Preliminary Discussion on Digital Sequence Information of Genetic Resources (Postprint)

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Date: 2023-07-26T00:00:00+00:00

Abstract

Digital Sequence Information (DSI) of genetic resources is a product of sequencing technology, encompassing at least sequence information of genetic materials such as DNA and RNA, as well as chemical structure information of natural products. Issues concerning its access and utilization, as well as the resulting benefit-sharing, have become hot topics and focal points in international processes such as the Convention on Biological Diversity (CBD). Since 2016, parties under the Convention on Biological Diversity framework have conducted fruitful discussions on this matter; however, fundamental disagreements persist in areas such as the scope of DSI, its relationship with genetic resources, open access, and monitoring the utilization of DSI. The issue of access to and benefit-sharing from DSI faces multiple challenges, including political contestation, technical obstacles, coordination between national and international law, and synergy among multiple conventions. As a major global provider and user of DSI, China must strengthen relevant work in the following four areas to effectively address the challenges and opportunities arising from DSI access and benefit-sharing: First, strengthen basic research related to DSI, particularly by enhancing interdisciplinary research and conducting pilot demonstrations of benefit-sharing; Second, formulate a management system for bioinformatics data in a timely manner, and systematically construct key institutions for biological resource data classification, submission, sharing, research, utilization, cross-border transfer, and benefit-sharing; Third, accelerate the establishment of an open, secure, shared, and mutually beneficial global infrastructure for biological resource data production and storage, and strengthen international cooperation on biological resource data; Fourth, give full play to the role of inter-departmental coordination mechanisms such as the China National Committee for Biodiversity Conservation, and continuously strengthen synergy and enhanced effectiveness in China's participation in discussions at DSI-related international forums.

Full Text

Preamble

Discussion on Digital Sequence Information on Genetic Resources

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Abstract

Digital sequence information on genetic resources (DSI) is the product of sequencing technologies, encompassing at minimum sequence information from genetic materials such as DNA and RNA, as well as chemical structure information of natural products. Issues surrounding its acquisition and utilization, along with the resulting benefit-sharing, have become hotly debated topics in international processes such as the Convention on Biological Diversity. Since 2016, stakeholders under the CBD framework have engaged in fruitful discussions, yet fundamental disagreements persist regarding DSI's connotation and denotation, its relationship with genetic resources, open access, and monitoring of DSI utilization. DSI access and benefit-sharing face multiple challenges including political contest, technical obstacles, coordination between domestic and international law, and multi-convention synergy. As a major global provider and user of DSI, China must strengthen its efforts in four key areas to effectively address these challenges and opportunities: First, enhance fundamental research on DSI, particularly through interdisciplinary approaches and pilot demonstrations of benefit-sharing; second, timely establish a biological information data management system with comprehensive institutions for classification, submission, sharing, research, utilization, cross-border transmission, and benefit-sharing of biological resource data; third, accelerate the development of open, secure, shared, and reciprocal global infrastructure for biological resource data production and storage while strengthening international cooperation; and fourth, fully leverage cross-departmental coordination mechanisms such as the China National Committee for Biodiversity Conservation to enhance synergies in China's participation in DSI-related international forums.

Keywords: Convention on Biological Diversity, Nagoya Protocol, genetic resources, digital sequence information, access and benefit-sharing

Digital sequence information on genetic resources (DSI) currently lacks a universally accepted definition, but it encompasses at minimum sequence information from DNA, RNA, and other genetic materials, as well as chemical structure information of natural products. DSI represents the product of large-scale sequencing applications, driven by the rapid development of cutting-edge life

