FACTSHEET

THE ISSUE OF DIGITAL SEQUENCE INFORMATION ON GENETIC RESOURCES

Digital Sequence Information refers to genetic data such as nucleotide sequence, protein sequence of organisms. It finds use in multiple areas, but its non-physical nature complicates the traditional methods of managing access and benefit-sharing established under the Convention on Biological Diversity to handle tangible genetic resources

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Recommendations will address questions such as how financial contributions from users of DSI should be calculated and how they should be shared equitably with Indigenous Peoples and Local Communities

At the 16th Conference of Parties to the Convention on Biological Diversity, being held in Colombia between October 21 and November 1, 2024, members would be debating on the crucial issue of digital sequence information on genetic resources.

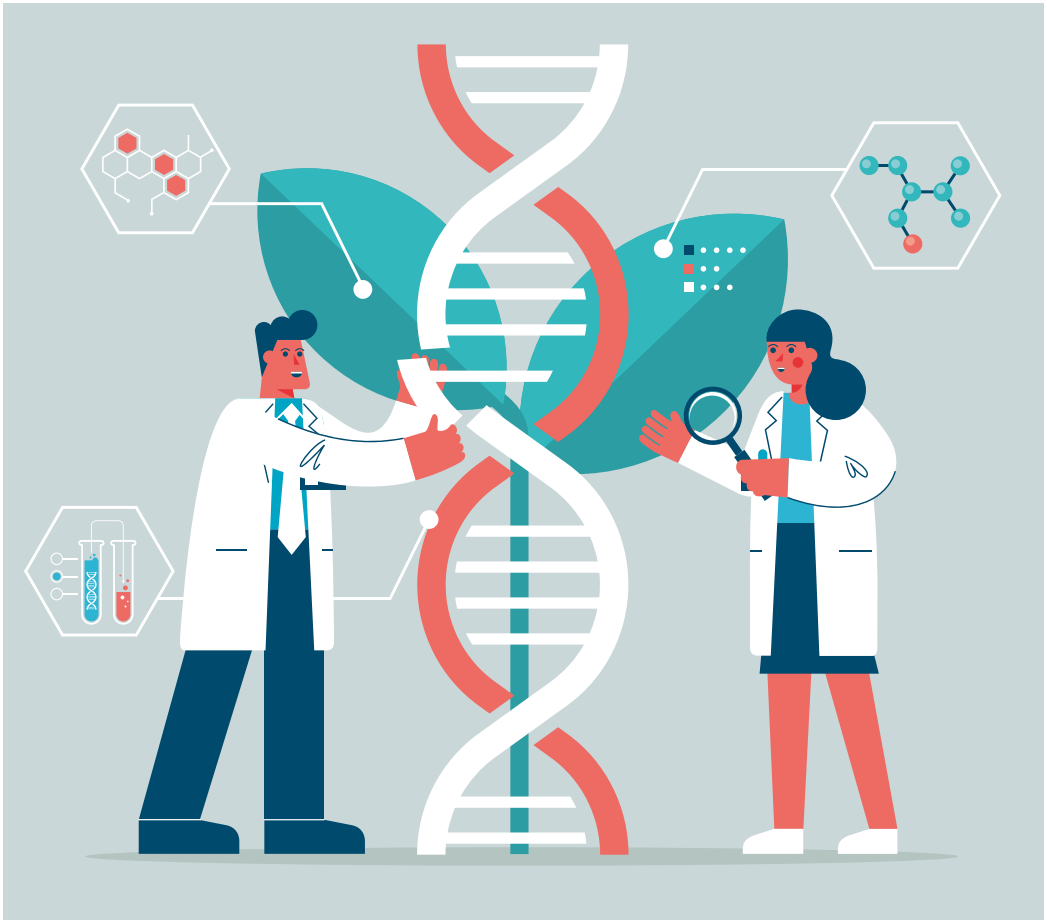
Parties are meeting for the first time since the Kunming-Montreal Global Biodiversity Framework (KMGBF) was adopted in December 2022 in Montreal, Canada. Other than reviewing the state of implementation of the KMGBF and progress towards meeting its 23 targets, Parties would also finalize and operationalize the multilateral mechanism on the fair and equitable sharing of benefits from the use of digital sequence information on genetic resources (see *Box: Principles of CBD*).

