29 April 2019

Submission by the EU and its Member States to CBD Notification 2019-012: Digital Sequence Information on Genetic Resources: Submission of views and information and call for expression of interest to undertake studies

The EU and its Member States are pleased to share their overall views and information on issues related to Notification 2019-012, in line with Decision 14/20 on digital sequence information, adopted at the fourteenth meeting of the Conference of the Parties to the Convention on Biological Diversity.

Pursuant to decision 14/20, paragraph 9, the notification invites "Parties, other Governments, indigenous peoples and local communities, relevant organizations and stakeholders to submit views and information: (a) To clarify the concept, including relevant terminology and scope, of digital sequence information on genetic resources and if and how domestic measures on access and benefit-sharing consider digital sequence information on genetic resources; (b) On benefit-sharing arrangements from commercial and non-commercial use of digital sequence information on genetic resources."

Pursuant to decision 14/20, paragraph 10, the notification invites "Parties, other Governments and indigenous peoples and local communities to submit information on their capacity-building needs regarding the access, use, generation and analysis of digital sequence information on genetic resources, in particular for the three objectives of the Convention."

While recalling that digital sequence information (DSI) is not defined and the term is used as a placeholder, the EU and its Member States recognise the complexity of the issue and the need to deepen the understanding of what situations and activities the term DSI might refer to. In our view, DSI is a broad issue with potential implications for the three objectives of the CBD. Hence, clarification of the concept and scope of DSI and the activities it is associated with should be carried out in a comprehensive manner, taking into account the broader CBD context and its three objectives.

The EU and its Member States emphasize the importance of adopting a science-based approach when exploring a possible common understanding of the scope, definition and concept of DSI. The process set up under decision 14/20 para 11 – namely the four studies and the establishment of an ATHEG - should provide such a science-based approach and assist in further clarifying the concept and the scope of DSI, as well as assist with the identification of possible appropriate terminology. We believe that it is important not to pre-empt the results of the scientific studies commissioned, as well as the outcomes of the AHTEG. That being said, the EU and its Member States would like to underline the following aspects with respect to decision 14/20 para 9, point (a) and (b).

A definition of DSI should be based on appropriate relevant terminology and clear terms. In our view, general terms, such as "information", that might be open to interpretation, do not bring further clarity to the concept and should be avoided. To identify appropriate and more precise terminology, it can be useful to explore the terms commonly used by the scientific community in the context of genetic research. These terms include, for instance, genetic sequence data, nucleotide sequence data, and genetic sequences. As pointed out in the Fact-finding study on DSI (CBD/DSI/AHTEG/2018/1/3), differences in scientific terminology reflect differences in the material referred to, as well as the speed and transformative nature of technological change of today. We are aware that this may constitute an additional challenge to the identification of harmonized terminology.

We note that relevant terminology is used also in international organizations in the context of their activities, such as the WHO. In particular, the WHO PIP Framework uses the term genetic sequence data, and defines genetic sequences as: "The order of nucleotides found in a molecule of DNA or RNA. They contain the genetic information that determines the biological characteristics of an organism or a virus". It would be useful to take into account relevant existing and agreed terms and definitions for the eventual establishment of a clear terminology for DSI.

The EU and its Member States consider that DSI is not equivalent to a genetic resource. We consider that within the framework of the CBD and the Nagoya Protocol the access to DSI, held in digital or in any other form, is not equivalent to access to genetic resources from which it is generated. In other words, PIC cannot and should not be required for access to DSI, including from publicly available databases.

That said, we note that conditions for generating and using DSI (in case of non-commercial as well as commercial use), which come from utilization of genetic resources within the scope of the Protocol, can be specified in mutually agreed terms (MAT) when a genetic resource is accessed in accordance with domestic measures on access and benefit-sharing. For instance, a permit granted for non-commercial use of genetic resources may envisage that the result of such utilization, including from activities producing DSI, are subject to the conditions set in that permit and can be limited to non-commercial purposes or set further conditions in case of future commercial purposes.

Generation, access to and use of DSI may have important and positive effects on the conservation and sustainable use of biological diversity. The sequenced data are the basis of a large number of biodiversity-related research activities, such as taxonomic research. Furthermore, DSI is widely used for *in-situ* and *ex-situ* conservation purposes, monitoring and implementation of protected areas and monitoring of invasive alien species.

We also stress that DSI is very important for protection of human, animal and plant health. The timely and unrestricted access to such data is crucial for the fast and effective reaction to threats to public health and for routine tasks in health protection. Examples of activities where DSI plays a crucial role include tracing of epidemic outbreaks, vaccine development, tackling antimicrobial resistance, food safety and surveillance and control of infectious diseases; these outcomes can be considered to be a form of non-monetary benefit sharing.

We also underline the importance of DSI in research and innovation and recognize that DSI is also used by other sectors. While fully respecting the rights of countries, we believe that accessibility to data for research purposes should not be subject to heavy administrative measures that could slow down the information sharing and may hinder further increase in knowledge.

We emphasize that public or open access databases are maintained by public funding, and data published in these databases are the results of researchers' work made available to freely share information, including DSI. Bearing this in mind, public databases and open access to their data are a form of non-monetary benefit sharing and contribute to the fair and equitable sharing of benefits.

With regard to decision 14/20, para 10, the EU and its Member States acknowledge that many countries may lack capacity to generate, access and use digital sequence information on genetic resources. Lack of capacity in this regard can hinder the successful implementation of the three objectives of the CBD.

The EU and its Member States strongly support the development, maintenance and increase of capacity in all States to generate, access and use DSI. In this context, we underline that open access to data and free circulation of information available in public databases, as well as the development and publication of tools to analyse the data, are at a basis of several education and scientific research projects, training and other activities carried out in the framework of development and cooperation by the EU and its Member States with other Parties. In effect, the EU and its MS are actively involved in research cooperation projects involving the study of genetic resources with many countries and their scientific institutions. This cooperation also contributes to build capacity building in relation to DSI in those countries and their research entities. That said, we are aware that additional capacities and appropriate technology may be needed to use DSI and we stand ready to further engage with the other Parties to consider the capacity-building needs and the appropriate means to support this.