



The Need for a Nagoya Protocol 'Plus'

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1. Introduction

The Nagoya Protocol on access to genetic resources and the fair and equitable sharing of benefits arising from their utilization (the Nagoya Protocol) reaffirms the sovereign rights of States over their natural resources and calls for fair and equitable sharing of benefits when such resources and associated traditional knowledge is used. It explicitly discourages anyone from using such resources and associated traditional knowledge without prior informed consent and mutually agreed terms for such use.

With 123 countries acceding to the Protocol as of November 2019, the Protocol receives much prominence in realising the objective of the Convention on Biological Diversity (CBD) and its Article 15. Several countries, both developing and developed, are currently working on national implementation of the Protocol by designing administrative, regulatory and legal regimes.

Parallel to this, recent advances in science and technology, especially biotechnology and synthetic biology, have been evolving with new ways of using the genetic sequence information which, in a number of instances, is displacing the need to have physical access to any genetic resource. Developments in the use of digital sequence information (DSI) over the past

decade make it possible to synthesize new organisms and products using DSI that are currently available publicly and are also held in private.

This has now resulted in debates within the CBD and the Nagoya Protocol, as well as other fora such as FAO and UNGA BBNJ, regarding implementation as to whether the developments in use of DSI and synthetic biology would potentially make the Protocol redundant when countries will have limited control over access to genetic sequence information and their subsequent use, over-riding the need for prior informed consent and mutually agreed terms in having access to genetic resources.

Added to this is the emerging dimension of the complex intellectual property regimes while dealing with DSI and synthetic biology and the impacts of major global initiatives such as the Earth BioGenome Project and the Amazon Bank of Codes on the future of Nagoya Protocol and its implementation.

2. Dealing with the future

Several countries do not address DSI as a part of their legislative, administrative, or policy measures related to access and benefit sharing (ABS). Also, issues related to DSI fall outside the scope of the definition of "genetic resources" found in the CBD and the Nagoya Protocol. Many national ABS frameworks, except for few such as Brazil, have limited or no provisions to deal with ABS while using DSI. Lack of awareness on how to deal with DSI related issues, especially when such information is already available in public domain, as well as the lack of capacities to track and trace developments based on DSI seems to be inhibiting the development of measures addressing DSI related issues at national level.

The Ad Hoc Technical Expert Group (AHTEG) on synthetic biology report on technological developments on DSI on genetic resources discussed some of

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these issues.³ Synthetic biology and sequencing technologies has the potential to bypass the Nagoya Protocol entirely. Researchers or hobbyists can take genetic code that has been uploaded online, and using a DNA synthesizer, recreate and modify that code to produce new substances and perhaps even new organisms, with no meaningful way to track the origin of the genetic information that formed the basis for the discovery.⁴

Nagoya framework was not construed to accommodate the “virtual” concerns that DSI creates. As a direct consequence, the effective benefit sharing in the genetic sequences are far more difficult to ascertain compared to tangible genetic resources. These challenges increase over time as sequences pass through multiple improvisations and the direct link for benefit sharing erodes. Key question in such situations include whether the benefit sharing apply to an indefinite number of transactions or is there an expiration point.

Another concern is with regards to the patenting regime. The digital libraries allow any entity to access genetic information for private use which can be commercialized as patented inventions. Most of synthetic biology applications are eligible for utility patent protection in many countries. Hence commercialization possibilities of synthetic biology inventions employing DSI do not benefit the provider countries.

3. The Challenges

To accommodate these concerns, some countries have started explicitly incorporating DSI-related language into

³ Report Of The Ad Hoc Technical Expert Group On Synthetic Biology Montreal, Available at <https://www.cbd.int/doc/c/aa10/9160/6c3fcedf265dbbee686715016/synbio-ahteg-2017-01-03-en.pdf>

⁴ Margo Bagley, “*Towering Wave or Tempest in a Teapot? Synthetic Biology, Access & Benefit Sharing, and Economic Development*”

their ABS legislative, administrative, and policy measures, or alternatively interpreting the language in their existing ABS measures to include DSI. We can find some examples of these in the national implementation of ABS in countries like Costa Rica and Namibia and the members of the Andean Community that are now enforcing access requirements for DSI. However, they do not include any benefit sharing possibilities. However countries like Brazil and India have opted for benefit sharing for the utilization of DSI.

Costa Rican national ABS authority CONAGEBIO has indicated DSI to be part of “access to genetic resources:”⁵ Because DSI is not considered to be within the definition of genetic resources, but instead is deemed to result from “access to genetic resources,” no access permits are required for DSI beyond the obligation to require prior informed consent and mutually agreed terms (PIC and MAT). The CONAGBIO is also authorized to impose restrictions and prohibitions in access permits on the further dissemination or deposit of genetic information in public databases to avoid the loss of control over DSI resulting from authorized access to genetic/biochemical resources.⁶ However, this is bound to

⁵ Costa Rica’s Biodiversity Law No. 7788 of 1998 deals with the ABS framework and the Government of Costa Rica has indicated to the CBD Secretariat that “DSI” is covered under the definition of access to genetic resources.

