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Sharing the benefits from genomic sequence data:

A key to financing protection of global biodiversity?

Key points

- The emergence of Digital Sequence Information (DSI) changed the preconditions for international rules on the fair sharing of benefits from genetic resources.
- After pressure from developing countries, a negotiation process has started under the UN Biodiversity Convention to develop a benefit-sharing mechanism from the use of DSI
- If concluded successfully, the mechanism could be a game changer for financing the protection of global biodiversity.





Sharing the benefits from genomic sequence data:

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Digital Sequence Information, or "DSI", is a term that refers broadly to genomic sequence data and other related digital data. This includes the details of an organism's DNA and RNA, which determine its characteristics and unique traits. Recent advances in sequencing technology and synthetic biology have made it easier to sequence, store, and share segments of DNA and RNA virtually, and DSI has already enabled significant advances in many fields of research. A global intergovernmental process is currently underway to determine how access to this technology could best be provided and how benefits from its use could be fairly and equitably shared to the benefit of developing countries, indigenous peoples and biodiversity. The first stage of the process has been promising in that regard.

Background

In addition to promoting the conservation and sustainable use of biodiversity, the UN Convention on Biological Diversity (CBD) has a third, lessknown objective: the fair and equitable sharing of benefits from the use of genetic resources. These are understood as material of plant, animal, microbial or other origin that contains functional units of heredity (genes) and is of actual or potential value. Genetic resources are essential to a significant proportion of the world's economic activity, for basic research and the development of products in sectors such as the pharmaceutical industry, agriculture, horticulture, cosmetics, and biotechnology.

In general, the developing countries (the "global South") have been endowed with the richest biodiversity and thereby the richest supply of genetic resources. During the negotiations that led to the 1992 CBD and global commitments to protect biodiversity,

they saw an opportunity to be reimbursed for what they saw as the unjust situation dating back to colonial times when the colonial powers of the Global North reaped huge benefits by exploiting natural resources in countries in the South, without providing any compensation. After tough negotiations, a legal regime was established as part of the CBD, based on the principle of national sovereignty and equity, and stipulating that the benefits obtained from the use of genetic resources are to be shared fairly and equitably with the provider countries of the resources. Access is subject to prior informed consent by the providing country and is to be mutually agreed between the providing country and the user.

In 2010, the CBD provisions on access and benefit sharing (ABS) were further specified through the adoption of the Nagoya Protocol on Access and Benefit-sharing.

However, the high expectations from the developing countries on shared benefits have not been fulfilled, for various reasons: There is still considerable lack of awareness of the international legal framework among the actors involved in the exchange of genetic resources, and many transactions have failed to make provision benefit-sharing arrangements. Moreover, this framework assumes only two main actors – providers, and users of genetic resources - whereas in practice there often is a longer value-chain, from accessing the resources to a final product with many stages and intermediaries. Moreover, the international minimum rules under the WTO for patents and other intellectual property rights on living material do not respect this regime, so a product is not automatically prevented from being patented or being granted a plant breeders' right if it is based

on genetic resources acquired illegally from a country.

The emergence of DSI

Another indication that developments have overtaken the current ABS regime in providing fair and equitable benefit-sharing has come with the rapid technological development of Digital Sequence Information (DSI). Its precise meaning and scope remain disputed, but the term refers to advances in bioinformatics, an interdisciplinary fie-Id of knowledge that develops and uses methods and software tools to extract knowledge from biological material. This development has reached the point where, once a genome has been deposited, its genes can be compared against hundreds of other genes for similarities and differences, helping to clarify its function and importance. Building on decades of scientific research, DSI is useful mainly in connection with the assembled data, rather than individual DNA sequences. DSI has a wide range of applications, including gene editing and synthetic biology.

Recent technological developments have significantly reduced the demand for physical genetic material: now it can be digitally sequenced relatively cheaply, with rapid exchange of data among researchers, institutions, countries, and databases.

Thus far, the use of DSI has not involved applying the concept of *benefit-sharing*, one reason being that it is generally difficult to identify the original source of the sequences.

