Digital Sequence Information on Genetic Resources: Submission of Views and Information on Terminology, Scope, and Domestic Measures on Access and Benefit Sharing

Submitted by the African Group of Negotiators on Biodiversity-Ad Hoc Group on Digital Sequence Information

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In a notification dates February 7, 2019, the CBD Secretariat, pursuant to decisions 14/20 and NP-3/12, respectively, invited 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.

In addition, Parties, other Governments and indigenous peoples and local communities were invited 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.

This paper represents the African Group's response to these invitations.

(a) Views and information 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.

I. <u>Terminology</u>

As noted by the CBD Draft Decision CBD/COP/14/L.36 in November 2018, there is an understanding that the phrase "digital sequence information" or "DSI" may not be the most appropriate phrase to capture the various types of information on genetic resources that may be relevant to the three objectives of the CBD/objective of the Nagoya Protocol. However, "DSI" is continuing to be used as a placeholder. There are, of course, other possible terms that could be used such as genetic information, natural information, genetic sequence data, and digital sequence data. In this regard we note with interest that on-going discussions to enhance the functioning of the multilateral system of ABS under the International Treaty on Plant Genetic Resources for Food and Agriculture have recently considered the possibility that DSI could be understood to be included in the terminology "associated available non-confidential descriptive information" used in Article 12.3.c) of the Treaty.

Our view is that a prolonged focus on terminology is not helpful for obtaining clarity on the concept of "DSI". The goal of a focus on terminology is to narrow the scope of applicability of the Nagoya Protocol, and have certain subject matter excluded from it. Moreover, any definition on which agreement could be reached would likely be overtaken by rapid technological innovation and outdated in short order. In fact, the very nature of the controversy engaged in by the COP-MOP regarding the scope of the phrase "genetic resources" – despite the record of CBD negotiations clearly showing that the term was intended to include both material resources and the information they encode – exemplifies this eventuality.

While we favour the use of a neutral and wide term like "natural information" or "genetic information," the African Group position is that the more relevant focus should be on utilization and not terminology, as precise terminology is not critical for this issue. This is because if information results from the utilization of genetic resources,[1] it is within the scope of the CBD and Nagoya Protocol (in particular Article 5.1) and subject to benefit sharing, regardless of the terminology used to define the information. This is important because as technology continues to advance, new and unanticipated products of genetic resource utilization are likely to appear that might not be covered by terminology to be adopted in 2020.

If our negotiating partners nevertheless insist on further discussions around terminology we would suggest that a useful approach could be to deconstruct the placeholder term "DSI" into a continuum that starts with raw genetic sequence data obtained from primary scans of naturally occurring sequences and then progresses through compiled whole genomes to annotated or isolated functional genes, eventually culminating in useful discoveries and/or inventions that can be patented and/or used for gene editing or other forms of genetic manipulation. Such an exercise would be most useful if it were conducted in the context of negotiating differentiated benefit sharing rates for different classes of natural information utilisation.

II. Scope

There remain widely divergent views on whether "DSI" should be viewed narrowly or broadly. Our view is that assessing the scope of "DSI" involves a determination of its relationship to the phrases "genetic resources" and "benefits arising from the utilisation of genetic resources". Several African countries currently include "DSI" in the definition of genetic material[2] and thus of genetic resources contained in their national legislation, while many more countries have initiated changes to their ABS laws to ensure that DSI is clearly included. The following African countries' approaches to DSI and ABS provide illustrative examples:

[1] "Utilization of genetic resources" is defined in Article 2 of the Nagoya Protocol as "to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention."

[2] "Genetic material" is defined in Article 2 of the CBD as "any material of plant, animal, microbial or other origin containing functional units of heredity."

Ethiopia

The Ethiopian revised ABS proclamation emphasizes the role that communities play in the conservation, enhancement, development and sustainable use of biodiversity resources. It also underscores the need for fair and equitable sharing of benefits arising from the utilization of Ethiopian genetic resources.

The revised draft law elaborates the definition of '*genetic resourc*e' as '*any material of biological resource containing genetic information having actual or potential values for humanity and includes derivatives and digital sequence information*'. The attending conditions of access to genetic resources have also been elaborated. Prior informed consent (PIC) of the institute (Ethiopian Biodiversity Institute) and the establishment of mutually agreed terms (MAT) is one condition of access. Likewise access to community knowledge is subject to the PIC of the concerned local community and the establishment of the MAT with the Institute.

