India's submission on Digital Sequence Information on Genetic Resources in response to CBD notification 2019-012 dated 5 February 2019 pursuant to decisions 14/20 and NP-3/12

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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.

Concepts Scope and terminology

Genetic sequence information is about the manner in which the base pairs of DNA and RNA are structured in an organism. Digital sequence information (DSI) on genetic resources (GRs) may include any information derived out of these nucleotide or amino acid sequences, their biochemical composition, gene locations, genetic maps, chromosome maps, localization details, functional expression details, genome sequences and their annotations, and applied aspects in decoding the sequence information. The scope of DSI thus would inter alia cover information on genetic or biochemical composition including nucleic acid sequence gene reads and associated data, sequence assembly, its annotation and gene mapping describing the genome, individual genes or fragments thereof, organelle genome, gene expressions, macromolecules and cellular metabolites.

The basic difference between the information content in tangible genetic resources and the digital sequence data lies in the fact that the digital format, as opposed to the genetic expression contained in the tangible genetic resource, converts the genetic information into a public good without changing the content as such. The digitised format makes it easily accessible and transferable.

Genetic sequence information in digitised format is often publicly available and accessible through various genome databases. With advanced genetic sequencing and synthesising technologies, the digitised genetic sequence information may preclude the need to access any genetic material in tangible format or physical access of the biological material.

As regards terminology, DSI is not a very appropriate term for the different kinds of information on genetic resources. The terminology therefore requires further consideration. Sequence Information, or Sequence Data are some suggestions, that merit consideration.

Benefit sharing arrangements from use of DSI on GRs

Rapid technological advancements have resulted in emergence and growth of digital sequence information as a faster, cheaper and more accurate tool, the use of which offers opportunities as well as challenges for realizing benefits.

There is a general recognition of positive potential role that DSI on GRs may have in conservation and sustainable use of biodiversity (i.e., the first two objectives of CBD). The fact that DSI enables access to genetic information of an organism without physically accessing it, directs much of the focus of discussions towards impact of DSI on sharing of benefits arising from utilization of GRs, which constitutes the third objective of CBD, operationalised through the Nagoya Protocol, while acknowledging that the three objectives of the Convention are interlinked and mutually supportive.

CBD defines genetic resource as "genetic material of actual or potential value" and genetic material is defined as "any material of plant, animal, microbial or other origin containing functional units of heredity". It is clear from these two definitions that the CBD as well as the Nagoya Protocol recognise both the tangible and intangible elements in the genetic material, i.e., the physical material as well as the value it contains. The value of the genetic material lies in the genetic information it contains, whether in the actual form or potential form.

The definition of utilization of genetic resources under the Nagoya Protocol reads as "research and development on the genetic and/or the biochemical composition of genetic resources, including through the application of biotechnology". As per this definition, utilization of genetic resources is not confined to R&D on the tangible genetic resources, but is extended to activities over the genetic and biochemical composition of such resources. Genetic as well as biochemical composition is nothing but the gene sequence whether digital or tangible. Synthesising the DNA with access from digital sequence would therefore fall within the scope of utilization under the Nagoya Protocol. In other words, accessing digital sequence information amounts to accessing the genetic resource itself, and its utilization would fall within the scope of CBD/Nagoya Protocol, qualifying for application of ABS regulatory framework even though there is no physical access of the genetic material. While for non-commercial research, simplified procedures may be considered, commercial utilisation would trigger benefit sharing as per the provisions of CBD/ Nagoya Protocol.

This argument is also supported by the non-exhaustive list of different uses of genetic resources by the CBD's Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches which formed the basis of the definition of utilization of genetic resources in the Protocol. This list expressly referred to the synthesis of DNA segments.

As was also concluded in the well-researched fact finding study commissioned by the Secretariat, the challenge in the context of ABS related to identification of contributors, users and provenance; and monitoring the utilization, including how to trace commercialization of use of DSI especially which is freely available in public database can be overcome with the use of technological tools, in line with the relevant provisions of the CBD and Nagoya Protocol. This is amply demonstrated by some of the examples that are given in that study (such as GSAID, use of unique identifiers, GGBN, Oldham's model etc).

How domestic measures on ABS consider DSI on GRs

In India, the ABS provisions of CBD and the Nagoya Protocol on ABS are implemented inter alia through the Biological Diversity Act, and regulations thereunder. While these do not include explicit reference to DSI or any such terminology, the relevant provisions in the Act can cover in their scope the utilization of DSI. For example, the term research as defined in Section 2 would cover DSI. Similarly, the requirement prescribed in Section 6 which refers to 'information on biological resource' would cover DSI.

Capacity building needs

There is a need for enhancing capacity to generate, analyse, access and use digital sequence information on genetic resources.

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