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Ministry of Environment, Forest and Climate Change
Government of India

राष्ट्रीय जैव विविधता प्राधिकरण
National Biodiversity Authority, India
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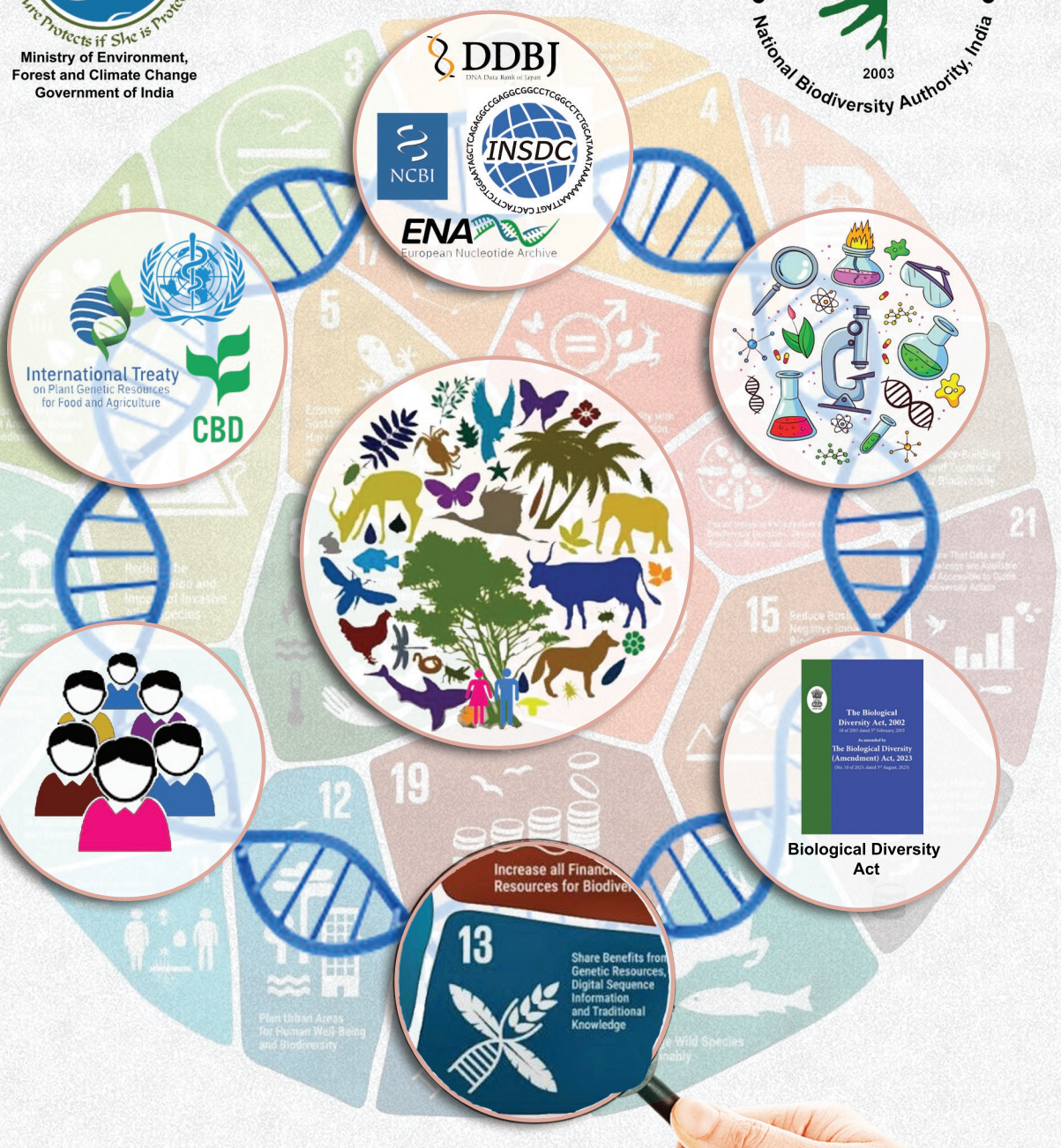

Looking at Digital Sequence Information with an Indian Lens

National Biodiversity Authority

Looking at Digital Sequence Information with an Indian Lens

National Biodiversity Authority

Published by NBA, India

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SECRETARY
GOVERNMENT OF INDIA
MINISTRY OF ENVIRONMENT, FOREST
AND CLIMATE CHANGE

MESSAGE

The publication on Digital Sequence Information (DSI), a subject of immense significance for biodiversity governance in the 21st century. The book offers a comprehensive overview of the journey of DSI: from its emergence as a transformative scientific tool to its current role as a foundational element in fields such as biotechnology, pharmaceuticals, agriculture, and synthetic biology. Importantly, it also engages with the crucial global discourse surrounding issues of access, equity, and benefit-sharing.

The publication is particularly timely as international deliberations under the Convention on Biological Diversity (CBD) and other multilateral fora continue to address the complexities surrounding DSI. It is noteworthy that India has consistently played a proactive role in these negotiations, safeguarding national priorities, upholding the principle of sovereignty over genetic resources, and advocating for a fair and equitable multilateral mechanism for benefit-sharing.

This book will be a valuable resource for policymakers, researchers, industry stakeholders, and civil society, offering both historical context and forward-looking perspectives on the way ahead. I commend the authors for their comprehensive treatment of this important subject, which will undoubtedly contribute to informed decision-making and constructive engagement in national and international platforms.

30/4

(Tanmay Kumar)

Place: New Delhi
Dated: April 30, 2026

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Dr. Rajesh Kumar

वीरेन्द्र तिवारी, भा.व.से. (सेवानिवृत्त)
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Chairperson

राष्ट्रीय जैव विविधता प्राधिकरण
भारत सरकार

National Biodiversity Authority
Government of India

Preface

In recent years, DSI has emerged as a cornerstone of scientific progress in genomics, biotechnology, agriculture, and conservation. DSI enables researchers and industries to study, modify, and engineer biological systems using sequence data often stored and shared in open-access databases. However, this technological leap presents deep challenges for international biodiversity governance.

The Convention on Biological Diversity (CBD), built on the principles of national sovereignty over genetic resources and fair and equitable benefit-sharing, finds itself at a crossroads. While physical access to genetic material traditionally triggered benefit-sharing obligations, the widespread use of DSI—frequently accessed without the involvement of the country of origin—has created a regulatory gap.

India has taken a principled and proactive stand in this debate. As a megadiverse country with rich traditional knowledge and genetic resources, India has repeatedly stressed the need to ensure that the use of DSI does not circumvent the core objectives of the CBD and the Nagoya Protocol. As noted in India's submission to the CBD in 2020:

"Continuing with the current unregulated access and utilization of DSI is detrimental to the basic tenets of the CBD. We must ensure that benefit-sharing provisions are extended to cover DSI comprehensively."

This book traces the evolution of DSI within global policy discussions, documents India's positions in international negotiations, and highlights the complex interplay between science, sovereignty, and equity. By doing so, it serves as a valuable resource for negotiators, academics, policymakers, and civil society engaged in shaping the future of global biodiversity governance worldwide.

Dated: 4th May, 2026

(Virendra Tiwari)

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Dr. Rajesh Kumar

Acknowledgement

The publication of "Looking at Digital Sequence Information with an Indian Lens" has been made possible through the collective efforts and support of many individuals and institutions who contributed to its development.

I express my sincere gratitude to the Ministry of Environment, Forest and Climate Change, Government of India, for its continued guidance and encouragement to the National Biodiversity Authority in advancing policy discourse and capacity building on Digital Sequence Information (DSI).

My special thanks are due to Shri Tanmay Kumar, IAS, Secretary to Govt. of India, MoEFCC as he attended various international DSI meetings and immensely articulated India's positions which were reflected in the CoP 16/2 decisions. His guidance, timely advice and valuable insights shaped the content of this publication to a great extent.

I would also like to place on record my appreciation for Shri Ashutosh Agnihotri, IAS, Additional Secretary for his guidance.

I place on record my deep appreciation to Shri Virendra R Tiwari, Chairman, National Biodiversity Authority, for his leadership and guidance in steering this publication. His encouragement and strategic direction were instrumental in bringing this volume to fruition.

I also place on record, sincere thanks to Shri Raghu Kumar Kodali, Scientist G, and Dr. Achuta Nand Shukla, Scientist E, MoEFCC, and Shri Sameer Dubey, Senior Young Professional, MoEFCC for their valuable contributions and support which have enriched this publication.

I also acknowledge with gratitude Shri C. Achalender Reddy, IFS (Retd.), Former Chairman, National Biodiversity Authority, for his vision and intellectual inputs that helped shape the conceptual direction of this work. He nudged the NBA to prepare such a write-up for the benefit of the country.

I extend my thanks to the members of the Expert Committees on DSI, subject experts, and stakeholders from academia, research institutions, and industry who shared valuable insights during consultations and discussions that informed this publication.

I would like to particularly appreciate Dr. Srirama Ramanujam for her dedicated efforts in drafting and compiling this book. Her commitment, scholarly engagement, and meticulous approach have been central to the development of the structure and content of this volume.

I also appreciate the contributions of the officers and staff of the National Biodiversity Authority, whose teamwork and support facilitated the review, coordination, and production of this publication. The cooperation extended by collaborating institutions and stakeholders is gratefully acknowledged.

It is hoped that this volume will serve as a useful reference for policymakers, researchers, and practitioners, and contribute to informed dialogue on biodiversity governance and the fair and equitable sharing of benefits arising from the use of Digital Sequence Information.

(Dr. B. Balaji, IFS)
Member Secretary, NBA


Dr. Rajesh Kumar.

Contents

Abbreviations

ABS	Access and Benefit Sharing
AHOEWG	Ad Hoc Open - Ended Working Group
AHTEG	Ad Hoc Technical Expert Group
AI	Artificial Intelligence
AT	Antarctic Treaty
BBNJ	Biodiversity Beyond National Jurisdiction
BCIL	Biotech Consortium India Limited
BD Act	Biological Diversity Act
BMC	Biodiversity Management Committees
CBD	Convention on Biological Diversity
CNA	Competent National Authority
COP	Conference of Parties
COVID-19	Corona Virus Disease - 2019
CRISPR	Clustered Regularly Interspaced Short Palindromic Repeats
DDBJ	DNA Data Bank of Japan
DNA	Deoxyribonucleic Acid
DSI	Digital Sequence Information
EC	Expert Committee
EMBL-EBI	European Molecular Biology Laboratory's database
ENA	European Nucleotide Archive
FAO	Food and Agriculture Organisation
GBFF	Global Biodiversity Framework Fund
GCF	Green Climate Fund
GEF	Global Environment Facility
GISRS	Global Influenza Surveillance and Response System
GMBSM	Global Multilateral Benefit Sharing Mechanism
GSD	Genetic Sequence Data
IAG	Informal Advisory Group
IGC	Intergovernmental Committee

INSDC	International Nucleotide Sequence Database Collaboration
IP	Intellectual Property
IPLC	Indigenous Peoples and Local Communities
ITPGRFA	International Treaty for Plant Genetic Resources for Food and Agriculture
KMGBF	Kunming Montreal Global Biodiversity Framework
MAT	Mutually Agreed Terms
MGRs	Marine Genetic Resources
MLM	Multilateral Mechanism
MLS	Multilateral System
MoEFCC	Ministry of Environment, Forests & Climate Change
MSMED Act 2006	Micro, Small and Medium Enterprises Development Act 2006
NP	Nagoya Protocol
NBA	National Biodiversity Authority
NCBI GenBank	National Center for Biotechnology Information's database
NGS	Next Generation Sequencing
PIC	Prior Informed Consent
R&D	Research & Development
RNA	Ribonucleic Acid
SBB	State Biodiversity Board
SBI	Subsidiary Body on Implementation
SBSTTA	Subsidiary Body of Scientific, Technical and Technological Advice
SIDS	Small Island Developing States
SMTA	Standard Material Transfer Agreement
SRA	Sequence Read Archive
ToR	Terms of Reference
UN	United Nations
UNCLOS	United Nations Convention on the Law of the Sea
USA	United States of America
WHO - PIP	World Health Organization - Pandemic Influenza Preparedness Framework
WIPO	World Intellectual Property Organization

Chapter - I

Introduction

The concept of Digital Sequence Information (DSI) emerged as technology advanced to allow the storage and sharing of biological sequence data in digital form[1]. DSI is a placeholder term used for digital data derived from genetic material such as DNA or RNA sequences and potentially other linked data like amino acid sequences and molecular structures.

In the early days of molecular biology, during the 1970s, sequencing was a manual, labor-intensive process. Key developments like Frederick Sanger's sequencing method allowed the first full genomes, such as that of the bacteriophage φX174, to be decoded, although early sequences were published in scientific articles rather than digital formats.

A revolution in terms of data generation has taken place since 1980s as sequencing technology improved in terms of efficiency and cost and data volumes grew. This led to the creation of major biological databases such as the National Center for Biotechnology Information's database (NCBI GenBank) in the United States (1982), the European Molecular Biology Laboratory's database (EMBL-EBI), and the DNA Data Bank of Japan (DDBJ). These institutions collaborated to ensure biological sequence data could be freely shared across borders. The "International Nucleotide Sequence Database Collaboration (INSDC)" is a long-standing partnership between three major biological data repositories: GenBank in the United States, the European Nucleotide Archive (ENA) at the European Bioinformatics Institute in Europe,

1 Laird, S. A., & Wynberg, R. (2018). A fact-finding and scoping study on digital sequence information on genetic resources in the context of the Convention on Biological Diversity and the Nagoya Protocol (CBD Technical Series No. 89). Secretariat of the Convention on Biological Diversity. https://www.cbd.int/doc/publications/cbd-ts-89-en.pdf

and the DNA Data Bank of Japan (DDBJ)[2] . Formed in the 1980s, the INSDC was created to ensure the free and global exchange of nucleotide sequence data. Each of these organizations independently collects and curates sequence information submitted by scientists worldwide, but through their collaboration, they synchronize and share data on a daily basis. This ensures that any nucleotide sequence submitted to one database is available in all three, promoting broad, consistent access for researchers everywhere (Figure 1). The INSDC follows a set of shared standards for data formatting, annotation, and quality control, which helps maintain the integrity and usability of the vast amounts of genetic information being generated. By promoting open access to nucleotide sequences, the INSDC has played a foundational role in advancing fields like genomics, bioinformatics, biotechnology, and medicine.

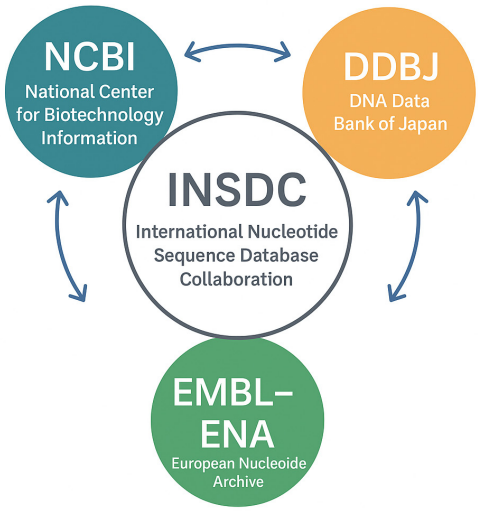


Figure 1: International Nucleotide Sequence Database Collaboration (INSDC)

The completion of the Human Genome Project in 2003 was a landmark moment that reinforced the principle that genomic information should be openly accessible to all researchers[3]. Around the same time, Next-Generation Sequencing (NGS) technologies began to emerge, exponentially increasing the amount of sequence data being generated and stored in new repositories such as the Sequence Read Archive (SRA) and the European Nucleotide Archive (ENA)[4,5].

2 Karsch-Mizrachi, I., Takagi, T., & Cochrane, G. (2012). The International Nucleotide Sequence Database Collaboration. Nucleic Acids Research, 40(Database issue), D33–D37. https://doi.org/10.1093/nar/gkr1006

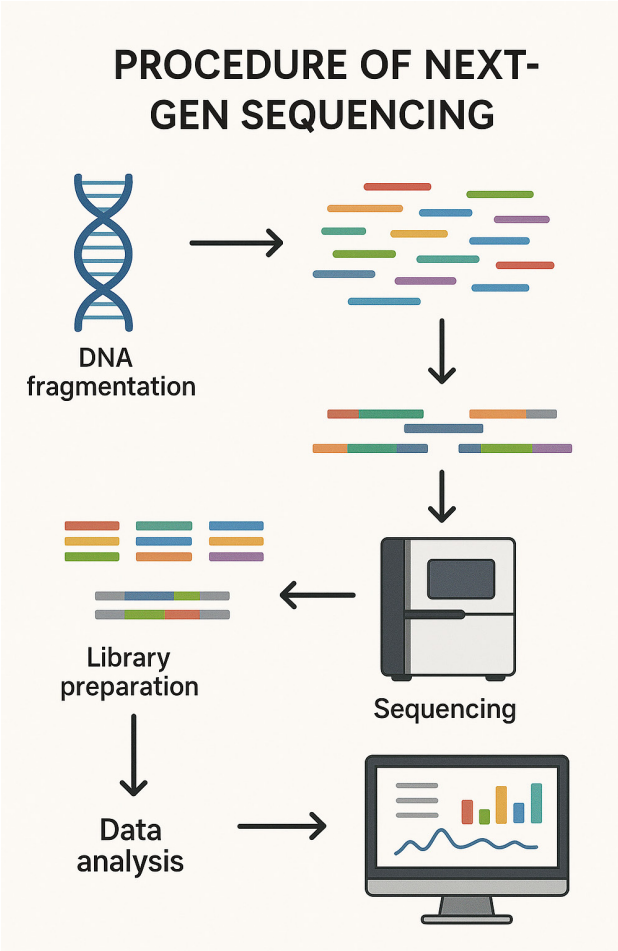
3 International Human Genome Sequencing Consortium. (2004). Finishing the euchromatic sequence of the human genome. Nature, 431(7011), 931–945. https://doi.org/10.1038/nature03001

4 Leinonen, R., Sugawara, H., & Shumway, M.; International Nucleotide Sequence Database Collaboration. (2011). The Sequence Read Archive. Nucleic Acids Research, 39(Database issue), D19–D21. https://doi.org/10.1093/nar/gkq1019

5 Mardis, E. R. (2008). Next-generation DNA sequencing methods. Annual Review of Genomics and Human Genetics, 9, 387–402. https://doi.org/10.1146/annurev.genom.9.081307.164359

These technologies drastically lowered the cost and time needed to sequence entire genomes, allowing researchers to generate massive amounts of genetic data. High-throughput sequencing also opened the door to sequencing entire ecosystems, a field known as metagenomics, which added even more complexity and richness to the DSI landscape. In addition to DNA and RNA sequences, multi-omics fields—such as proteomics, transcriptomics, epigenomics, and metabolomics—began contributing vast datasets that are often stored and analyzed alongside traditional sequence information.