Refer p. 45 of the Fact-finding Study on How Domestic Measures Address Benefit-sharing Arising from Commercial and Non-commercial Use of Digital Sequence Information on Genetic Resources and Address the Use of Digital Sequence Information on Genetic Resources for Research and Development, As requested by decision 14/20 (paragraph 11 (e)) from the 14th CBD COP, 25 October 2019. Available at https://www.cbd.int/abs/DSI-peer/Study4_domestic_measures.pdf

⁶ For example, granted permit No. Permit R-CM-089.2010-OT of January 9 2010, contains the following restriction:

cause issues related to research and publication of results from such results involving sequence information since all such publications need mandatory depositing of sequence information in public databases.

In the African region, Namibia has opted for a similar approach regarding access permits.⁷ Namibia's ABS legislation

"For the DNA (genetic material) extracted from the requested genetic resources the Technical Office of CONAGEBIO restricts the publication of complete/full genomic information on the national and international databases, meaning that the entire genomes cannot become public, only the information related to molecular markers. Likewise, before publishing the sequences of DNA of the molecular markers developed or used for project purposes, the applicant shall inform the TO in advance and later submit the accession number of the sequences".

Refer p 45 of the Fact-finding Study on How Domestic Measures Address Benefit-sharing Arising from Commercial and Non-commercial Use of Digital Sequence Information on Genetic Resources and Address the Use of Digital Sequence Information on Genetic Resources for Research and Development, As requested by decision 14/20 (paragraph 11 (e)) from the Fourteenth Conference of the Parties to the Convention on Biological Diversity, 25 October 2019

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

⁷ 8. Access permit

(1) A person who intends to access biological and genetic resources in Namibia, found in both in situ or ex situ conditions or parts of such biological and genetic resources, their derivatives, products, including synthetic products, and wherever applicable, intangible components, including genetic information or gene sequences, and associated traditional knowledge, must apply for an access permit in the prescribed form and manner prior to carrying out any -
(a) research leading to commercialisation;
(b) scientific research with a commercial purpose;
(c) commercialization, including industrial application and bioprospecting;
(d) export; or
(e) any other use as may be prescribed.

requires users who intend to access biological and genetic resources and their intangible components (read DSI) found in *in situ* or *ex situ* conditions, to apply for an access permit for research leading to commercialization, scientific research with a commercial purpose and others.

Countries like Peru and Colombia from the Andean Community has been working towards implementing Decision 391 defining genetic resources as including "intangible components", which is being interpreted to cover DSI.⁸

Some megadiverse countries like Brazil and India have gone beyond access requirements and included benefit sharing provisions for utilization of DSI. Brazil, have in their domestic Access legislation clauses exerting their rights over DSI even if held outside their borders. The Brazilian law of 2015 on "Access and Benefits Sharing of Genetic Resources and Associated Traditional Knowledge"⁹ expands the interpretation of "access to genetic resources" to include research related to molecular taxonomy, phylogeny, molecular ecology, and molecular epidemiology as well as the use of information from genetic sequences published in databases.¹⁰

4. Are we heading for a Nagoya Protocol "Plus"?

Brazil has adopted the "Nagoya plus" approach defining the term "Genetic

Available at

<https://namiblii.org/akn/na/act/2017/2>

⁸ Decision No. 391 Establishing the Common Regime on Access to Genetic Resources

Available at

<https://wipolex.wipo.int/es/text/223610>

⁹ Law (13.123/15) Provisional Act, No 2,186-16 2001 (Brazil), Title II, Art 7, para I Law No. 13.123 of May 20, 2015 (Access and Benefits Sharing of Genetic Resources and Associated Traditional Knowledge)

Available at

<http://www.wipo.int/wipolex/en/details.jsp?id=15741>

¹⁰ PNAS, "Earth BioGenome Project: Sequencing life for the future of life"

Heritage” that includes information on “Genetic Resources”. It has also expanded to include genetic resources accessed from within the Brazilian territory and also extending to the continental shelf or exclusive economic zone. ‘Access’ has been expanded to all research or “technological development” conducted on a sample of genetic heritage or associated traditional knowledge. The 2015 legislation requires users of Brazilian genetic resources to register their use through the SisGen online system prior to applying for patent rights.

