21 September 2017

Submission by the EU and its Member States to CBD Notification 2017-037: Views on any potential implications of the use of digital sequence information on genetic resources

Notification 2017-037 invites "Parties, other Governments, indigenous peoples and local communities, and relevant organizations and stakeholders to submit views and relevant information on any potential implications of the use of digital sequence information [DSI] on genetic resources for the three objectives of the Convention" in line with CBD COP Decision XIII/16. Pursuant to Decision NP-2/14, paragraph 2, these submissions should also include information relevant to the Nagoya Protocol.

Based on Decision XIII/16, paragraph 3 b), the fact-finding and scoping study is to clarify the terminology and concepts related to DSI on genetic resources and to assess the conditions of the use of DSI on genetic resources in the context of the Convention and the Nagoya Protocol. This study should assist the understanding of the extent and the terms and conditions of the use of DSI on genetic resources, and appropriate evaluation of its potential benefits and associated risks in relation to conservation of biological diversity, sustainable use of biodiversity components, and fair and equitable benefit-sharing.

The European Union (EU) and its Member States consider that the issue of potential implications of the use of DSI on genetic resources should be handled in a comprehensive way, taking into account all three objectives of the Convention.

Technological changes of recent years, including next-generation sequencing (NGS), whole-genome sequencing, high-density marker mapping, and environmental sequencing, all of which are generating and/or using DSI, make it possible to gain greater insight in the genomes of genetic resources, and to exchange the resulting information at an increasingly rapid pace and at global scale. These technologies have become easily accessible and routinely used in many types of contemporary research, both commercial and non-commercial. These recent developments need to be analyzed in respect to both risks for the three objectives of the Convention and potential positive impacts.
In this context, while stressing that more information and comprehensive analysis is needed to come to any conclusive views on the topic, the EU and its Member States would like to underline the following aspects:

The EU and its Member States believe that DSI can be very useful for the conservation and sustainable use of biological diversity. DSI is used widely for purposes of ex-situ conservation and as a base for conservation planning and management. In particular, it has become a key tool for taxonomy. In that respect, it is important to recall CBD COP decision XI/29 on the Global Taxonomy Initiative. Moreover, genetic information is gathering importance in addressing questions related to the ecology and evolution of species and ecosystems. Thus the application of next-generation sequencing technology is quickly becoming an important tool for ex-situ and in-situ conservation management.

The technologies mentioned above and resulting digital information are also becoming important tools for monitoring and control purposes in the implementation of nature protected areas, for implementation of CITES and related enforcement activities, and for the monitoring of invasive alien species. In particular, developing quick and low-cost identification methods based on sequencing technologies provides valuable support for, among others, the rapid and accurate detection of invasive species and the cost-effective control of wildlife trafficking. Identification, characterization and evaluation of genetic resources – which are greatly facilitated by the use of DSI – constitute also important steps towards sustainable use of biodiversity more generally.

In-field rapid sequencing is also becoming increasingly important for protecting public health and is commonly used in molecular epidemiology and phylogenetic outbreak tracing. This was used, for example, in the Zika and Ebola outbreaks and would likely be deployed in other future public health emergencies (human, plant and animal).

The availability and exchange of the resulting information, including DSI, considerably contributes to the expansion of knowledge which is fundamental for the achievement of the first and second objectives of the Convention. In this context, the EU and its Member States would like to draw attention to the importance of generation, publication and availability of DSI for non-commercial research. Much of this DSI is made available in public databases, which are spread among developed and developing countries; many are also located in non-Parties to the Protocol. When material is submitted to the depositaries, current database management policies require making the DSI publicly available and ensure free access for everyone. This global exchange and free access facilitates and promotes international research in both developed and developing countries and contributes to faster advancement of science globally.

The EU and its Member States thus believe that when discussing potential implications of the use of DSI for the three objectives of the Convention, and in particular in relation to its Artt. 17 and 18, the role of databases storing DSI needs to be considered, taking into account their managerial policies as well as the global context in which they operate.

The primary goals of non-commercial research are the expansion of knowledge, i.e. the creation of public goods, and the transfer of such knowledge in the form of publications. Publications are especially important in presenting the results of research. When researchers publish the results of their work, they do so in order to extend the knowledge, and information is thus freely shared, including DSI on genetic resources. Bearing this in mind, it is clear that making available DSI in public databases contributes to the fair and equitable sharing of the benefits arising out of the utilization of genetic resources. In the same vein, the Annex to the Nagoya Protocol on Monetary and Non-monetary Benefits mentions that “Non-monetary benefits may include, but not be limited to: (a) sharing of research and development results; […] (e) admittance to ex situ facilities of genetic resources and to databases; […] (k) Access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies”.

In addition, while fully respecting the rights of countries, the EU and its Member States are concerned that disproportionate restrictions on sequencing of the genetic resources and the publication of DSI could result in a slowing down of research progress on a global scale due to decreased accessibility of information. Any such restrictions may also result in a reduction in research on biodiversity, more specifically research on genetic resources coming from jurisdictions where national legislations have introduced restrictions – thus also reducing our ability to protect biodiversity and ecosystems. Restrictive conditions applicable to sequencing of genetic resources might also result in deposits being rejected by collection holders, because standard protocols for validating material at its entry through sequencing cannot be carried out. Overall, such an approach could restrict the further development of knowledge critical for the conservation and sustainable use of biodiversity, and thus possibly limit the attainment of the three objectives of the Convention.

To address these and other concerns, it is important to thoroughly assess how DSI, its exchange and the way it is managed (including by domestic legislation or database managerial polices) may affect the three objectives of the Convention and the objective of the Protocol. This should be done in light of Articles 12, 16, and 18 of the CBD, and in particular in light of Article 17 which requires Parties "*to facilitate the exchange of information, from all publicly available sources, relevant to the conservation and sustainable use of biological diversity"*, and of Article 8a) of the Nagoya Protocol, according to which Parties *"shall create conditions to promote and encourage research which contributes to the conservation and sustainable use of biological diversity […] including through simplified measures on access for non-commercial purposes, taking into account the need to address a change of intent for such research".*

While acknowledging the fact that utilization of digital sequence information may be subject to requirements at domestic level as well as MAT and benefit-sharing requirements, the EU and its Member States are of the view that access to information is not equivalent to access to genetic resources within the meaning of the CBD and the Nagoya Protocol.

Finally, the EU and its Member States also believe that the considerations on DSI on genetic resources under the CBD and the Nagoya Protocol need to take into account the discussions on DSI happening in other fora, such as the International Treaty on Plant Genetic Resources for Food and Agriculture and the Pandemic Influenza Preparedness (PIP) Framework under the World Health Organization, in accordance with decision NP-2/5. Such discussions are especially relevant in the context of Article 8c) of the Nagoya Protocol which requests Parties to consider the importance of genetic resources for food and agriculture and their special role for food security, as well as in the context of Article 8b) in relation to cases of present or imminent emergencies that threaten or damage human, animal or plant health.

The European Union and its Member States are aware that there are many challenges and opportunities linked to the issue of DSI on genetic resources. We strongly believe that discussions on DSI should not affect the integrity of the CBD or the Nagoya Protocol, and we consider that, on the basis of the fact-finding study, all relevant aspects should be carefully considered in the process.

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