Principles of CBD

CBD was established in 1992 and has three aims: Conservation of biological resources, sustainable use of these resources and ensuring that the benefits arising from the use of genetic resources are shared fairly and equitably with the communities that have protected them for long and that hold the knowledge about their use. The Convention acknowledges that countries have sovereign rights over their genetic resources, and these principles were further detailed in the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, which came into force in 2014.

Access and Benefit-Sharing (ABS) is a system designed to ensure that when genetic resources, like plant samples or animal tissues, are used for research or commercial purposes, the benefits are shared fairly. Before using these resources, researchers or companies must get permission from the source country or local communities. This permission, known as Prior Informed Consent (PIC), must be fully informed and voluntary. Once access is granted, the users are required to share the benefits that come from their research. These benefits can be financial, like royalties or compensation; non-financial, such as sharing research results or co-owning patents; or in the form of capacity building, like providing technology transfer and training programmes.

Source: CBD, 2010. *Introduction to access and benefit-sharing.* Accessed at https://www.cbd.int/abs/infokit/brochure-en.pdf)



The discussion at COP16 is crucial as access and benefit sharing is an integral part of the Convention but it fails to lay down any rules for the use of digital sequence information (DSI). Though DSI finds use in multiple areas, its non-physical nature complicates the traditional methods of managing access and benefit-sharing (ABS), which were established under the Convention on Biological Diversity to handle tangible genetic resources. DSI refers to the digital data derived from the genetic material of biological organisms such as plants, animals and viruses (see *next page*).

Why is lack of regulation a problem?

DSI can be used to evade benefit-sharing requirements and there are some concrete cases of such "biopiracy". Inf'OGM, a citizens' watchdog on GMOs, biotechnologies, patents and

What is DSI and why is it important?

Digital Sequence Information can be nucleotide sequences (DNA and RNA), protein sequences, entire genomes, genetic variants, epigenetic information, metagenomic sequences, functional genomic data, structural genomic data, comparative genomic data, and proteogenomic information. All these are essential for various biological and technological applications.

The exact definition of DSI is still debated and the term itself is being used as a placeholder for the time being. But, over the years, it has been seen that DSI is fundamental to modern biological research and is widely used in the development of commercial products, including biotechnological innovations, pharmaceuticals, and food products. It also plays a key role in non-commercial research, contributing to advancements in fields like biodiversity conservation, medicine, and agriculture.

Basic science
Helps understand biological processes and gene functions. It allows researchers to investigate how genes interact with each other; helps in evolutionary studies by enabling the exploration of genetic changes over time and understanding the relationships between different species; combined with other types of genomic data, it helps create maps of complex biological networks; genetic sequences can be used to design and engineer new biological systems such as microorganisms for biofuel production.

Medicine
Plays a vital role in personalized medicine and tailors treatments to an individual's genetic make-up has application in cancer therapies to figure out how patients may respond to specific cancer treatments.

Cosmetics
Improves product safety, traceability, and personalization using genetic data; helps in batch coding for tracking ingredients and ensuring quality, as well as tracing ingredients for safer products; provides personalized skincare recommendations based on DNA profiles and specific skin issues; provides 3D skin models to test how different ingredients work with various skin types.

Conservation
Helps assess genetic diversity in various species and in identifying effective strategies to protect vulnerable populations; helps scientists understand how species adapt to changing environments. In restoration projects, it is used to add healthy genetic variation to endangered populations, which is crucial for their survival.

Agriculture
DSI helps to develop crops with better traits, such as drought tolerance and disease resistance. In livestock breeding, it identifies desirable genetic traits for better animal performance. It is also important for pest management, where genetic data creates pest-resistant crops, supporting agricultural productivity. DSI can be used for engineering genetically modified organisms (GMOs).

Biotechnology
DSI helps develop products like insulin and biofuels. Tools such as CRISPR-Cas9 use DSI to make precise changes in an organism's DNA. This allows researchers to correct genetic defects and create stronger crops. Similarly, in agriculture, DSI can help improve crop traits like disease resistance and drought tolerance.

