

**Third World Network¹ submission of views on “Issues for Further Consideration”
under CBD Decision 15/9 on “Digital Sequence Information on Genetic Resources”**

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Context

In decision 15/9, the Conference of the Parties (COP) to the Convention on Biological Diversity (CBD) decided to establish a multilateral mechanism for benefit-sharing from the use of digital sequence information (DSI) on genetic resources, including a global fund. It also established a fair, transparent, inclusive, participatory and time-bound process to further develop and operationalize the mechanism. Among other things, this process includes the

¹ We gratefully acknowledge the inputs and contributions of IT4Change (<https://itforchange.net>)

establishment of an Ad hoc Open-Ended Working Group on Benefit-Sharing from the Use of Digital Sequence Information on Genetic Resources to undertake further development of the multilateral mechanism, including the elements identified in the annex to the decision and to make recommendations to the COP at its sixteenth meeting. The process also includes the submission of views on the issues set out in the annex.

Accordingly, further to decision 15/9, paragraph 20, the Executive Secretary invited Parties, other Governments, indigenous peoples and local communities and relevant organizations to submit views on the issues set out in the annex to decision 15/9.

It is also expected that the Working Group will define the scope of the multilateral mechanism such that it is consistent with the Convention and Nagoya Protocol, including the sovereign rights of the Parties over their genetic resources. Furthermore read with Paragraph 7 of Decision 15/9, it is also expected that exceptions to the multilateral mechanism will be identified in the course of work of the Working Group. The issues identified in the annex need to be therefore analysed in this light.

The issues identified in the annex are as follows:

- a. Governance of the fund;
- b. Triggering points for benefit-sharing;
- c. Contributions to the fund;
- d. Potential to voluntarily extend the multilateral mechanism to genetic resources or biological diversity;
- e. Disbursement of monetary benefits, including information on geographical origin as one of the criteria;
- f. Non-monetary benefit-sharing, including information on geographical origin as one of the criteria;
- g. Other policy options for the sharing of benefits from the use of digital sequence information on genetic resources, including as identified through further analysis, as referred to in paragraphs 6 and 7 of the present decision;
- h. Capacity development and technology transfer;
- i. Monitoring and evaluation and review of effectiveness;
- j. Adaptability of the mechanism to other resource mobilization instruments or funds;
- k. Interface between national systems and the multilateral mechanism on benefit-sharing;
- l. Relationship with the Nagoya Protocol;
- m. Role, rights and interests of indigenous peoples and local communities, including associated traditional knowledge;
- n. Role and interests of industry and academia;
- o. Linkages between research and technology and the multilateral mechanism on benefit-sharing;
- p. Principles of data governance.

For the ease of the analysis and conceptual understanding, we have divided the elements into three categories and rearranged the above list as follows. However the alphabets within brackets “()”, are the same as in the Decision Annex, for easy identification.

Fundamental issues	Elements of the multilateral mechanism	Other elements
<p>(k) Interface between national systems and the multilateral mechanism on benefit-sharing;</p> <p>(l) Relationship with the Nagoya Protocol;</p> <p>(p) Principles of data governance.</p> <p>(m) Role, rights and interests of indigenous peoples and local communities, including associated traditional knowledge;</p> <p>(b) Triggering points for benefit-sharing;</p> <p>(e) Disbursement of monetary benefits, including information on geographical origin as one of the criteria;</p> <p>(f) Non-monetary benefit-sharing, including information on geographical origin as one of the criteria;</p> <p>(h) Capacity development and technology transfer;</p> <p>(i) Monitoring and evaluation and review of effectiveness;</p> <p>(n) Role and interests of industry and academia;</p>	<p>(a) Governance of the fund;</p> <p>(c) Contributions to the fund;</p> <p>(d) Potential to voluntarily extend the multilateral mechanism to genetic resources or biological diversity;</p> <p>(j) Adaptability of the mechanism to other resource mobilization instruments or funds;</p> <p>(o) Linkages between research and technology and the multilateral mechanism on benefit-sharing;</p>	<p>(g) Other policy options for the sharing of benefits from the use of digital sequence information on genetic resources, including as identified through further analysis, as referred to in paragraphs 6 and 7 of the present decision;</p>

The Submission is divided into three parts. Part 1 deals with Fundamental Issues; Part 2 deals with Elements of the Multilateral Mechanism and Part 3 deals with Other Elements and miscellaneous issues.

General Comment

It is our view that the DSI solution cannot be inconsistent with the CBD and its Nagoya Protocol on Access and Benefit Sharing, which recognize national sovereignty over national resources including genetic resources² and also impose an obligation on the Parties to adopt legislative, administrative and policy measures with the aim of fair and equitable sharing of benefits arising from the utilisation of genetic resources.³

As such, the problem of DSI in the context of the present decision is that it enables the dematerialization of genetic resources whereby access to genetic resources can be made digitally through varied channels and this opportunity is misused in order to circumvent the obligations of benefit sharing.⁴ Furthermore, the current practices of sharing DSI through the databases, which have no accountability to the Parties to the CBD, enable storage of the DSI, otherwise known as genetic sequence information, perpetually outside the territory of the country of origin of the source genetic material from which a sequence is extracted (hereafter, country of origin).⁵ On the other hand, most of these, including the largest database INSDC, practise very little due diligence to ensure benefit sharing. Interestingly, many of these databases retain unilateral rights to suspend access to any user or any part of the dataset contained therein. Recently, this has raised issues not only regarding data availability for public health purposes but also on data use and governance.⁶ Such practices could also potentially lead to biosecurity concerns as identified in the Ad Hoc Technical Expert Group report.⁷

² Articles 2 and 15(1) of CBD.

³ Article 15(7) of CBD.

⁴ Edward Hammond (2019), “Ebola: Company avoids benefit-sharing obligation by using sequences”, Third World Network, <https://twon.my/title2/biotk/2019/btk190501.htm>; See also AHTEG (2020), Combined study on digital sequence information in public and private databases and traceability, <https://www.cbd.int/doc/c/1f8f/d793/57cb114ca40cb6468f479584/dsi-ahteg-2020-01-04-en.pdf> at p.56

⁵ Nithin Ramakrishnan and Chetali Rao (2023), ““Open” Databases Undermine Access and Benefit Sharing”, Third World Network, <https://twon.my/title2/health.info/2023/hi230301.htm>

⁶ Scientific Advisory Group for the Origins of Novel Pathogens (SAGO) Statement on newly released SARS-CoV-2 metagenomics data from China CDC on GISAID, <https://www.who.int/news/item/18-03-2023-sago-statement-on-newly-released-sars-cov-2-metagenomics-data-from-china-cdc-on-gisaid>; See also, GISAID comments on the speculations surrounding data availability, which admits that they regulated data sharing unilaterally, <https://gisaid.org/statements-clarifications/data-availability/>; See also Marin Ensernik (2023), “Dispute simmers over who first shared SARS-CoV-2’s genome”, *Science*, 29th March 2023, <https://www.science.org/content/article/dispute-simmers-over-who-first-shared-sars-cov-2-s-genome>

⁷ See also AHTEG (2020), Combined study on digital sequence information in public and private databases and traceability, <https://www.cbd.int/doc/c/1f8f/d793/57cb114ca40cb6468f479584/dsi-ahteg-2020-01-04-en.pdf> at p.56

Thus it is clear that the advocacy of “open access” of DSI, *without adequate safeguards*, has the potential for rampant misuse and extractivism.⁸ It also leads to certain dominant groups – usually large and powerful corporations – being able to access this DSI without any accountability, and potentially locking up of this information within their intellectual property.⁹

Therefore, the development of the DSI solution should take place in a manner which addresses the above concerns, ensures fair and equitable benefit sharing and at the same time it must be less invasive of sovereignty over genetic resources. This, in our view, is possible only through robust development of national capacities in facilitating and appropriately regulating DSI extraction from genetic materials, its sharing and processing. The multilateral mechanism should therefore aid such capacity building and development in Parties as well as act as a complementary mechanism in cases where countries are unable or unwilling to regulate DSI usage such that benefit sharing is maximised.