sciences such as genomics, proteomics, and metabolomics, and the swift convergence of biological, information, and computer sciences. DSI finds applications across multiple fields including synthetic biology, industrial production, healthcare, and agriculture. From a biodiversity research perspective, it can be used for species description and identification, pest and disease control, early prevention of biological invasions, understanding pollination patterns, monitoring habitat changes, tracking illegal trade, maintaining crop genetic diversity, and responding to health emergencies (Li & Xue, 2019). In healthcare, for instance, synthetic genome technology enables the rapid and accurate synthesis of biologically active influenza viruses using openly accessible DSI (Dormitzer et al., 2013), with these synthetic viruses offering advantages over laboratory-cultured strains in antigenic similarity, stability, and production time, making them more suitable for vaccine manufacturing (Suphaphiphat et al., 2016). As the bio-economy—powered by life sciences and biotechnology—becomes central to future national strategies for science, economy, and security, DSI has emerged as a novel production factor in the bio-industry, making its access, utilization, and benefit-sharing hot-button issues under the Convention on Biological Diversity (CBD).

1. Progress in CBD DSI Consultations

The CBD and its Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization have established an access and benefit-sharing (ABS) regime based on national sovereignty, prior informed consent, and mutually agreed terms for fair benefit-sharing (Xue, 2011; Zhao, 2022). This provides clear international legal grounds for developing countries—typically providers of genetic resources—to protect their resources and share benefits equitably. The advent and large-scale application of sequencing technologies have enabled DSI production and utilization, potentially replacing the need for physical genetic resources. Significant capacity gaps exist between developed and developing countries in DSI production, preservation, research, and commercial development, and open access to DSI may undermine the bilateral ABS mechanism established under the CBD and its Protocol (Zhao et al., 2017; Zhang, 2021; Rohden & Scholz, 2022). At COP13, the CBD Conference of Parties introduced DSI as a cross-cutting issue potentially affecting all three CBD objectives (SCBD, 2016). COP14 mandated the Open-Ended Working Group on the Post-2020 Global Biodiversity Framework (OEWG) to make recommendations to COP15 on addressing DSI within the framework's context (SCBD, 2018). Following OEWG authorization, mechanisms including the Ad Hoc Technical Expert Group on DSI (DSI-AHTEG) and the Informal Advisory Group on DSI (DSI-IAG) were established, enabling formal and informal parallel consultations that culminated in the "Kunming-Montreal Global Biodiversity Framework" (the Framework) and a package of decisions at COP15.2, provisionally resolving DSI disputes.

The COP15.2 decision (CBD/COP/DEC/15/9) established a multilateral mech-

anism for DSI benefit-sharing, including a global fund, as part of the Framework. To further develop and operationalize this mechanism, COP15.2 established an ad hoc open-ended working group on benefit-sharing from DSI use to refine the multilateral mechanism fairly, transparently, inclusively, participatorily, and time-bound before COP16, for adoption at COP16 and review of its effectiveness at COP18. Additionally, COP15.2 identified 16 pressing technical and policy issues requiring short-term research and discussion, including global fund management and contributions, benefit-sharing triggers, capacity building and technology transfer, relationship with the Protocol, and data governance principles.

2. Future DSI Controversies

Despite the political foundation laid by COP15.2 resolutions, the international community must exert greater effort to resolve numerous outstanding technical, policy, and legal issues. These controversies constitute the core of the DSI multilateral mechanism and reflect divergent interests between developed and developing countries.

2.1 Connotation and Denotation of DSI

Scientific research and database industries commonly use terms such as genetic sequence data, nucleotide sequence data, nucleotide sequence information, and genetic sequence (Laird & Wynberg, 2018). Multilateral processes including the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGREA) and WHO's Pandemic Influenza Preparedness Framework (PIP Framework) employ terms like sequence data, resources in silico, digital sequence data, genetic sequence data, and genetic information (Laird & Wynberg, 2018; Houssen et al., 2020; FAO, 2022). The recent UN General Assembly adoption of the Agreement under UNCLOS on Marine Biological Diversity of Areas Beyond National Jurisdiction (BBNJ Agreement) also addresses benefit-sharing of digital sequence information on marine genetic resources (UNGA, 2023). Under the CBD framework, DSI's connotation and denotation are primary concerns for providers and users, as they provide legal certainty for mechanism design and implementation (ICF et al., 2020). However, since 2016, CBD parties have failed to reach consensus on terminology, and COP15.2 retained "DSI" as a placeholder term.