Source: Synthesized from multiple sources

seeds has documented two case studies of how DSIs can be used for biopiracy.[1]

Potato: In March 2020, the African Diversity Center, along with Pelum and Andes, both NGOs critical of GMO introduction, examined the case of a genetically modified (GM) potato developed by the International Potato Center (CIP) in Peru. This potato, which has enhanced resistance to mildew, was created using genes from the Latin American variety for the purpose of commercializing it in Uganda and Rwanda. The modified potato has three specific genes sourced from plants in Latin America, but two of the genes were not collected directly from the plants. Instead, they were synthesized from genetic sequences found in the US GenBank database. The researchers claimed commercial rights to these genes even though they were synthesized from publicly available sequences.

These two genes are Rpi-vnt1.1 and Rpi-blb2 derived from *Solanum venturii*, collected in Argentina and *Solanum bulbocastanum* collected from Mexico, respectively. Rpi-vnt1.1 was sequenced by Sainsbury Laboratory in the UK and stored in GenBank in 2010, while Rpi-blb2 was collected before 1957 and sequenced by researchers in the Netherlands, and added to GenBank in 2005. The financial and scientific collaborations behind the GMO potato involve various entities, including major foundations and companies from the US and the UK. However, there is little mention of benefit sharing with local farmers.

Ebola: In 2014, an Ebola outbreak began in West Africa when a patient in Guinea was identified with the virus. The Pasteur Institute in France and the Nocht Institute in Germany were responsible for isolating and studying the virus. The Nocht Institute sequenced the Ebola virus from the Guinean patient, labelling it as the C15 sample. They sent the virus samples to various labs under a Material Transfer Agreement (MTA), which aimed to ensure that Guinea would receive benefits if patents or commercial uses occurred. But the sequence was

also uploaded to US GenBank, making it free for anyone to access without any obligations to Guinea.

The US company Regeneron used the C15 genetic sequence to create a monoclonal antibody treatment called REGN-EB3, funded by more than US $400 million from the US government. Each dose of the treatment costs around US $10,000, making it unaffordable for any African government to provide to its citizens. Regeneron did not make any benefit-sharing agreements with Guinea for using the C15 sample as US laws do not require such agreements. The C15 sample was collected without consent from the patient and raises ethical concerns.

Digital Sequence Information (DSI) complicates the traditional ABS system set under the Nagoya Protocol under the CBD. DSI exists in digital form and can be shared and accessed online and is difficult to track and regulate. There are open-access databases which store vast amounts of genetic data. There are more than 1,700 databases and repositories of biological data around the world. The International Nucleotide Sequence Database Collaboration (INSDC), which consists of three large databases, receives over 23 million sequences per year. EMBL-EBI (European Bioinformatics Institute), which is part of the ENA, a database under INSDC stores around 390 petabytes of raw data, encompassing around 25 billion files and objects.

Database Name	Location	DSIs stored
European Nucleotide Archive (ENA)	United Kingdom	~500 billion raw and assembled sequences consisting of ~50 trillion base pairs
GenBank	United States	9.9 trillion base pairs from over 2.1 billion nucleotide sequences for 478,000 formally described species
DNA Data Bank of Japan (DDBJ)	Japan	2,750,856,069 sequences and 18,755,444,190,605 base pairs of sequence data

Source: International Nucleotide Sequence Database Collaboration (INSDC). Accessed on October 10, 2024 at https://www.insdc.org/about-insdc/
Rasko Leinonen et al., 2011. 'The European Nucleotide Archive (ENA)' in *Nucleic Acids Research.* Accessed at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3013801/
Eric W Sayers et al., 2021. 'GenBank' in *Nucleic Acids Research.* Accessed at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7778897/
Yasuhiro Tanizawa et al., 2023. 'DNA Data Bank of Japan (DDBJ) update report 2022' in *Nucleic Acids Research.* Accessed at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9825463/)

At COP15 in Montreal in December 2022, Parties agreed that a multilateral system for sharing benefits would be put in place. The multilateral mechanism is a departure from the current bilateral mechanism under which governments facilitate the access to genetic resources and benefit sharing between the countries and the users.