Alongside technological innovation, there was significant growth in the infrastructure needed to store and share DSI. Public repositories such as GenBank, the European Nucleotide Archive (ENA), and the DNA Data Bank of Japan (DDBJ) expanded exponentially to accommodate the surge in data. The rise of cloud computing platforms, such as Google Cloud's genomics services and Amazon Web Services' open data programs, further accelerated accessibility, enabling researchers worldwide to store, share, and analyze DSI on a massive scale. International research projects like the Human Microbiome Project and the Earth Bio Genome Project also contributed billions of new sequences, highlighting a global shift toward collaborative data generation. Even non-specialists, through citizen science initiatives, began to participate in sequencing and contributing to DSI repositories. The growth in the submission of sequences to the NCBI database is given in Figure 2.



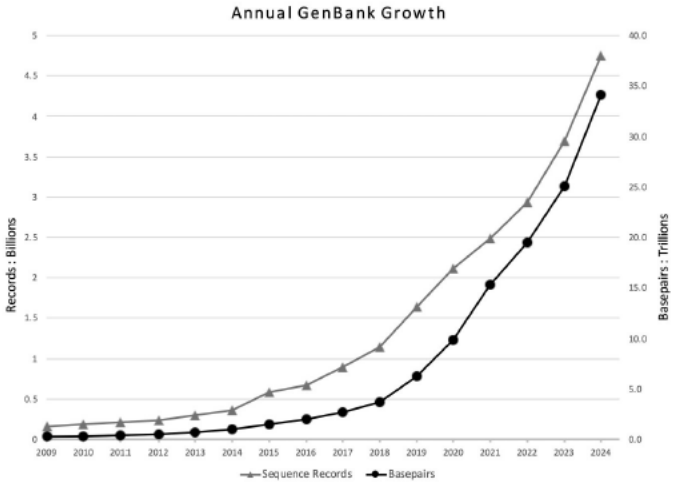


Figure 2: Growth of GenBank recorded in both base pairs (circles) and the number of sequence records (triangles). Each point represents the GenBank release in August of each year, starting with release from 2009 till 2024.(reproduced from Sayers et al 2025)[6]

As shown in the Figure 2, there is an exponential growth of sequences being submitted to the INSDC. In this regard, a study has been conducted by Scholz *et al* 2021[7] to analyze the quantum of DSI provided by the various user countries to the INSDC in comparison with the use of the DSI by the user countries (Figure 3). Scholz *et al* 2021 reported that the largest providers of DSI are the United States, China, Canada, and Japan, providing about half of the global dataset followed by countries such as India and Brazil. Further, it is also observed that the developed countries such as the United States, Germany and United Kingdom are the highest users of DSI from the INSDC.

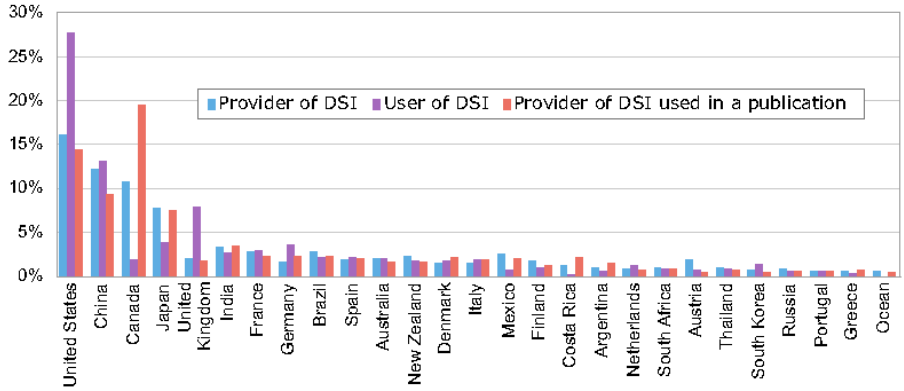


Figure 3. Bar graph comparison of each country's provision of DSI (i.e., where it is the country of origin) for DSI relative to its proportion of users (authors in scientific publications that reference DSI) and the proportion of its DSI cited. (reproduced from Scholz *et al* 2021)

6 Sayers, E. W., Cavanaugh, M., Frisse, L., Pruitt, K. D., Schneider, V. A., Underwood, B. A., Yankie, L., & Karsch-Mizrachi, I. (2025). GenBank 2025. Nucleic Acids Research, 53(D1), D56–D61. https://doi.org/10.1093/nar/gkae1114

7 Scholz, A. H., Lange, M., Habekost, P., Oldham, P., Cancio, I., Cochrane, G., & Freitag, J. (2021). Myth-busting the provider-user relationship for digital sequence information. GigaScience, 10(12), giab085. https://doi.org/10.1093/gigascience/giab085

The unregulated and commercial use of biological information has emerged as a central contentious issue and has been deliberated in multiple international fora such as the CBD, the International Treaty for Plant Genetic Resources for Food and Agriculture (ITPGRFA) the Pandemic Influenza Preparedness (PIP) framework, the Antarctic Treaty (AT) and the Biodiversity Beyond National Jurisdiction (BBNJ) negotiations under the auspices of the United Nation Convention on the Law of the Sea[8,9,10,11] .

Here, the issues raised in the Convention on Biological Diversity over the years from the period of the 13th Conference of Parties till the decision adopted at the 16th Conference of Parties (Decision 16/2) on operationalizes a multilateral mechanism for benefit-sharing from the use of Digital Sequence Information (DSI) on genetic resources aiming to ensure the fair and equitable sharing of benefits arising from the commercial utilization of DSI has been discussed comprehensively. The detailed deliberations that took place at the CBD and the chronological events of discussions and meetings are given in Table 1.

Table 1 The journey of DSI in CBD

Year	Event	Date & Location	Key Details
Pre-2016	CBD & Nagoya Protocol context	—	DSI not explicitly addressed; Nagoya Protocol (2010) focuses on genetic resources and benefit-sharing.
2016	COP 13	4–17 Dec 2016, Cancún, Mexico	DSI formally recognized as a relevant issue; Decision XIII/16 calls for further discussion and information gathering.
2017	AHTEG on DSI	15–19 May 2017, Montreal, Canada	Assessed implications of DSI for ABS; initiated groundwork on technical, legal, and policy aspects.

8 Laird, S. A., & Wynberg, R. (2018). A fact-finding and scoping study on digital sequence information on genetic resources in the context of the Convention on Biological Diversity and the Nagoya Protocol (CBD Technical Series No. 89). Secretariat of the Convention on Biological Diversity. https://www.cbd.int/doc/publications/cbd-ts-89-en.pdf

9 Halewood, M., Noriega, I. L., & Louafi, S. (2018). Digital sequence information on plant genetic resources for food and agriculture: Opportunities and challenges. FAO Commission on Genetic Resources for Food and Agriculture Background Study Paper No. 89. http://www.fao.org/3/ca1335en/CA1335EN.pdf

10 World Health Organization (WHO). (2016). PIP Framework: Public health, innovation and intellectual property. Geneva: WHO. https://apps.who.int/iris/handle/10665/246710

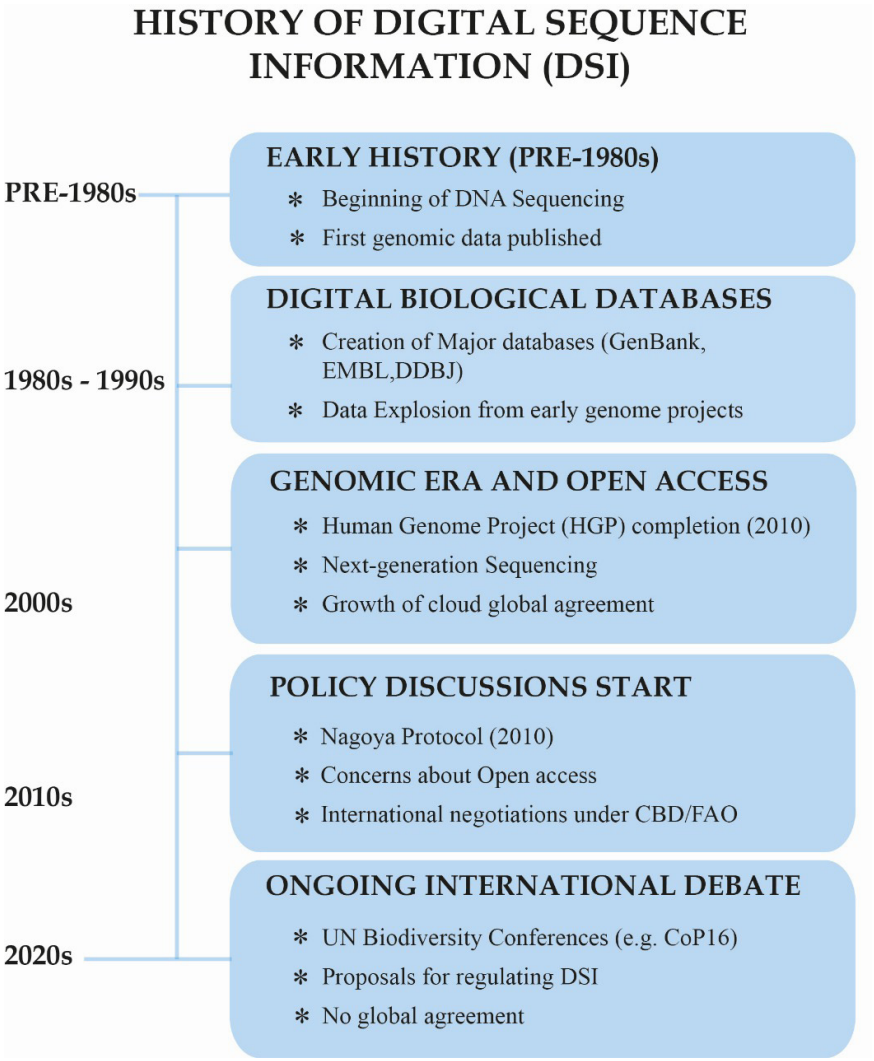
11 Blasiak, R., Jouffray, J. B., Wabnitz, C. C. C., Sundström, E., & Österblom, H. (2018). Corporate control and global governance of marine genetic resources. Science Advances, 4(6), eaar5237. https://doi.org/10.1126/sciadv.aar5237

Year	Event	Date & Location	Key Details
2018	COP 14	17–29 Nov 2018, Sharm El-Sheikh, Egypt	Decision XIV/20 mandates more studies, dialogues, and capacity-building on DSI and ABS linkages.
2021	AHTEG on DSI (Virtual)	17–19 March 2021, (Virtual)	Focused on scope, concepts, and policy options for DSI benefit-sharing.
2020–2022	Virtual consultations (COVID period)	Throughout 2020–2022	Informal virtual discussions, regional consultations, and written submissions keep momentum amid pandemic disruptions.
2022	COP 15	7–19 Dec 2022, Montreal, Canada	Adoption of Kunming-Montreal Global Biodiversity Framework; Decision 15/9 mandates creation of a multilateral benefit-sharing mechanism and global fund for DSI.
2023	AHTEG on DSI	14-18 November 2023, Geneva, Switzerland	Provided recommendations on modalities and institutional arrangements for the DSI mechanism and fund.
2024	IAG on DSI	19 May 2024, Nairobi, Kenya	Provided additional recommendations on modalities and institutional arrangements for the DSI mechanism and fund.
2024	AHTEG on DSI	12-16 August 2024, Montreal, Canada	Developed recommendations on operationalizing the multilateral benefit-sharing mechanism, including models for benefit-sharing and governance.
2024	COP 16	21 Oct – 1 Nov 2024, Cali, Colombia	Adoption of decision 16/2 - DSI on genetic resources
2025	COP 16 Resumed Session	25–27 Feb 2025, Rome, Italy	Final agreement on 'Cali Fund' for DSI benefit-sharing and roadmap to mobilize US$200B annually by 2030 for biodiversity conservation.

Further, the Chapter II provides the glimpses of the importance of DSI in various sectors including biotechnology, pharmaceutical etc, in development of products and commercialization. The Chapter III explains the journey of deliberations on DSI in the CBD in the context of the benefit sharing arrangements starting from the CoP-13 till date which also includes the deliberations that took place in the Ad Hoc Open-Ended Working Group (AHOEWG) and Ad Hoc Technical Expert Group (AHTEG) meetings. The following Chapter IV elaborates on the position taken by India in the CBD meetings and its reflections in the CBD decisions. India played a major role in these negotiations and also made sure that the national

priorities and sovereignty over the DSI on genetic resources is ascertained. Chapter V provides the detailed submissions of India's views on the additional modalities that are needed to implement the multilateral mechanism. Chapter VI highlights in brief, the status of benefit-sharing using DSI in other international fora such as ITPGRFA, WHO-PIP and BBNJ. Further, Chapter VII presents the way forward for operationalizing the multilateral mechanism for the fair and equitable sharing of benefits from the use of DSI on genetic resources, including a global fund based on the India's negotiations. Lastly, Chapter VIII concludes that there is a long way to go for the effective implementation of the multilateral mechanism.

Box - 1



Chapter - II

Importance of DSI: A Global and Indian Perspective

DSI has become an indispensable component of modern life sciences, biotechnology, agriculture, and medicine, and its importance is rapidly growing with advances in genomics and synthetic biology.

Globally, DSI underpins innovation in numerous sectors:

a) **Public Health and Drug Development:** During health emergencies like the COVID-19 pandemic, rapid sharing of pathogen genome sequences enabled real-time surveillance, diagnostics, vaccine development (e.g., mRNA vaccines), and drug discovery. For example:

Ebola Virus: DSI and Outbreak Response

The 2014–2016 Ebola virus outbreak in West Africa marked a watershed moment in how DSI could be mobilized globally to respond to pandemics. Within days of the outbreak being confirmed, researchers from Guinea, Liberia, and Sierra Leone, in collaboration with international partners, sequenced the Ebola virus genome. These sequences were uploaded to public databases like GenBank, enabling the global scientific community to analyze the virus's genetic evolution, transmission patterns, and potential vaccine targets in near real-time.

One of the most notable outcomes was the accelerated development of the rVSV-ZEBOV Ebola vaccine, which relied heavily on DSI for designing a recombinant vesicular stomatitis virus expressing a glycoprotein from the Zaire Ebola virus. This vaccine, initially developed by Canadian and U.S. researchers, was fast-tracked through clinical trials and later received WHO prequalification.

India's role in the Ebola response and vaccine development underscores its growing capacity in genomic science, manufacturing, and global health diplomacy. India's National Institute of Virology (NIV), Pune, under the Indian Council of Medical Research (ICMR), actively analyzed Ebola virus sequences to enhance domestic surveillance and preparedness. Moreover, India's vaccine manufacturer, Bharat Biotech, developed an investigational inactivated Ebola vaccine candidate based on DSI available through public databases. Although not ultimately deployed in the field, this effort showcased India's potential to contribute to global vaccine research using publicly available digital genetic resources.

In addition, India played a humanitarian role by supplying medical aid and protective equipment to African countries during the outbreak and supporting WHO-coordinated responses. This case demonstrates how open access to DSI not only

accelerates global R&D but also empowers countries like India to independently engage in countermeasure development, surveillance, and technology transfer—cementing their role in global health security and bio-diplomacy.

b) **Agricultural Innovation:** DSI aids in the breeding of climate-resilient crops, disease-resistant varieties, and genetically improved livestock, supporting global food security. For example:

India's Rice Genomics Initiative

India's contribution to rice genomics has been significant, with sequencing efforts on diverse indigenous varieties. Through projects like the Indian Rice Genome Project, DSI has been used to identify stress-resilient and high-yielding traits. These efforts have contributed to breeding programs aimed at food security and climate resilience, demonstrating India's leadership in applying DSI for public agricultural benefit.

c) **Environmental Conservation and Bio-monitoring:** DNA barcoding and metagenomic analysis using DSI enable identification and monitoring of species and ecosystems, crucial for biodiversity conservation and ecological restoration. One of the most transformative tools enabled by DSI is environmental DNA (eDNA) monitoring, where genetic material left by organisms in soil, water, or air is collected and analyzed to identify species presence and abundance without direct observation or capture.