Our inputs into the “issues for further consideration” contained in the Annex are made with this framework in mind.

Part I : Fundamental Issues

[note: alphabet in the brackets indicates the numbering of the issue in the Annex to CBD Decision 15/9]

I.1. (k) Interface between national systems and the multilateral mechanism on benefit-sharing; and (l) Relationship with the Nagoya Protocol;

Addressing the present situation where the DSI is not geo-tagged (many of the source materials and countries of origins are either not identified or not disclosed), a multilateral mechanism is considered as the best way out for the DSI benefit-sharing conundrum.

However, a multilateral mechanism on the sharing of benefits arising from the use of DSI *should not be incompatible with the sovereignty of States to regulate access to its genetic resources, including access to any knowledge associated with it*. If it infringes the same then the multilateral mechanism becomes unqualified under paragraph 9(g) of CBD Decision 15/9 which states that the solution should “*not be incompatible with international legal obligations.*”

Articles 2 and 15 of the Convention, and Articles 5 and 6 of the Nagoya Protocol recognize the sovereign rights of Parties over their natural resources. The Convention and Nagoya

⁸ Parminder Jeet Singh and Anita Gurumurthy (2021), “Economic Governance of Data Balancing individualist-property approaches with a community rights framework”, It for Change, at pp 25.29, See at <https://itforchange.net/sites/default/files/1880/Economic-governance-of-data.pdf>

⁹ Edward Hammond (2009), Some Intellectual Property Issues related to H5N1 Influenza Virus, Research and Vaccines, *Third World Network*, at p.8 <https://www.twn.my/title2/IPR/pdf/ipr12.pdf>

Protocol thereby allow Parties to regulate access to genetic resources and utilization of genetic and/or biochemical composition of such resources, which includes application of biotechnology as well as sharing of benefits arising therefrom.

Therefore, the application of the multilateral mechanism, including the global fund, in our view requires Parties to provide for such application or use of the multilateral mechanism for sharing of benefits arising from DSI in their national law. The same multilateral mechanism should also automatically apply when there is no national law applicable, for example, benefits arising from DSI use whose source material's geographic origin is unknown.

If a country is actively regulating its genetic resources and any form of knowledge or data associated with it, they are protected under the principle of sovereignty not just under the CBD, but also under customary international law as well as general principles of international law.¹⁰ This means that if a country regulates sharing of DSI via its legislation, the multilateral solution or fund cannot carve out benefits from the processes covered therein unless otherwise provided by the said legislation. Therefore, if a country prescribes tracking and tracing of DSI from the genetic materials sourced from its jurisdiction then the users should abide by the same. As recommended above, a system of disclosure and establishment of regulatory checkpoints by Parties will not only be compatible with the CBD and its Nagoya Protocol but also will maintain an orderly discipline at the interface between national and multilateral mechanisms.

Further, existing or new specialised regimes of access and benefit sharing that address specific concerns should also not be affected by the operation of the multilateral mechanism. For example,

1. Sharing of pathogens and their genetic sequence data
2. Sharing of plant genetic resources for food and agriculture.

It must be noted that Articles 8 and 4 of the Nagoya Protocol provide for special considerations for such cases and exceptions respectively. It is also possible under Article 8 of the Nagoya Protocol to have simplified access rules for developing country scientists, researchers and users.

I.2. (p) principles of data governance

DSI is unquestionably a form of data in digitised format, and therefore principles, rules or regulations governing data collection, and processing etc. should clearly apply to the use of DSI. Data governance is distinct from data management, where the latter is more about making data processing efficient, while the former is about ensuring the right thing is done with the data being collected or processed.

¹⁰ Article 2(1) of the Charter of Economic Rights and Duties of States, U.N. General Assembly resolution 3281 (XXIX), of 12 December 1974 read with the Declaration on Principles of International Law concerning Friendly Relations and Cooperation among States in accordance with the Charter of the United Nations (1970) and supported by the Peoples' right over national resources and wealth recognized under Article 1 of International Covenant on Economic, Social and Cultural Rights.

Although CBD Decision 15/9 acknowledges the FAIR and CARE principles, the framework for data governance provided by the Organisation for Economic Co-operation and Development (OECD) “Recommendation on Enhancing Access to and Sharing of Data”, and the recommendations set out in the United Nations Educational, Scientific and Cultural Organization (UNESCO) “Recommendation on Open Science”, these do not enjoy backing of all Parties in the sense that they do not constitute international law on data. While FAIR principles have nothing to do with benefit sharing directly and are more about data management than about data governance, CARE principles recognize benefit sharing for indigenous people and are more about data governance.

The OECD recommendation speaks about maximising benefits, however with regard to the sharing of benefits, it uses an ambiguous term “benefits of data access and sharing arrangements”, rather than “benefits arising from the utilization of data”. It takes an incentive-based approach for the promotion of distribution of benefits.¹¹ Further, the UNESCO Recommendation on Open Science treats “Collective Benefits” as one of the core values, although the recommendation seeks to build on the intellectual property system, which itself may create double-standards in the practices of benefit sharing from open science, due to the monopolistic nature of intellectual property.

Therefore the DSI solution should transcend all these soft law approaches and ensure that proper data governance systems are in place to provide legal certainty with respect to fair and equitable sharing of benefits arising from the utilization of genetic resources. *It is both a matter of data sovereignty as well as an obligation under Article 15(7) of the Convention.*

Data sovereignty entails that data are subject to the laws and jurisdiction of the Party where they are physically located.¹² Therefore, it is purely upon the Parties to place conditions of data collection, storage, processing, cross border data transfer and destruction, including access controls, scope of processing, third party transfer, change of purpose or intent, repatriation of data or any further information, measures to protect or promote the interests or needs of the developing countries etc. Parties can also exercise some of its sovereign rights on the data stored outside its territorial jurisdiction, especially if such data belong to its nationals or natural resources provided there exists international comity with the State in which data is physically stored.¹³

¹¹ Article VI(d) of the OECD Recommendation reads thus: “Promote appropriate incentive mechanisms that enable the fair distribution of the benefits of data access and sharing arrangements and ensure that stakeholders are enabled, encouraged, recognised, and rewarded for engaging in data access and sharing arrangements;” See <https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0463>

¹² Commentary to Rule 9 of *Tallinn Manual 2.0 on The International Law Applicable To Cyber Operations*, prepared by the International Groups of Experts at the Invitation of the NATO Cooperative Cyber Defence Centre of Excellence, at para.1 <https://www.cambridge.org/core/books/tallinn-manual-20-on-the-international-law-applicable-to-cyber-operations/E4FFD83EA790D7C4C3C28FC9CA2FB6C9>

¹³ See Rule 11, Tallinn Manual.