This situation has brought ABS into the spotlight again, with sharply divided views between North and South on how to deal with DSI. Many developing countries have feared that the open access to and exchange of DSI will undermine the third objective of the CBD – the fair and equitable sharing of benefits from the use of genetic resources – and thereby also the incentives to protect biodiversity. They have argued that DSI should be fully included in the ABS regime, and with obligations on sequences mirroring those for genetic resources collected in the

field. As to the legal aspect, they have held that, as sequence information must originate from a physical source at some point, this is a subsequent use derived from access: therefore, the use of sequence information entails utilisation of genetic resources and is subject to the rules for fair and equitable benefit-sharing.

By contrast, the developed countries (or Global North) argue that DSI concerns descriptive information and is thus beyond the regulatory scope. They stress that free accessibility is essential, and that setting barriers to the already well-established principles of free access and exchange would undermine research and industrial development, to the detriment of developed and developing nations alike.

The topic of DSI had a significant impact on the negotiation process and the outcome of the overall post-2020 Global Biodiversity Framework (GBF) with goals and targets adopted at the 15th Meeting of the Conference of the Parties to the CBD (COP 15) in December 2022. As with the CBD negotiations in the early 1990s, developing countries made progress on benefit-sharing conditional on support for further commitments on conservation and sustainable use.

After hard negotiations, agreement was reached on a decision that establishes open access to DSI and recognises that the benefits from the use of DSI - monetary and non-monetary shall be shared fairly and equitably. In the process leading up to this decision, the legal disagreements on whether DSI is covered by the existing ABS regime were gradually set aside. A pragmatic approach was adopted, acknowledging "that tracking and tracing of all digital sequence information on genetic resources is not practical". To this end, it was decided to establish a multilateral mechanism for benefitsharing from the use of DSI, including a global fund as well as a time-limited process to develop and operationalise the mechanism further. This work is to be finalised at COP 16 in 2024.

The decision on DSI and benefit-sharing was part of an overall GBF package which included global biodiversity go-

als and targets, the GBF monitoring framework, a capacity-building plan for the GBF, and an agreement on increased financing for biodiversity conservation strategies.

The decision has already had implycations (and is likely to have more) for other international forums addressing DSI: In June 2023 a new global treaty was adopted on the conservation and sustainable use of marine biodiversity in areas beyond national jurisdiction as an implementing agreement under the Law of the Seas Convention. The treaty also addresses ABS in relation to genetic resources including DSI, and its benefit-sharing mechanism has important similarities with the CBD mechanism on DSI. The CBD decision also influences negotiations on DSI under the FAO International Treaty on Plant Genetic Resources for Food and Agriculture and the ongoing negotiations under the WHO of a new international pandemic treaty which is likely to address also international sharing of pathogens and derived genetic sequence data, among other things.

The DSI process towards COP 16

The adoption of the DSI decision is in itself an important milestone. However, much work remains to be done across the scientific, technical, and policy community to develop the mechanism further, for adoption at COP16 in 2024. The 2023–24 process offers opportunities for various different voices to be heard. It includes commissioned studies, submissions, and the creation of an Open-Ended Working Group under the CBD. This group met in Geneva from 12–18 November 2023 for the first time to discuss modalities for the mechanism.

Participants and observers have generally viewed the meeting as constructive and as a promising start of the process. However, the meeting also revealed serious disagreements, leaving many questions on important issues unanswered.

Notably, there was no agreement as to whether contributions to the global

fund established to provide monetary benefit sharing shall be mandatory or voluntary – the latter is preferred by some developed countries. If it is made mandatory (as supported by a large majority of countries) a further question remains: what shall be the trigger for payments to the fund. Such triggers might include access to DSI, use of DSI or commercialisation of products and other revenues generated from the use of the DSI. This leads to the question of who the contributors shall be: all users of DSI, including academia and industry? Will governments also be contributors? And what shall be the scale of contributions? Some developing countries have suggested at least 1% of all sales of products derived from DSI in addition to contributions from other sources.

As noted, developing countries have feared that that the open exchange of DSI will undermine their rights as providing countries to determine access to genetic resources and to negotiate terms with users for the sharing of benefits. At the November 2023 meeting of the working group, it became clear that for some countries these fears had not disappeared with the COP decision to establish a multilateral mechanism for monetary and non-monetary benefits in return for open access to DSI. For these countries, "open access" is not the same as "free access". They advocate for "hybrid approaches" to harmonize the multilateral mechanism with national legal systems, some of which include DSI alongside with physical genetic resources. They want to ensure that funding allocations remain based - at least in part – on the geographical origin of the genetic resources from which the DSI is derived. Such approaches can hardly avoid tracking and tracing of DSI.