Target 13 of the KMGBF aims to increase the sharing of benefits from genetic resources, digital sequence information and traditional knowledge. To meet this target, countries would need to put in place legal, policy, administrative and capacity-building measures. Though a specific numerical value is not part of the Target, countries would need to ensure that by 2030, there is a significant increase of the benefits shared.[2]

The COP15 established the Ad Hoc Open-ended Working Group on Benefit-sharing from the Use of DSI on Genetic Resources to undertake further development of the multilateral mechanism (decision 15/9). Since December 2022, the Ad Hoc Open-ended Working Group on Benefit-sharing from the use of DSI on Genetic Resources has met twice to discuss the global fund and the multilateral mechanism for sharing the benefits. Using these discussions, the Secretariat has prepared a note for the Parties to be discussed at COP16.

The last version of this note was shared on August 22, 2024. Nearly all text is within brackets and negotiators would need to work hard to resolve the issues.[3]

In brief, Parties would deliberate over 29 modalities for operationalization of the multilateral mechanism for the fair and equitable sharing of benefits from the use of digital sequence information on genetic resources, and the global fund. All users would need to contribute to the fund and four options have been proposed for how much needs to be contributed. Other than users, entities like philanthropies can also contribute to the Global Fund. Once this money is in the Global Fund, systems need to be set up for its distribution. Parties would also deliberate over the sectors that would

TIMELINE: DSI IN DIFFERENT FORUMS

2011

The World Health Assembly adopts the Pandemic Influenza Preparedness Framework. This establishes guidelines for the sharing of influenza viruses and Digital Sequence Information to enhance global preparedness for influenza pandemics. The framework includes reference to "genetic sequence data" and benefits-sharing implications.

2013

The issue of DSI emerged in international discussions at the Food and Agriculture Organization's ITGRFA, focusing on enhancing the Multilateral System, which stalls the adoption of a new Standard Material Transfer Agreement.

2016

The 20th Subsidiary Body on Scientific, Technical, and Technological Advice (SBSTTA) meeting of CBD held informal discussions on synthetic biology and the implications of DSI for biodiversity. Later in the year, the topic of DSI was introduced at COP13 in Cancun, Mexico and discussions began on its potential impact on biodiversity and synthetic biology.

2018

During the 22nd SBSTTA, extensive discussions took place on the implications of DSI for the objectives of CBD. The same year, at COP 14 held in Egypt, CBD established the Ad Hoc Technical Expert Group (AHTEG) on DSI to study its implications and make recommendations for benefit-sharing mechanisms. The same month, WHO emphasised DSI's importance for public health, particularly for influenza preparedness.

2020

The AHTEG released a report detailing key issues around DSI and its implications for biodiversity and the Nagoya Protocol. This report provides recommendations on how to integrate DSI into benefit-sharing mechanisms.The COVID-19 pandemic put the spotlight on the role of DSI, with the World Health Organization (WHO) highlighting the critical need for transparent sharing of genetic sequence data to speed up vaccine development and pandemic response. FAO initiated conversations on how DSI could support the International Treaty on Plant Genetic Resources for Food and Agriculture by enhancing the conservation and sustainable use of these vital resources.

2021

In August CBD Secretariat highlighted documents from the AHTEG at a meeting. Discord amongst the developing countries and the developed countries was visible. Developing countries wanted an ABS system to be put in place along with equitable access to DSI. Developed countries preferred open access to DSI, suggesting that monetizing DSI would be a distraction from research and inconsistent with the CBD. The same year, WHO emphasised the criticality of DSI for pandemic preparedness, noting that timely sharing of data can enhance response times during outbreaks.

2022

In September, the FAO Governing Body adopted a resolution on DSI to address its role in food and agriculture. In December, COP 15 adopted Decision 15/9, towards establishing a multilateral mechanism for benefit-sharing from DSI, including a global fund to ensure equitable distribution of benefits. WHO also integrated DSI into the Pandemic Treaty, advocating for equitable access to DSI within global health strategies to ensure inclusive benefits during health crises.