Tallinn Manual 2.0 on The International Law Applicable To Cyber Operations, reads thus in its first paragraph to the commentary on its Rule 1:

“Sovereignty is a foundational principle of international law. Its Latin origin – sui juris, esse suae potestatis, superanus or summa potestas – indicates that sovereignty refers to the supreme authority of the prince or king or, applied to modern international law, the State. This Rule recognises that various aspects of cyberspace and State cyber operations are not beyond the reach of the principle of sovereignty. In particular, States enjoy sovereignty over any cyber infrastructure located on their territory and activities associated with that cyber infrastructure. Although territoriality lies at the heart of the principle of sovereignty, in certain circumstances, States may also exercise sovereign prerogatives such as jurisdiction over cyber infrastructure and activities abroad, as well as over certain persons engaged in those activities. Finally, the territorial nature of sovereignty also places restrictions on other States’ cyber operations directed at cyber infrastructure located in sovereign territory.”

Although framework principles for data governance in general are applicable, the process and content of “data-fication” differ from sector to sector and need sector specific data governance.¹⁴ Information about bodies, natural worlds, and sociality is constantly being converted into a dematerialized data form, but all of these types of data cannot be treated as a monolith and governed in the same manner.

In the context of sharing DSI, the principle of data sovereignty may be therefore translated as the principle of genetic data sovereignty in combination with sovereignty rights over natural resources and genetic materials as recognized under the Convention and Nagoya Protocol. This means Parties should have the policy space in terms of deciding modes of collection of data from or on genetic resources, its storage, processing, sharing or transfer of storage, and deletion or destruction. However, Parties should actively use this policy space to ensure fair and equitable benefits as a matter of obligation under Article 15(7). A DSI solution should respect this principle of genetic data sovereignty.

1.2.1. Developing Conditions for Data Upload and Use

States should place minimum conditions to regulate the behaviour of databases and the same should be enlisted in the DSI solution. This is not only a necessary implication of genetic data sovereignty but also as an obligation flowing from Article 15(7) of the Convention on Biological Diversity.

According to Article 15(7), the Contracting Party shall take legislative, administrative or policy measures with the aim of sharing in a fair and equitable way benefits arising from the commercial and other utilisation of genetic resources with the Contracting Party providing

¹⁴ Irma Klünker, Heiko Richter, Digital Sequence Information between Benefit-Sharing and Open Data, *Journal of Law and the Biosciences*, Volume 9, Issue 2, July-December 2022, Isac035, <https://doi.org/10.1093/jlb/Isac035>

such resources. Therefore, in order to avoid the circumstances mentioned in the beginning where benefit sharing has been bypassed by the users of DSI,¹⁵ Parties are obliged to use their sovereignty to regulate the acts of the persons, natural as well as juridical, in the digital space and the use of the cyber infrastructure within their territories, to ensure benefit sharing.

This means Parties are obliged to develop a data governance framework, within which DSI is uploaded and processed, in order to ensure benefit sharing. It may take varied forms starting from simple prescriptions of due diligence standards to development of a new protocol for sharing of DSI. The legal, administrative or policy measures should, in our view, mandate databases to place minimum terms and conditions for data upload, sharing, processing and usage such as (i) requiring country of origin of source material as a necessary condition for uploading, (ii) mandatory reporting formats for research results, (iii) subjecting large-scale users to data audit and inspection, (iv) deletion or destruction or repatriation of data if necessary, (v) limiting the use to peaceful purposes that shall not lead to biosecurity, biosafety and biopiracy concerns.

Unfortunately, the apparent developed country vision of “open access” promotes a view that sequences must be given to companies (and others) without obligations, and that they may commercially capitalise on DSI, without benefit sharing. This version of “open access” is clearly flawed because in order to be consistent with the CBD and Nagoya Protocol, open access cannot mean that DSI is distributed with “no strings attached”.¹⁶ Open washing of data, as seen in the debates around treating Food Security and Nutrition (FSN) data as public good, without adequate protections against takeover by digital corporations, needs to be curbed so as to prevent evasion of the ABS mechanism.¹⁷ As use of DSI is arguably amply covered within the phrase “utilization of genetic resources” under the Nagoya Protocol, taking due diligence standards to ensure benefits arising from use of DSI is obligatory.

An important question that needs to be addressed here is whether a genuine idea of “open access” is contrary to the idea of having an effective data governance framework. The answer is “no”, because with effective governance by States, open access is guaranteed.¹⁸ Data will be accessible to all users, provided they agree to some basic standards of data collection and processing that would facilitate benefit sharing. In fact such basic standards will also discharge individual researchers from the blame of flouting any benefit sharing laws of a country.

¹⁵ See general comment.

¹⁶ Edward Hammond (2018), “Pressure Mounts for a Solution on Benefit Sharing for Digital Sequence Information”, Third World Network, <https://twon.my/title2/biotk/2018/btk181101.htm>

¹⁷ Anitha Gurusurthy and Nandini Chami (2023), “The Global Debate on Food Security Data: More Open-washing?”, see <https://botpopuli.net/harnessing-the-data-revolution-for-world-food-security-is-a-global-public-good-approach-good-enough/>

¹⁸ Nithin Ramakrishnan and Chetali Rao (2023), ““Open” Databases Undermine Access and Benefit Sharing”, Third World Network, <https://twon.my/title2/health.info/2023/hi230301.htm>

For instance, putting in place mandatory disclosure of the “country of origin of the genetic material from which DSI is sourced” and uploading of “documentary evidence showing legal right to sequence the genetic material” as necessary conditions for uploading of DSI into databases will have huge positive impact on the way data are now being governed. Such steps will not only promote traceability, but will also deflect blame from the submitter for either violating the law or wrongfully entering country of origin data.¹⁹

According to the AHTEG study, referred to above, only patent nucleotide sequence data entry has information on the country of origin, in Genbank.²⁰ The current models of databases rely on “submitter diligence”²¹ or “user diligence” to promote order and discipline in data access and usage. It’s highly ineffective, for example with respect to finding out the country of origin of the source material of DSI. On the other hand, a DSI can be traced to genetic resources only if the submitter (sequencer or uploader) reports it.²² This shows the high relevance and inevitable nature of the submitter’s duty towards the State and people.

At the same time, what is required from the submitter-researcher is minimal, i.e. to share basic meta-data of the DSI. Any basic reporting which they would do for their research projects should contain the temporal and geographical information of the materials and data which would be used. Requiring the same for the governmental purposes of monitoring the utilisation of their natural or genetic resources should not be deemed as excessive. There should be an obligation on the databases to require such mandatory fields for data uploading such that users would naturally be habituated in providing correct meta-data and obtaining legal rights to sequence genetic materials. This will protect real and genuine academic users and such protection should not overburden them. It must be noted that an academic-researcher cannot be stripped of their public responsibility towards the people and the States in providing adequate reporting of their use and research on the genetic sequence information.

