



POLICY PAPER

Digital Sequence Information (DSI), Nagoya Protocol (NP) and the role of Indigenous Peoples and Local Communities (IPLCs)¹

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Background

The Convention on Biological Diversity (CBD) and its Nagoya Protocol (NP) considers, Indigenous Peoples and local communities (IPLCs) not only as custodians of biodiversity but also as the holders of traditional knowledge (TK) – which can lead researchers to potential uses of genetic resources (GR).³ The Nagoya Protocol helped recognize and mainstreamed the rights of IPLCs as a crosscutting concern in international fora and negotiations. The core link between the utilization of genetic resources and the associated traditional knowledge cannot be ignored .

The preamble of the Protocol contains seven paragraphs relevant to IPLCs and TK. These paragraphs include reference to Article 8(j) of the CBD, the interrelationship between GR and TK and their inseparable nature, the diversity of circumstances in which TK is owned or held, the identification of the rightful holders of TK, the U.N. Declaration on the Rights of Indigenous Peoples and the non-extinguishment of existing rights.⁴ The Nagoya Protocol

¹ This is second in a series of policy papers prepared by FLEDGE to further discussions on issues of digital sequence information under the Convention on Biological Diversity. The first paper focuses on the need for a Nagoya Protocol 'Plus' approach needed now to deal with issues of digital sequence information and synthetic biology.

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³ The Nagoya Protocol on Access and Benefit-sharing and Traditional Knowledge at <https://www.cbd.int/traditional/Protocol.shtml>

⁴ The Nagoya Protocol on Access and Benefit-sharing and Traditional Knowledge at <https://www.cbd.int/traditional/Protocol.shtml>
<https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf>

thus aims to include the full and effective participation of IPLCs and that too on an equal footing with other stakeholders.

New Challenges in dealing with Digital Sequence Information

The Protocol entered into force in 2014 and, in the span of the last five years, fresh challenges have cropped up for the NP framework as implementation proceeds, science and technology developments accelerate and several of the outstanding and ignored issues surrounding the Protocol negotiations move to the forefront of current global policy discussions. One of such key challenge is the use of genetic sequence information (Digital Sequence Information - DSI) that is stored online, both at public and private databases, and the potential of using the sequence information to develop commercial products without physically accessing the GR. The pace at which the digital sequence information (DSI) is being generated and stored and the potential for appropriation of this information during commercialisation of GR and associated knowledge are issues of concern for IPLCs and others when principles of access and benefit sharing (ABS) can potentially be undermined significantly with limited or no benefit sharing options available. Further, in this scenario the rights of traditional knowledge holders could be in jeopardized and the requirement for prior informed consent eschewed.⁵ In this rapidly evolving technology landscape, the objectives and implementation of NP could be potentially undermined, as could the CBD itself. It follows that in addition to any specific DSI targeted policy responses agreed to at the international level, periodic monitoring is required in the years ahead needed to ensure the goals of ensuring social justice and reasonable expectations of life and livelihood for IPLCs are not compromised due to use of emerging technology(ies).

DSI is presently being accumulated at a rate faster than it can be completely utilized. This is because of the new generation sequencing (NGS) technologies that has the ability to sequence the genetic information from GR very rapidly and at less cost. The advances in synthetic biology, genomics and other sciences to utilize this information are growing rapidly. As a result, from a commercial perspective accumulating sequences is virtually synonymous with depositing money in the bank as it can be confidently foreseen that effective future uses will emerge and can be effectively capitalized.⁶

⁵ The World Network, Comments from the Third World Network, at <https://www.cbd.int/abs/DSI-views/2019/TWN-DSI.pdf>

⁶ Comments of Third World Network on Digital Sequence Information, June 2019 at <https://www.cbd.int/abs/DSI-views/2019/TWN-DSI.pdf>

Current State of Play

The international debate within and outside the CBD/ Nagoya framework currently is focusing on a landscape shifting from genetic resources to DSI and the need for IPLCs to be entitled to equitable benefit sharing requirements in accordance with their needs and priorities as per the objectives of the CBD and its NP. Parties have the obligation to take measures to monitor the access and utilization of genetic resources and the obligation should be extended in matters concerning DSI. The process should ensure prior and informed consent (PIC) and mutually agreed terms (MAT) using culturally appropriate methods, where the rights of these communities have been recognized.