2023

In July, the FAO Commission on Genetic Resources for Food and Agriculture considered DSI's role in food security and agricultural biodiversity. It informed that nearly 1.3 million scientific publications cited DSI, showcasing its significance in advancing agricultural science. In November, the first meeting of the Ad Hoc Open-ended Working Group on DSI of CBD discussed key themes, sparking intense debates on monitoring, funding, data governance, and IPLC rights.

2024

In May, the 26th SBSTTA meeting discussed the implications of DSI for the Nagoya Protocol and how DSI governance intersects with benefit-sharing obligations. The same month, the WIPO adopted the Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge, which mandates patent applications to disclose the source of any genetic resources or traditional knowledge used in their inventions. The second meeting of the Ad Hoc Open-ended Working Group of CBD happened. In October, COP 16 is expected to finalize decisions on the operationalization of the multilateral fund.

Source: • Convention on Biological Diversity https://www.cbd.int/ • Food and Agriculture Organization https://www.fao.org/home/en • World Health Organization https://www.who.int/ • World Intellectual Property Organization https://www.wipo.int/portal/en/index.html • International Institute for Sustainable Development https://www.iisd.org/

use DSI and could contribute to this fund. The group will also discuss the formula for allocation along with allocation methodology.

These funds can be used broadly for conservation and sustainable use of biodiversity while also helping the overall development of communities. The Parties while finalizing the multilateral mechanism would also need to ensure that it is mutually supportive of other access and benefit sharing mechanisms in place (see *Timeline: DSI in different forums*).

The Ad Hoc group has recommended that a database for digital sequence information on genetic resources should be set up under the clearing-house mechanism. Developing countries that lack capacity to generate and manage their genetic data would be supported. It would be mandatory to indicate the source of the digital sequence information submitted to this database or any other database. The sequence would be accepted only after proof is submitted that this has been obtained through due process of prior informed consent and on mutually agreed terms. Users would need to contribute money to the global fund and they would also need to provide non-monetary benefits to the communities who are the custodians of biodiversity. This would be over and above monetary benefits.

There are ongoing discussions about whether the existing structures, such as the Global Environment Facility, are suitable for the funding needs of implementing these plans as there are concerns about the organization's bias towards developed countries.

Progress on these processes would be reported at the 18th COP of CBD. This COP would also provide the opportunity for course correction.

