DSI SCIENTIFIC NETWORK

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Submission of views on issues for further consideration for digital sequence information on genetic resources

In response to notification SCBD/NPU/DC/KG/CGA/90785 on "*views on issues for further consideration for digital sequence information on genetic resources*", the DSI Scientific Network is pleased to submit its contribution to selected topics contained in the Annex to the decision 15/9.

The DSI Scientific Network is composed of researchers with experience in the generation, use and management of DSI, who are contributing to biodiversity conservation, public health, and food security. Members are committed to enabling informed decision-making on access and benefit-sharing considerations at the international level, taking into account the immense importance of open access and the need for solutions that allows for fair and equitable benefit-sharing, including monetary benefits. The Network comprises 75 experts from 26 countries, representing Africa, Asia, Latin America and the Caribbean, Europe, North America, and Oceania, and disciplines as diverse as microbiology, medicine, plant genomics, taxonomy, and many others.

Introduction

DSI underpins vast swathes of current research in the life sciences, and has contributed to significant advances in medicine, conservation, agriculture, and other fields. All countries use and provide DSI (Scholz, A. H. *et al*, 2021) and it is used for basic and applied research in both the public and private sectors. The adoption of CBD COP15 decision 9 (CBD/COP/DEC/15/9), in particular the mandate to develop a multilateral system for benefit-sharing, is an important and positive step forward in recognizing the need to maintain and promote the use of DSI to support conservation while ensuring fair and equitable benefit sharing.

The multilateral approach to benefit sharing is fundamental for researchers' ability to access DSI and is compatible with the use of DSI in the service of scientific progress and sustainable development. A bilateral system for tracking and enforcing mutually agreed terms at the level of individual sequences would be extremely complicated, expensive, and challenging to develop and maintain. A multilateral mechanism addresses many of these challenges, enabling predictable and near-term benefit-sharing in accordance with the way DSI is used today.

The Network's submission focuses on five of the topics listed in the Annex: 1) trigger points for benefit sharing; 2) non-monetary benefit sharing; 3) other policy options for sharing of benefits; 4) capacity development and transfer of technologies; and 5) principles of data governance.

Most of the points made here were initially developed in a joint publication by members of the Network (Scholz, A.H., Freitag, J., Lyal, C.H.C. *et al*, 2022). These issues are the focus of the submission as they best represent points where the Network members have the most expertise and experience, which would directly impact how research is conducted depending on how they are addressed.

References:

Scholz, A.H., Freitag, J., Lyal, C.H.C. *et al*. **Multilateral benefit-sharing from digital sequence information will support both science and biodiversity conservation**. Nat Comm. 13, 1086 (2022). https://doi.org/10.1038/s41467-022-28594-0https://doi.org/10.1038/s41467-022-28594-0

Scholz, A. H. *et al*. **Myth-busting the provider-user relationship for digital sequence information**, *GigaScience* (2021). https://doi.org/10.1093/gigascience/giab085

1- Triggering points for benefit-sharing

Key takeaways:

- Non-monetary benefit-sharing happens organically when researchers share sequences in global databases. Open access to DSI is a common good for the worldwide research community and drives the bioeconomy in every country. The trigger point for benefit-sharing should not be at the point of access to DSI in public databases (e.g., subscription models and paywalls). Open access to global DSI databases underpins many international research collaborations and capacity building initiatives that enable countries to perform large-scale genomic and bioinformatics analyses and generate locally relevant knowledge.
- A trigger for monetary benefit sharing could be linked to the commercialisation of products made using DSI. Alternatively, a mechanism decoupled from the production and commercial use of DSI could be implemented (e.g., voluntary contributions, levies, payments from high-income countries, sector-specific financial obligations, or other innovative financial mechanisms).
- Mechanisms should be tested: 1) to determine whether they could deliver monetary benefit-sharing; 2) to ensure they do not hinder research (e.g., upstream of DSI generation or downstream of DSI use); and 3) whether they can be avoided (jurisdiction-shopped) to escape mandated financial contributions.