Therefore, the current data governance model which relies on “submitter diligence” must be reformed to place reliance on the “database service provider’s due diligence”. States can and should absorb the diligence responsibilities from individual non-commercial users and develop legislative, administrative or policy measures to ensure due diligence on the part of the database service providers.

¹⁹ Currently, the blame is on those actors who submit DSI to the database; even the CBD commissioned studies suggest it's their oversight and ignorance that contribute to the problem. See AHTEG (2020), Combined study on digital sequence information in public and private databases and traceability, <https://www.cbd.int/doc/c/1f8f/d793/57cb114ca40cb6468f479584/dsi-ahteg-2020-01-04-en.pdf> at 52 (oversight) and 54 (insufficient awareness).

²⁰ AHTEG (2020), Combined study on digital sequence information in public and private databases and traceability, <https://www.cbd.int/doc/c/1f8f/d793/57cb114ca40cb6468f479584/dsi-ahteg-2020-01-04-en.pdf> at p.54

²¹ *ibid* at 48, 52, 54, 58.

²² *ibid* at p.3.

These requirements of due diligence and standards of data use may vary according to usage models as well as the nature of the users. For example, individual academics who use the search and download functions for basic activities of academic curiosity may be subjected to less stringent set of terms and conditions for reporting the results, while large scale academic institutions, industry users or academic partners of academic-industry partnerships that use "File Transfer Protocols" for periodic and regular download of entire datasets from the databases could be subjected to comprehensive reporting obligations. They must also be subjected to audits/inspections by governmental authorities, if concerns about the misuse or abuse of the shared data are raised by the governments of countries of origin.

1.2.2. Cloud Genomics and addressing the issue of tracking downloaded data

It has also been explicitly laid down that tracking and tracing are possible as long as data do not leave the digital/internet space.²³ That means that by limiting downloadable content using cloud genomics and workbench platforms, one can actively track and trace DSI. As long as data remains in the digital space, the possibility of tracing based on accession number and various other techniques is possible, as reflected in the CBD commissioned study.

An interesting model of data governance can be developed with the usage of cloud genomics and workbench facilitations.²⁴ Cloud genomics would mean providing storage space, computational power and technological tools such as data links and data hooks to users from different parts of the world. Such users can use workbenches such that the data are not removed out of the sovereign's jurisdiction. According to the AHTEG report, the datasets of DSI in this case are not downloaded but stored in the shared cloud space where researchers conduct their analyses. These collaborations also show that cross border data transfers in the name of access to DSI is not anymore warranted. However, there could be a transition period in the expansion of cloud genomics and developing national capacities for the same. This period may be subjected to more stringent data use, reporting and deletion requirements.

Tracking and tracing are recognized as possible by the CBD decision, although it notes tracking and tracing of "all" DSI is not practical. This means tracking and tracing are feasible in limited cases, especially in future uploads. In order to safeguard those limited cases, tracking and tracing mechanisms must be implemented.

Databases should also try to expand application of such mechanisms, and also the proposed requirement to clearly disclose the country of origin for all the sequences uploaded from the date of adoption of the Nagoya Protocol. They should try to find out and disclose the country of origin regarding existing sequences to the fullest extent possible.

Above all, traceability is not a technical concern, it is essentially a political choice. Most of the corporate compliance actually works on the basis of reporting and certain checks and balances in order to ensure reporting takes place promptly and honestly. *A system of*

²³ ibid pp.56-57

²⁴ ibid at p.62

disclosure rules and regulatory checkpoints by Parties will be compatible with CBD and its Nagoya Protocol.

1.2.3. Potential Creation of CBD-Coordinated Network of Databases

It must be noted that there is a special interest to the international community in handling data governance related to DSI in a much more orderly manner. This will require some jurisdictional competence in terms of sharing access to DSI. It is ideal that countries of origin themselves digitise their genetic materials or sequence information related thereto and take measures to retain sovereign rights over data generated and other States stop activities within their jurisdiction which would undermine the country of origin's sovereignty over DSI. However, it is plausible that the countries actively collectively, globally or regionally, can share their digital resources and establish a trust based mechanism for data governance.

This, in our view, is best achieved by the development of a CBD-coordinated open network of databases. The databases in the network would then be accountable to CBD Parties and to the respective Parties within which they are registered and where they are providing services, including the Parties whose data they host or share. *The central node of this network could be a database maintained by the CBD Secretariat.* which would provide options for both uploading the data directly as well as establishing datalinks to other databases or servers. Existing databases, those who are willing to abide by the terms of reference of the CBD-coordinated network, can become part of this network, and thereby legitimise their operations and get more trust from the users and Parties.

Therefore, the DSI solution should explicitly recognize the principle of genetic data sovereignty and the obligation under Article 15(7) to take legislative, administrative and legal measures. Operationalizing this would, in our view, require:

- 1. facilitating the establishment of national and/or regional databases with workbench facilitations such that cross border data transfers and downloads are effectively limited. Capacity building support should be provided for the same. These databases, once established by Parties, could also be designated as platforms for uploading the information for the DSI extracted out of material sourced from the respective Party. All other databases can establish links with the national and /or regional database to continue with their services.*
- 2. Parties taking legislative measures, prospectively, so as to prohibit within their territories uploading, storing, recreating, copying or downloading of DSI of the genetic resources belonging to other Parties, unless otherwise expressly allowed by such Parties.*
- 3. facilitating repatriation of genetic data stored to the countries of origin, and destruction of other copies thereafter, if a request to that effect was made by the country of origin.*
- 4. establishment and promotion of **a CBD-coordinated network of databases**, including **a global database maintained by the CBD Secretariat**, which will be accountable to Parties. All databases in this network could place minimum data use terms and*

conditions which will ensure fair and equitable sharing of benefits arising from the utilisation of data consistent with the CBD and Nagoya Protocol. The data from national databases, once they join the network, may be accessed through this global database, although data storage should remain within the territories of the respective countries of origin. All databases, existing or future, could become part of the network and benefit from its shared resources, subject to the conditions that they will apply minimum data use terms and conditions on their users.

5. *States to respect, preserve and promote the rights of indigenous peoples and local communities (IPLCs) over the DSI associated with genetic materials held by them or associated with their traditional knowledge.*
6. *Parties to adopt minimum due diligence standards for databases registered within their jurisdiction, especially on those that are accessible by the public, irrespective of their commercial or non-commercial nature, such as:*
 - a. *user registration with verified accounts;*
 - b. *minimum requirements for uploading of the DSI and in particular providing for information on country of origin and evidence for legal rights;*
 - c. *providing a mandatory accession number indicating country of origin; (a universal accession number format may also be developed by the Parties)*
 - d. *pro-active notification to the nationally designated focal points about the usage of DSI, including detailed disclosures on request for file transfer protocols from commercial actors including their academic counterparts or other institutional actors;*
 - e. *proactive dissemination of “DSI use conditions” to the users, especially through user agreements such as subscription agreements or accession agreements, which would provide legal certainty about what the users need to do with respect to their DSI usage such as:*
 - i. *their disclosure to responsible authorities;*
 - ii. *cooperation with responsible authorities including the need for abiding by the terms and conditions for benefit sharing;*
 - iii. *reporting requirements back to databases.*
 - f. *ensuring databases that commercially utilise sequence data, pay fair and equitable share of monetary benefits with the countries of origin*
 - g. *promoting databases to collect, curate and provide information on the utilisation of the DSI to which access is provided by the respective database.*
7. *require Parties to provide mutual legal assistance especially in terms of audits or inspection of the database usage located within their respective territories.*

I.3. (m) Role, rights and interests of indigenous peoples and local communities, including associated traditional knowledge;

The rights of indigenous peoples and local communities (IPLCs) are recognized under the Convention and its Nagoya Protocol. Article 8(j) of the Convention respects, preserves, and maintains knowledge, innovation and practices of indigenous and local communities with

respect to biodiversity. It also promotes the wider application and also equitable sharing of the benefits arising from the utilisation of knowledge, innovation and practices. The wider application is also subject to the approval and participation of the holders of such knowledge.