Globally, DSI-based monitoring has been instrumental in detecting invasive species, tracking endangered populations, and understanding ecosystem health. For example, in the Great Lakes of North America, researchers have used eDNA and DSI to detect the presence of invasive Asian carp before their physical capture, enabling timely mitigation strategies. Similarly, the Barcode of Life Data Systems (BOLD) and international barcoding initiatives have created massive reference libraries of DSI linked to taxonomically validated species, facilitating rapid assessments of ecological changes and species richness in habitats like coral reefs, rainforests, and wetlands.

In the Indian context, the application of DSI in bio-monitoring is gaining momentum. The Zoological Survey of India (ZSI) and the Botanical Survey of India (BSI) have undertaken DNA barcoding of thousands of plant and animal species. These sequences, deposited in public databases, are now being used to monitor biodiversity in protected areas and biodiversity hotspots such as the Western Ghats, Eastern Himalayas, and the Sundarbans. In a recent initiative, researchers used eDNA and metagenomics to assess aquatic biodiversity in the Ganga River basin, revealing microbial and fish species diversity and pollution indicators. This

data provides crucial insights for conservation policy, habitat restoration, and river rejuvenation efforts under programs like Namami Gange.

Furthermore, the Long-Term Ecological Observatories (LTEO) Network, supported by India's Ministry of Environment, Forest and Climate Change (MoEFCC), is integrating genomics and DSI-based approaches to monitor climate-induced biodiversity changes across major Indian ecosystems.

This case demonstrates that DSI, when coupled with field ecology and policy frameworks, can provide robust, scalable, and cost-effective tools for conservation planning, species protection, and environmental governance.

d) **Biotechnology and Synthetic Biology:** Industries use DSI to develop enzymes, biofuels, and novel biomaterials. For example, enzymes derived from extremophiles (via DSI) are used in detergents and industrial processes.Through access to digital genetic data stored in global repositories, researchers can identify functional genes, pathways, and regulatory elements, which are then used to engineer microbes, plants, and synthetic systems for a wide range of applications—from medicine to sustainable manufacturing.

A prominent global example is the development of artificial enzymes and biosynthetic pathways for industrial applications. For instance, companies like Novozymes and Ginkgo Bioworks leverage DSI to mine microbial genomes for novel enzymes that can be used in detergents, food processing, textiles, and biofuels. Using high-throughput bioinformatics tools, researchers analyze thousands of genetic sequences to identify and optimize candidates with desired properties, such as heat resistance or substrate specificity. These enzymes are then synthesized and expressed in host organisms like *E. coli* or yeast using synthetic biology platforms, all powered by DSI.

In India, DSI-driven synthetic biology is gaining ground, supported by institutions like the Institute of Genomics and Integrative Biology (IGIB), National Institute for Plant Genome Research (NIPGR), and startups under the Department of Biotechnology's Bioeconomy Mission. Indian researchers have used DSI to engineer microbes for bioremediation, where genetically modified strains degrade pollutants such as plastics and industrial effluents. A recent example is the identification of genes responsible for plastic-degrading enzymes from marine bacteria through open DSI databases, followed by synthetic expression and characterization in Indian labs.

Another emerging field is DSI-based vaccine platforms and diagnostics, where synthetic gene sequences are used to design antigens or CRISPR-based diagnostic tools. For example, during the COVID-19 pandemic, Indian companies like Genova

Biopharmaceuticals developed mRNA vaccine candidates using SARS-CoV-2 sequence data from global databases. Similarly, CRISPR-based diagnostic kits developed by Indian startups (like Tata MD Check) relied on viral genomic DSI for target design.

e) **Artificial Intelligence (AI) and Life Sciences:** Integration of DSI with AI has accelerated predictive biology, personalized medicine, and computational drug discovery. For instance, AI algorithms, particularly those based on deep learning and natural language processing, are trained on vast datasets of DSI—including genomic, transcriptomic, proteomic, and metagenomic sequences—to derive insights that would be impossible to obtain through traditional methods alone.

A landmark global example is DeepMind's AlphaFold, which used DSI from public databases like UniProt and the Protein Data Bank to train an AI model that predicts protein 3D structures from amino acid sequences with remarkable accuracy. This breakthrough has opened new frontiers in understanding diseases, identifying drug targets, and designing biologics, potentially shortening the drug development pipeline from years to months.

Pharmaceutical companies now routinely use AI-powered platforms trained on DSI to identify gene-disease associations, design CRISPR guides, and predict drug responses. For instance, AI platforms like BenevolentAI, Insilico Medicine, and Recursion integrate DSI with clinical and biochemical data to generate novel hypotheses for drug development.

In India, the convergence of AI and DSI is being explored in initiatives such as the IndiGen Program and the Genome India Project, where large-scale human genome sequencing is coupled with machine learning to identify population-specific genetic variants linked to diseases like diabetes, cancer, and cardiovascular disorders. Indian biotech startups and research groups are developing AI models to predict antimicrobial resistance (AMR), optimize vaccine targets, and analyze cancer genomics using DSI from both national and global datasets.

A notable Indian innovation is the use of AI-based platforms for precision agriculture, where plant and soil microbiome sequences are analyzed to recommend genotype-environment management strategies. Platforms integrating AI with DSI are also being tested to identify early warning signals for zoonotic spillovers by monitoring viral metagenomes in animal reservoirs.

This clearly indicates that different sectors *viz* Biotechnology, pharmaceutical companies etc increasingly rely on DSI for various product developments. This commercial expansion has brought new economic opportunities but also intensified concerns about fair benefit-sharing. Companies across biotechnology,

pharmaceuticals, agriculture, and synthetic biology are increasingly dependent on public and proprietary sequence data to develop products, technologies, and services. (Table 2, Figure 4)

Table 2: Key Sectors utilizing DSI (a global indicative list)

Sector	Examples of Use	Representative Companies
Pharmaceutical	Drug target identification, vaccine design, gene therapies	Pfizer, Moderna, Roche
Agricultural Biotechnology	Crop trait improvement, pest resistance, precision breeding	Bayer CropScience, Syngenta, Corteva
Industrial Biotechnology	Enzyme discovery for detergents, biofuels, food technology	Novozymes, DSM, DuPont
Synthetic Biology	Genome engineering, biosensor development, bio-based manufacturing	Ginkgo Bioworks, Amyris, Twist Bioscience
Diagnostics	Pathogen detection, molecular diagnostics tools	Thermo Fisher, Illumina, Qiagen

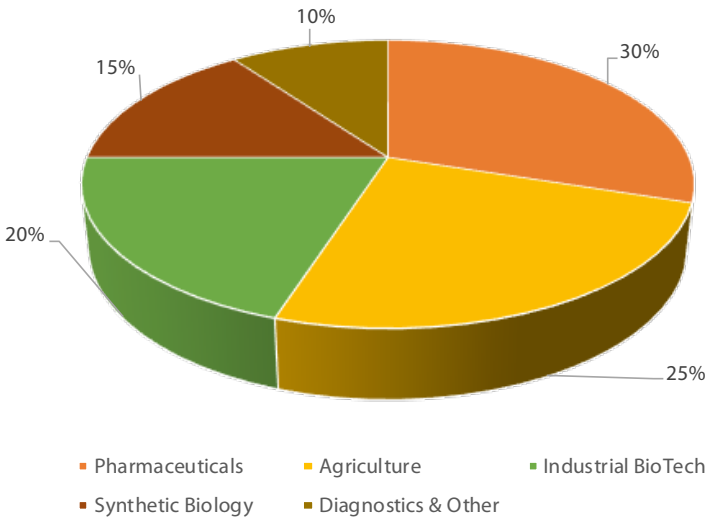


Figure 4: Estimated share of DSI use (%) by commercial sectors (This is illustrative estimates based on trends reported by OECD, CBD, and recent NCBI usage patterns. Exact figures are challenging due to proprietary restrictions[12,13,14,15]

12 Sayers, E. W., et al. (2025). GenBank 2025. Nucleic Acids Research, 53(D1), D56–D61. https://doi.org/10.1093/nar/gkae1114
13 Laird, S. A., Wynberg, R., & Rourke, M. F. (2020). Access and Benefit-Sharing in a Digital World. CBD Technical Series.
14 OECD (2021). Digital Sequence Information and Genetic Resources.
15 NCBI Insights & GenBank Updates (https://ncbiinsights.ncbi.nlm.nih.gov/)

Tracing the use of DSI for commercial purposes from the International Nucleotide Sequence Database Collaboration (INSDC) databases is highly complex and not feasible in most cases due to several interrelated factors. These INSDC databases operate on an open-access model, allowing unrestricted data download without requiring user identification or registration[16]. As a result, there is no built-in mechanism to track who accesses the data or how it is subsequently used. Furthermore, while some sequences include metadata such as the country of origin, this information is often inconsistently provided or entirely missing, making it difficult to determine the provenance of specific sequences. The absence of standardized attribution practices means that companies or researchers using DSI in product development or intellectual property filings rarely cite specific database accession numbers, further obscuring traceability[17]. However, it may be noted that recently, the WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge was adopted on May 24, 2024[18]. The Treaty establishes a mandatory patent disclosure requirement – this requires patent applicants to disclose the country of origin of the genetic resources and/or the Indigenous Peoples or local community providing the associated traditional knowledge, if the claimed inventions are based on genetic resources and/or associated traditional knowledge. The information would be useful to ensure transparency, prevent misappropriation, and promote fair sharing of benefits derived from the use of biological resources and traditional knowledge.

The global, decentralized nature of bioinformatics research, combined with the rapid pace and volume of data generation, exacerbates these challenges. Collectively, these issues hinder efforts to monitor commercial use of DSI and pose challenges in the implementation of fair and equitable sharing of benefits under international frameworks like the CBD and the Nagoya Protocol. Examples to show where the commercial use of DSI could be linked are given in Figure 5. An example demonstrating the complexity in monitoring and traceability of the DSI is given in (Box 2)

16 Scholz, A. H., et al. (2022). Multilateral benefit-sharing from digital sequence information will support both science and biodiversity. Nature Communications, 13(1), 1056. https://doi.org/10.1038/s41467-022-28594-0

17 Bagley, M. A., & Tobin, B. M. (2023). Digital sequence information and the access and benefit-sharing regime of the Convention on Biological Diversity. Life Sciences, Society and Policy, 19(1), 3. https://doi.org/10.1007/s40504-023-00296-

18 WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge, https://www.wipo.int/treaties/en/ip/gratk/#:~:text=The%20Treaty%20establishes%20a%20mandatory,on%20genetic%20resources%20and/or

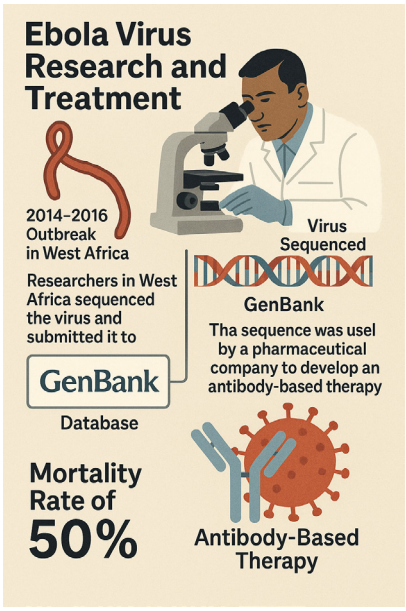


Figure 5: Examples to show that the DSI used in the products may be traced back to the origin of the bioresources

Box - 2

Complexity of sharing the benefits from the use of DSI[19 20 21]

Moderna's patent US-10702600-B1

Betacoronavirus mRNA vaccine, filed in February 2020 for respiratory viruses the genus that includes SARS-CoV-2, which causes COVID-19.

The patent draws on **176** publicly available (via INSDC) DSI from different respiratory viruses, from a large range of cauntries

(e.g, Saudi Arabia, UK, UAE, Jordan, France, USA, Qatar, Thailand, Oman, China)

Some are similar or identical to existing public sequences, others represent engineered or modified versions of sequences already referenced elsewhere in the patent document

96 new sequences submitted to public DSI databases alongside the patent

Many are labelled as "Artificial Sequence" and have no country of origin

Not one SARS-CoV-2 sequence is listed in the patent

Interestingly, the mRNA present in the vaccine is only **70%** identical to any natural SARS-CoV-2 found in the INSDC

19 DSI Scientific Network (2023) COVID-19: Using digital sequence information (DSI) to design an mRNA vaccine. Available at: https://dsiscientificnetwork.org/wp-content/uploads/2024/10/DSI-Scientific-Network-Case-Study-1-COVID-19-Using-DSI-to-design-an-mRNA-vaccine-2023.pdf

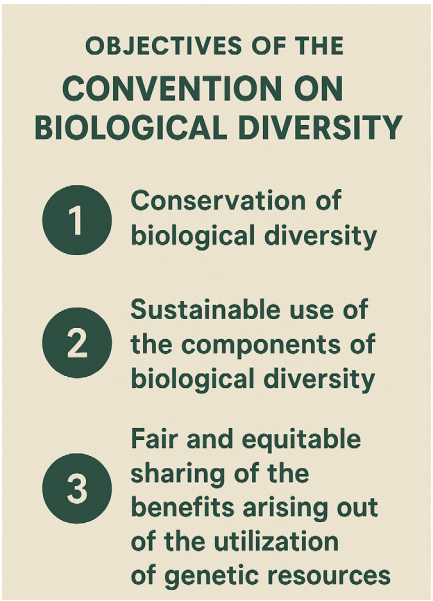
20 König, T., Rourke, M. and Scholz, A.H. (2024) 'Harmonize rules for digital sequence information benefit-sharing', Nature Biotechnology. Available at: https://pmc.ncbi.nlm.nih.gov/articles/PMC11464523/

21 ModernaTX, Inc. (2020) Prefusion coronavirus spike proteins and their use. Patent application (e.g., WO2020060606). Available via: https://patentscope.wipo.int/

Chapter - III

DSI under the Convention on Biological Diversity (CBD)

Convention on Biological Diversity (CBD) under its Article 1 states; the objectives of this Convention, to be pursued in accordance with its relevant provisions are the conservation of biological diversity, sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources including by appropriate access to genetic resources and by appropriate transfer of relevant technologies taking into account all rights over those resources and to technologies, and by appropriate funding[22]. "Access to genetic resources and the fair and equitable sharing of benefits" (ABS) has become, arguably, the most studied and reflected upon concept in the CBD process since 1992.



A discussion on DSI brought new interest and dimensions to the scope of ABS provisions as countries debated whether or not DSI should fall within the scope of the Nagoya Protocol, a supplementary agreement under the CBD[23]. This debate also took place in other policy fora, including International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) of FAO, as well as its Commission on Genetic Resources, Pandemic Influenza Preparedness (PIP) Framework of WHO on influenza, the UN Convention on the Law of the Sea (UNCLOS) and the World Intellectual Property Organization (WIPO)[24].

Parties to the CBD were finding it challenging to deal with the topic of DSI on genetic resources in its current form as it has the potential to replace physical access to biological material.

3.1 Origin of debate on DSI

CBD defines genetic resource in Article 2 as "genetic material of actual or potential value" and genetic material is defined as "any material of plant, animal, microbial

22 United Nations. (1992). Convention on Biological Diversity. https://www.cbd.int/doc/legal/cbd-en.pdf
23 CBD Decision 14/20 (2018): Digital Sequence Information on Genetic Resources (CBD/COP/DEC/14/20)
24 CBD Technical Series No. 96 (2020)-Fact-finding and scoping study on DSI on genetic resources in the context of the CBD and the Nagoya Protocol

or other origin containing functional units of heredity". It has been argued that both the definitions recognize tangible and intangible elements in the genetic material, i.e., the physical material as well as the value it contains and the value of the genetic material that lies in the genetic information it contains, whether in the actual or potential form.

The definition of 'utilization of genetic resources' under the Nagoya Protocol reads as "research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology"[25]. As per this definition, utilization of genetic resources is not confined to R&D on the tangible genetic resources, but is extended to activities over the genetic and biochemical composition of such resources.

India and few stakeholders argued that genetic composition are nonetheless gene sequences whether digital or tangible. Further, synthesizing the DNA with access from a digital sequence would therefore fall within the scope of utilization under the Nagoya Protocol. In other words, accessing digital sequence information amounts to accessing the genetic resource itself, and its utilization would fall within the scope of CBD/Nagoya Protocol, qualifying for application of ABS regulatory framework even though there is no physical access of the genetic material. While for non-commercial research, simplified procedures may be considered, and commercial utilisation would trigger benefit sharing as per the provisions of CBD/ Nagoya Protocol.

However, there were others who indicated that DSI will not fall under the scope of CBD and hence, this was an major issue in CoP for deliberations.

Box - 3

Is DSI within the scope of the CBD/ Nagoya Protocol?

DSI is a "Genetic Resource"

"Genetic resources" means genetic material of actual or potential value, and "genetic material" means any material of plant, animal, microbial or other origin containing functional units of heredity. (CBD *Article. 2*)

"Utilization of genetic resources" means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention (NP *Article. 2(c)*)

"Biotechnology" as defined in Article 2 of the Convention means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use." (NP *Article. 2(d)*)

25 Secretariat of the Convention on Biological Diversity. (2011). Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity. Montreal: CBD Secretariat. https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf

In the Indian context:

Section 2 (c) of the Biological Diversity (Amendment) Act, 2023- **"biological resources"** include plants, animals, micro-organisms or parts of their genetic material and derivatives (excluding value added products), with actual or potential use or value for humanity, but does not include human genetic material.