Rationale:

Non-monetary benefit-sharing:

The scientific practice of sharing sequences in open access databases is the major non-monetary benefit sharing that contributes to the first two objectives of the CBD. It is unnecessary to develop specific triggers for non-monetary benefit sharing from the use of DSI, perhaps other than requiring open-access submission of DSI by funding bodies. It is crucial, though, to reduce inequalities in the capacities of researchers worldwide to generate and use this common good.

Monetary benefit-sharing:

A mechanism for monetary benefit-sharing from the use of DSI must consider its effectiveness, avoid adding regulatory complexity, be consistent with open data policy, take into account differences between private and public databases, avoid stalling research and innovation, and be interoperable with other international fora and tools.

Any trigger point for benefit-sharing established at the point of access to DSI (for e.g., a subscription model where users have to pay to see, download, use or compare sequences or perform more specific analysis), will affect open access to data, and hinder research and innovation as a consequence. It is essential to avoid this to be consistent with the principles in CBD COP15 decision 9 (CBD/COP/DEC/15/9).

In order to assess whether a trigger or mechanism maintains open access, it is vital to have a common understanding of what is needed. According to Sara et al. (2022), open access to DSI in the International Nucleotide Sequence Database Collaboration (INSDC) and other large biological data repositories is characterized as follows:

- *"Anonymous access: Most of the large DSI databases do not require a log-in to access data. This anonymity enables immediate use of the dataset and greatly simplifies automated use of the database via remote interfaces (computer-to-computer) transactions.*
- *Free of charge: Public DSI databases do not cost money to use. There are no financial barriers in place to use the data regardless of the purpose or outcome of the DSI use.*
- *Free of restrictions: INSDC databases have terms of use that do not pass on any restrictions to their users. Smaller 'downstream' databases often take a similar approach or do not have explicit terms or licenses.*
- *Interoperable: This concept applies in both a technical and legal sense. As described above and in Figure 2, there is a frictionless flow of information across databases and applications that allows infinite re-uses of the DSI for any imaginable scientific purpose. The dataset is available for download and reuse to copy, analyse, re-process, pass to software, and so on, without distinction or discrimination as to purpose, user or country of origin.*

- *Transparency and reproducibility: The scientific community strongly encourages the attribution and recognition of previous scientific work and clear attribution to the work of others. However, there are no legal obligations to track and trace the use of DSI. Similarly, geographical or provenance information is important for the scientific record but legal implications of this information are scarce in the open access system."*

The DSI Scientific Network members believe that the following options for controlling and triggering benefit sharing should not be considered:

- Use of a paywall (paid subscription) system for DSI access: A paywall system would undermine DSI-based research and technology by stalling its interoperability and Open Access.
- Payment for the use of specific sequences, subsets or batches of DSI (sequences or analysis of results): This option will need a tracking system for all DSI (to prove and disprove which DSI was used) and would shift the burden of controls to DSI databases and millions of individual users, and require onerous technical management of DSI flows.

Instead, the DSI Scientific Network (see Scholz et al. 2022) supports at least three different non-mutually exclusive options for triggering benefit sharing, which are consistent with and supportive of the implementation of CBD COP15 decision 9:

- Triggering of benefit-sharing upstream of DSI generation and use, via micro levies (perhaps only in developed countries) on reagents, laboratory or equipment, or infrastructure used to generate DSI, and/or on commercial bioinformatics software and tools used for analysis. However, additional thought should be given to whether this could impede the medical sequencing of human genomes (e.g., for cancer diagnosis).
- Triggering of benefit sharing downstream of use of DSI, based on patent royalties, percentage of the revenue from sales of products, or application of levies on the commercialization of certain bioproducts obtained through the use of DSI or, as proposed by the African Group, even on biodiversity-based commercial products at the point of retail. It could also be based on sales by companies (or sectors) generating the commercial products, or on retails at the final sale points.
- Triggering of benefit-sharing decoupled from the production, use and commercial use of DSI, through voluntary contributions from philanthropies or non-parties, payments by high-income nations into a common fund based on the nation's intrinsic parameters, or other innovative financial solutions.

