

**India's submission on Digital Sequence Information on Genetic Resources in response to CBD notification no.86500 dated 25 April 2017, and no. 86630 dated 12 June 2017.**

Genetic sequence information is the way in which the base pairs of the DNA and RNA are structured in an organism. Digital sequence information may include any information derived out of the nucleotide or amino acid sequences, gene locations, genetic maps, artificial chromosome maps, localization details, functional expression details, genome sequences and its annotations, and applied aspects in decoding the sequence information.

Digital sequence information coupled with modern techniques of DNA synthesis and gene editing may find use for an array of activities in conservation, pre-breeding and breeding of genetically engineered organisms production of pharmaceutical products, nutraceuticals, bio-fuels and in a wide variety of other sectors.

With rapid advances arising from research and development in biotechnology regarding the use of digital sequence information on genetic resources of various living organisms (such as plants, insects, marine organisms, bacteria including pathogenic bacteria, and viruses such as pandemic influenza, etc.), it is imperative to analyze and consider the impact and implications of digital sequence information for the three objectives of Convention on Biological Diversity (CBD), and for the Nagoya Protocol on Access and Benefit Sharing (ABS).

In the context of the first objective of CBD, digital sequence information may have a role in maintenance and recovery of viable populations of species with high conservation concern. It may also find some use in forestry in distant future, for example, in enhancing the productivity of plantation forests and judicious control of pest infestation. However, it is felt that digital sequence information may not have any major effect or may have only negligible impact for the first objective of CBD, at least in the near future.

In the context of the second objective of CBD, use of digital sequence information has the potential to support sustainable use of biodiversity, for example by reducing dependence on bioresources and preventing their overharvesting and depletion.

The fact that digital sequence information enables access to genetic information of a species/organism without physically accessing it, directs the focus of discussions towards the impact of digital sequence information on sharing of benefits arising from the utilization of genetic resources which constitutes the third objective of the CBD, operationalized through the Nagoya Protocol.

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. This may create a situation where there is no physical access of the biological material. The pertinent question is when there is no physical access, is there a requirement for benefit sharing, as envisaged under the CBD or its Nagoya Protocol. To answer this, a clear understanding of sequence data as expressed in the genetic resource and the digitised format is warranted.

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, as compared to the physical restrictions that may be there on the tangible genetic resource. In the context of digitisation, there is a change only in the nature of information but not in its character or content. The genetic resource could thus be equated to a handwritten manuscript, while the digital sequence could be equated to its digital copy without any difference in the information it contains.

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, any such activity after accessing the digital information would amount to utilization 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.

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.

Accessing of genetic information amounts to accessing the genetic resource itself, and commercial utilization derived from its products or seeking IPR over them



would trigger benefit sharing with the country of origin subject to national legislation. In short, use of digital sequence information implies utilization of genetic resources, and hence it is clear that the scope of CBD as well as the Nagoya Protocol would cover digital sequence information also.

However, operationalising ABS mechanism in instances of access and utilization of digital sequence information may pose certain challenges. For example, in the absence of physical access, the applicability of the PIC and MAT for the bilateral transfer between the provider and the user needs to be customised to the nature of digital access, the elements of which would require careful consideration. Perhaps, some national legislations may already be envisaging or practising benefit sharing from use of genetic information irrespective of its digitised format.

Notwithstanding the above, effect of digital sequence information on the third objective of the CBD and the Nagoya Protocol on ABS is an important issue which deserves urgent consideration, so as to prevent possible misappropriation or unauthorized use of digital sequence information.

Towards this, the Ad Hoc Technical Expert Group on Digital Sequence Information on Genetic Resources established vide CoP decision XIII/16 may not only clarify the concept, but also identify the different kinds of digital sequence information on genetic resources that are relevant to CBD and its Nagoya Protocol, and examine its potential implications for the three objectives of the CBD and the objective of Nagoya Protocol. The outcomes of the Group may then be considered by SBSTTA.

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