Discussions relating to DSI on genetic resources emerged as a main theme under the CBD as well as the Nagoya Protocol at the CoP-13 and CoP-MoP 2 held on 2-17 December, 2016 at Cancun, Mexico.

3.2 CBD- 13th Conference of Parties

Persuant to decision CBD 13/16 taken in CoP-13 an Ad Hoc Technical Expert Group (AHTEG) was established to address the challenges in the implementation of the

third objective of the CBD, 1992 *viz.*, the fair and equitable sharing of benefits arising from the utilization of genetic resources. The umbrella of biological information in digital formats was called as DSI in all discussions. Nevertheless, DSI is a placeholder term and merits the identification of a new holistic terminology for its proper representation[26].

The Parties decided to consider, at its 14th meeting, any potential implications of the use of the DSI on genetic resources for the three objectives of the Convention. Pursuant to COP decisions, a compilation and synthesis of views and information was prepared by the Executive Secretary and a Fact Finding study commissioned to clarify relevant terminology and concepts. An Ad Hoc Technical Expert Group

26 Decision adopted by the Conference of the Parties to the Convention on Biological Diversity at its thirteenth meeting. Decision XIII/16: Digital sequence information on genetic resources.Cancun, Mexico, 4-17 December 2016, https://www.cbd.int/doc/decisions/cop-13/cop-13-dec-16-en.pdf

(AHTEG) addressed the issue on the basis of this information and the Subsidiary Body of Scientific, Technical and Technological Advice (SBSTTA) considered the results of the meeting at its twenty-second meeting.

3.3 CBD- 14th Conference of Parties

The COP-14 held on 17-29 November, 2018 at Sharm El-Sheikh, Egypt, considered the recommendation of the SBSTTA on potential implications of the use of DSI on genetic resources for the three objectives of the Convention and a draft decision was adopted from SBSTTA recommendation (22/1).

UN BIODIVERSITY CONFERENCE
Investing in biodiversity for people and planet
COP 14 - CP/MOP9 - NP/MOP3
Sharm El Sheikh, Egypt, 2018

CoP-14 *vide* decision 14/20 established an extended AHTEG including the participation of indigenous peoples to :

i. Compile and synthesize the views and information submitted by the parties.

ii. Commission a science-based peer-reviewed fact-finding study on this subject.

Accordingly, AHTEG made recommendations to the COP-15 on how to address DSI on genetic resources in the context of the post-2020 global biodiversity framework.

Consequently, CBD invited Parties, other Governments, indigenous peoples and local communities, relevant organizations and stakeholders to submit views and information on the following as per decision of COP:

i. To clarify the concept, including relevant terminology and scope of DSI on genetic resources and if and how domestic measures on access and benefit-sharing consider DSI on genetic resources;

ii. On benefit-sharing arrangements from commercial and non-commercial use of DSI on genetic resources[27]

3.4 CBD- 15th Conference of Parties

Kunming-Montreal Global Biodiversity Framework (KMGBF) was adopted in COP-15 (Decision 15/4). This historic framework chartered an ambitious pathway to reach the global vision of a world living in harmony with nature by 2050. The key elements of GBF includes 23 action-oriented targets that need to be completed by 2030, in line with the UN Sustainable Development Goals Agenda, to enable achievement of four (4) outcome-oriented goals set for 2050. At COP 15, the parties agreed to develop a solution for the sharing of benefits arising from the use of DSI (Decision - 15/9).

Photo by IISD/ENB

27 Decision adopted by the Conference of the Parties to the Convention on Biological Diversity at its fourteenth meeting. Decision 14/20: Digital sequence information on genetic resources. Sharm El-Sheikh, Egypt, 17–29 November 2018, https://www.cbd.int/doc/decisions/cop-14/cop-14-dec-20-en.pdf

The Target 13 of the KMGBF states ***"Take effective legal, policy, administrative and capacity-building measures at all levels, as appropriate, to ensure the fair and equitable sharing of benefits that arise from the utilization of genetic resources and from DSI on genetic resources, as well as traditional knowledge associated with genetic resources, and facilitating appropriate access to genetic resources, and by 2030 facilitating a significant increase of the benefits shared, in accordance with applicable international access and benefit-sharing instruments"[28].***

This was intended to build an equity dimension amongst countries providing the DSI and those utilizing the same with the dual objective of providing incentives for conservation and sustainable use of biodiversity and mobilizing new resources redirected towards biodiversity. Achieving Target 13 would in turn aid in attaining Goal C of the KMGBF which is specified as

"The monetary and non-monetary benefits from the utilization of genetic resources and DSI on genetic resources, and of traditional knowledge associated with genetic resources, as applicable, are shared fairly and equitably, including, as appropriate with indigenous peoples and local communities, and substantially increased by 2050, while ensuring traditional knowledge associated with genetic resources is appropriately protected, thereby contributing to the conservation and sustainable use of biodiversity, in accordance with internationally agreed access and benefit-sharing instruments."

Decision 15/9, adopted at COP-15 confirmed that the benefits from the use of digital sequence information on genetic resources should be shared fairly and equitably[29].

In summary, the decision acknowledged the vital role of DSI in scientific research, innovation, and biodiversity conservation, while also recognizing the concerns of many developing countries about the fair and equitable sharing of benefits arising from its use. To address this, the Parties agreed to establish a multilateral mechanism for benefit-sharing from the use of DSI, including the creation of a global fund to support conservation, sustainable use, and capacity-building efforts, especially in biodiversity-rich nations. This mechanism will accommodate both monetary contributions (from commercial users and other stakeholders) and non-monetary benefits, such as knowledge sharing and technology transfer. Importantly, the decision upheld the principle of open access to DSI, avoiding restrictive approaches while still promoting equity through a decoupled system of

28 Kunming-Montreal Global Biodiversity Framework (2022), Adopted at the fifteenth meeting of the Conference of the Parties to the Convention on Biological Diversity (COP-15), Montreal, Canada, December 2022, https://www.cbd.int/doc/c/4d44/1fa3/04f005978b17c49d4b0a6c23/cop-15-l-25-en.pdf

29 CBD Decision 15/9 (2022), Decision adopted by the Conference of the Parties to the Convention on Biological Diversity at its fifteenth meeting. Decision 15/9: Digital sequence information on genetic resources. Montreal, Canada, 7–19 December 2022 https://www.cbd.int/doc/decisions/cop-15/cop-15-dec-09-en.pdf

benefit-sharing. A dedicated working group was tasked to design the mechanism's modalities—such as triggers, governance, and distribution criteria—for adoption at COP-16.

Box - 4

The important paragraphs of the decision 15/9 are as follows:

Paragraph 6.: Also recognizes that a multilateral approach on the sharing of the benefits arising from the use of digital sequence information on genetic resources has the potential to meet the criteria identified in paragraph 9 of the present decision.

Importantly, the paragraphs 9 and 10 of the decision 15/9 sets the principles to follow for a solution for fair and equitable benefit sharing on DSI which is as follows:

Paragraph 9: Also agrees that a solution for fair and equitable benefit-sharing on digital sequence information on genetic resources should, inter alia:

a) Be efficient, feasible and practical;
b) Generate more benefits, including both monetary and non-monetary, than costs;
c) Be effective;
d) Provide certainty and legal clarity for providers and users of digital sequence information on genetic resources;
e) Not hinder research and innovation;
f) Be consistent with open access to data;
g) Not be incompatible with international legal obligations;
h) Be mutually supportive of other access and benefit-sharing instruments;
i) Take into account the rights of Indigenous peoples and local communities, including with respect to the traditional knowledge associated with genetic resources that they hold.

Paragraph 10: Recognizes that the monetary and non-monetary benefits arising from the use of digital sequence information on genetic resources should, in particular, be used to support conservation and sustainable use of biological diversity and, inter alia, benefit Indigenous peoples and local communities;

The CBD, in paragraph 18 of the 15/9 decision, decided to establish an Ad Hoc Open-Ended Working Group (AHOEWG) on benefit-sharing from the use of DSI on genetic resources to undertake further development of the multilateral mechanism, including the elements identified as the issues to be considered, and to make recommendations to the COP-16. The overall workflow of the CBD to arrive at a decision on DSI is given in Figure 6.

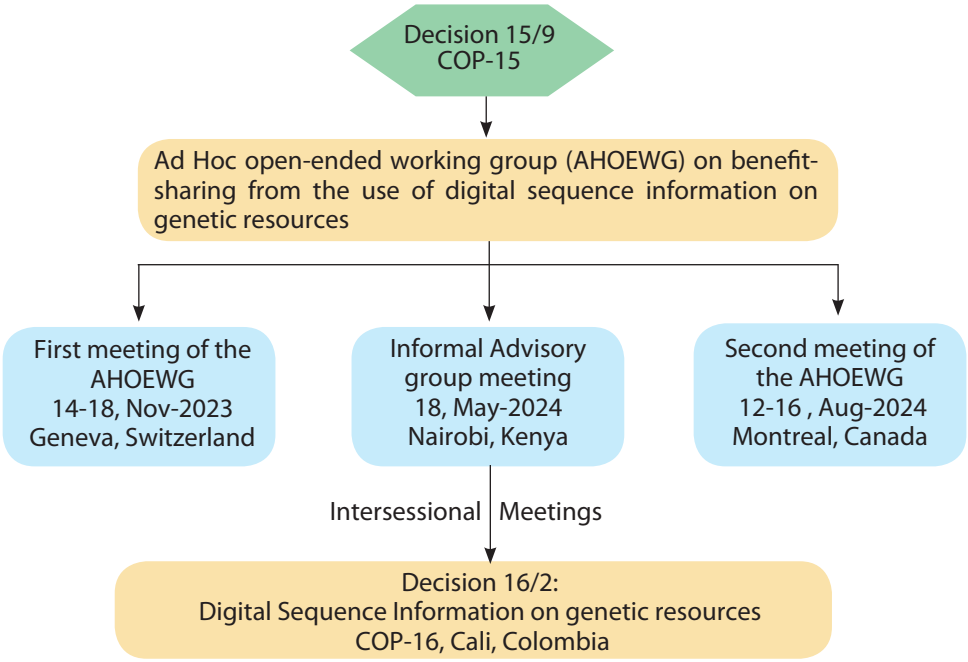


Fig 6: Workflow followed by the CBD to arrive at the decision on DSI

The issues considered by the Ad Hoc Open-Ended Working Group (AHOEWG) were:

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.

3.5 First meeting of the AHOEWG on benefit sharing from the use of DSI on genetic resources

The first meeting of the AHOEWG on benefit-sharing from the use of DSI on genetic resources was held on 14-18 November 2023 at Geneva, Switzerland.

Photo by IISD/ENB

The Working Group developed possible elements of a multilateral mechanism for benefit-sharing from using digital sequence information on genetic resources, including a global fund.

The Working Group members further identified the issues mentioned above into five clusters such as[30]:

a) Contributions to the DSI fund;

b) Fund disbursement;

c) Non-monetary benefit-sharing;

d) Governance;

e) Relation to other approaches and systems

In continuation to the First meeting of the AHOEWG on benefit sharing from the use of DSI, an Informal Advisory Group (IAG) was formed during the intersessional period. Dr. B. Balaji, IFS, Secretary, National Biodiversity Authority (NBA) was nominated as a member from India. The IAG met monthly online and deliberated on the various issues discussed in the AHOEWG.

Further, an informal discussion on DSI on Genetic Resources was held on 19th May 2024 at Nairobi, Kenya for which Shri. Tanmay Kumar, IAS, Additional Secretary, Ministry of Environment, Forests & Climate Change (MoEFCC) and Secretary, NBA participated from India.

3.6 Second meeting of the AHOEWG on benefit-sharing from the use of DSI on genetic resources

The Second meeting of the AHOEWG was held from 12-16 August 2024 at Montreal, Canada. The group after deliberations provided recommendation on the further development of the multilateral mechanism on benefit-sharing from DSI use, including a global fund and the modalities for operationalization of the mechanism in an annex. Several options were provided in key provisions of the modalities as indicated by bracketed text[31].

In this regard, the Working group also endorsed a proposal of the Co-Chairs of the Committee for inter-sessional activities, which included information-sharing activities, informal regional consultations and an informal advisory group on DSI. The outcomes of the inter-sessional activities are summarized in document CBD/WGDSI/2/INF/2. Further, the Executive Secretary commissioned the studies requested in decision 15/9, namely,

i. study to analyze and model the extent to which a multilateral mechanism meets the criteria in paragraphs 9 and 10 of the decision.

30 CBD Decision 15/9 (2022) — Annex II "Elements of a Multilateral Mechanism for Benefit-sharing from the Use of Digital Sequence Information on Genetic Resources" https://www.cbd.int/doc/decisions/cop-15/cop-15-dec-09-en.pdf

31 Square brackets are used to indicate optional or alternative language, or text that has not yet been finalized or agreed upon by all parties. They signal that the bracketed text is not yet part of the definitive agreement and may be subject to further negotiation or modification.

Photo by IISD/ENB

ii. study on the options for revenue-generating measures at different points along the value chain, the feasibility of their implementation and their costs relative to their potential revenue.

The Co-Chairs also submitted their reflections on the elements of a multilateral mechanism identified by the Working Group at its first meeting, considering the outcomes of the inter-sessional activities and the combined studies. The reflections intended to facilitate deliberations of the Working Group by building on areas of convergence, offering initial ideas on resolving areas of divergence and developing the rationale underpinning the elements of a draft recommendation, as contained in document CBD/WGDSI/2/2[32].

3.7 CBD- 16th Conference of Parties

The COP 16 was held in Cali, Colombia from October 21 to November 1, 2024 wherein Decision 16/2 was adopted that operationalizes a multilateral mechanism for benefit-sharing from the use of DSI on genetic resources aiming to ensure the fair and equitable sharing of benefits arising from the commercial utilization of DSI. A central feature of this mechanism was the establishment of the "Cali Fund for the Fair and Equitable Sharing of Benefits from the Use of Digital Sequence Information on Genetic Resources, designed to collect and disburse monetary benefits derived from DSI applications"[33].

32 Report of the second meeting of the Ad Hoc Open-ended Working Group on Benefit-sharing from the Use of Digital Sequence Information on Genetic Resources (CBD/DSI/WG/2024/2/4). Montreal: CBD Secretariat. https://www.cbd.int/meetings/DSI-WG-2024-02

33 CBD Decision 16/2 -Operationalizing the Multilateral Mechanism for Benefit-sharing from the Use of Digital Sequence Information on Genetic Resources, https://www.cbd.int/doc/decisions/cop-16/cop-16-dec-02-en.pdf

This decision is crucial in establishing the framework for how countries and Parties should manage DSI from genetic resources. In particular, COP 16 Decision 16/2 recognizing the growing importance of DSI on genetic resources and need for appropriate mechanisms for the fair and equitable sharing of benefits arising from their use, it was also decided to explore the modalities of the multilateral mechanism, including

a) Possible additional modalities that take products and services into account,

b) New tools and models for making DSI publicly available and accessible.

Photo by IISD/ENB

The COP invited the parties and others to submit relevant views and requested the Secretariat to: synthesize these views; commission a study on options for making DSI publicly available and accessible; and prepare a study on national and international standards for the identification of small, medium, and large entities as well as on contribution rates, including implications for revenue generation and economic competitiveness.

The modalities for operationalizing the multilateral mechanism were annexed to the decision and are summarized below.

i. All users of DSI on genetic resources under the multilateral mechanism should share benefits arising from its use in a fair and equitable manner.

ii. Users of DSI on genetic resources in sectors that directly or indirectly benefit from its use in their commercial activities should contribute to the global fund 1% of their profits or 0.1% of their revenue, as an indicative rate, according to their size[34] .

iii. The modalities further include provisions for non-monetary benefit-sharing and for entities operating databases, and tools and models dependent on DSI.

iv. Parties and non-parties are invited to take administrative, policy, or legislative measures, consistent with national legislation, to incentivize contributions to the Cali Fund, which are expected to be made directly.

v. Funding should be allocated in a fair, equitable, transparent, accountable, and gender-responsive manner, and should support the realization of the objectives of the CBD in developing countries, in particular least developed countries, small island developing states (SIDS), and countries with economies in transition.

vi. A formula for funding allocation will be determined by COP 17.

vii. Funding will be disbursed through direct allocations to parties, which are to designate or establish a relevant national entity that will be responsible for resource allocation through a country- or community-driven process and accountable for transparent distribution.

viii. Where appropriate and subject to national circumstances, at least half of the funding allocated from the global fund should support the self-identified needs of IPLCs, including women and youth within those communities.

ix. The COP may set aside a proportion of funds to support capacity building.

x. The fund will be administered by the UN through the UN Multi-Partner Trust Fund Office, under the authority of the COP.

xi. The multilateral mechanism will be implemented in a way that is mutually supportive of and adaptive to other international ABS instruments on DSI.

xii. The effectiveness of the multilateral mechanism, including the global fund, will be regularly reviewed, starting at COP 18. The decision contains six enclosures, namely:

    a) An indicative list of sectors that may directly or indirectly benefit from the use of DSI on genetic resources;

34 It may be noted that scientific assessment on the % arrived at are not well established

b) An indicative list of criteria for funding allocation;

c) Terms of reference (ToRs) for the Ad-Hoc Technical Expert Group on Allocation Methodology;

d) ToRs of the Steering Committee to oversee the operations of the Fund's host;

e) Functioning of the Secretariat; and

f) Factors to be considered in the review.