The three approaches could be seamlessly integrated into a multilateral benefit-sharing system that would allow for more widespread management of benefit-sharing. For example, funds could be directed towards efforts to support the conservation and sustainable use of biological diversity, with Indigenous Peoples and Local Communities (IPLCs) as key beneficiaries. Furthermore, they also:

- Do not affect the practice of open science and open access to DSI currently in place, and do not encourage changes in DSI generation and user practices.
- Allows fair and equitable distribution of benefits. In the case of product levies, it could be possible to design adjustments in the allocations based on local economies.
- Do not impose additional financial burdens and technical complications on non-profit DSI users such as research institutions and universities.
- Allow clear legal framing compatible with the implementation in national legislation.
- Enable compatibility and synergy with other benefit-sharing mechanisms that might be implemented in other international conventions /fora.

References:

Sara, Rodrigo, Andrew L. Hufton, and Amber H. Scholz. **Compatible or Incompatible? DSI, Open Access and Benefit-sharing**. SocArXiv. 2021. doi:10.4324/9781003301998.doi:10.4324/9781003301998.

2- Non-monetary benefit-sharing, including information on geographical origin as one of the criteria

Key takeaways:

- Open access DSI and the knowledge arising from the generation, utilization and sharing of DSI is a key driver for the conservation and sustainable use of biodiversity and to promote bioeconomy worldwide. For example, environmental DNA (eDNA) is an essential and widespread tool for species detection and ecosystem monitoring.
- The ability of the mechanisms and fund to support non-monetary benefit sharing should be considered among the core criteria in weighing different approaches. The tendency to focus on monetary benefits has led to under-development of the equally important non-monetary benefits that are linked to open access of DSI.
- Even though access to DSI is open and free, the capacity to use and analyse the sequences is uneven around the world. Building scientific expertise, including through joint international research initiatives, and ensuring the multilateral benefit sharing fund supports capacity - building, technology transfer, and other initiatives, will make it possible for more researchers to effectively use the global DSI infrastructure and share their data. This is in turn will contribute to more non-monetary benefits to be generated and to benefit more countries around the world - (*see section 5 on capacity building*).

Rationale:

Many non-monetary societal benefits of an open approach for DSI were demonstrated during the SARS-CoV-2 pandemic and showed the potency of both regional and global collaboration and cooperation promoting global health security. To ensure that there is equity in the ability of countries to utilize DSI that is openly accessible, strong support for tailored joint international scientific research, R&D and innovation initiatives for scientific and technical capacity building, access and technology transfer and sharing information is required to enhance non-monetary benefits for long term biodiversity conservation and valorisation as well as social and public health.

The scientific practice of sharing sequences in open access databases accessible for everyone, and contributing to the common good, is the major non-monetary benefit sharing that contributes to the first two objectives of the CBD and enables bioeconomy. The DSI Scientific Network does not see a need at present to develop specific triggers for non-monetary benefit sharing from the use of DSI. However, indicators that can measure the non-monetary benefits of open DSI are urgently needed. Our group would like to actively contribute to these discussions. Furthermore, in the context of capacity building, it is necessary to reduce the gap in abilities to generate non-monetary benefits from DSI and pursue equality in the capacities to generate and use this common good.

References:

Carly Cowell, Alan Paton, James S. Borrell, **Uses and benefits of digital sequence information from plant genetic resources: Lessons learnt from botanical collections**. 2021. doi.org/10.1002/ppp3.10216

Carly Bert Visser, Robin Pistorius, Rob van Raalte, Derek Eaton, and Niels Louwaars. **Options for non-monetary benefit-sharing: an inventory**. 2004.

Ruth Raymond and Cary Fowler. **Sharing the non-monetary benefits of agricultural biodiversity**. 2001.