The crux of the problem is once the DSI is placed in private databases or placed in the “public domain” or through “open access” that does not respect the rights of the genetic resource providers, the ability of IPLCs to protect their traditional rights could be impaired. At the same time, it would be unwise to exempt public or private academic users from benefit sharing obligations when several inventions based on DSI are being churned out in user countries.

The benefit sharing obligations when it takes effect can be through the use of “data access and use agreements” that DSI users must agree to before accessing this information. Data access and use agreements, (including using blockchain technologies) offer the potential to permit DSI to remain in the public domain while protecting the interests of provider countries and IPLCs. However there are several constraints at a practical level with the availability of ABS bypass tools in user countries, including lack of capacities and finances to put systems to deal with these at the national level for many countries.

A further reason to apply the CBD/Nagoya framework on DSI is the fact that the trade of some genetic resources from provider countries could be fast replaced by synthetic biology (SB) products made utilizing DSI. The SB alternatives can wipe away the economic demand of the original biological resource and can impair the livelihoods of the IPLCs that are dependent on these resources. Synthetic biology copies of rare and expensive natural products including saffron, vanillin, artemisinin, stevia, and several others are already on the market or in development.⁷

⁷ ETC Group, “Synthetic biology, Biodiversity and Farmers”, April 2016 at http://www.etcgroup.org/sites/www.etcgroup.org/files/files/etc_synbiocasestudies_2016.pdf

The development of synbio-Artemisinin, which was previously only available from the sweet wormwood plant, was undoubtedly a major scientific breakthrough and is a good case study for this topic. The fluctuations in price and supply due to weather conditions of this resource meant in some years global supplies of the drug were not available to meet the demand.⁸ However, the synthetic alternative has dramatically altered the market for sweet wormwood with local communities no longer able to command fair prices. If the company, Amyris is able to stabilize the production, it will eventually effectively eliminate the market for the natural product.

Also within SB products, there is a distinction between “Naturally unnatural” products and “Unnaturally natural” products. Naturally unnatural products use a natural host but the final end product is unnatural. The case of artemisinin, vanilla, stevia and saffron falls within “unnaturally natural” products, where the end products were natural. The status of ‘unnaturally natural’ products created from synthetic biology organisms remains as “biological resources” and this needs further clarification at a labelling and regulatory level.⁹ If these products are referred as ‘nature identical’, then consumers could be confused regarding the origin of the product. It follows that IPLCs could witness replacement of natural products with the proliferation of SB products on the global market.

Addressing the Interests of IPLCs in the context of DSI related Issues

CBD COP 14 Decision 14/20 recognizes that access to and use of DSI contributes to scientific research, and that further capacity with which to access, use, generate, and analyze DSI is needed in many countries. The Decision notes that some Parties have adopted domestic measures that regulate the access to and use of DSI as part of their ABS frameworks, and that there is a divergence of views among Parties regarding benefit-sharing from the use of DSI. The COP decided to establish a science and policy-based process, which involves inviting governments, IPLCs, and stakeholders to submit their views and information to clarify the concept, including relevant terminology and scope, and if and how domestic ABS measures consider DSI, and on benefit-sharing arrangements from commercial and non-commercial use of DSI, inviting governments, IPLCs, and others

⁸ Talea Miller “Bio-Tech Breakthrough Could End Malaria Drug Shortages”, 31 October 2011, PBS News at <http://www.pbs.org>

⁹ Balakrishna Pisupati, “ Open Source DNA Data, Information and the future of the Nagoya Protocol” 30 June 2018

to submit information on capacity-building needs; and establishing an extended Ad hoc Technical Expert Group (AHTEG), including participation of IPLCs.