Box - 5

Criteria to be considered for DSI on genetic resources under the multilateral mechanism as per CBD decision 16/2

1. That is made publicly available, in compliance with national legislation, where applicable;
2. That is not subject to mutually agreed terms established at the time of access to the genetic resources from which the digital sequence information is derived, unless those terms allow for the making of the digital sequence information on genetic resources freely available;
3. For which the fair and equitable sharing of benefits from the use of digital sequence information on genetic resources is not provided for under other international instruments on access and benefit-sharing, unless the multilateral mechanism is chosen for that purpose under those instruments.

Post–Decision 16/2 developments

The adoption of decision 16/2 at the Sixteenth Conference of the Parties (COP-16) marked a watershed moment in the CBD's approach to DSI, shifting the discourse decisively from normative debate to institutional and operational implementation. A central outcome of Decision 16/2 was the establishment of the Cali Fund for the Fair and Equitable Sharing of Benefits from the use of Digital Sequence Information on Genetic Resources. The fund is intended to serve as the financial vehicle for channeling monetary contributions arising from the commercial use of DSI toward biodiversity conservation, capacity-building, and the needs of Indigenous Peoples and Local Communities (IPLCs). The Cali Fund reflects a novel approach within the CBD framework. Contributions are not linked to individual genetic resources or countries

of origin but are instead pooled at the global level. Decision 16/2 emphasizes that a significant proportion of resources should support IPLCs, reflecting growing recognition of their role as custodians of biodiversity and holders of traditional knowledge.

To oversee the multilateral mechanism and the Cali Fund, Decision 16/2 established a Steering Committee as a central governance body. The Committee's composition reflects the CBD's emphasis on balanced representation and inclusivity, comprising representatives from Parties across United Nations regions, representatives of Indigenous Peoples and Local Communities, and observers from civil society, scientific institutions, and relevant international organizations.

The mandate of the Steering Committee includes providing strategic guidance on the implementation of the multilateral mechanism, advising on governance and operational procedures for the Cali Fund, monitoring equity and transparency considerations, and reporting to the Conference of the Parties through the Subsidiary Body on Implementation (SBI).

Steering Committee Meetings

The Steering Committee commenced its work in 2025, marking the beginning of the implementation phase of the DSI mechanism.

The first meeting, convened in a virtual format, held on 16–18 June 2025, was primarily organizational. Discussions focused on clarifying roles and responsibilities, adopting working modalities, and identifying priority issues arising from Decision 16/2. This meeting laid the procedural foundation necessary for subsequent substantive deliberations.

The second meeting, held later in 2025 (3–6 September 2025) in an in-person format, reflected a gradual transition toward operational matters. The Committee was engaged with issues related to the governance and administration of the Cali Fund, coordination with the CBD Secretariat and United Nations administrative arrangements, and principles of transparency and accountability. Initial discussions were also held on benefit-allocation considerations, including how to reflect the commitment to ensure meaningful support for Indigenous Peoples and Local Communities.

Role of the CBD Secretariat and Technical Support Bodies

Parallel to the work of the Steering Committee, the CBD Secretariat was tasked with extensive follow-up activities. These included inviting submissions from Parties and stakeholders, commissioning studies on contribution models, thresholds, and economic implications, and preparing synthesis reports for consideration by

the Subsidiary Body on Implementation. Decision 16/2 also established an Ad Hoc Technical Expert Group (AHTEG) to support the development of methodologies for allocating resources from the Cali Fund.

Early Implementation Challenges

The period between COP-16 and COP-17 represents a critical transitional phase for DSI governance under the CBD. Several key elements remain under development, including contribution methodologies, allocation frameworks, monitoring mechanisms, and indicators of effectiveness. These issues are expected to be further refined through the SBI process and considered by Parties at COP-17. Despite the formal launch of the Cali Fund in early 2025, the initial phase of implementation has been marked by limited financial inflows. In November 2025, the Cali Fund received its first publicly reported financial contribution of USD 1,000 from a UK company named TierraViva AI. This small contribution was widely noted as a symbolic first step toward engaging the private sector, with the CBD Secretariat.

Chapter - IV

India's perspectives on the Digital Sequence Information

4.1 Importance of DSI in India

DSI holds significant importance for India, both in terms of scientific advancement and national interest. As one of the world's richest countries in terms of biological diversity - with ecosystems ranging from the Himalayas to coastal mangroves and rich agricultural systems - India possesses a vast reservoir of genetic resources. In line with global trends, Indian scientists are working to digitize, study, and utilize this biodiversity for purposes like developing new medicines, improving crop varieties, and conserving endangered species[35]. In agriculture, for instance, DSI is crucial for breeding climate-resilient crops and enhancing food security, especially in the face of climate change. In biotechnology and healthcare, Indian researchers use genomic data to advance precision medicine, understand disease patterns, and create vaccines and diagnostics, as seen during the COVID-19 pandemic when rapid genome sequencing played a key role. These activities will get a fillip as Artificial Intelligence (AI) gets increasingly embedded in scientific research.

India actively engages in both the usage and submission of DSI, reflecting its commitment to leveraging genetic data for scientific advancement and biodiversity conservation. According to a study in 2021, USA, China, Canada and Japan were the largest providers of genetic resources and contributed to 52% of the global DSI databases held by the International Nucleotide Sequence Database Collaboration (INSDC). India was the genetic resource provider for 3.46% of DSI available in the INSDC. As many as 94 countries used Indian DSI and Indian scientists were using DSI in INSDC from at least 150 countries[36].

DSI is central to India's future scientific endeavours in fields of synthetic biology, bioinformatics, and pharmaceutical innovation, which are increasingly contributing to the economy under initiatives such as the "Make in India" and "Bioeconomy 2030" visions. However, DSI represents a strategic concern in the context of access and benefit sharing.

India has advocated strongly in CBD and other international forums for equitable access and benefit-sharing (ABS) mechanisms related to DSI. There is a fear

35 National Biodiversity Authority (India). (2020). India's submission to the Convention on Biological Diversity on Digital Sequence Information on Genetic Resources.

36 Secretariat of the Convention on Biological Diversity (2021)-Fact-finding study on how domestic measures address benefit-sharing arising from commercial and non-commercial use of digital sequence information on genetic resources and on the contribution of digital sequence information on genetic resources to research and development CBD/DSI/AHTEG/2020/1/3 https://www.cbd.int/doc/c/3064/7495/8d4902d3bcfc7762d2c84f0f/dsi-ahteg-2020-01-03-en.pdf

that without proper global rules, foreign companies could exploit India's rich genetic heritage digitally without fair compensation or acknowledgment — a concern often referred to as "digital bio piracy." Hence, India supports developing international frameworks to ensure that nations providing genetic resources also share in the economic benefits derived from their use. In short, DSI is deeply tied to India's goals for scientific leadership, sustainable development, economic growth, and sovereignty over its biological resources.

4.2 India's perspectives on DSI at CBD

In the year 2017, India submitted its views on the DSI to the CBD Secretariat in response to CBD notification No.86500 dated 25 April, 2017 and No.86630 dated 12 June, 2017; wherein, India submitted that accessing of genetic information amounts to accessing the genetic resource itself, and commercial utilization derived from its products or seeking IPR over them would trigger benefit sharing with the country of origin subject to national legislation. In short, use of DSI implies utilization of genetic resources, and hence it is clear that the scope of CBD as well as the Nagoya Protocol would cover digital sequence information also.

Further, India submitted its views on DSI on genetic resources in response to CBD notification 2019-012 dated 5 February 2019 pursuant to decisions 14/20 and NP-3/12, wherein it was stated that, in India, the ABS provisions of CBD and the Nagoya Protocol on ABS are implemented inter alia through the Biological Diversity Act, and regulations thereunder. While these do not include explicit reference to DSI or any such terminology, the relevant provisions in the Act can cover in their scope the utilization of DSI. For example, the term 'research' as defined in Section 2 (m) of the BD Act would cover DSI. Similarly, the requirement prescribed in Section 6 of the BD Act which refers to 'information on biological resource' would cover DSI. [37]

4.2.1 Expert Committee on DSI constituted by the National Biodiversity Authority

In order to develop a comprehensive country position on DSI including to advise on the scope of DSI that can be regulated under the ABS laws, the National Biodiversity Authority constituted an Expert Committee on DSI *vide* Office Memorandum NBA/Tech/EC/9/14/36/20-21 dated 18 April, 2020 which was chaired by Shri. C. Achalender Reddy, IFS. The terms of reference of the Committee are as follows:

a) To suggest an appropriate terminology reflecting DSI and related subject matter.

37 The Biological Diversity Act, 2002. New Delhi: Ministry of Environment, Forest and Climate Change. https://nbaindia.org/uploaded/pdf/BD_Act_2023.pdf

b) To advise on the scope of DSI that can be regulated under ABS laws, based on the subject matter grouping referred in the proposal.

c) To understand the challenges and feasibility of assessing, traceability of DSI ,and DSI based products and processes.

d) To contribute to developing India's position on DSI in the AHTEG meetings and COP 15.

4.2.1.1 Recommendations by the Expert Committee on DSI

As DSI is a placeholder, India proposed the terminology as "genetic sequence data and/or information" instead of "digital sequence information on genetic resources', considering that, in the context of digitization, there is change only in the nature of information on the genetic resources and not in its character or content.

It was advisable for India to negotiate the DSI subject matter groupings under Group 3 (DNA and RNA sequence data + data/information concerning proteins + metabolites). In addition:

i. The definition of 'research' covers the utilization of DSI by consisting text "technological application on the living organisms or derivatives thereof". Thus, access to DSI would be a regulated activity under the provisions of the BD Act. If required, the use of DSI implies the utilisation of genetic resources, and hence it is clear that the scope of the CBD as well as the Nagoya Protocol would also cover DSI. While it may not be necessary in the light of the above, the Act may be amended suitably to state the above propositions explicitly and bring clarity in this respect.

ii. The scope of CBD as well as the Nagoya Protocol would cover DSI also since use of digital sequence information implies utilization of genetic resources. While bio piracy has conventionally meant the physical removal of a material from a community into private hands, synthetic biology enables digital biopiracy.

iii. While, India's position on regulation of access to DSI on genetic resources is still under consideration, India's domestic legislation *viz.,* Biological Diversity Act, 2002 have the necessary competence to regulate the access to DSI on genetic resources under sections 3, 4 and 6 of the BD Act.

iv. If necessary, simplified procedure for obtaining PIC and MAT may be provided for access to DSI from the open access databases for the purpose of non-commercial research, if such DSI comprises the information on country of origin.

v. The benefit-sharing formula provided in Guidelines on Access to Biological Resources and Associated Knowledge and Benefits-Sharing Regulations, 2014 may be applicable for commercial and non-commercial use of DSI on genetic resources, on a case by case basis, including technology transfer.

vi. While operationalising ABS mechanism on access and utilization of DSI on genetic resources, it may pose certain challenges like issue of establishment of country of origin, traceability and monitoring on subsequent use.

vii. Depositories/Gene Banks may insist the publisher/depositor to provide the country of origin while submitting the sequence information in their databases which would provide a space to the provider country to enforce their domestic legislation. Alternatively, the provider country may fall back on provisions of Nagoya Protocol to secure benefit sharing for accessing DSI originating from it.

4.3 Reconstituted Expert Committee on DSI

The Expert Committee (EC) submitted its interim report in 2021 and the tenure of the committee has since, ended. The Kunming-Montreal Global Biodiversity Framework (KMGBF) was adopted in the COP -15 held at Montreal in December 2022. In the KMGBF, Target 13 is to create effective legal, policy, administrative and capacity-building measures in order to ensure fair and equitable sharing of benefits that arises from the utilization of genetic resources, associated traditional knowledge and DSI.

In view of rapid scientific developments in the field of DSI and in the light of Target 13 of Kunming-Montreal Global Biodiversity Framework, it was decided to re-constitute an Expert Committee in the exercise of powers conferred under Sub section (2) of Section 13 of the Biological Diversity Act, 2002 read with Rule 11 of the Biological Diversity Rules, 2004 under the Chairmanship of Smt Uma Devi, IFS (Retd), Former Additional Secretary, MoEFCC and other members from various disciplines including line Ministries, World Health Organisation, BCIL, Industry association etc.

The First meeting of this EC was convened on 6th November, 2023. The members of the EC on DSI deliberated and gave their recommendations for the India's position in the First meeting of the Ad-Hoc Open-Ended Working group.

4.4 India's position in the First meeting of the Ad-Hoc Open-Ended Working Group on benefit sharing from the use of DSI on genetic resources

Based on the Expert committee's recommendations, the India considered their position at the first meeting of the Ad Hoc Working Group that DSI solution cannot be inconsistent with the CBD and Nagoya protocol on ABS which recognizes national sovereignty over national resources including genetic resources as voiced by many Parties as per Articles 2 and 15(1) of CBD 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 utilization of genetic resources as per Article 15(7) of CBD. It was further stated:

a) On contributions to the fund- India stressed that benefit-sharing should be triggered upon commercialization.

b) On disbursement of the funds- India supported using the origin of genetic resources as one of the criteria for benefits' disbursement.

c) On non-monetary benefit-sharing, India stressed that the multilateral mechanism needs to promote the creation and development of national databases.

Photo by IISD/ENB

d) On governance, the monetary benefits can be shared under the multilateral mechanism through Global Biodiversity Framework Fund (GBFF) mirroring the process of the GEF/GCF. The funds can be channelized through the Competent National Authority (CNA). It should be the designated agency responsible for receiving and administering contributions and disbursement of the fund.

e) On relation to other approaches and systems India stressed that existing national systems operating under bilateral approaches using free, prior and informed consent and mutually agreed terms, should be prioritized over the multilateral approach.

4.5 Developing India's position in the Informal discussion on DSI on Genetic Resources held on 19th May 2024 at Nairobi, Kenya.

The reconstituted expert committee on DSI had the second meeting on 25th & 26th April, 2024. The members deliberated on the elements for which there is a need for further discussion based on the Report of the first meeting of the Ad Hoc Open-ended Working Group on Benefit-sharing from the use of DSI on Genetic Resources (CBD/WGDSI/1/13 dated 18 November 2023)[38].

Further, a National Workshop on DSI and the Global Multilateral Benefit-Sharing Mechanism (GMBSM) from the use of DSI on Genetic Resources (GR) using Bilateral Mechanism was held on 12th and 13th of July 2024 in Hyderabad which was organized by National Biodiversity Authority (NBA) under the guidance of Ministry of Environment, Forest and Climate Change (MoEFCC). This workshop was attended and participated in by different groups and sectors of people, including Expert committee members, Line departments, Institutions, Industries, Domain experts, Member Secretaries of State Biodiversity Boards, Forest Department, etc.

The participants deliberated on the following documents circulated by the CBD with a view to prepare India's position namely:

a) Synthesis of information for the further development of the multilateral mechanism established under decision 15/9, including elements of a draft recommendation (CBD/ WGDSI/2/2).

b) Reflections of the Co-Chairs on the possible elements identified by the Working Group on Benefit-sharing from the use of Digital Sequence Information on genetic resources at its first meeting (CBD/WGDSI/2/2/ Add.1).

38 Report of the first meeting of the Ad Hoc Open-ended Working Group on Benefit-sharing from the Use of Digital Sequence Information on Genetic Resources (CBD/DSI/WG/2023/1/4). Montreal: CBD Secretariat. https://www.cbd.int/doc/c/43d4/2765/376f5e786fe1cc9c8d6a0dbb/dsi-wg-01-04-en.pdf

c) Executive summary of the studies commissioned pursuant to decision 15/9 on digital sequence information on genetic resources (CBD/WGDSI/2/2/Add.2).

The participants were then divided into three different Breakout Groups as per the clusters of elements on DSI identified by the CBD and to deliberate and prepare India's position in the forthcoming meetings of CBD *viz.* the second meeting of the Ad-Hoc Open-Ended Working Group (AHOEWG) on DSI to be held on 12-16 August 2024, and the Conference of Parties (COP)-16 to the Convention on Biological Diversity scheduled on 21st October- 1st November 2024 at Cali, Columbia.

4.6 Second meeting of the Ad-Hoc Open-ended Working Group on benefit-sharing from the use of DSI on genetic resources held from 12-16 August 2024 at Montreal, Canada.

The recommendations of the second meeting of the Expert Committee on DSI and the National workshop on DSI were considered in the second meeting of the Ad Hoc Open-ended Working Group on Benefit-sharing from the use of DSI on Genetic Resources, and the major India's position is given below:

a) India advocates graded slabs to levy ABS on companies/ other users using DSI from genetic resources rather than levying a fixed percentage that is being contemplated at the moment.

b) All users, subject to their individual circumstances, should share non-monetary benefits arising from the use of DSI. India emphasizes that it must be ensured that non-monetary benefits and the monetary contributions by the users are independent of each other.

c) The CBD website/clearing house mechanism may provide information on the non-monetary benefit sharing.

d) The entities operating the public databases on DSI should be encouraged to raise awareness of the multilateral benefit-sharing mechanism and of obligations to share benefits arising from the use of DSI in a fair and equitable manner.

e) The monetary contributions to the global fund may be routed through the competent national authority.

f) The allocation of funds to IPLCs from the global fund should be through the designated competent national authority.