The Nagoya Protocol: Available at: https://www.cbd.int/abs/text/articles/?sec=abs-37

3- Other policy options for the sharing of benefits from the use of digital sequence information

Key takeaways:

- Learn from past experiences: The Nagoya Protocol has shown that bilateral, non-standardized systems can result in high transaction costs and have often not delivered the benefits that many hoped for. It is important to learn from this experience as we build a new system for DSI.
- Keep it simple: multiple combined options or bilateral exceptions to any DSI multilateral mechanism will add complexity, incompatibility, and encourage avoidance behavior. A single, global and predictable set of rules for benefit sharing would be easier for users to navigate and would more efficiently support benefit sharing.
- Single entry point: Ensure there is a unique entry point to the multilateral mechanism for benefit sharing for users. The multilateral mechanism itself could deal with the complexity of redistributing the benefits to IPLCs, as a way to avoid exceptions, while making it easy for users so as not to hinder research and development.
- Simple rules and broad scope are a good combination to increase benefit sharing. This could make the system compatible with other UN fora and encourage a universal approach to benefit sharing for DSI.

Rationale:

The concept of ABS emerged in the 1990s as people became more aware of the potential value of genetic resources, partly due to the increasing importance of intellectual property rights for product development. This was accompanied or driven by the fear of countries losing control over biological and, therefore, genetic resources - particularly endemic ones. Legally binding international agreements became a way to respond to these trends, and agreements such as PIC and MATs set a bilateral approach to dealing with these concerns. However, later agreements have also acknowledged the potential of multilateral approaches (for example, the IT-PRGRFA).

To ensure efficiency and relevance over time, a mechanism for DSI needs to be able to respond to change and keep pace with scientific and technological developments. The biological world is global and highly interconnected; therefore, rules and values must also be developed with such a mindset. The decisions taken at COP15 in Montreal set this way forward. This is especially the case for the DSI world, where analyses of individual sequences generate value by comparison and integration (by mixing many sequences with each other and with other biological data sources).

While many options were presented and discussed in the lead-up to and during CBD COP15, a multilateral approach that decouples access and use of DSI from benefit sharing is the most suitable option to support research and innovation while ensuring fair and equitable sharing of benefits and has the potential to meet the criteria identified in paragraph 9 of the COP decision 15/9.

Simplicity should be the guiding principle for the new mechanism. Every exception to the multilateral approach will increase friction and uncertainty. This includes national bilateral approaches to dealing with DSI and carve-outs for specific subtypes of DSI (e.g., pathogens or DSI generated from biodiversity beyond national jurisdiction).

- Bilateral negotiations are complex, costly and usually take a long time. In practice, DSI users work with the global dataset, not just a few sequences from one country. A bilateral approach could pose significant administrative problems for providers to create and run the systems, and for users to comply with them.
- If bilateral exceptions are included in the multilateral mechanism, stakeholders (regulators, users, providers) will likely deal with major challenges to ensure efficiency and compliance. It will be legally complex to establish thresholds, cut-offs, and definitions of what “counts” as use, and what to do if a single sequence from an exception is used as part of a larger dataset or commercial outcome.
- Exceptions requested by some Parties and relevant stakeholders during COP15 negotiations could instead be addressed during the distribution of benefits from the multilateral mechanism.

- In addition, direct monetary benefits could be delivered to Parties based on their DSI contribution to the global dataset and their development status. Using the country field[1], the country of origin of the genetic resource used to produce DSI can be determined. This would make it possible to see DSI contribution of low- and middle-income countries (LMIC) to open access databases - for example, as a report from International Nucleotide Sequence Database Collaboration (INSDC) - without the need to develop a tracking and tracing system. A recent update in INSDC policy to increase transparency in this dataset is an important step forward to make this feasible.[2] This would enable the use of existing bioinformatic infrastructure instead of creating complex and high-cost new systems (see Scholz et al. (2022)).

In the same way, as essential custodians of biodiversity and generators and holders of traditional knowledge, IPLCs must receive monetary benefits. Instead of establishing exceptions to the multilateral approach, it should ideally provide for direct payments to IPLCs where possible. Such a mechanism could be developed with their active participation and ensure sacred species and traditional knowledge are handled with respect and integrity.

References:

Laird, S. et al. **Rethink the expansion of access and benefit-sharing**. Science 367, 1200–1202 (2020).

