

# Regulation of ABS Obligations in Digital Sequence Information over Genetic Resources: The Legal Conundrum under CBD and Nagoya Protocol Framework

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## DESCRIPTION

Access and Benefit Sharing (ABS) mechanism provided under the Convention on Biodiversity (CBD) and Nagoya Protocol (NP) is a significant feature in the process of exploitation of genetic resources. The objective of this explicit international framework provided under CBD-NP was to facilitate “fair and equitable” distribution of benefits associated with the collection, sharing and utilization of such resources between users and individuals/groups in provider countries to promote innovation by sustainable use and the conservation of biodiversity. It represents a legally enforceable reciprocal agreement between user and actual holder of genetic resources for sharing pecuniary and non-pecuniary benefits as *quid pro quo* for its utilization.

Genetic sequencing or Digital Sequence Information (DSI), the placeholder term used by CBD, has emerged as a new concept, in contrast to genetic resources allowing researchers to use digital information relating to gene sequences as a functional equivalent to tangible samples of the genetic material.

Quadrillions of sequencing information on various genetic resources is uploaded and shared by researchers all over the world on private as well as open source public databases as a general practice and are available for download for reconstruction and utilization in research related activities. This practice allowed circumvention of the requirement of prior informed consent (PIC) for access and benefits sharing on mutually agreed terms (MAT) for the utilization of genetic resources under CBD-NP, highlighting the inherent gap in the ABS framework.

Divergent positions and disagreements among member countries appeared on whether the definition of genetic resources covers DSI or not, whether DSI should fall under the ABS regime or whether open access is sufficient as a form of benefit sharing. Some argue for open access to DSI in biotechnological research conducted on the lines of achieving food security, climate control and pandemic control. Others, majorly provider countries, consider that it facilitates biopiracy and are unfair to the interests of individuals and local communities investing in the conservation of such biological diversity. This debate over

coverage of the informational dimension or non-tangible aspect of genetic resources under ABS rules finally reached the 14th Conference of Parties to the CBD in 2018.

The debate highlighted the conceptual flaws within the CBD-NP framework regarding the application of ABS rules to DSI. This legal conundrum over DSI is because the concept of ‘genetic resources’ is not clearly understood. The concept has not been used with one single, consistent meaning across different international treaties like ITPGRFA, WIPO & WTO, UNCLOS etc, and national laws and range from purely physical dimension to informational or associated knowledge to purely digitised information. Hence no legally binding conclusions could be drawn regarding the specific meaning of ‘genetic resources’ as it is used in the CBD-NP framework. The lack of consistency creates legal uncertainty and affects enforceability. The concept is capable of having multiple dimensions and requires much broader understanding in international regime on ABS. The informational/knowledge and digital information dimension add economy to the concept, excluding which could remove valuable ways of realizing the potential value of functional units of heredity under international regime of ABS to the detriment of indigenous people & communities who seek to protect such genetic resources and the associated traditional knowledge [1-3].

Secondly, the definitions of ‘genetic resources’ and ‘genetic material’ as given under Article 2 of CBD rests on the understanding of the term ‘functional units of heredity’ which has not been defined by the Convention but was considered to be roughly synonymous with the genes / DNA material, the tangible part only. Absence of coverage of DSI under this mechanism substantially defeats the whole purpose of ABS when biotechnological research today relies heavily on use of DSI available in online genomic databases.

## CONCLUSION

Diverse approaches have been followed. Several provider countries like India, Costa Rica, Namibia etc. have incorporated necessary provisions/amendments in their laws, policies and procedure extending ABS to DSI to safeguard the interests of

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their indigenous and local communities and counter biopiracy. India in its official communication to CBD, emphasized that expressions like “genetic material” and “bio-products” in the definition of “biological resources” under Section 2(c) of Biodiversity Act, 2002 (BDA), is a gene sequence digital or tangible. Accessing the digital resource itself and its utilization would fall under the scope of CBD/NP and subject to mandatory ABS obligations through compliance and regulatory mechanism provided under BDA and Patents Act, 1970 even though there is no physical access to genetic material. However, this approach has not found support on ground and scientific community contend that BDA and Rules and Guidelines need to be amended to be collaborative research friendly and a more flexible, progressive and facilitating approach regarding ABS need to be adopted. One can conclude that although country

specific provisions have been adopted by different countries, uniformity can be brought by international binding framework only.

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