4.7 India's position at the COP-16

India played a vital role in COP 16, influencing discussions and outcomes concerning DSI. Shri. Tanmay Kumar, IAS, Special Secretary, MoEFCC, and Dr. B. Balaji, IFS, Member Secretary, NBA assisted by Dr. R Srirama, Young Professional, NBA actively participated in all the meetings at the COP-16 including

Photo by NBA

the plenary, contact group, and Friends of Chair. The India's key negotiations and interventions are as follows:

a) The Multilateral fund/ Cali Fund should be under the management of CBD.

b) All the users including large, medium and small entities who use DSI and benefit from its use in their commercial activities should contribute a proportion of their revenue to the global fund according to their sizes. Medium and small industries will be considered after studies in this regard. Further, India wanted that the review has to be done on 17th COP itself and it should not be dragged to 18th COP.

c) Non-monetary benefits such as capacity building, technology transfer should be over and above monetary benefits.

d) Disbursement of funds should be based on the biodiversity richness of the country.

e) Funds should be directly allocated to the parties. Parties, as per their national legislation, circumstances and priorities, can allocate the self-identified capacity needs of indigenous people and local communities.


Photo by IISD/ENB

f) The databases should have an obligation on the uploaders to provide country of origin of genetic resources from which DSI was derived.

g) The Parties funding or hosting the databases should ensure that the entities operating such databases take measures to ensure the effective implementation of the multilateral mechanism.

The interventions provided by India has been reflected and incorporated in the text of the decision appropriately and are as follows:

a) Preambular Para of CBD/COP/DEC/16/2 (Accepted)

Acknowledging the vital role of digital sequence information on genetic resources, and open access to digital sequence information on genetic resources, in scientific research and sustainable development,

b) Preambular para of CBD/COP/DEC/16/2

Recognizing that the approach to the fair and equitable benefit sharing from the use of digital sequence information set out in the present decision is without prejudice to national access and benefit sharing measures and does not affect the rights and obligations of any Party deriving from any existing international agreement,

c) Operative Para 4 of CBD/COP/DEC/16/2 (Accepted)

Also decides to explore possible new tools and models, such as databases, for making digital sequence information on genetic resources publicly available and accessible in a transparent and accountable manner to all Parties;

d) Para 1 of Annex of CBD/COP/DEC/16/2 (Accepted)

1. The multilateral mechanism for the fair and equitable sharing of benefits from the use of digital sequence information on genetic resources covers digital sequence information on genetic resources:

(a) That is made publicly available, in compliance with national legislation, where applicable;

e) Para 3 and 4 of Annex of CBD/COP/DEC/16/2 (Accepted)

3. Users of digital sequence information on genetic resources in sectors that directly or indirectly benefit from its use in their commercial activities should contribute a proportion of their profits or revenue to the global fund, according to their size. Having regard to paragraph 13, entities which on their balance sheet dates exceed at least two out of three of these thresholds (total assets: USD 20 million Sales; USD 50 million; Profit: USD 5 million) averaged over the preceding three years, should contribute to the global fund one percent of their profits or 0.1 percent of their revenue, as an indicative rate. An indicative list of sectors to which such users may belong is contained in enclosure A.

4. In light of the studies commissioned on national and international standards for the identification of small, medium and large entities and on contribution rates, including implications for revenue generation and economic competitiveness, the COP at its seventeenth meeting will establish thresholds and contribution rates, and keep these periodically under review thereafter.

f) Para 6 of the Annex of CBD/COP/DEC/16/2 (Accepted)

6. All users of digital sequence information on genetic resources should share non-monetary benefits in a fair and equitable manner, as appropriate. Non- monetary benefit-sharing is complementary to the provisions regarding monetary benefit-sharing included in these modalities

g) Para 7 of Annex of CBD/COP/DEC/16/2 (Accepted)

7. Non-monetary benefit-sharing should support self- identified capacity and technical development needs and priorities including, inter alia, capacity building for the generation of, access to and use and storage of digital sequence information on genetic resources.

h) Para 10(b) of the Annex of CBD/COP/DEC/16/2 (Accepted)

10. Entities operating databases, and tools and models dependent on digital sequence information on genetic resources, that make digital sequence information on genetic resources publicly available should:

1. (b) Inform those submitting data of the requirement to comply with applicable national and international access and benefit-sharing obligations;

i) Para 10 (c) of the Annex CBD/COP/DEC/16/2 (Accepted)

10. Entities operating databases, and tools and models dependent on digital sequence information on genetic resources, that make digital sequence information on genetic resources publicly available should:

(c) Require the provision of information on the country of origin of the genetic resources from which digital sequence information was derived, where known, as well as, when appropriate, metadata associated with the genetic resources from which the digital sequence information was derived, including indicating the use of traditional knowledge associated with genetic resources and its origin or source

j) Para 11 of the Annex of CBD/COP/DEC/16/2 (Accepted)

11. Parties funding, sponsoring or hosting sequence databases should ensure that entities operating such databases take measures to ensure the effective implementation of the present decision and other relevant future decisions of the Conference of the Parties

k) Para 12 of the Annex CBD/COP/DEC/16/2 (Accepted)

12. Other Governments funding, sponsoring or hosting sequence databases are encouraged to ensure that entities operating such databases will take measures to ensure the effective implementation of the present decision and other relevant future decisions of the Conference of the Parties.

l) Para 13 of the Annex of CBD/COP/DEC/16/2 (Accepted)

13. Parties and non-Parties are invited to take administrative, policy or legislative measures, consistent with national legislation, to incentivise contributions from users in their jurisdiction to the global fund in line with the modalities of the multilateral mechanism.

m) Page 4, para 14 of the Annex (Accepted)

14. Contributions to the global fund are expected to be made directly but may be made through a national authority. Receipts will be issued at the point of contribution to the global fund.

n) Para 15 of the Annex of CBD/COP/DEC/16/2 (Accepted)

15. For each year that users make monetary contributions to the fund in line with the modalities of the multilateral mechanism, they are considered to have fairly and equitably shared monetary benefits arising from the use of digital sequence information on genetic resources under the multilateral mechanism and will receive a certificate accordingly. Such a certificate excludes the user from any expectation to share further monetary benefits from the use of digital sequence information on genetic resources within the scope of the multilateral mechanism for that year.

o) Para 19 of the Annex of CBD/COP/DEC/16/2 (Accepted)

19.Funding will be allocated taking into account the overall level of funding available in the global fund and an indicative list of criteria, as set out in enclosure B. A formula will be determined by the Conference of the Parties at its seventeenth meeting on the basis of the work of a group established with the terms of reference provided in enclosure C.

p) Para 20 of the Annex of CBD/COP/DEC/16/2 (Accepted)

20. Funding to Parties will be disbursed through direct allocations to countries, as described in paragraph 21. Each recipient Party is invited to designate or establish, as appropriate, a national entity, such as a national biodiversity fund, to receive funds and to distribute them in a transparent way to support the activities described in paragraph 18. Such entities may allocate resources on the basis of projects developed though a country-driven or community- driven process and should be accountable for ensuring the funds are used for the self-identified purposes for which they are distributed in a transparent manner. They should operate according to internationally accepted fiduciary standards, and provide reports on the activities undertaken by the fund and their impacts.

q) Para 21 of the Annex of CBD/COP/DEC/16/2 (Accepted)

21. Where appropriate and subject to national circumstances, at least half of the funding of the global fund should support the self-identified needs of indigenous peoples and local communities, including women and youth within those communities, through government or by direct payments through institutions identified by indigenous peoples and local communities.

r) Para 23 of the Annex of CBD/COP/DEC/16/2 (Accepted)

23. The fund will be administered by the United Nations through the United Nations Multi-Partner Trust Fund Office, in accordance with decisions of the COP, and under the authority of and accountable to the COP.

s) Para 26 of the Annex of CBD/COP/DEC/16/2 (Accepted)

26. Without prejudice to national access and benefit sharing measures, where Parties put in place national measures on access and benefit-sharing from digital sequence information on genetic resources, they are invited to align them with the multilateral mechanism, such that there is no duplication of expectations to share the benefits arising from the use of digital sequence information on genetic resources under the multilateral mechanism.

t) Para 28 of the Annex of CBD/COP/DEC/16/2 (Accepted)

28. The multilateral mechanism, including the global fund, will operate under the authority and guidance of and be accountable to the COP. To support the COP in its role as the governing body of the mechanism, a steering committee is established with the terms of reference and composition in enclosure D, under the guidance of the COP. A Secretariat with the terms of reference in enclosure E is established to serve the steering committee and to support the functioning of the mechanism. The operations of the multilateral mechanism will be financed by the global fund.

u) U. Enclosure B of CBD/COP/DEC/16/2 (Accepted)

"level of development deleted"

Biodiversity richness, and other biodiversity-related criteria for which data is readily available at the national level.

The geographical origin of the genetic resources from which digital sequence information in the database was derived (noting that this data is currently often incomplete or unrepresentative).

Capacity needs for the conservation and sustainable use of biodiversity, taking into account the circumstances of developing countries, in particular the least developed countries and small island developing States and those with economies in transition, and of indigenous peoples and local communities.

Further, India insisted on including national obligations on access and benefit sharing in

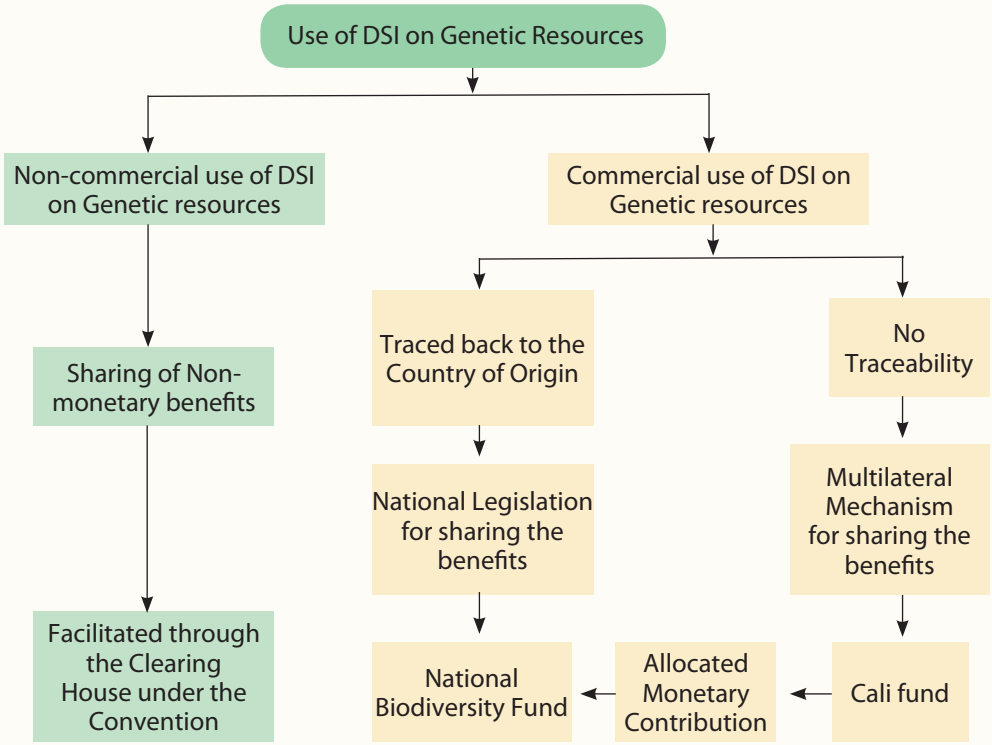
Para 1 (c) of the Annex

1(c) For which the fair and equitable sharing of benefits on the use of digital sequence information on genetic resources is not provided for by other international agreements or national obligations on access and benefit sharing, except if those instruments choose the multilateral mechanism for that purpose.

Presidential acceptance: India's intervention was considered and was accepted to be incorporated in the Para-1 of the Annex: 1. The multilateral mechanism for the fair and equitable sharing of benefits from the use of digital sequence information on genetic resources covers without prejudice to national legislation digital sequence information on genetic resources.

Box - 6

India's perspective of sharing of benefits from the use of DSI on genetic resources in a nut shell.



Chapter - V

Progress made Post-Decision 16/2- Digital Sequence Information (DSI) on genetic resources

The CBD, after adopting the decision on DSI on genetic resources at the sixteenth meeting of the Conference of Parties (CoP-16) *vide* CoP Decision 16/2 also adopted the modalities for operationalizing the multilateral mechanism, including the global fund, which is set out in the annex to the decision 16/2. Additionally, a set of intersessional work was put forth.

In this regard, CBD requested the National Focal Points of the Parties to submit views or information on the following issues:

i. views on possible additional modalities of the multilateral mechanism, including, in the context of paragraph 7 of decision 15/9 and the annex to decision 16/2, to take products and services into account; *vide CBD notification 2024-114*

ii. views on possible new tools and models, such as databases, for making digital sequence information on genetic resources publicly available and accessible in a transparent and accountable manner to all Parties *vide CBD notification 2024-115*

iii. information on national, regional or international standards on thresholds determining small, medium and large entities *vide CBD notification 2024-116*

To this, NBA constituted sub-committees of the Expert Committee on DSI to deliberate on the issues mentioned above and provide reports. The sub-committees submitted the reports/Minutes, which were examined and elaborated.

5.1 India's views on possible additional modalities of the multilateral mechanism, including, in the context of paragraph 7 of decision 15/9 and the annex to decision 16/2, to take products and services into account

The proposed modalities of the multilateral mechanism as provided under 16/2 for the use of DSI are intended to cover:

a) Digital sequence information (DSI) that has been made publicly available.

b) DSI that is not subject to mutually agreed terms.

c) DSI for which benefit-sharing is not provided under other international instruments on access and benefit-sharing.

The decision 16/2 (Paragraph 3) could also garner international consensus for including products and services within the scope of the multilateral mechanism. While this decision represents a significant step forward in achieving the CBD's objectives, the complexities inherent in its implementation, particularly concerning the inclusion of products and services within the scope of the multilateral mechanism, necessitate a deeper and more nuanced understanding. This report argues for the critical need for a dedicated, in-depth study to be commissioned by the CBD. Such a study is essential to explore additional modalities for DSI benefit-sharing, address stakeholder concerns, and provide a robust foundation for effective implementation. Furthermore, it emphasize the importance of allowing sufficient time for national stakeholder engagement to ensure inclusivity and well-informed decision-making.

5.1.1 The COP16 Decision: Operationalizing Benefit-Sharing for DSI:

COP16's decision to include products and services within the scope of the multilateral mechanism reflects a growing recognition of the pervasive role of DSI in modern research, development, and innovation. DSI, is now fundamental to a wide range of sectors, including pharmaceuticals, biotechnology, agriculture, and cosmetics. By extending the benefit-sharing mechanism to products and services, the CBD seeks to ensure that the benefits derived from the commercial use of DSI across various sectors are shared equitably. This approach upholds the principle of fair and equitable benefit-sharing, reinforcing the CBD's commitment to ensuring that the utilization of genetic resources benefits all stakeholders. Additionally, it generates resources that can support conservation efforts and the sustainable use of biological diversity. These resources can also be directed to provider countries and Indigenous Peoples and Local Communities (IPLCs), recognizing their contributions and ensuring they receive fair compensation. Overall, this expansion strengthens the CBD's objectives by fostering greater equity, sustainability, and inclusivity in the management of genetic resources.

5.1.2 Challenges and Complexities in Implementation:

While the COP16 decision sets a clear direction, its practical implementation is fraught with challenges and complexities. These challenges necessitate further exploration and analysis to ensure that the multilateral mechanism is effective, efficient, and equitable. Key challenges include:

i. Definition Refinement:

To date there has been little explicit basis for a definition of DSI. The term 'Digital Sequence Information' appears to be largely limited to the CBD process, being brought into the mainstream of discussion in CBD COP decision XIII/16. COP decision XIV/2037 notes "the term "digital sequence information" may not be the most appropriate term, and ... it is used as a placeholder until an alternative term is agreed". The WHO PIP framework is discussing the issue under the terms 'genetic sequences' and 'genetic sequence data' (GSD) and 'Digital Sequence Data'. The ITPGRFA has used both DSI and 'Genomic Information 'and the UNCLOS process on BBNJ is using 'genetic sequence data', 'digital sequence data' and *in silico*. Other terms used in various sectors include genetic sequence data, genetic sequences, genetic sequence information, genetic resource sequence data, digital sequence data, genetic information, dematerialized genetic resources, intangible genetic resources, *in silico* utilization, information on nucleic acid sequences, nucleic acid information, nucleotide sequence data, natural information and sequences; while the term 'DSI' is used in CBD discussions it is not used anywhere else, at least in the scientific world, and the CBD process has not so far defined it. It needs elaboration that what types of digital sequences are included? (e.g. raw sequencing reads, assembled genomes, functional annotations, protein structures derived from sequences, etc. Since the DSI and the nature of technology will span various sectors, its definition is critical, and the definition will drive the MLM process.

ii. Defining the Scope of Products and Services:

A key challenge is determining the range of products and services covered by the mechanism. Should it be limited to those that explicitly contain DSI, or should it take a broader approach, including a wider set of products and services developed using DSI? A narrower focus could provide a more precise framework, targeting direct DSI use. However, it poses significant difficulties in tracking and tracing DSI within products, a process that is technologically intricate and costly. On the other hand, a broader approach may be easier to implement but requires agreement on the specific products, services, or sub-sectors to be included, making it a complex and politically sensitive issue.

iii. Tracking and Tracing DSI in Products:

If the mechanism targets products and services that contain DSI, establishing efficient tracking and tracing systems becomes essential. This raises concerns about the feasibility, cost, and administrative burden of implementing such systems. Additionally, there are questions about their potential impact on research and innovation, as they could increase costs and introduce regulatory challenges.

iv. Benefit-Sharing Modalities:

The following parameters would need consideration:

a. **Financial Contributions:** Clarification is required on what are the specific events or milestones that would trigger a financial contribution to the MLM (e.g. commercialization of a product, patent application including research grants, high-revenue sales, etc.).

b. **Contribution Rates:** More clarity is required on the indicative rate of payment of 1 per cent of the profits or 0.1 per cent of their revenue as the benefit sharing from the use of DSI. There is a need for elaboration in the context of a tiered systems based on company size, product type, geographical location etc.

c. **Collection Mechanism:** There is a need for elaborating on the collection mechanism i.e. How will these contributions be collected efficiently (while encouraging national research and local industry development) and transparently? (e.g. a centralized international fund, existing national collection mechanisms, or individual payments, etc.)

d. **Non-Monetary Benefits:** The decision 16/2 states that "*Non-monetary benefit-sharing should support self-identified capacity and technical development needs and priorities, including capacity-building for the generation of, access to and use and storage of digital sequence information on genetic resources, as well as the self-identified needs of indigenous peoples and local communities, including women and youth within those communities. The sharing of non-monetary benefits builds on ongoing activities and will be facilitated through the long-term strategic framework for capacity-building and development of the Convention on Biological Diversity and its mechanism to strengthen technical and scientific cooperation in support of the Kunming-Montreal Global Biodiversity Framework*".