Humphries, F., Rourke, M., Berry, T., Englezos, E., & Lawson, C. **COVID-19 Tests the limits of biodiversity laws in a health crisis: rethinking "Country of Origin" for virus access and benefit-sharing**. J. Law Med. 28, 684–706 (2021).

4- Capacity development and technology transfer

Key takeaways:

- Meeting the capacity development needs for the production and use of DSI is essential to achieve CBD goals and Sustainable Development Goals (SDGs).
- The key issues that need to be addressed by capacity building and technology transfer are the build-up of bioinformatics and database expertise, as well as reliable access to international data infrastructures and computing facilities. However, capacity building and technology transfer will ultimately yield benefits where DSI is openly accessible and allows knowledge generation through large scale analysis, enabling innovation and “leapfrog” development.
- Different countries have different needs with regards to benefit sharing measures enabled by a multilateral mechanism. In many cases, these still need to be identified. Ensuring activities and funding in this space in response to national priorities is essential.
- Scientists and researchers, as users and generators of DSI, should be clearly identified as key stakeholders in the process of mapping needs and in being recipients of capacity building and technology transfer.
- In addition, needs mapping should consider both the technical aspects and policy elements needed to encourage the development of DSI use and generation. In the long term, this will help contribute to more non-monetary benefits from DSI.

Rationale:

Open DSI provides the opportunity to generate knowledge through large scale comparative analysis efficiently. In particular, significant advances are expected when different data types can be linked. Open DSI provides the basis for building up capacities for biodiversity monitoring, tracking endangered or invasive alien species, generating the knowledge needed to improve agriculture and One Health, and developing a sustainable bioeconomy. While all countries have equal open access

[1] https://www.ncbi.nlm.nih.gov/genbank/collab/country/

[2] https://www.insdc.org/news/insdc-spatiotemporal-metadata-minimum-standards-update-03-03-2023/

and all use and produce DSI, there nevertheless remain significant inequalities - LMIC-based scientists h

ave on average 40% less DSI-based publications than their OECD-based peers. In 2010, COP-MOP 1 took up the pre-CBD concept as an element of the strategic framework for capacity development, which includes the "Capacity of countries to develop their endogenous research capabilities to add value to their genetic resources".

Practical issues in LMICs ranging from more expensive access to molecular biological reagents (compared to reagent costs in HICs), slower internet bandwidth that limits high-throughput analyses, financial limitations for research funding, limited bioinformatics training and career development opportunities, as well as brain drain, routinely create limits for researchers in LMICs. The benefit-sharing framework for DSI must support technical and scientific capacity building focused on genomics, bioinformatics and AI. The goal should be to facilitate a "leapfrog" effect in which LMIC scientists are trained to exploit DSI even while inequalities in high-tech sequencing or laboratory infrastructure, including technology transfer, are still being addressed. With advances in cloud computing, open-source software, and open access DSI databases, the gaps are easier to fill than ever before if strategic and well-targeted investments are made.

Science-focused capacity development within the CBD must be aimed both at conservation and building up the bioeconomy through sustainable use and valorization of bioresources. Local scientists and regional or national science academies should be involved in agenda-setting. Matchmaking platforms could be established that connect scientists across the globe and build up human capital enabling sustainable development.

For DSI to be used as an equitable tool for sustainable development, new capacity building efforts and strategies adapted to the needs of individual countries and research institutions are required in the following areas:

- Comprehensive stakeholder mapping and analysis for better understanding of DSI across the value chain.
- Science and technology innovation to close the technology gap between North and South.
- Analysis and processing of large data related to DSI informatics.
- Increased effective access to international databases and their use by researchers in developing countries.
- Multilateral networking between public-private research institution and industry
- Sustainable human resources, infrastructure, and commodity-related labs extension services for DSI with health, food and nutrition, or any commercial and scientific value.
- Knowledge, data and database governance capacity.
- Engage with IPLCs to share benefits with the custodians of biodiversity.

In addition, government and non-government institutions should be encouraged to adopt strategies to promote and support capacity development initiatives in line with the Kunming-Montreal Global Biodiversity Framework (GBF) and ensure alignment and synergy with the SDGs and other relevant national and global processes. There is an urgent need for mechanisms that could provide strategic leadership and foster coordinated DSI capacity development action at the global, regional and national levels.