Physical access to genetic resources by persons outside of the country (foreigners) in addition to the requirement of PIC and MAT is required to be accompanied by a personnel of the Institute or any other relevant body to be designated by the institute. Indeed this emphasizes the level of importance attached to access requirements by the governing law of Ethiopia. In cases of research the Ethiopian ABS law also requires that the research be based in Ethiopia with the participation of Ethiopian nationals unless it proves to be impossible to arrange for this. This condition is in relation to ensuring that non-monetary benefit sharing are also at hand by way of technology transfer in researches conducted. As a provider country Ethiopian law anticipates utmost collaboration between Ethiopia and the users of its genetic resources in an informed and transparent manner. Non-monetary benefit sharing may among others also extend to joint ownership of intellectual property rights.

In the same token among the conditions of denial of access relate to instances where the requested access to the genetic resource is of an endangered species and where the access does not relate to research for rehabilitation of endangered species, the access is intended for use of genetic resources for purposes contrary to national laws of Ethiopia and where the genetic resource is of special cultural value or socioeconomic interest to the country.

In situations where the same genetic resource is found *in situ* within Ethiopian jurisdiction and other Parties transboundary cooperation is encouraged. Similar transboundary cooperation is required where traditional knowledge is shared by Ethiopia and other Parties to the Protocol. In such instances, considerations for common ABS frameworks with neighboring country Parties with the view of ensuring common equitable benefit sharing mechanisms based on common MAT is at hand.

Nevertheless, it is unclear how PIC would be obtained for sequence information from Ethiopian genetic resources (which may not be identified as such) which are already available in publicly and privately accessible databases hosted outside of Ethiopia. In

addition, it is not evident how non-compliance with the PIC requirement for such sequence information would be tracked, or how benefit sharing obligations apply for both non-commercial and commercial uses of DSI.

Malawi

Malawi regulates access to, and benefit sharing of biological resources in accordance with the Environment Management Act (Cap. 60:02 of the Laws of Malawi) as well as other sectoral legislation. The Environmental Management Act states that the *biological and genetic resources of Malawi shall constitute an integral part of the natural wealth of the people of Malawi and shall be protected, conserved and managed for the benefit of the people of Malawi; and shall only be exploited or utilized in accordance with the provisions of the Act or any other written law of Malawi*. The Act empowers the Minister to facilitate development of legislative proposals, issue guidelines and prescribe measures for the protection, conservation and sustainable management and utilization of genetic resources; prescribe measures to regulate access to genetic resources by non-citizens or non-residents of Malawi; ensure PIC of communities is obtained and is an essential component for any arrangement in bio-prospecting, ensure effective equitable sharing of benefits and sustainable business mechanisms for the transfer of biotechnology; protect intellectual property rights of communities; prohibit or restrict any trade or traffic in any component; provide for fees payable in respect of accessing the resources and the export thereof; provide guidelines for reviewing of genetic materials and patenting requirements for indigenous species; regulate the collection, characterization, evaluation and documentation of plant genetic resources for food, agricultural and medicinal purposes; and regulate any other matters considered necessary for the sound management of the genetic resources.

Based on the provisions of the Act, Malawi has developed Guidelines on Access to Biological Resources and the Fair and Equitable Sharing of Benefits arising from their Use to provide clarity and certainty to Users and Providers of biological resources. The guidelines clearly indicate that Malawi considers all activities involving the collection and export and utilization of physical biological resources, traditional knowledge associated with genetic resources, use of genetic information or any forms of DNA/RNA sequences or sequence data in any format including in microbiological, digital or synthetic or in any other format associated with genetic resources to trigger benefit sharing obligations. Hence Users of DSI of genetic resources that originate from Malawi are required to comply with the provisions of the laws of Malawi.

Malawi has observed from most of the applications for access, export and utilization of biological resources that in most research projects there is an obligation to make sequence data or any other genetic information digitally available online. As such under current MATs a section addressing use of genetic information or any forms of DNA/RNA sequences or sequence data in any format is included.

ABS contracts indicate that in any digital publication of sequence data or any other digital expression of the genetic resources or results from the genetic resources, full

acknowledgement is to be given to the Government of Malawi, the project enabled by the contract, and the following clause shall be enclosed in the digital publication: *"The government of Malawi has commercial rights or other further use rights in products or processes developed based on the research results or this DSI, and any use requires a contract of use with the Government of Malawi."* Making research results or alike available online shall require the User of the information to be bound by a standard clause respecting the economic interests of Malawi, by a 'click-wrap', using a standard online accept-condition. Access shall be conditioned to the filling in of information about "name, affiliated institution, interest in accessing the digitalized information and the intended use" including an acceptance of the requirement in the Malawian Regulation of having a contract if embarking on using the information. The click-wrap shall send a cookies notifying Malawi about the one accessing the information.