Based a request from COP, the Secretariat has prepared a set of informative studies on the concept and scope of DSI, ongoing developments in the field of traceability, public and, to the extent possible, private databases of DSI¹⁰; and how domestic ABS measures address benefit-sharing arising from commercial and non-commercial use of DSI¹¹.

With the Ad hoc Technical Expert Group (AHTEG) on DSI scheduled to meet soon, it is important for all to consider the following issues and to address the interests of IPLCs.

First, as mentioned in the policy paper on the options for a 'Nagoya Protocol Plus' by the authors¹², different countries are using different approaches to deal with issues of ABS in the context of DSI. None of them seem to explicitly consider the links between benefit sharing and the role of traditional knowledge associated with GR. This needs to be addressed carefully at the national level, especially in countries that are currently developing and finalizing the national ABS frameworks (for example, for those being supported by the UNDP GEF global project on ABS). The benefit sharing options and approaches related to mutually agreed terms (MATs) that consider elements of prior informed consent (PIC) should receive more attention in order that the interests of IPLCs can be sufficiently addressed.

Second, considering a significant amount of DSI-related information is already available in the public domain and to a large extent the source of information regarding the material from which such sequence information is source is not available, Parties need to consider providing space and opportunities to discuss issues related to DSI and traditional knowledge-based benefit sharing within the scope of the global benefit sharing mechanism that is being actively discussed within and beyond the NP. A global benefit sharing mechanism is said to offer a number of potential benefits to IPLCs (e.g., providing increased fairness and equity in benefit sharing for widely dispersed associated traditional knowledge) but many challenges lie ahead if such a mechanism is to be established (e.g.,

¹⁰ <https://www.cbd.int/abs/DSI-peer/Study-Traceability-databases.pdf>

¹¹ https://www.cbd.int/abs/DSI-peer/Study4_domestic_measures.pdf

¹² Sachin Sathyarajan and Balakrishna Pisupati 2020 The need for a Nagoya Protocol "Plus". FLEDGE Policy Paper, FLEDGE, India.

key questions regarding legitimate representation, consultation and participation of IPLCs would need to be addressed).¹³

Third, discussions in developing the future programme of work regarding traditional knowledge and related governance mechanisms under discussion within the CBD need to consider the links between IPLCs, progress made thus far in implementing actions under Article 8(j) that is inclusive of issues related to DSI.

Fourth, the AHTEG meetings related to both DSI and synthetic biology should consider the issues of protecting the IP of information and information based knowledge in the context of commercial utilization of GR, associated knowledge that include sequence information.

Lastly, the IPLCs, with support, should work on developing capacities and awareness related to issues of maintaining tracking and monitoring of GR, information and data related to GR and associated knowledge using modern tools, and encourage working with Parties to establish platforms like block chain technology based provision of access for future ABS applications.

While the concerns of IPLCs might be viewed by some as complicating an already complex issue and fracious debate. However, in the absence of a full understanding of the interests and concerns of IPLCs regarding DSI, the credibility of any resulting decisions, and of the CBD and Nagoya Protocol, could be eroded.



Other Policy Papers from FLEDGE on related issues:

- 1. The Need for a Nagoya Protocol 'Plus';*
- 2. Enhancing Synergies between the CBD, Cartagena Protocol and the Nagoya Protocol;*
- 3. Dealing with Digital Misappropriation.*

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¹³ Report of the Third ABS Dialogue on Key Challenges and Practical Ways Forward for the Full Implementation of the Nagoya Protocol and Its Contribution to the 2030 Sustainable Development Agenda, in <https://www.cbd.int/doc/c/6c66/00cf/271fe36fb09070049da1821b/mexicodialogueabs-en.pdf>