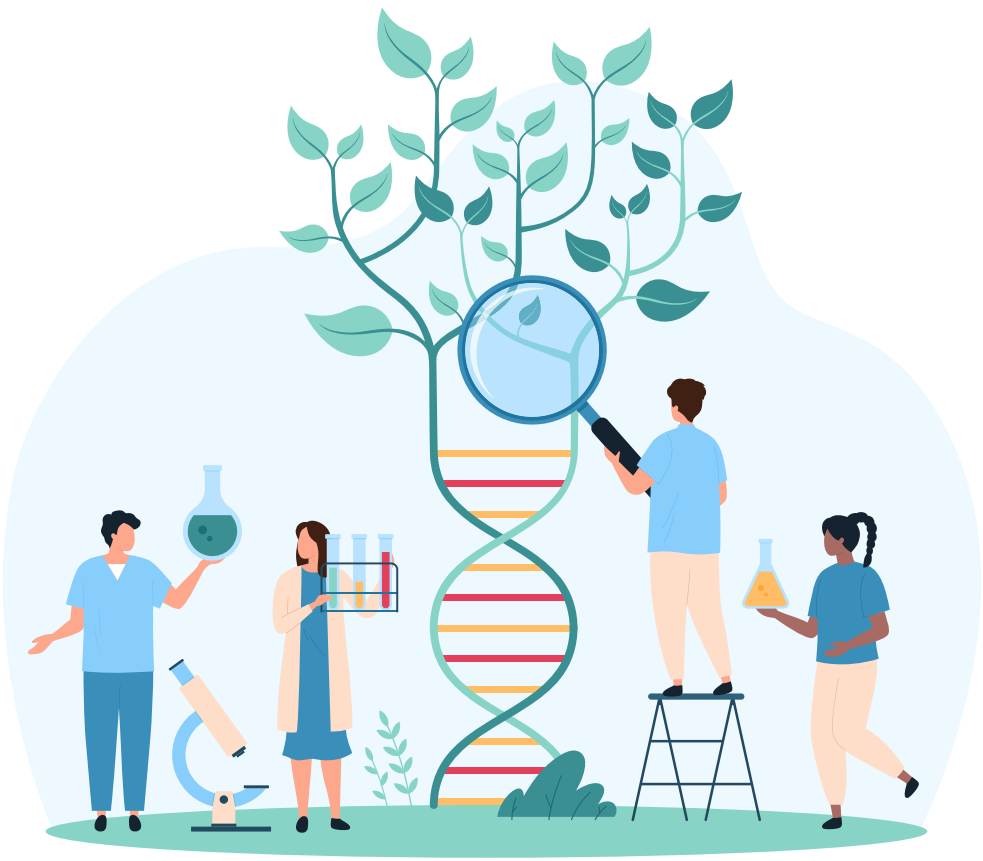
DSI in different forums

The decisions taken at COP16 on DSI would inform the discussions on the issue in other forums. The Food and Agriculture Organization of the United Nations (FAO) has been

trying to understand the potential implications of the use of DSI under the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). Similarly, DSI is part of World Health Organization's (WHO) and Pandemic Treaty; United Nations Convention on the Law of the Sea's (UNCLOS) Biodiversity Beyond National Jurisdiction agreement (BBNJ); and World Intellectual Property Organization's (WIPO) Treaty on Intellectual Property, Genetic Resources and Traditional Knowledge. The decision at COP16 will inform all these crucial discussions (see *Timeline: DSI in different forums*).

What is the way ahead?

COP16 will finalise the mechanism for the fair and equitable sharing of benefits derived from use of DSI. Negotiators will set down a system for operationalization of the mechanism and prepare a clear framework to ensure equitable benefit sharing.



Delegates will address how both monetary and non-monetary benefits are to be divided among users and local communities, while ensuring inclusivity and representation.

At COP16, Parties are expected to refine and finalize a set of draft recommendations addressing questions such as how financial contributions from users of DSI should be calculated and how they should be distributed equitably with IPLCs. Parties are also expected to reach a consensus on how national circumstances should influence these allocation decisions to ensure fairness and equity in benefit-sharing agreements.

This is not going to be easy as discussions of the Ad Hoc Open-ended Working Group on Benefit-sharing revealed. The group, formed during COP15, held two important meetings; one in November 2023 and another in August 2024 to discuss various issues pertaining to DSI.[4,5]

These meetings revealed the clear differences in views between developed and developing countries regarding contributions to the fund, how to allocate funds, data governance, and the rights of Indigenous Peoples and Local Communities (IPLCs).

On the issue of contribution to funds, developing countries, especially India, Brazil, Colombia, and Argentina, want a clear system to track benefit-sharing, as outlined in the CBD Decision 15/9 to ensure fairness in distributing benefits and promoting a holistic implementation of the proposed framework. In contrast, developed countries such as the US argue against mandatory contributions, opting instead for an incentive-based system that encourages voluntary donations. This difference illustrated the overall disagreement between developed and developing. The African Group wants a legally binding one per cent retail levy on DSI-derived products to create a strong funding mechanism. This proposal too faces resistance from developed countries like the USA. It should be noted here that USA is not a Party to the CBD but uses DSIs extensively.

On the issue of fund allocations, developed nations like Canada, Japan, and the UK support that the funds be directed specifically to IPLCs and developing countries as this approach

would empower local communities, ensuring they benefit directly from the mechanism. Brazil wants the inclusion of social justice principles to ensure that poorer nations have fair opportunities. Fiji's proposal for project-based funding to meet local needs found supported by developing nations.