References:

DSI Scientific Network. **Event: What capacity building for digital sequence information can offer.** December 12, 2022. Montreal, Canada. Available at: https://www.dsiscientificnetwork.org/?event=cop15-science-policy-forum-dsi-session-what-can-capacity-building-for-digital-sequence-information-offer

The ABS Capacity Development Initiative. Webinar Report: **Webinar report: "Assessing capacity development needs for the use of DSI"**. 2021. Available at: https://www.abs-biotrade.info/fileadmin/Downloads/EVENT%20REPORTS/2021/202106-ABSI-I-DSI-Webinar-Report-Assessing-Capacity-Development-Needs..pdf

The ABS Capacity Development Initiative, the South African National Department of Forestry, Fisheries and the Environment, and the Norwegian Government. **Report: Second (virtual) Global**

Dialogue on Digital Sequence Information on Genetic Resources. 2021. Available at: https://www.cbd.int/doc/c/2342/ec94/36766da5013cca697ca52b04/report-2nd-global-dialogue-dsi-en.pdf

Convention on Biological Diversity, Subsidiary Body on Implementation. **Note by the Executive Secretary: Capacity Development, Technical and Scientific Cooperation and Technology Transfer.** CBD/SBI/3/. 2020. Available at: https://www.cbd.int/doc/c/cf21/fbf7/0cca399ca79a0b890c9bf19a/sbi-03-07-en.docx

5- Principles of data governance

Key takeaways:

- The original purpose of open access databases for DSI was to ensure reproducibility in science and to enable peer review and accountability. DSI governance practices should set and uphold the highest standards of data quality and accuracy whilst supporting the collection, storage, management, and utilization of DSI in a consistent, reliable, and secure manner.
- Data governance should promote transparency and accountability in the management and use of DSI by establishing clear rules (for example build off the FAIR and CARE principles), procedures, and processes for collecting, analyzing, and sharing data. DSI should also be managed in compliance with international and national legal and ethical requirements regarding data protection laws, data privacy regulations, and ethical principles related to access and use of genetic resources, especially for human and human-related genetic resources. Rules should be standardized and harmonized across various UN for a rather than the splintered development of 4+ DSI governance rules (CBD, WHO, FAO, BBNJ).
- Recognition of Indigenous Peoples' rights and Local Communities' interests: In addition to respecting all national and international legal and ethical requirements, when engaging with DSI that is associated with or that belongs to IPLCs, generators and users of DSI should also consider IPLCs rights, policies, practices and protocols to ensure that culturally aware data governance practices are implemented.
- Supporting innovation and discovery: Open data governance facilitates the use of DSI for scientific, medical, agricultural, and environmental applications that contribute to the advancement of knowledge, the improvement of human well-being and the achievement of CBD goals.
- Inclusion of metadata associated with DSI: DSI governance must include comprehensive metadata. Metadata provides the necessary context to the DSI, increases its longevity, and maximizes its scientific utility for future uses. In particular, where applicable, it should include the place of origin (spatiotemporal information), its association with traditional knowledge, its associated permit number, and its provenance from IPLCs at a minimum.

Rationale:

In recent decades, nucleotide and amino acid sequences have been predominantly stored in three large global databases interconnected under the International Nucleotide Sequence Database Collaboration (INSDC). Moreover, these databases are used by or even connected with thousands of smaller public and private databases.

Millions of DSI are uploaded and downloaded daily from these databases, and there is a need to define and maintain data governance rules that will help streamline DSI management globally.

Over the past few years, there has been an effort to update DSI governance and, building upon this momentum, we urge the CBD to engage in this dialogue by supporting responsible DSI governance and coordination with other UN fora. In particular, DSI should remain available promptly and in an approachable, machine- and human-readable, and actionable format, in compliance with robust open and responsible science data governance and stewardship standards, particularly the FAIR (Findable, Accessible, Interoperable, and Reusable) and CARE (Collective benefit, Authority to control, Responsibility, and Ethics), and their respective sub-principles.