India requires benefit-sharing for DSI, although the requirement is currently determined on a case-by-case basis.¹¹ Benefit-sharing obligations in India are specified as a percentage of the user’s commercial gains, so non-commercial use of a biological resource or associated knowledge would not ordinarily give rise to commercial prospects.¹²

Some Nagoya Protocol “Plus” mechanisms are adopted by net users of genetic resources, such as the member states of the European Union (EU) and Japan.¹³

¹¹ p 26 of the Fact-finding Study on How Domestic Measures Address Benefit-sharing Arising from Commercial and Non-commercial Use of Digital Sequence Information on Genetic Resources and Address the Use of Digital Sequence Information on Genetic Resources for Research and Development, As requested by decision 14/20 (paragraph 11 (e)) from the Fourteenth Conference of the Parties to the Convention on Biological Diversity ,25 October 2019

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

¹² Indo-German Biodiversity Programme / Access and Benefit Sharing Partnership project (2019) Access and Benefit Sharing Monitoring Tool Available at <http://indo-germanbiodiversity.com/pdf/publication/publication07-06-2019-1559912567.pdf>

¹³ Under the EU Regulation 511/2014 “[u]sers shall exercise due diligence to ascertain that genetic resources and traditional knowledge associated with

The EU Guidance Document, which is non-binding in nature, explains that users must respect any conditions in MAT that deal with DSI¹⁴ while EU clearly stated that open access to DSI is a significant non-monetary benefit.¹⁵

Given the developments and debates, both within the Nagoya Protocol and its implementation, as well as those beyond the Protocol, it is clear that DSI related issues need to be discussed as an additional and critical dimension of

genetic resources which they utilise have been accessed in accordance with applicable access and benefit-sharing legislation or regulatory requirements, and that benefits are fairly and equitably shared upon mutually agreed terms, in accordance with any applicable legislation or regulatory requirements.”

¹⁴ EU Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union (2016/C 313/01) “[T]he use or publication of such data might be covered by conditions set in the mutually agreed terms, which should be respected. In particular, those who accessed the genetic resources and obtain sequence data from them should respect the conditions of the agreement entered into, and inform subsequent actors about any rights and obligations attached to the data obtained and related to any further uses of it.”

Available at [https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016XC0827\(01\)&from=EN](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016XC0827(01)&from=EN)

¹⁵ p 19 of the Fact-finding Study on How Domestic Measures Address Benefit-sharing Arising from Commercial and Non-commercial Use of Digital Sequence Information on Genetic Resources and Address the Use of Digital Sequence Information on Genetic Resources for Research and Development, As requested by decision 14/20 (paragraph 11 (e)) from the Fourteenth Conference of the Parties to the Convention on Biological Diversity ,25 October 2019. Available at

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

future implementation and compliance to the objectives of CBD and the Protocol.

It is time for countries that are in the final stages of developing their national ABS frameworks to consider whether they would prefer to include DSI related components for access and benefit sharing as the Nagoya Protocol 'Plus' approach since any immediate and future decisions from the Protocol on DSI could potentially affect national implementation significantly.

If there is one issue that will surely emerge to challenge the Nagoya Protocol and its efficiency to deal with implementing the third objective of the CBD, it will be the decisions that will be made by the Parties to Protocol and the CBD on how to consider the DSI and synthetic biology related dimensions. This 'Plus' approach needs to be discussed as soon as possible, especially when countries are working towards a new global biodiversity framework beyond 2020 and when the Parties decided to enhance more synergies between the Convention and its Protocols.

In order to do so, discussions within the Nagoya Protocol should focus on the following:

1. Clear and evidenced based considerations on impacts of DSI and synthetic biology on the Nagoya Protocol and implications for national implementation,
2. Linking discussions between the Nagoya and Cartagena Protocols on issues related to DSI and synthetic biology that are to an extent being discussed separately. The forthcoming meeting of the third Subsidiary Body on Implementation (SBI 3) in 2020 should create an opportunity to have a joint expert group that will identify options for the synergies,
3. Develop elements for the Nagoya 'Plus' approach under the Protocol focusing on specifics such as bringing DSI related issues

under the purview of the Protocol, re-designing the research and publication criteria for results involving genetic sequence information,

4. Draw a set of options for dealing with intellectual property issues that combine the focus on issues of ABS and emerging technological developments,
5. Have a committed discussion that clarifies the future of the Nagoya Protocol that will be responsive and supportive of the objectives of the Protocol that calls for fair and equitable benefit sharing that is ethical, moral and legally correct, and
6. Map the capacity needs of Parties to the Nagoya Protocol to deal with the recommendations emanating from SBI 3 and CBD COP 15 meetings.



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Other Policy Papers from FLEDGE on related issues:

1. *Digital Sequence Information (DSI) and the role of Indigenous Peoples and Local Communities (IPLCs)*
2. *Enhancing synergies between the CBD, Cartagena Protocol and the Nagoya Protocol*
3. *Dealing with Digital Misappropriation.*