On the issue of access to data, Switzerland, Canada, and the Republic of Korea opine that open access to genetic data is best for data governance. The EU says that all references to data governance should be completely removed from the proposed mechanism, asserting that it shouldn't function merely as a data repository. Switzerland wants open-access databases to emphasize transparency. USA too has raised concerns about strict data access regulations, stating that unnecessary restrictions could significantly hamper scientific research and innovation. On the other end of the spectrum, the African Group has proposed a centralized database to ensure fair benefit-sharing. This directly conflicts with the preferences of several developed nations. This would need to be resolved at COP16.

On a positive note, there is agreement on the need to recognize the rights of IPLCs throughout the negotiations. For example, countries like Uganda and members of the EU, together with Norway and Belarus have emphasized the importance of strongly committing to protecting IPLC rights. They have stressed on the fact that any agreement should include rights related to genetic resources. The importance of Free, Prior, and Informed Consent (FPIC) was prominent and the International Indigenous Forum on Biodiversity specifically asserts that no genetic resources should be taken from Indigenous territories without FPIC. The US recognized these rights but preferred more flexible frameworks that would allow access to genetic resources without strict consent requirements, fearing that rigorous regulations could slow progress.

As negotiators prepare for COP16, hopes remain high. The insights gained since COP15 will play an important role in shaping a fair governance framework for DSI.

REFERENCES

1. Inf'OGM, 2021. 'Biopiracy on Digitalized Sequences: Two Examples'. Accessed on October 10, 2024 at https://infogm.org/en/article_journal/biopiracy-on-digitalized-sequences-two-examples/
2. CBD, 2022. 'Target 13: Increase the sharing of benefits from genetic resources, Digital Sequence Information and traditional knowledge'. Accessed on October 10, 2024 at https://www.cbd.int/gbf/targets/13
3. CBD, 2024. 'Compilation of draft decisions for the sixteenth meeting of the Conference of the Parties to the Convention on Biological Diversity.' Accessed at https://www.cbd.int/doc/c/aa76/53dd/5d044b00d5223ee0b646f385/cop-16-02-rev1-en.pdf
4. Earth Negotiations Bulletin, 2023. 'Twelfth meeting of the Open-ended Working Group on Article 8(j) and related provisions and discussions on Digital Sequence Information (DSI) on Genetic Resources.' Accessed on October 10, 2024 at https://enb.iisd.org/article8j-oewg-12-digital-sequence-information-genetic-resources-dsi-cbd
5. Earth Negotiations Bulletin, 2024. 'Second meeting of the Open-ended Working Group on Digital Sequence Information (DSI) on Genetic Resources.' Accessed on October 10, 2024 at https://enb.iisd.org/oewg-2-digital-sequence-information-genetic-resources-dsi-cbd

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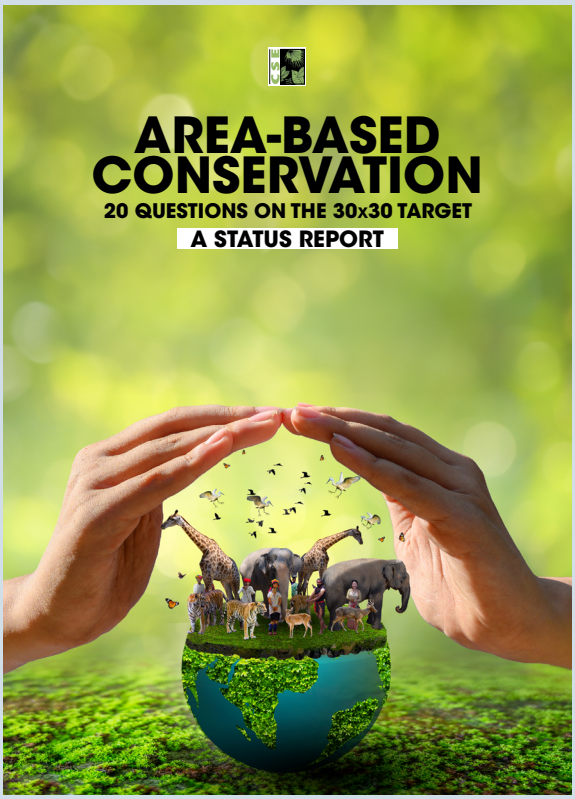

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