (and apply to all uses of such genetic resources).

If Parties decide to apply rules of a specialised instrument to all genetic resources for specific uses (for example all genetic resources used for the purpose of non-commercial research), there is nothing in the wording of Article 4(4) which precludes that. Similarly, in line with Article 4(4) of the Protocol Parties may decide on a specialised instrument that covers specific group of genetic resources (for example microbes) but which can be used for all purposes. As stressed above, it is a sovereign decision of the Parties whether they apply the ABS legislation implementing the Nagoya Protocol or a specialised international ABS instrument.

Annex to the EU submission to the CBD Notification 2019-025

Examples of how specialised international access and benefit sharing instruments are treated under national (access) measures

SPAIN

Regarding **CBD Notification 2019-25** (Submission of views and information further to decision NP-3/14 on Article 4, Paragraph 4, of the Nagoya Protocol) information on how specialized international access and benefit-sharing instruments, in particular the International Treaty on Plant Genetic Resources for Food and Agriculture has been addressed in Spanish domestic measures about access and benefit-sharing is presented below.

Spain has regulated access to its genetic resources, in situ and ex situ, from wild taxa for their utilization Bylaw 124/2017, that entered into force on 15 March 2017, with a view to putting in place the required administrative procedures in relation to accessing Spanish genetic resources. This bylaw applies only to access of genetic resources from wild taxa. Therefore, this bylaw does not regulate access to plant genetic resources for food and agriculture (PGRFA), which are regulated by Law 30/2006, of 26 July, on *seeds and plants from garden centers and plant genetic resources* (Ley 30/2006, de 26 de julio, de *Semillas y Plantas de Vivero y de Recursos Fitogenéticos*).

The Ministry of Agriculture, Fisheries and Food, is the National Focal Point on all of these matter related to the PGRFA and is currently on the last stage of the process of developing new legislation to regulate access to PGRFA taking into account the provisions of both ABS International Instruments, the International Treaty on Plant Genetic Resources for Food and Agriculture and Nagoya Protocol on Access and Benefit-Sharing.

This new regulation has taken into account the Bylaw 124/2017. It has been implemented by a Royal Decree, and covers plant genetic resources when the purpose is the use as food and agriculture, so that access to all plant genetic resources in Spain will be covered by national measures on access. It is pending regulatory approval and it will probably be adopted by the Government in 2019.

Representatives of different sectors and stakeholders have participated on the process of development of this regulation. The Ministry made the drafts of the Regulation available to members of other ministries, farmers associations, autonomous communities and private entities to take into account their suggestions and comments.

This royal decree develops the Title IV of Law 30/2006 on seeds, nursery plants and plant genetic resources and adapts it to the international treaties ratified by Spain. There has been established procedures to formalize access to Spanish PGRFA, differentiating between International Treaty on Plant Genetic Resources for Agriculture and Food or Nagoya Protocol. Its scope includes Annex I and no Annex I material, and in situ and ex situ conserved PGRFA. The royal decree provides for the creation of a National Commission on access to PGRFA that will regulate cooperation and collaboration between the competent public administrations.

Taking into account the explained regulatory framework, regarding the access to Spanish PGRFA, can be found the following situations, with different access procedures:

- Access under the terms of the Multilateral System (MLS) of the International Treaty (Annex I). This applies to ex situ and in situ PGRFA (including crop wild relatives) under control of the State. The MLS includes all PGRFA listed in Annex I that are under the management and control of the Contracting Parties and in the public domain. Therefore, those in situ PGRFA that are included in the Treaty's Annex I and that are located in the public domain fall within the scope of the MLS. That is, they will be provided with a Standard Material Transfer Agreement (SMTA) when the intended uses are among the ones established by the Treaty (i.e. research, breeding and training for food and agriculture).
- Access to PGRFA not included in the SML of the International Treaty or whose access is carried out for a purpose different from those established by it, would fall within the scope of the Nagoya Protocol as long as the access is carried out for its "utilization" as the Nagoya Protocol has defined. PIC and MAT are necessary under the Nagoya Protocol.
- Access under the terms of Law 30/2006 (Title IV, Chapters I and II), for species not included in the scope of the International Treaty or Nagoya Protocol.

Nevertheless, the regulatory development we have prepared, allows access under the terms and conditions of the SMTA, for purposes of the provisions of the International Treaty, to all PGRFA, regardless of whether or not they are included in the Annex I.

Examples of national measures implementing International Treaty on Plant Genetic Resource for Food and Agriculture

SWEDEN

The Swedish regulation (2011:474) on simplified access to plant genetic resources stipulates that a governmental authority holding such plant genetic resources referred to in Annex I of the International Treaty on Plant Genetic Resources for food and agriculture may enter into agreement with a natural or legal person on simplified access to the resources in accordance with Article 12 (4) of the Treaty.