DSI on genetic resources is also being included in Malawi's ABS regulations which are under development because Malawi considers DSI and the use of genetic information or any forms of DNA/RNA sequences or sequence data in any format, including in microbiological, digital or synthetic or in any other format as a way of conveying, presenting or expressing genetic resources using a particular arrangement or sequences which still translate and provide useful information to the User on the functioning, characteristics and other traits of the original genetic resources.

Capacity building and technology transfer is one of Malawi's priorities in benefit sharing arrangements. Malawi desires to develop capacity and technologies that allows it to participate in the value creation of biological resources and DSI. Malawi would like its researchers and communities to be co-inventors of products and processes from its genetic resources and relevant DSI and support its science and technology agenda. The impact of capacity building and technology transfer is based on the potential to provide long term benefits on transforming livelihoods and empowering communities. Benefit sharing funds have the potential to address some of the science and technology needs of Malawi through development of good research and development infrastructure and value creation centers for its genetic resources to generate benefits and incentives for communities. The quest to obtain information on each of the thousands of genes, gene products and other characteristics of genetic resources indicates the demand for DSI for commercial and scientific users. Malawi needs capacity to develop its own data banks so that it is able to store and maintain this information in a way that will allow it to benefit from any value creation thereafter.

Conservation and ensuring sustainable use of biological resources requires financial, human and infrastructure investments. It is only fair that communities and countries that have dedicated their resources to ensure that genetic resources are available for the scientific and commercial users benefit from their contribution. Capacity is therefore also needed on how to help communities and institutions develop good business arrangements with Users of DSI for fair and equitable benefit sharing.

South Africa

The 2013 amendment to the National Environmental Management: Biodiversity Act, 2004 (Act No. 10 of 2004) ensures that the nation's indigenous genetic and biological resources are developed and utilized in an ecologically sustainable manner while promoting social and economic development in particular in the areas where the indigenous genetic or biological resources and associated traditional knowledge are accessed, as one of its intentions.

These amendments included the following definitions which are linked to DSI: *"Derivative",* in relation to an animal, plant or other organism, means any part, tissue or extract of an animal, plant or other organism, whether fresh, preserved or processed, and includes any genetic material or chemical compound derived from such part, tissue or extract; "*Genetic material*", means any material of animal, plant, microbial or other biological origin containing functional units of heredity; "*Genetic resource*", includes any genetic material; or the genetic potential, characteristics or information of any species. These resources may be gathered from the wild or accessed from any other source.

PIC and establishment of the MAT are compulsory requirements for requesting commercial access to indigenous genetic and biological resources and also for access to traditional knowledge associated with indigenous genetic and biological resources.

South Africa believes that creation of sequence information from genetic resources depends on the physical access to the genetic resources. Therefore, the MAT and the permit templates contain mandatory clauses that address third party transfer terms and conditions which could include the utilization of DSI on genetic resources, whether stored in public or private databases. The majority of academic researchers are obliged to include sequence data in order for their research results to qualify for publication in peer-reviewed journals. Most journals require that the sequence data included in the paper are published in a globally accessible repository. However, there is no direct benefit-sharing for the use /access to such sequence data.

It is clear from the South African example that the Parties to the Nagoya Protocol on ABS should continue their work towards finding innovative/creative international policy solutions aimed at ensuring fair and equitable sharing of benefits with the country of origin of the original genetic resources which contributed to the creation of sequence data.

Uganda

In Uganda, the National Environment Act No. 5 of 2019 defines genetic resources to mean genetic material of actual or potential value. It is the intention of the government of Uganda to revise and update its National Environment (Access to Genetic Resources and Benefit Sharing) Regulations (mapped against the Bonn Guidelines) to further elaborate on the scope of the definition of genetic resources. But suffice it to say that the intention is to incorporate digital advancements in science and technology that are traceable to the original genetic resources accessed from Uganda.

So far, the discussions in this realm are that Uganda will not be held back by seeming uncertainly about how far the word “derivatives” can be stretched. The country is well aware that at this point in the discussion the elements of PIC and MAT are still very hazy; nevertheless, we are also equally aware that rapid advances in science and technology tends to outpace the development of regulatory tools. It is therefore imperative to develop legislation that will enable the country to put in place measures to ensure benefit sharing.

The African Group consider DSI to result from the utilization of genetic resources, a view that is not limited to developing/provider countries.[3] The African group is also of the view that the phrase “*genetic resources*” encompass DSI. Therefore, Uganda must consider what constitutes the genetic resources and work on a definition that explicitly makes reference to the genes or genetic material which constitute a genetic resource.