Further, more clarity is required on the basis of development in different sectors and for the following:

1. **Technology Transfer:** Specific mechanisms to facilitate the transfer of relevant technologies to developing countries, ensuring they have the capacity to use and benefit from DSI.
2. **Capacity Building:** Target programs to enhance scientific and technical capacity in developing countries, enabling them to generate, analyze, and utilize DSI including training programs, access to equipment, and support for research institutions.

3. **Data Sharing Platforms:** Develop user-friendly platforms that allow for the equitable access and sharing of DSI, particularly for researchers in developing countries.
4. **Joint Research:** Promote collaborative research projects involving researchers from both developed and developing countries, focusing on biodiversity conservation and sustainable use.

v. Attribution and Causation:

Creating a clear and verifiable connection between specific DSI and particular products or services is inherently challenging. This difficulty in attribution can lead to legal complexities, making it harder to determine who should contribute to the benefit-sharing mechanism and how benefits should be allocated. Additionally, it raises concerns about the potential for disputes and litigation. As both a user and provider of DSI, this issue is particularly significant for India, requiring careful consideration in policy and regulatory frameworks.

vi. Implementation and Enforcement:

The successful execution of benefit-sharing mechanisms for products and services depends on strong legal frameworks, efficient administrative structures, and effective enforcement at both national and international levels. This entails establishing clear regulations and procedures, implementing monitoring systems, and ensuring the capacity to address non-compliance. Understanding the implications for national governments in developing these implementation structures is crucial.

vii. Potential Impacts on Research and Innovation:

Benefit-sharing mechanisms must be designed carefully to avoid unintentionally obstructing research, development, and innovation. Achieving a balance between fair and equitable benefit-sharing and fostering scientific progress presents a significant challenge. Overly complex or burdensome mechanisms risk discouraging research and development, especially in developing countries. For a country like India, where both equitable benefit-sharing and increased research using DSI are vital, it is essential to develop a framework that supports both objectives without creating unnecessary barriers. While ensuring that India captures the maximum benefit-sharing potential, it is equally important to safeguard the interests of its industries and research institutions. Greater clarity is needed on the inclusion of products and services to prevent excessive regulatory burdens that could undermine innovation and industrial growth.

5.1.3 Key Challenges and Considerations

The proposed multilateral mechanism faces several fundamental challenges that must be addressed to ensure its effectiveness.

i. A key issue is conceptual ambiguity, as the lack of clear definitions for core criteria and options has led to differing stakeholder interpretations, creating uncertainty and slowing progress.

ii. Additionally, evaluating the mechanism's effectiveness presents a major hurdle, as there are no standardized methodologies to assess whether it truly upholds principles of fairness, equity, and efficiency.

This lack of clarity raises concerns about accountability and evidence-based decision-making. Furthermore, stakeholder alignment remains a significant challenge, with diverse actors holding competing interests and priorities, making consensus-building difficult. Given these foundational challenges, the inclusion of products and services - while crucial for a comprehensive benefit-sharing framework - requires detailed and careful consideration to ensure that its implementation does not further exacerbate existing complexities.

5.1.4 Limitations of existing studies and the need for further investigation and study:

While past studies have provided valuable insights into DSI benefit-sharing, they have not sufficiently addressed the complexities of including products and services within the mechanism. This gap highlights the need for a dedicated, in-depth study to offer clarity and guidance for implementing the COP16 decision.

One of the key limitations is the generalized focus of existing studies, which have largely examined DSI benefit-sharing at a broad level, assessing various modalities and their potential impacts. However, they often fail to provide a detailed analysis of the specific challenges and implications of including products and services in the mechanism. This omission is significant because the inclusion of products and services introduces additional layers of complexity, such as determining which products and services should be covered, how to track and attribute DSI within them, and how to ensure equitable benefit-sharing without stifling innovation and industry growth. Without a focused study that directly addresses these issues, there remains a critical gap in understanding how the integration of products and services will function in practice, making it difficult to develop a robust and workable framework.

Another major concern is stakeholder disagreement and divergent interpretations regarding the inclusion of products and services in the benefit-sharing mechanism.

Surveys conducted in previous studies have revealed significant differences in how stakeholders perceive key criteria such as "efficiency," "feasibility," and "practicality" in the context of incorporating products and services. Some stakeholders worry that tracking and tracing DSI within final products could be overly complex and costly, while others question the administrative burden and legal implications of broadening the scope of benefit-sharing. Additionally, concerns persist about how to measure and assess the contribution of DSI within products and services, which directly impacts how benefits should be distributed. These uncertainties highlight the urgent need for further dialogue and research to establish a shared understanding and facilitate consensus on whether and how products and services should be integrated into the multilateral mechanism.

Given the limitations of existing work and the complexities inherent in implementing the COP16 decision, a commissioned study by the Indian government and the CBD is not merely desirable but essential. The study should conduct a comprehensive analysis of the potential impacts of different modalities for including products and services in the benefit-sharing mechanism, ensuring that all relevant stakeholders are considered. For researchers, it is essential to assess how such inclusion might affect scientific research, innovation, and data-sharing practices, including potential constraints or incentives for open access and collaboration. For industries, particularly in pharmaceuticals, biotechnology, and agriculture, the study should examine the regulatory, economic, and market implications, assessing potential compliance costs and competitiveness. Provider countries, which supply genetic resources and DSI, need a thorough evaluation of both potential benefits and administrative challenges that could arise from the implementation of new modalities. Similarly, the study should evaluate the impacts on Indigenous Peoples and Local Communities (IPLCs), ensuring that their rights, interests, and traditional knowledge are adequately recognized and protected. A balanced approach is necessary to consider both positive and negative outcomes, potential trade-offs, and the broader economic, social, and environmental consequences. This will help provide evidence-based recommendations that ensure the mechanism is equitable, practical, and minimizes unintended disruptions across different stakeholder groups.

The study must incorporate broad stakeholder engagement, including governments, industry representatives, researchers, Indigenous Peoples and Local Communities (IPLCs), and civil society organizations, to ensure diverse perspectives are considered. It should include in-depth case studies to analyze the practical implications of different approaches in real-world contexts. A rigorous economic assessment is essential to evaluate costs, revenue potential, and distributional effects, ensuring equitable and efficient outcomes. Additionally, a comprehensive legal analysis should examine the compatibility of proposed mechanisms with existing international frameworks, including intellectual property, trade, and

human rights obligations. By integrating these elements, the study can provide a well-rounded, practical, and legally sound foundation for effective policy recommendations. To avoid redundancy, the study should build upon existing research by identifying knowledge gaps and focusing on areas that provide new insights and added value. Additionally, it must define clear objectives and collaborate with ongoing initiatives to ensure coordination, minimize duplication, and enhance synergies.

5.1.5 The Strategic Importance of National Stakeholder Engagement:

While advocating for a comprehensive India study as well as CBD-commissioned study, India emphasizes the necessity of sufficient time for national stakeholder engagement as a complementary and essential component of an effective process. Meaningful national consultations enable countries to gather diverse perspectives, consider national circumstances, and submit well-informed positions to the CBD. Although the CBD's 3-month timeframe is appreciated, it may be inadequate for conducting in-depth consultations, making it crucial to propose an extension to ensure all voices are heard. A phased approach could be adopted, where initial views are submitted within the 3-month period, highlighting key priorities while stressing the need for further engagement. Once the CBD study is available, countries should be given additional time to conduct comprehensive national consultations, ensuring a more inclusive and well-informed decision-making process.

5.2 India's views on possible new tools and models, such as databases, for making DSI on genetic resources publicly available and accessible in a transparent and accountable manner to all Parties

The following additional points need consideration:

a) DSI Registration Platforms

A global registration platform could be developed where researchers and companies would be required to register obtain an ID. This BIO-ID will be a free, unique and persistent identifier for individuals who aim to submit data derived from genetic resources, access DSI for innovation, education, capacity building and research activities including knowledge (publishing research papers) and generation of technology with potential to commercialize. BIO-ID could be used in all downstream activities such as funding documents, publications, education, training, commercialization, etc.

b) Integrated ABS-compliant databases

This integrated database could be developed to link DSI to national access and benefit-sharing frameworks. These databases would provide metadata about the genetic resources, including information on the origin, prior informed consent (PIC), and mutually agreed terms (MAT) for the use of genetic resources. This will eventually allow countries to verify whether the genetic resource was accessed according to the Nagoya Protocol and also ensure that data on genetic resources is traceable back to the countries or communities that provided it.

c) Parties may be encouraged to develop their own DSI database

This may be linked to International Nucleotide Sequence Database Collaboration (INSDC) in a replicative or non-replicative manner. A decentralized set up of databases may increase trust in the Multilateral mechanism (MLM) and provide opportunities to Parties developing innovative mechanisms that help MLM succeed.

d) Real-Time Tracking of DSI Use

These databases could be designed to not only house sequence data but also track where and how genetic resources are being used, whether for research, development, or commercialization. They could be integrated with global systems like the INSDC and include tools for tracking transactions (such as licensing agreements or benefit-sharing contributions) associated with genetic data.

e) A more advanced and innovative solution could involve the use of block chain technology combined with smart contracts. Such a system could enforce ABS terms by embedding conditions directly into the block chain when DSI is uploaded to a database. This could include conditions for benefit-sharing agreements, licensing, and profit/revenue sharing, and would ensure compliance.

f) INSDC databases may develop a dedicated webpage that has, in simple and clear language, the following:

i. Dos and Don'ts of DSI access
ii. Obligations of the DSI user
iii. Exact procedures of shifting from non-commercial to commercial user

g) Artificial Intelligence (AI) tools may be explored to facilitate awareness, education, access and benefit sharing related to DSI. Additionally, AI tools may also be explored to assist in harmonizing compliance and avoid leakage across CBD, ITPGRFA, WHO Pandemic Agreement (proposed), BBNJ agreement, etc.

h) **Further, the Para 8 of the Annex to decision 16/2 states that**

The sharing of non-monetary benefits will be facilitated through an existing clearing-house under the Convention, which will primarily provide information on demand for capacity-building needs, knowledge exchange and the showcasing and reporting of ongoing non-monetary benefit-sharing activities.

In this regard, India is of the view that there should be interlinkages between the databases that house the DSI and the clearing-house under the convention for effective implementation of the MLM with respect to both monetary and non-monetary benefits.

5.2.1 Conclusion

The evolving landscape of DSI, coupled with the need for fair and equitable benefit-sharing mechanisms, calls for the development of new approaches and modalities. These databases should be designed to ensure that the information on genetic resources are publicly available and accessible in a transparent and accountable manner to all Parties while also ensuring compliance with the Nagoya Protocol. In this regard, there is a need of integrating the databases with the national ABS framework and/or parties may be encouraged to develop their own database which may be linked to the INSDC.

Finally, the goal is to develop systems that balance openness, transparency, and innovation with equity, accountability, and respect for traditional knowledge and rights.

5.3 India's views on the national standards for the identification of small, medium and large entities

5.3.1 Introduction

The Conference of the Parties, in the annex to decision 16/2, included thresholds for contributions to the Cali Fund for the entities that are users of DSI on genetic resources in sectors that directly or indirectly benefit from its use in their commercial activities.

The paragraph 3 of the annex to decision 16/2 states that

Users of digital sequence information on genetic resources in sectors that directly or indirectly benefit from its use in their commercial activities should contribute a proportion of their profits or revenue to the global fund, according to their size. Having regard to paragraph 13, entities that, on their balance sheet dates, exceed at least two out of three of thresholds (namely, total assets: 20 million United States dollars, sales: 50 million dollars, and profit: 5 million dollars) averaged over the preceding three years

should contribute to the global fund 1 per cent of their profits or 0.1 per cent of their revenue, as an indicative rate. An indicative list of sectors to which such users may belong is contained in Enclosure I.

Enclosure I

Indicative list of sectors that may benefit directly or indirectly from the use of digital sequence information on genetic resources;

1. Sectors that may benefit directly or indirectly from the use of digital sequence information on genetic resources include:

a) Pharmaceuticals;

b) Nutraceuticals (food and health supplements);

c) Cosmetics;

d) Animal and plant breeding;

e) Biotechnology;

f) Laboratory equipment associated with the sequencing and use of digital sequence information on genetic resources, including reagents and supplies;

g) Information, scientific and technical services related to digital sequence information on genetic resources, including artificial intelligence.

The classification of small, medium, and large entities plays a crucial role in the equitable benefit-sharing of DSI, particularly under the CBD.

In this regard, the national standards for the identification of small, medium and large entities in India are categorized as the Micro, Small, and Medium Enterprises based on the enactment of the Micro, Small and Medium Enterprises Development (MSMED) Act in 2006. This Act provided clear definitions for micro, small, and medium enterprises based on their investment in plant and machinery or equipment, for the manufacturing and enterprises rendering services. As per the latest classification (from April 2025), the following is the categorization:

	Investment not more than:		**Annual Turnover, not more than:**	
	Indian Rupees	USD (@ Rs 85.81)	Indian Rupees	USD (@ Rs 85.81)
Micro	2.5 crore	291,342	10 crore	1.2 million
Small	25 crore	2.9 million	100 crore	11.6 million
Medium	125 crore	14.6 million	500 crore	58.3 million
Large	>125 crore	>14.6 million	> 500 crore	>58.3 million

Additionally, the Biological Diversity Act, 2002 is a legislation enacted by the Government of India to conserve the country's rich biological resources, ensure their sustainable use, and promote fair and equitable sharing of benefits arising from their utilization. The Act was formulated in response to India's international obligations under the CBD. Recognizing India's vast and diverse biological wealth, as well as the deep traditional knowledge held by its indigenous communities, the Act seeks to prevent bio piracy and unauthorized exploitation of genetic resources. It establishes a three-tier institutional structure comprising the National Biodiversity Authority (NBA) at the central level, State Biodiversity Boards (SBBs) at the state level, and Biodiversity Management Committees (BMCs) at the local level. These bodies are responsible for regulating access to biological resources, advising governments, and ensuring that benefits from the use of these resources are shared with the local communities that have traditionally conserved and used them.

In this regard, the Access and Benefit Sharing (ABS) Regulation, 2014 was introduced by the National Biodiversity Authority (NBA) under the provisions of the Biological Diversity Act, 2002, to operationalize India's commitments under the Convention on Biological Diversity (CBD) and the Nagoya Protocol. This regulation aims to ensure that benefits arising from the use of India's biological resources and associated traditional knowledge are shared fairly and equitably with the local communities and knowledge holders who are the custodians of this biodiversity.

The ABS Regulation mandates that any foreign individual, company, or non-resident Indian must obtain prior approval from the NBA before accessing biological resources or traditional knowledge from India. Additionally, it requires Indian entities to share benefits if the resources are used for commercial purposes. These benefits can be monetary-such as royalties, license fees, upfront payments, non-monetary- such as technology transfer, training, or infrastructure support.

The Regulation 4 of the ABS Regulations 2014 states that

When the biological resources are accessed for commercial utilization or the bio-survey and bio-utilization leads to commercial utilization, the applicant shall have the option to pay the benefit sharing ranging from 0.1 to 0.5 % at the following graded percentages of the annual gross ex-factory sale of the product which shall

be worked out based on the annual gross ex-factory sale minus government taxes as given below:

Annual Gross ex-factory sale of product		Benefit-sharing component
Indian Rupees	**USD (@ Rs 85.81)**	
Up to 1 crore	Up to 116,536	0.1%
Above 1 crore to 3 crore	116,537 up to 349,610	0.2%
Above 3 crore	Above 349,610	0.5%

India has recently amended the Act through the Biological Diversity (Amendment) Act 2023 to promote ease of doing business for domestic companies. In this regard, the amendment to the ABS Regulations *viz* Regulation 4 of the ABS Regulation 2025 states that:

Regulation 4: When the biological resource including digital sequence information or knowledge associated thereto, is accessed for commercial utilisation, the applicant shall have to pay benefit sharing amount as per the table given below:

Sl No.	Annual turnover of the person		Amount payable on account of Benefit- sharing for access to biological resources for commercial utilization [Percentage of annual gross ex-factory sale price of the product excluding Government taxes]
	in Indian rupee	In USD (@ Rs 85.81)	
1	Up to 5 crore	Up to 591,685	Nil
2	Above 5 crore to 50 crore	591,685-5.92 millions	0.2%
3	Above 50 crore to 250 crore	5.93 millions- 29.6 millions	0.4%
4	Above 250 crore	Above 29.6 millions	0.6%

India is of the view that the monetary benefits in the context of the biological resources is based on the sale of the products as it can be traced back. However, the scenario in the case of DSI is different, and India supports the decision that DSI on genetic resources in sectors that directly or indirectly benefit from its use in their commercial activities should contribute a proportion of their profits or revenue to the global fund, according to their size or turnover.