The Nagoya Protocol, which recalls this provision of the Convention and notes the interrelationship between genetic resources and traditional knowledge and their inseparable nature, provides for fair and equitable sharing of benefits arising not only from the utilisation of genetic resources held by indigenous knowledge but also from the utilisation of the traditional knowledge associated with the genetic resources. These are again subject to appropriate access based on the measures for (i) prior and informed consent or approval (PIC), (ii) involvement of indigenous and local communities and (iii) mutually agreed terms (MAT) with the communities holding such knowledge.²⁵

Article 31 of the United Nations Declaration of the Rights of the Indigenous People (UNDRIP) 2007 states thus: “*Indigenous peoples have the right to maintain, control, protect and develop their cultural heritage, traditional knowledge and traditional cultural expressions, as well as the manifestations of their sciences, technologies and cultures, including human and genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures, designs, sports and traditional games and visual and performing arts. They also have the right to maintain, control, protect and develop their intellectual property over such cultural heritage, traditional knowledge, and traditional cultural expressions.*”

Article 31, UNDRIP 2007 also recognizes the corresponding obligation of the State to take effective measures to recognize and protect the exercise of the above rights. Apart from these formal sources of law, a group of academicians have proposed a decent set of principles to govern indigenous rights over their data, widely known as CARE Principles. The term stands for “Collective Benefit, Ability to Control, Responsibility and Ethics.”²⁶

Digital sequence information on genetic resources held by indigenous peoples and local communities is arguably subject to rules of appropriate access and fair and equitable sharing of benefits arising from its utilization. Moreover, sequence information underlying the traditional knowledge or practices associated with biological diversity is also plausibly subject to rules of appropriate access and fair and equitable benefit sharing.

The Resource Kit on Indigenous Peoples’ Issues, Prepared by the Secretariat of the United Nations Permanent Forum on Indigenous Issues, states thus: “*Data collection should follow the principle of free, prior and informed consent at all levels and respect the human rights of*

²⁵ See Nagoya Protocol, Articles 5(3), 5(5) and 7.

²⁶ Carroll, S, et al. 2020. The CARE Principles for Indigenous Data Governance. Data Science Journal, 19: XX, pp. 1–12. DOI: <https://doi.org/10.5334/dsj-2020-042> See https://static1.squarespace.com/static/5d3799de845604000199cd24/t/6397b1aff7a6fb54defdf687/1670885815820/dsj-1158_carroll.pdf

indigenous peoples. For indigenous peoples living in voluntary isolation, data collection exercises should not be used as a pretext for establishing forced contact."²⁷ However privatisation of indigenous data without prior full and informed consent has been overlooked by governance institutions through the "servicification" of traditional activities, such as food production, or utilising natural resources, such as seed and plants.²⁸

The U.N. Special Rapporteur on the Right to Privacy has in addition recognized indigenous data sovereignty, and has encouraged governments and corporations *to recognize the inherent sovereignty of indigenous peoples with respect to data about them or collected from them, and which pertain to indigenous peoples' knowledge systems, customs or territories.*²⁹ It is practised through indigenous data governance that comprises principles, structures, accountability mechanisms, policy relating to data governance, privacy and security, and legal instruments. According to the report, indigenous data sovereignty frameworks can be applied to internally controlled and owned nation/tribal data, as well as data that is stored or managed externally.³⁰

Therefore, in order to operationalize the rights of IPLCs, the DSI solution would need to satisfy the following:

1. *The sequencing of genetic resources belonging to indigenous peoples and local communities (IPLCs) and the subsequent utilization of the DSI should be subject to approval of the community, involvement of the community and ensure benefits to the community. A minimum standard of PIC could be achieved by mandating persons who sequence genetic materials belonging to IPLCs or associated with their traditional knowledge with additional obligations to obtain PIC before they sequence and upload DSI. They should communicate the probable uses of DSI, especially the potential to recreate the specimen somewhere else using biosynthetic technologies and the varied known commercial and non-commercial uses to IPLCs before obtaining PIC.*
2. *IPLCs have the right to place terms and conditions³¹ including restrictions, and limitations on the use of DSI, such as (i) pre-commercialization notification and (ii)*

²⁷ DESA 2008, Resource Kit on Indigenous Peoples' Issues, at p.19, https://www.un.org/esa/socdev/unpfii/documents/resource_kit_indigenous_2008.pdf

²⁸ Notes in file from Presentation by Prof. Jane Kelsey, eCommerce Week 2022: Data and Digitalization for Development, 25 - 29 April 2022 Geneva and Online , Switzerland. Event page: <https://unctad.org/eweek2022>

²⁹ Joseph A. Cannataci(2018), Right to Privacy, Report submitted in accordance with Human Rights Council resolution 28/16, 17 October 2018, See <https://documents-dds-ny.un.org/doc/UNDOC/GEN/N18/324/46/PDF/N1832446.pdf?OpenElement> at para 52.

³⁰ Ibid at para 74.

³¹ For a brief understanding of the current landscape of what these terms and conditions could look like: Carroll SR et.al (2022), Extending the CARE Principles from tribal research policies to benefit sharing in genomic research. Front. Genet. 13:1052620. doi: 10.3389/fgene.2022.1052620, See (Table 2: TABLE 2 Operationalizing the CARE principles: Tribal expectations for benefit sharing) <https://static1.squarespace.com/static/5d3799de845604000199cd24/t/637acdc59cc1b65057118e99/1668992455706/fgene-13-1052620.pdf>

need for further agreements on benefit sharing of those conditions. In addition, Parties and their responsible authorities must provide provisional benefits that will ipso facto apply in the absence of a signed benefit sharing agreement by user.