The DSI-AHTEG previously proposed four expert options for DSI scope (SCBD, 2020): (1) DNA and RNA; (2) DNA, RNA, proteins, and epigenetic modifications; (3) DNA, RNA, proteins, epigenetic modifications, metabolites, and other macromolecules; and (4) DNA, RNA, proteins, epigenetic modifications, metabolites, other macromolecules, and other relevant information (e.g., ecological environment information, traditional knowledge). Some argue DSI should include only DNA and RNA to minimize regulation of genetic resource-related data. Others contend it should encompass proteins, epigenetic modifications,

metabolites, macromolecules, and derivatives beyond DNA and RNA. Still others emphasize the need to consider traditional knowledge related to DSI. The choice of scope closely reflects stakeholder interests and has evolved from pure scientific-technical divergence into a matter of interests and positions. This issue's resolution will profoundly impact the operation and effectiveness of the DSI benefit-sharing multilateral mechanism.

2.2 Relationship Between DSI and Genetic Resources

The CBD and its Protocol apply to "genetic resources," defined as "genetic material of actual or potential value," with "genetic material" meaning "any material of plant, animal, microbial or other origin containing functional units of heredity." Some argue that since "genetic resources" are tangible physical materials while DSI is intangible data, DSI does not constitute genetic resources, necessitating CBD/Protocol amendments or a new legally binding instrument specifically for DSI benefit-sharing (Kobayashi, 2019). Others contend that "other origin" may include DSI. Another view holds that while DSI is not "genetic resources," it results from utilization of genetic resources or subsequent applications and commercialization, thus falling under the Protocol's ABS rules requiring prior informed consent and mutually agreed terms for fair benefit-sharing. This debate essentially concerns whether DSI falls under the CBD/Protocol ABS regime, affects the Protocol's effectiveness that developing countries have painstakingly built, and represents a struggle between biodiversity-rich countries and biotech-advanced nations for control over biological information data as a crucial production factor.

2.3 Connotation of Open Access

Open access emerged as a principled consensus on DSI access mechanisms during consultations. The COP15.2 decision adopted the FAIR principles—Findable, Accessible, Interoperable, Reusable—published by FORCE11 (a non-profit organization of scholars, librarians, archivists, publishers, and funders promoting knowledge creation and sharing) and endorsed by international organizations including the Research Data Alliance, International Science Council, and UNESCO. Additionally, the CARE principles (Collective benefit, Authority to control, Responsibility, Ethics) proposed by the Global Indigenous Data Alliance (GIDA) were accepted as FAIR supplements. However, endorsement of these principles may not end open access debates. Biotech-advanced countries with strong DSI storage and analysis capabilities favor unrestricted open access to promote research and international cooperation, maximizing DSI value. Countries with weaker biotech and DSI capacities support open access but argue it does not equal free access and should have rules, standards, and terms. These countries are typically biodiversity-rich genetic resource providers. Some argue strict data access restrictions should be avoided, particularly for public health emergencies, as rapid genome data sharing played a crucial role in COVID-19 response (Harrison et al., 2021). These three perspectives will continue accom-

panying subsequent multilateral mechanism development.

2.4 Monitoring DSI Utilization

Under the CBD/Protocol bilateral ABS mechanism, sharing benefits from DSI utilization requires identifying the DSI's country of origin and the genetic resources from which it was derived. Some argue monitoring DSI access and utilization presents technical challenges, risks unnecessary administrative controls, and is costly. International Nucleotide Sequence Database Collaboration (INSDC) practice shows that monitoring nucleotide sequence data (NSD) utilization through accession numbers (ANs) and digital object identifiers (DOIs) requires providers to report data origin countries and source genetic resources. However, only 6% of INSDC entries have clear links to disclosed genetic resources, and only 16% list origin countries in metadata (Rohden et al., 2020). Given DSI's data and intangible nature, solutions from monitoring physical genetic resources offer little guidance. Since monitoring involves key elements like sovereign interests of resource countries and benefit-sharing from research and commercial development, many countries hope to employ new information technologies like blockchain. Geographic origin labeling and monitoring systems will be further discussed in the ad hoc working group on DSI benefit-sharing.