However, a major challenge in the DSI benefit-sharing system is tracking and enforcing obligations where companies and researchers freely access open genetic databases. For instance, startups and university spin-offs, though classified as small entities may be backed up by large multinational corporations. In this regard, strengthening of legal frameworks, ensuring corporate accountability, and promoting international harmonization are necessary steps to achieve fair and equitable benefit-sharing.

To conclude, benefit-sharing in the context of DSI can be categorized based on both products and turnover. Entities using DSI for commercial applications from sectors such as pharmaceuticals, biotech, cosmetics and agriculture typically have higher financial obligations. Additionally, classification by turnover ensures that large corporations contribute more, while small and academic institutions receive exemptions or reduced financial obligations. This tiered approach helps balance innovation with fair and equitable benefit-sharing.


Dr. Rajesh Kumar

Chapter - VI

DSI in other International Fora

6.1 ITPGRFA

The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), in force since 2004 with over 150 member countries, aims to ensure the conservation, sustainable use, and fair and equitable sharing of benefits arising from plant genetic resources for food and agriculture (PGRFA). Its core feature is the Multilateral System (MLS), which facilitates access to 64 key crops and forages through a Standard Material Transfer Agreement (SMTA).

However, since 2019, negotiations to enhance the MLS—by expanding crop coverage and revising benefit-sharing mechanisms—have stalled, largely due to disagreements over how to handle DSI.

Within the ITPGRFA, negotiations remain deadlocked, with provider countries (mostly from the Global South) advocating for benefit-sharing from DSI use and user countries (largely from the Global North) expressing concerns about limiting open access to sequence databases.

The Eleventh Session of the Governing Body of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), held in Lima in November 2025, constituted an important moment in ongoing deliberations on strengthening the Treaty's MLS and addressing emerging issues such as Digital Sequence Information (DSI), but did not result in definitive outcomes on these matters.

The Governing Body considered the enhancement of the functioning of the MLS on the basis of extensive intersessional work undertaken by the Ad Hoc Open-ended Working Group. While acknowledging the substantial progress made and the recommendations presented, Parties were unable to reach consensus on a package of measures. Efforts to bridge differences included informal consultations and the development of a Chair's compromise proposal outlining possible intersessional processes and issues for further consideration. The Governing Body ultimately took note of this proposal, without adopting a decision to finalize or implement MLS enhancement at this stage.

With regard to DSI, the Governing Body considered the issue in the context of the Treaty's objectives and adopted a dedicated resolution. However, discussions did not lead to an agreed substantive approach on how DSI should be governed within the Treaty framework. Instead, the decision reflects a continued process of

consideration, indicating that the issue remains under deliberation and subject to further work in future sessions.

Overall, the session highlighted both the central importance of the MLS to the Treaty's functioning and the complexity of achieving consensus on its enhancement, particularly in light of evolving scientific and policy developments such as DSI. The Governing Body adopted a pragmatic approach, advancing ongoing work through resolutions and intersessional processes while deferring key unresolved issues for future consideration.

6.2 Pandemic Influenza Preparedness (PIP) Framework

The Pandemic Influenza Preparedness (PIP) Framework, adopted by the World Health Assembly in 2011, is a global system designed to improve the sharing of influenza viruses with human pandemic potential and to ensure equitable access to benefits such as vaccines, antivirals, and diagnostics. The WHO PIP Framework uses the term genetic sequence data, and defines genetic sequences as: "The order of nucleotides found in a molecule of DNA or RNA containing the genetic information that determines the biological characteristics of an organism or a virus" [39]. This term is also used by the Global Initiative on Sharing All Influenza Data (GISAID), that acts as the main collection of genetic sequence data of influenza viruses and related clinical and epidemiological data for the global community. It may be noted that terms more commonly employed by the scientific community and databases include genetic sequence data, nucleotide sequence data, nucleotide sequence information, and genetic sequences. Differences in terminology in scientific circles reflect differences in the material referred to, as well as the speed and transformative nature of technological change today, which make it difficult to harmonize terminology.

In ABS policy discussions, differences in terminology often reflect divergent views of what falls within the scope of the Nagoya Protocol and national laws [40]. The WHO PIP Framework operates on a virus-sharing and benefit-sharing model, specifically for influenza, with the Global Influenza Surveillance and Response System (GISRS) as its backbone.

Providers: The main providers of GSD from influenza viruses are GISRS laboratories. Other providers include national public health laboratories and public and private laboratories that may sequence influenza viruses. GSD can be uploaded to one or more databases by the sequencing laboratory.

39 A Fact Finding and Scoping Study on Digital Sequence Information on Genetic Resources in the Context of the Convention on Biological Diversity and Nagoya Protocol Technical Report · January 2018, https://www.researchgate.net/publication/321005788_A_Fact_Finding_and_Scoping_Study_on_Digital_Sequence_Information_on_Genetic_Resources_in_the_Context_of_the_Convention_on_Biological_Diversity_and_Nagoya_Protocol (last accessed 16 September 2021)

40 A Fact Finding and Scoping Study on Digital Sequence Information on Genetic Resources in the Context of the Convention on Biological Diversity and Nagoya Protocol Technical Report · January 2018, https://www.researchgate.net/publication/321005788_A_Fact_Finding_and_Scoping_Study_on_Digital_Sequence_Information_on_Genetic_Resources_in_the_Context_of_the_Convention_on_Biological_Diversity_and_Nagoya_Protocol (last accessed 16 September 2021)

Users: GISRS laboratories, academia and industry are the main influenza GSD users. They generally use the data to conduct risk assessment and monitor the emergence and evolution of influenza viruses; develop diagnostics; generate candidate vaccine viruses; and produce new types of vaccines such as recombinant vaccine and vaccines using synthetic candidate vaccine viruses.

The Framework mandates the sharing of physical virus samples but does not explicitly regulate DSI, which has emerged as a significant issue as genomic sequencing has become central to influenza surveillance and research. Over the past few years, discussions have intensified within the World Health Organization (WHO) about whether and how DSI should be incorporated into the PIP Framework's benefit-sharing arrangements.

Many developing countries argue that benefits should be shared not only when physical samples are exchanged but also when DSI derived from those samples is used. As of 2025, the PIP Framework is undergoing a review process, with member states debating potential updates to address DSI governance explicitly.

WHO Pandemic Agreement negotiated in World Health Assembly, WHA78, 2025

WHO Pandemic Agreement was negotiated in WHA78, 2025. Article 12 Pathogen Access and Benefit-Sharing System defines WHO position on ABS under the mechanism. It also acknowledges the deliberations under CBD on the subject.

Article 12 recognizes the sovereign right of States over their biological resources and the importance of collective action to mitigate public health risks, and underscores the importance of promoting the rapid and timely sharing of "materials and sequence information on pathogens with pandemic potential" ("PABS Materials and Sequence Information") and, on an equal footing, the rapid, timely, fair and equitable sharing of benefits arising from the sharing and/or utilization of PABS Materials and Sequence Information for public health purposes.

A multilateral system for safe, transparent, and accountable access and benefit-sharing for PABS Materials and Sequence Information, the "WHO Pathogen Access and Benefit-Sharing System" (the "PABS System") is, to be developed. The provisions governing the PABS System, including definitions of pathogens with pandemic potential and PABS Materials and Sequence Information, modalities, legal nature, terms and conditions, and operational dimensions, will be an annex.

Further, having regard to Article 4.4 of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their utilization to the Convention on Biological Diversity (hereinafter the "Nagoya Protocol"), the PABS Instrument shall be consistent with, and not run counter to, the objectives of the Convention on Biological Diversity and the Nagoya Protocol,

The resolution mandates that the PABS Instrument referred to in paragraph 2 of this Article, shall contain provisions regarding, inter alia, the following:

a) the rapid and timely sharing of PABS Materials and Sequence Information and, on an equal footing, the rapid, timely, fair and equitable sharing of benefits, both monetary and non-monetary, including annual monetary contributions, vaccines, therapeutics and diagnostics arising from the sharing and/or utilization of PABS Materials and Sequence Information for public health purposes;

b) modalities, terms and conditions on access and benefit sharing that provide legal certainty;

c) implementation in a manner to strengthen, facilitate and accelerate research and innovation, as well as the fair and equitable sharing and distribution of benefits[41] ;

6.3 World Intellectual Property Organization

The World Intellectual Property Organization (WIPO) has been engaging with the topic of DSI primarily within the broader context of intellectual property (IP), genetic resources, and traditional knowledge. Although WIPO does not directly regulate access and benefit-sharing (ABS) regimes like the CBD or the ITPGRFA, it plays a crucial role in addressing how genetic resources — and increasingly their associated DSI — intersect with intellectual property systems, particularly patent applications.

For over two decades, WIPO's "Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC)" has been negotiating an international legal instrument to address IP-related issues around genetic resources and associated traditional knowledge. The negotiations culminated in the adoption of a "WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge" in May 2024. This treaty requires patent applicants to "disclose the country of origin or source" of genetic resources and, where applicable, associated traditional knowledge when inventions are based on such resources. However, the treaty "does not explicitly define or directly regulate DSI", nor does it establish binding benefit-sharing obligations for DSI use.

Discussions on whether DSI falls within the scope of "genetic resources" under the treaty remain open, and WIPO acknowledges that its work complements but does not duplicate ongoing ABS discussions in other fora like the CBD and the ITPGRFA. As of 2025, WIPO member states continue to monitor and assess how emerging interpretations of DSI in ABS regimes might affect disclosure obligations and IP practices under the new treaty framework.

41 Intergovernmental Negotiating Body to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response; https://apps.who.int/gb/ebwha/pdf_files/WHA78/A78_10-en.pdf

6.4 Biodiversity Beyond National Jurisdiction

The Agreement on Biodiversity Beyond National Jurisdiction (BBNJ), often called the "High Seas Treaty", was formally adopted in June 2023 under the United Nations Convention on the Law of the Sea (UNCLOS). Its goal is to ensure the conservation and sustainable use of marine biodiversity in areas beyond national jurisdiction, which cover nearly half the planet's surface. A key component of the BBNJ Agreement is the governance of marine genetic resources (MGRs), including questions of access and benefit-sharing (ABS).

During the treaty negotiations, "Digital Sequence Information (DSI)" became a major point of contention, mirroring debates seen in other ABS regimes like the CBD and the ITPGRFA. Many developing countries argued that benefit-sharing should apply not only to physical marine genetic resources but also to DSI derived from them. The final BBNJ Agreement acknowledges the importance of DSI but does not establish binding obligations specific to DSI; instead, it mandates that parties continue discussions and develop modalities for benefit-sharing from both physical MGRs and associated DSI.

As of 2025, the BBNJ Agreement is in the signature and ratification phase and has not yet entered into force. Consequently, discussions on how DSI derived from marine genetic resources in areas beyond national jurisdiction might be addressed remain prospective rather than operational. Importantly, the Agreement explicitly calls for mutual supportiveness with other relevant international instruments, notably the Convention on Biological Diversity. In this context, the emergence of a CBD-wide multilateral mechanism for benefit-sharing from the use of DSI under Decision 16/2 is increasingly viewed as the primary global framework that could, in practice, address benefit-sharing concerns related to marine DSI as well.

Chapter - VII

Operationalizing the multilateral mechanism for the fair and equitable sharing of benefits from the use of DSI on genetic resources, including a global fund- Way Forward

At its fifteenth meeting, the Conference of the Parties (COP) to the Convention on Biological Diversity decided to establish (Decision 15/9), as part of the Kunming-Montreal Global Biodiversity Framework, a multilateral mechanism for benefit-sharing from the use of DSI on genetic resources, including a global fund.

At its sixteenth meeting, the Conference of the Parties adopted the modalities for operationalizing the multilateral mechanism, including the global fund (Decision 16/2), which are set out in the annex to the decision, and decided that the global fund will be known as the Cali Fund for the Fair and Equitable Sharing of Benefits from the Use of DSI on Genetic Resources.

While this decision represents a significant step forward in achieving the CBD's objectives, the complexities inherent in its implementation, particularly concerning the inclusion of products and services within the scope of the multilateral mechanism, necessitate a deeper and more nuanced understanding. Though the COP16 decision sets a clear direction, its practical implementation is fraught with challenges and complexities. These challenges necessitate further exploration and analysis to ensure that the multilateral mechanism is effective, efficient, and equitable.

In this regard, the way forward for operationalizing the multilateral mechanism for the fair and equitable sharing of benefits from the use of DSI on genetic resources are as follows:

a) To date, there has been little explicit basis for a definition of DSI. It needs elaboration that what types of digital sequences are included? (e.g., raw sequencing reads, assembled genomes, functional annotations, protein structures derived from sequences, etc.). Since the DSI and the nature of technology will span various sectors, its definition is critical, and will drive the Multilateral mechanism process.

b) The inclusion of products and services introduces additional layers of complexity, such as determining which products and services should be covered, how to track and attribute DSI within them, and how to ensure equitable benefit-sharing without stifling innovation and industry growth.

This calls for a focused nationalized study that directly addresses these issues and provide an understanding of how the integration of products and services will function in practice.

c) The study should also conduct a comprehensive analysis of the potential impacts of different modalities for including products and services in the benefit-sharing mechanism, ensuring that all relevant stakeholders are considered. For researchers, it is essential to assess how such inclusion might affect scientific research, innovation, and data-sharing practices, including potential constraints or incentives for open access and collaboration. For industries, particularly in pharmaceuticals, biotechnology, and agriculture, the study should examine the regulatory, economic, and market implications, assessing potential compliance costs and competitiveness.

d) An integrated database could be developed to link DSI to national access and benefit-sharing frameworks. These databases would provide metadata about the genetic resources, including information on the origin, prior informed consent (PIC), and mutually agreed terms (MAT) for the use of genetic resources.

e) Parties may be encouraged to develop their own DSI database. This may be linked to International Nucleotide Sequence Database Collaboration (INSDC) in a replicative or non-replicative manner.

f) These databases could be designed to not only house sequence data but also track where and how genetic resources are being used, whether for research, development, or commercialization. They could be integrated with global systems like the INSDC and include tools for tracking transactions (such as licensing agreements or benefit-sharing contributions) associated with genetic data.

g) A more advanced and innovative solution could involve the use of block chain technology combined with smart contracts. Such a system could enforce ABS terms by embedding conditions directly into the block chain when DSI is uploaded to a database. This could include conditions for benefit-sharing agreements, licensing, and profit/revenue sharing, and would ensure compliance.

h) Artificial Intelligence (AI) tools may be explored to facilitate awareness, education, access and benefit sharing related to DSI. Additionally, AI tools may also be explored to assist in harmonizing compliance and avoid leakage across CBD, ITPGRFA, WHO Pandemic Agreement (proposed), BBNJ agreement, etc.

i) There should be interlinkages between the databases that house the DSI and the clearing-house under the convention for effective implementation of the MLM with respect to both monetary and non-monetary benefits.

j) The benefit-sharing in the context of DSI can be categorized based on both products and turnover. Entities using DSI for commercial applications from sectors such as pharmaceuticals, biotech, cosmetics and agriculture typically have higher financial obligations. Consequently, classification by turnover ensures that large corporations contribute more, while small and academic institutions receive exemptions or reduced financial obligations. This tiered approach helps balance innovation with fair and equitable benefit-sharing.

Chapter - VIII

Conclusion

Even though the CBD decision 16/2 adopting the initial modalities for operationalizing a multilateral mechanism to share benefits arising from the use of digital sequence information on genetic resources was a landmark move, the modalities adopted are still incomplete, with critical elements of accountability and compliance still missing.

For instance, the term DSI is still a placeholder and not been defined. It needs elaboration that what types of digital sequences are included? (e.g., raw sequencing reads, assembled genomes, functional annotations, protein structures derived from sequences, etc.). Since the DSI and the nature of technology spans across various sectors, its definition is critical, and will drive the multilateral mechanism process.

While this decision 16/2 represents a significant step forward in achieving the CBD's objectives, there are complexities inherent in its implementation, particularly concerning the inclusion of products and services within the scope of the multilateral mechanism. Though this sets a clear direction, it is utmost necessary to further explore and analyze studies in this regard to ensure that the multilateral mechanism is effective, efficient, and equitable. According to CBD Decision 15/9, exceptions to multilateral approaches are also need to be developed.

Additionally, thresholds and rates for monetary contributions to the Cali Fund need to be finalized, along with a fund allocation formula to fairly distribute funds to countries. The focus of additional modalities will be on these elements, as well as improved data governance elements to ensure that, when DSI is made publicly accessible, there is accountability to, and transparency for, all Parties.

Hence, to conclude, achieving the effective implementation of the present decision is still a long way to go.

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