3. *Terms and conditions placed by the relevant IPLCs should be respected, especially with regard to uploading of DSI into public databases. Ideally, sequences from IPLC materials should only be uploaded to those databases that are willing to attach digital notices to DSI datasets on IPLC's terms and attach conditions on the use of their data. Databases should in turn allow uploads of DSI belonging to IPLC materials only after the mandatory filing of the IPLC's PIC statement or certificate. Databases in the proposed CBD-coordinated network of databases should ensure maximum safeguards to protect the rights and interests of IPLCs.*
4. *If "individualised" PIC and MAT are considered problematic, given the volume of DSI usage through "open databases", then it should be the legal duty of Parties and these databases to ensure that IPLCs are informed about the usage of DSI relating to genetic materials held by IPLCs or associated with their traditional knowledge. In this regard, an "automated notification system" should be established by databases, to inform the concerned Party and the Party must be able to curate the notifications received by its focal point, for the scrutiny and information of the IPLCs. Transparency is the key to ensure the rights of IPLCs with regard to usage of DSI.³² Legally non-binding digital tools, labels or notices are not enough to safeguard legal rights of IPLCs. Such digital practices³³ are welcome, but a DSI solution should advance the system from passive notifications to active notifications that reach out to the concerned states and IPLCs.*
5. *By virtue of Article 6(g) of the Nagoya Protocol, IPLCs should have the ability to enter into agreements that clearly articulate terms on (i) benefit sharing including any intellectual property rights arising therefrom, (ii) third party use and (iii) change of intent. The concerned Party should assist IPLCs in negotiating and arriving at consensus with the DSI users, should they wish to do so.*
6. *The right to innovation by the traditional and local communities should not be curtailed by the intellectual property rights granted on products or processes developed using such DSI.*

³² The importance of transparency in the affairs of indigenous in the context International Treaty on Plant Genetic Resources for Food and Agriculture and DSI, See Edward Hammond (2019), Crunch Time for the Seed Treaty: A review of some outstanding issues in the negotiation, African Centre for Biodiversity, at p.12-13 See https://twm.my/title2/susagri/2019/sa774/Crunch_Time_for_the_Seed_Treaty_A_review_of_some_outstanding_issues_in_the_negotiation_Will_the_effort_to_fix_ITPGRFAs_broken_benefit_sharing_system_measure_up_to_expectations.pdf

³³ See footnote 2, Carroll, S, et al. 2020. The CARE Principles for Indigenous Data Governance. Data Science Journal, 19: XX, pp. 1–12 at p.7. DOI: <https://doi.org/10.5334/dsj-2020-042> See https://static1.squarespace.com/static/5d3799de845604000199cd24/t/6397b1aff7a6fb54defdf687/1670885815820/dsj-1158_carroll.pdf; See also https://localcontexts.org/wp-content/uploads/2021/07/LC-CI-Notices-Usage-Guide_2021-07-20.pdf for comparable idea of Cultural Institution Notices.

7. *A dispute settlement clause that is accessible to the concerned communities and guarantee of cooperation and assistance in legal processes.*

I.4. (b) triggering points for benefit sharing

Generally, it is argued that there is a need for identifying triggering points for benefit sharing, and most often the triggering point is the generation of benefits after utilisation of the genetic resource begins. On the other hand, this is not a watertight approach. The fluid nature of the activities associated with genetic resources, right from its exploration to diverse market opportunities that the unique value of the biochemical composition contained in the genetic resources presents, make it very difficult to explain where the utilisation begins and where it ends.

However, in the context of the Nagoya Protocol, “utilisation of genetic resources” acquires a specific meaning, i.e. conduct of research and development on genetic and/or biochemical composition of genetic resources, including application of biotechnology.³⁴ Further, it must be noted that the benefit sharing happens not only when this utilisation takes place, but also when there are subsequent applications and commercialization of the same by virtue of Article 5 of the Nagoya Protocol.

Therefore the moment the scientists or an individual starts looking for specific or unique biochemical features of a biological organism contained in its genetic material, the utilisation begins as the “search for the genetic composition” is on. This is one reason why the Nagoya Protocol treats pre-collection training or capacity building via participation in genetic research and product development as probable benefits in its Annex 1.

In other words, it's very difficult to pinpoint the triggering points where benefit sharing should begin. The way out for policy makers is to mainstream benefit sharing in every stage of the utilisation of genetic resources, right from exploration to the consumption by the end user. Nevertheless, the person or entities who sequence the genetic material should have acquired prior informed consent from the national authorities.

When it comes to utilisation of the DSI, this should not be different. At all stages, right from the planning to build digital architecture facilitating access to DSI to the end consumption of the products developed using DSI, fair and equitable benefit sharing should be mainstreamed. A question should be asked, at every stage, how benefits should be shared fairly and equitably, ever since the sequence information was extracted from the genetic material. The most popular ways of benefit sharing at each stage are mentioned below.

We propose that the DSI solution should take into account these forms of benefit sharing:

Stages	Benefit Sharing
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³⁴ Article 2(c) of Nagoya Protocol.

Extraction of DSI	submission of the same to the designated or national database of the country of origin of genetic material.
Access to DSI in paid databases	share of the access fee
Known scientific application and reasonable anticipation of product / process / technological development	(1) opportunities for countries of origin of genetic material to host the research; (2) in cases where the country of origin is not interested or unable to host research, opportunities to send their nationals to participate in the research.
Explorative research on DSI	opportunities for participation for collaborators from the country of origin of genetic material; cost of participation may be self-funded by the collaborators, or the State of country of origin, or principal investigators/ users.
Emergence of a byproduct or intermediate research outcome that has separate utility or value	notification of such results to the database and country of origin of genetic material - including offers or plans for collaboration for further utilisation of such outcomes
Emergence of the final product or research outcomes	notification of such results to the database and country of origin of genetic material - including offers or plans for collaboration for further utilisation of such outcomes
Any other subsequent application including curation of data and further dissemination of information	depends upon of the nature of the subsequent application
Commercialization of research results including final and intermediate outcomes	(1) licence for production in country of origin, or if a global public good is commercialized, such as vaccines, then permission for scaling up of production around the globe. (2) share of manufactured goods (3) percentage of sales, royalties etc.

Further, there could be click-wrap agreements to the databases containing DSI, indicating that the users are bound by the respective country of the origin of genetic material's rules and regulations regarding the utilisation of genetic resources, including terms for fair and equitable sharing of benefits arising from the utilisation of DSI.

I.5. (e) Disbursement of monetary benefits, including information on geographical origin as one of the criteria;

The recommendations below are developed based on the benefits as listed in Annex 1 of the Nagoya Protocol

Monetary Benefit	Who Should Pay?	To Whom?	When?	How?
Access Fees	Databases that charge fees	Respective Countries	Annually	Based on the usage statistics of the DSI sourced from countries
		MLS Fund	Annually	Based on usage of DSI, free from national obligations or whose source is unknown
Up-front payments	Users who have commitment with Countries	Respective Countries	As per the schedule of the commitment.	As defined in the commitment.
Milestone payments	Users who have commitment with Countries	Respective Countries	As per the schedule of the commitment.	As defined in the commitment.

Payment of royalties	IPR holder on the product/process arising out of utilisation of the use of the DSI	Countries (designated national authority)	Annually or actual basis	As per the schedule of the commitment.
		MLS Fund	Annually, in cases where the used DSI is free from national obligations or is from a source unknown.	
Licence fees in case of commercialization	Proprietor of the product/technology developed using DSI	Countries (designated national authority)	Annually or actual basis	As per the schedule of the commitment.
		MLS Fund	Annually, in cases where the used DSI is free from national obligations or is from a source unknown.	
Special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity	All actors who have prescribed such a fee	Country	As may be prescribed by relevant law	As may be prescribed by relevant law

		MLS	As may be prescribed by relevant law	As may be prescribed by relevant law
Salaries and preferential terms where mutually agreed	Users who have commitment with Countries	Respective Countries	As per the schedule of the commitment.	As defined in the commitment.
Research funding	Users who have commitment with Countries	Respective Countries	As per the schedule of the commitment.	As defined in the commitment.
Joint ventures	Users who have commitment with Countries	Respective Countries	As per the schedule of the commitment.	As defined in the commitment.
Joint ownership of relevant intellectual property rights.	Users who have commitment with Countries	Respective Countries	As per the schedule of the commitment.	As defined in the commitment.