There is also convergence on some important issues:

Developed and developing countries are united in their wish for the funds under the mechanism to be used for to the conservation and sustainable use of biodiversity – especially in developing countries, where most of the world's biodiversity is found. Many would argue that this should also be

the case for revenues generated under the existing bilateral ABS system for exchange of physical genetic resources. However, this has not been spelled out as clearly as now in the context of the DSI mechanism. Target 19 of the GFB calls on countries to substantially and progressively increase the level of financial resources in order to mobilize at least \$200 billion per year by 2030 for biodiversity safeguarding. At the meeting of the working group, many countries highlighted the high potential of the DSI mechanism for meeting this target - indeed, even for moving beyond the target and towards closing the biodiversity financing gap, estimated at around USD 700 billion annually.

Another subject on which there has seemed to be wide agreement across the developed-developing countries divide is that a major beneficiary of the DSI funds shall be indigenous peoples and local communities (IPLC) for their role as custodians of estimated 80% of the world's remaining biodiversity. The meeting of the DSI working group was held in conjunction with a meeting of the CBD working group on the protection of the traditional knowledge held by IPLCs. It is likely that this meeting arrangement contributed to raise awareness of IPLC interests in relation to DSI.

Lastly, there is broad agreement that non-monetary benefits triggered by the mechanism should include extensive capacity development in developing countries, including technology transfer and development on DSI.

The role of Norway

Norway has played a prominent role in the process. At COP15, the then Norwegian Minister for Climate and Environmental Protection, Espen Barth Eide (now Minister of Foreign Affairs) co-lead the final negotiations among ministers leading to the decision on the DSI multilateral mechanism. Moreover, Norway provides financial support for the intersessional work towards COP 16 to enable broad and inclusive work, including regional consultations.

Closing remarks

The decision to establish a multilateral mechanism for access to and benefit sharing from DSI did not receive much public attention — at least, compared to other proceedings in December 2022 at CBD COP15, in particular, Global Biodiversity Target 3, calling for 30% of the earth's land and sea to be conserved by 2030. Not many in the wider public were aware that without this hard-fought decision on DSI (with Norway in a leading role), there would not have been the 30+30' target and many of the other global targets that have been highly praised afterwards.

The DSI mechanism was meant to fill a gap in terms of equity and fairness which the existing ABS regime under the CBD and the Nagoya Protocol had left open because of the declining demand for physical genetic resources. However, the ongoing process on DSI now points at another major issue: the USD 700 billion gap in financing the protection of our global biodiversity. A wider understanding that the revenues from the mechanism are meant for biodiversity conservation and sustainable use, combined with the potential scale of revenues that can be generated from a well-designed mechanism, could be the game changer for resource mobilization.

However, creating such an intergovernmental mechanism is not easy, and the meeting in November 2023 revealed disagreements among countries on many issues. Besides, with COP 16 taking place in Colombia already from 21 October to 1 November 2024, there is little time for so much to be accomplished. Thus, the CBD process for the remaining time limited will be crucial. Moreover, with so much at stake for both fair and equitable benefit-sharing and for biodiversity conservation, it will be important to raise high-level political awareness on the issue. Here, there are lessons to be learned from COP15 in 2022, where unprecedented political attention proved crucial for the successful adoption of the major decisions taken there. This applies even more today, as the CBD outcome on a



Senior Researcher
Christian Prip
cprip@fni.no

DSI mechanism is likely to influence other ongoing treaty processes under FAO, UNCLOS and WHO where DSI is also an important matter.

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Fridtjof Nansens vei 17 1366 Lysaker | Norway Telephone (+47) 47 48 06 80 E-mail post@fni.no | www.fni.no

About the author

Christian Prip is a Senior Researcher at the Fridtjof Nansens Institute. He is specialized in international environmental, natural resources policy and law; Policy and law on the protection of the marine environment; Arctic environmental governance; Synergies in environmental governance.