The above mentioned National Environment Act provides the legal basis for the sustainable management and utilization of the genetic resources of Uganda for the benefit of the people of Uganda. The said law requires the establishment of appropriate arrangements for access of genetic resources by non-citizens, measures for regulating the export and import of genetic resources and the sharing of benefits derived from genetic resources originating from Uganda.

The Act provides the basis for the revision and update of the National Environment (Access to Genetic Resources and Benefit Sharing) Regulations whose development was informed by the Bonn Guidelines on ABS. Now that Uganda has ratified the Nagoya Protocol and is a key negotiator on DSI, Uganda is convinced that it is imperative to develop national capacity to operationalize the Nagoya Protocol by way of ingraining the salient features of genetic resources and their derivatives in national legislation and in tracking use of Uganda’s genetic resources.

University training and capacity development of research institutions in this regard is important. It is equally important to develop the capacity of regulatory institutions for environment, science and technology, in terms of knowledge enhancement as well as provision of equipment. It is then that Uganda will adequately be able to understand the dimensions of her genetic resources and the multiple uses to which they are or can be employed. This is not only important for conservation and sustainable use purposes, but is also crucial for socio-economic development. Hence, it is important to understand the connection between understanding genetic resources and their derivatives and the other 2 objectives of the CBD, as well as their contribution to socio-economic development.

[3] *See, e.g.*, Kaspar Sollberger, *Digital Sequence Information and the Nagoya Protocol: Legal Expert Brief on behalf of the Swiss Federal Office for the Environment*, (Apr. 7, 2018) (concluding that “sequencing activities qualify as research and development, which makes them come under the concept of utilization of genetic resources according to Art. 2(c) of the Nagoya Protocol.”)

(b) Views and Information on benefit-sharing arrangements from commercial and non-commercial use of digital sequence information on genetic resources.

As explained above, the African Group is of the view that the phrase "*genetic resources*" or the phrase "*utilization of genetic resources*" should be deemed to encompass "DSI" and also making DSI subject to benefit sharing obligations. The African Group is aware of the many concrete benefits of the fairly open access to DSI that researchers around the globe enjoy currently. We also agree that everyone benefits from advancements enabled by open "DSI" sharing. However, changes in research patterns are expanding the use of DSI in place of tangible material, a decoupling which threatens to undermine the viability of the CBD/NP ABS scheme. In this regard it is important to consider the extent to which access to DSI is and can be used as a substitute for access to material genetic resources.

As such, we do not see such diffuse gains as sufficient to preclude monetary benefit sharing under the CBD/NP. In the same way that the public benefits from many patented technologies, yet the patent holders are still entitled to monetary benefits, providers of genetic resources and the "DSI" obtained from their utilization, are still entitled to the possibility of monetary and specific non-monetary benefits DSI utilization. It should be noted, however, that the African Group sees merit in exploring the development of a benefit sharing approach for DSI that would attach to commercialized products and not hinder academic research.

The African Group has noted with concern the misplaced focus of industry and academic users of genetic information on possible measures to control access to DSI. In our view it would be far more productive to concentrate on ensuring benefit sharing when DSI is utilised. In the absence of a benefit sharing solution many African countries, as noted above, either already control access to DSI or have initiated measures to do so, as a way of ensuring that benefits arising from the utilisation of DSI are shared fairly and equitable.

(c) Information on capacity-building needs regarding the access, use, generation and analysis of digital sequence information on genetic resources

As indicated in the above country examples regarding domestic legislation, the African Group is of the view that practical capacity building needs such as the need for sequencing equipment and related training will be critical. Foundry support for synthesizing modified/synthetic sequences for R&D and economic development purposes will also be required to fill the capacity gaps regarding engagements with DSI. However, capacity building is just one sub-component of benefit sharing and cannot be a substitute for monetary benefit sharing when monetary benefits arise from utilization.

Country submissions will and should additionally stipulate further specific capacity-building needs with regards to transactions on DSI, taking into account national needs and priorities, and the capacity of any particular country to make productive use of capacity building and technology transfer.

Finally by way of conclusion, considering the rate at which advances in technology are happening, the fate of biological resources rests on how well technology advances contribute to the conservation and sustainable use of biodiversity through ensuring that communities that have contributed to the conservation and generation of knowledge on the genetic resources benefit from the value creation of genetic resources and are not left behind as technology continues to advance. As the discourse on DSI under the CBD continues, it is critically important to constantly be cognizant of the following:

1. As technology continues to advance, functional genomic studies continue to generate extraordinary amounts of information from genetic resources for scientific investigations and for commercial applications of biotechnology without benefitting the communities from whom the genetic resources have been obtained;
2. Sequence data and its by-products have been made easily accessible to Users but the benefits have not been made easily accessible to Providers; and
3. Biodiversity loss continues.

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