I.6. (f) *Non-monetary benefit-sharing, including information on geographical origin as one of the criteria;* & (h) *Capacity development and technology transfer;*

The Nagoya Protocol recognizes an indicative list of the non-monetary benefits, based on which the same may be analysed.

Non-Monetary Benefit	How and when
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Sharing of R&D results (knowledge outcomes)	DSI users should try their best to publish in open access journals.	Copies of publication may be shared with national authorities as per the regulations.	joint ownership over IP rights or limiting IP rights
Sharing of R&D results (Products and by products)	As agreed upon with the relevant national authorities or intergovernmental institutions such as WHO or FAO or OIE		
Sharing of R&D results (technological outcomes)	As agreed upon with relevant national authorities or international agencies like WHO with clear terms of deployment of technology for downstream purposes, for example emergency scaling up of production during a pandemic.		
Scientific cooperation and collaboration in biotech	DSI users should offer proposals for collaboration, participation and cooperation to the countries of origin. Countries of origin may nominate or provide the users with a list of eligible and interested collaborators and participants, including natural persons or institutions. Based on mutually agreed terms these collaborations may be executed. Considerable linkages between the use of genetic material and use of DSI that may happen during such projects may also be taken into account.		
Participation in product development			
Cooperation in training and education			
Institutional capacity building			

I.7. (i) Monitoring and evaluation and review of effectiveness;

The *Subsidiary Body of Implementation* established by COP Decision XII/26 pursuant to Article 23 would be the appropriate body to undertake the monitoring, evaluation and review of the effectiveness of the DSI solution, with a view to enhance sharing of benefits arising from the use of DSI.

Articles 29, 30 and 31 of the Nagoya Protocol may also be applied for monitoring, evaluation and review of the effectiveness of DSI solution with a view to enhance sharing of benefits.

I.8. (n) Role and interests of industry and academia;

Three key factors need to be taken into account while discussing the role and interests of the industry and academia. First, their role and interests are not generally identical³⁵. Second, industry and academia are only two types of stakeholders in the issue under consideration, and their combined interests cannot suffice as “the public interest” of the issue under consideration.³⁶ The implications of the role and interests of industry and academia are not just complimentary to the public interests, sometimes they are competing or even worse, at times conflicting as well. i.e. the industry’s and academia’s attitude towards public interest is ambivalent. Third, the circumstances and requirements of the industry and academia varies significantly between developed and developing countries. Parties to the Convention and Nagoya Protocol are under an obligation that the industry and academia, whether from governmental or non-governmental sectors, promote capacity building, technology transfer and other forms of benefit sharing, especially for developing countries and their actors.³⁷ These factors should be taken into account in designing the DSI solution.

The interests of industry and academia are popularly identified as different. The former’s primary interest is assumed to be in profit making, while the latter’s in knowledge discovery, and dissemination. However, academia is often known to engage in the “process of bringing patentable scientific knowledge and technology to market” in the form of licensing, patenting and university spin-offs.³⁸ The interests in “commercial utility” and “quest for new knowledge” often collide with each other, leading to the formation of partnerships, patronage,

³⁵ For an overview of interests/values of organisational culture of academia and industry, see Figure 1 in Dominic Ehrismann and Dhavalkumar D. Patel (2015), University – Industry collaborations: models, drivers and cultures, Swiss Med Wkly. 2015;145:w14086, <https://smw.ch/index.php/smw/article/view/1978/2836> This can be further compared to that of public interests.

³⁶ Association with industry alters the decision of the academic institution which developed Coronavirus Vaccine: See Joel Lexchin (2020), “Are academia–pharma partnerships essential for novel drug discovery in the time of the COVID-19 pandemic?”, The Politics of Medicines (e-Encyclopaedia), See <https://haiweb.org/encyclopaedia/academia-pharma-partnerships/>

³⁷ Article 17 and 18 of the Convention on Biological Diversity as well as Article 8 of the Nagoya Protocol.

³⁸ Woodfield et.al (2023), “Commercialisation patterns of scientific knowledge in traditional low- and medium-tech industries”, Technological Forecasting and Social Change, Volume 189, April 2023, 122349, at <https://www.sciencedirect.com/science/article/pii/S0040162523000343#bb0255>

and other forms of collaboration³⁹ between academic and industrial or commercial actors, including lobbying networks for policy change and philanthropic funds.

These forms of collaboration often define the role played by the industry and academia respectively in the utilisation of the DSI. The commercial utility in new knowledge discovery *can arise at many different stages* - at times it can be perceived even before the discovery, some times at the time of discovery and many times it arises several months or years after knowledge discovery. *All these scenarios must be well taken into consideration while deciding the checkpoints* for collecting or receiving information or taking measures relating to expanding access to DSI as well as sharing of benefits arising therefrom. In a general scenario, commercialization takes place when *technology, and the knowledge embodied in it, are transferred from a university or research institute to an organisation that is converting the technology into marketable products.*⁴⁰

However, this does not exclude the possibility of academia themselves turning into a market party and they may or may not invite partnership from business or industrial entities. In the biotechnology field however, the partnership between academic and industry takes place quite often at an early stage, because it brings financial and technological resources together. This is also seen as a leverage for attracting further financial resources⁴¹ including through public grants from the government in such partnerships. This partnership between academia and industry sometimes acquires long standing patronage of academic institutions that are not only involved in scientific research but also involved in the articulation of the policy relating to use of scientific knowledge and regulation of scientific activities.

Given this context, the DSI solution should distinctly address the genuine needs of academia and delineate them from the policy campaigns of industrial users. The Convention provides for scientific and technical cooperation under Article 18 and requires Parties to promote establishment of joint research programmes and joint ventures for development of the technologies relevant to the said Convention. They are also required to promote exchange of the experts and training of personnel. Their *interests in exchange of information including the exchange of the results of the technical, scientific, and socio-economic research, information on training and surveying programmes, specialised knowledge, indigenous and traditional knowledge* have been recognized and promoted by Article 17.

The Convention also mandates under Article 17 *repatriation of the information* as well as to take into account the special needs of the developing countries. The institutions of developing

³⁹ Ankrah and Al-Tabbaa (2015), “Universities–industry collaboration: A systematic review”, Scandinavian Journal of Management, Volume 31, Issue 3, September 2015, Pages 387-408, at <https://www.sciencedirect.com/science/article/abs/pii/S0956522115000238?via%3Dihub>

⁴⁰ Kirchberger, M.A., Pohl, L. Technology commercialization: a literature review of success factors and antecedents across different contexts. *J Technol Transf* 41, 1077–1112 (2016). <https://doi.org/10.1007/s10961-016-9486-3>

⁴¹ Biotechnow. “Why University-Industry Collaborations in Biotechnology Matter”, Jan 2016, <https://www.bio.org/blogs/why-university-industry-collaborations-biotechnology-matter>

countries, both governmental and non-governmental, academia and industry, can benefit from technical and scientific cooperation as well as technology transfer. Similarly, the Nagoya Protocol also provides for capacity building and technology transfer. However most importantly, Article 8(a) reads thus:

“In the development and implementation of its access and benefit-sharing legislation or regulatory requirements, each Party shall: (a) Create conditions to promote and encourage research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries, including through simplified measures on access for non-commercial research purposes, taking into account the need to address a change of intent for such research”.

Therefore, a DSI solution should take into account the ambivalent relationship between public interest and the interests of the industry and academia and place proper checks and balances at different stages of genetic research, product development and commercialization in order to ensure benefits including technology transfer and capacity building, particularly to developing countries. This would include:

- 1. Requiring Parties to mandate databases to develop separate access schemes (using click wrap agreements or other forms of smart contracts) for commercial users and for other non-commercial users such as individual academic users to the databases. All for-profit organisations including any academia-industry initiatives should access the databases only through commercial schemes. More stringent terms and conditions could be applied to commercial users.*
- 2. Requiring Parties to establish checkpoints in their patent offices or in other offices which gives marketing clearances for full disclosure of the DSI used in the process of the development of patented products or process, along with the information on countries of origin of source material.*

Part 2: Elements of the Multilateral Mechanism

II.1. (a) Governance of the fund;

A key governance consideration will be the need to ensure proper oversight by Parties to the CBD, over the fund envisaged in decision 15/9. This would require the fund to be established under the authority of the COP.

As such, the decision making authority would be intergovernmental in nature, whatever may be the institutional structure of the fund. The intergovernmental decision making authority shall determine the everyday operation, fund policy and strategy, fund application format and the evaluation criteria of the applications, and the distribution of funds. The COP may adopt the decisions on these based on the determination of the decision making authority, after due consideration. COP will be eligible to alter the determination provided there is consensus in that regard.

The fund must be accountable to CBD governing bodies and provide adequate information on its practices, operations and implementation to the CBD's subsidiary bodies.

The fund, irrespective of where it is located, must be made accountable to the COP and must abide by the decisions of the COP.

II.2. (c) Contributions to the fund;

The basic question that needs to be asked is: who, when and how will contributions to the fund be made. There are at least a few types of monetary benefits that are envisaged in the Nagoya Protocol Annex, based on which these questions may be answered (see the table above under section I.5.)

It must be made clear that payments into the benefit sharing fund are obligations. Donations or other "voluntary" payments into any other financial mechanism under the auspices of the CBD should not be considered as offsetting benefit sharing obligations.

II.3. (d) Potential to voluntarily extend the multilateral mechanism to genetic resources or biological diversity;

Article 10 of the Nagoya Protocol prescribes a multilateral mechanism for genetic resources occurring in transboundary situations or when it is not possible to obtain prior informed consent. The multilateral mechanism can be extended to these situations provided it is applied on the basis of consent of affected Parties.

Further, prior informed consent should not be considered as not obtainable for use of all DSI. When the country of origin of the source material is known, the use of the DSI should be subject to the consent and notice of the respective Party, unless it indicates otherwise. Prior informed consent of the Party may be deemed to have been obtained through standard agreements or terms and conditions the Party may develop or assign for the purpose. A Party may provide that acceptance of certain standard terms and conditions provided by the databases may suffice as prior informed consent.

II.4. (j) Adaptability of the mechanism to other resource mobilisation instruments or funds;

Although benefits and in particular monetary benefits can be channelled for the purposes under the Convention, it cannot be equated to a resource mobilisation instrument. Benefit sharing is an obligation, not a discretionary decision made by the user of genetic resources or DSI. It's therefore a legal instrument, unlike a resource mobilisation instrument which is largely made up of economic policy measures. It must be noted that the danger of mutual offsetting must be avoided, which means no derogation of benefit sharing obligations. in order not to result in lesser and lesser financial resources at Parties' disposal.

Part 3: Other Elements

III.1. (g) Other policy options for the sharing of benefits from the use of digital sequence information on genetic resources, including as identified through further analysis, as referred to in paragraphs 6 and 7 of the present decision;

The proposed policy options for a solution on benefit-sharing from the use of DSI as contained in the annex to recommendation 5/2 of the Open-ended Working Group on the Post-2020 Global Biodiversity Framework are not mutually exclusive. Therefore it is important to identify the benefit sharing models identified amongst the policy options as elements. The options 2.1. (country MAT), 2.2 (global MAT), 3.1. (access fee), 3.2.1 (DSI research related services and products), 3.2.2 (bonds/labels), 3.2.3. (levy on products from DSI), 4 (enhanced technological and scientific cooperation and capacity building), 6 (1% on retail sales of GR related products) can be considered as elements that may be pursued by the multilateral mechanism or by Parties themselves, notwithstanding the multilateral DSI solution. We provide our views on each element below.

Elements (note: numbers below correspond to the policy options numbering as found in the IAG Co-Leads Report)	Views
2.1. Country MAT	An option applicable to all DSI for which source material and its country of origin is known. The country level (MAT) may be linked to the open databases and smart click options can be provided to the users for accepting such terms and conditions.
2.2. Global MAT	DSI, for which the country of origin of the genetic material is unknown, may be accessed through element 2.2. global MAT, executed between the CBD Secretariat and the users.
	A standard global MAT may also be used on all databases, which could further bind users to country level MATs or global MAT with the CBD Secretariat, as the case may be, depending on their usage.
	A sole standard global MAT applied by all countries is not very desirable, since the countries should have policy space to negotiate their terms and conditions and their requirements may also vary from country to country.
3.1. Benefit Sharing in the form of access fee	Any “access fee” collected by the commercial database or any other databases which charge fees from users, should be subjected to benefit sharing. The amount of access fee collected should be shared with the global fund and national authorities as the case may be.
	The current large scale database collaborations such as INSDC

	<p>which give commercial and industrial stakeholders facilities such as FTP may also consider charging such stakeholders a fee. The academic users collaborating with their commercial actors or industrial actors should ensure due diligence such that their collaborators pay access fees to the databases concerned.</p>
	<p>Industrial users from developing countries should be able to access these databases freely for a specified period and the COP may review this decision after a specified period and thereafter every x number of years.</p>
<p>3.2.1., 3.2.2., 3.2.3 other types of collecting monetary benefits</p>	<p>These may be applied by the Parties or by the multilateral mechanism as the case may be.</p>
<p>4. Enhanced scientific and technological collaboration, including capacity building</p>	<p>Whether mediated through the multilateral mechanism or not, there needs to be country specific programmes benefiting all developing countries. These should be subject to qualitative, and quantitative assessment of the collaboration and capacity building.</p>
<p>6. 1 percent contribution of retail sales</p>	<p>In addition to all forms of benefit sharing, as a part of their common but differentiated responsibilities, the developed countries should pay 1 percent levy on all returns of retail sales of genetic resource related products in their countries to the global fund. The funds may be collected through tax systems or may be cumulatively paid by the respective Party annually.</p>