3.1 The Essence of Scientific-Technical Disputes is Interest-based Contest

Although important controversies including DSI scope and terminology, DSI-genetic resources relationship, open access connotation, and DSI utilization monitoring involve scientific and technical issues, pure scientific-technical advice alone cannot bridge the interest-based conflicts among parties.

Once DSI scope and terminology are determined, they delimit the range of genetic resource-related data requiring benefit-sharing, transforming the issue from pure science to interest-based contest and political coordination. Undeniably, access to genetic sequencing data is the source of scientific innovation and cooperation, while downstream research and development create major added value, and stricter regulation could hinder innovation and problem-solving (Gaffney et al., 2020). Thus, open access disputes ultimately target benefit-sharing, representing the external manifestation of interest-based contest between DSI providers and users over access and benefit-sharing, requiring balance between data management and open access. Necessity, methods, and tools for monitoring DSI utilization are closely tied to the multilateral mechanism's final model. DSI gains tangibility, controllability, specificity, and transferability through digitization and information technology as "semantic sequence symbols" (Tang, 2022). Genetic information is both the reason genetic material has hereditary function and the key to its identification as genetic resources. Computer technology has expanded genetic information carriers from organisms to modern technological platforms like computers and networks (Chen,

2020). Therefore, disputes over the DSI-genetic resources relationship remain manifestations of interest-based contest.

3.2 DSI's Undefined Attributes Increase Benefit-Sharing Complexity

As products of genetic resource sequencing requiring biotechnology and computer technology for generation, storage, and utilization, DSI's basic attributes—including scope, terminology, and relationship with genetic resources—remain undefined. Only its potential link to specific genetic materials as physical resources can be confirmed. Genetic sequencing data utilization typically involves multiple datasets and sources, while gene editing and synthetic biology applications may create multiple "creation subjects" for one or more sets of sequencing information, potentially far removed from originally sequenced data. Benefit-sharing must inevitably link to value-creation behaviors and subjects, making identification and determination of "value" and "creation subjects" extremely difficult. Collecting, organizing, standardizing, and maintaining large datasets is a massive undertaking, and how to characterize the value of database builders, operators, and managers in DSI management and storage must be considered in multilateral mechanism design.

3.3 Difficulty in Coordinating Current Domestic DSI Measures with International Systems

Legal certainty is a primary concern for DSI discussion participants. As CBD and Protocol parties, the final model of international DSI access and benefit-sharing rules will directly impact national measure formulation and revision. Despite ongoing international negotiations, nearly 16 countries have issued and implemented national DSI measures. Some combine DSI with physical genetic resources, imposing constraints through permits or contracts (e.g., Namibia, Panama). Others extend genetic resource management measures to cover DSI (e.g., Bhutan, Colombia). Some stipulate that DSI utilization triggers benefit-sharing obligations without restricting DSI access (e.g., Brazil, India). Others manage DSI through compliance or monitoring mechanisms (e.g., EU, Switzerland) (Bagley et al., 2020). These diverse national bilateral DSI management measures present serious issues for constructing the CBD multilateral mechanism, adding complexity and difficulty to developing specific multilateral models.

3.4 Multi-Convention Synergy on DSI is Necessary and Urgent

The multilateral benefit-sharing mechanism under ITPGRFA and the PIP Framework's access and benefit-sharing mechanism for PIP biological materials do not include DSI benefit-sharing (Zhao et al., 2017). FAO and WHO have

noted that DSI discussions require coordination with CBD/Protocol consultation processes (WHO, 2019; SCBD, 2021; SCBD, 2022). The Commission on Genetic Resources for Food and Agriculture (CGRFA) includes DSI on its regular agenda and conducts thematic studies. The ITPGRFA Governing Body's 18th session incorporated DSI into its multi-year work program, and its process for strengthening the multilateral benefit-sharing mechanism will also consider DSI (SCBD, 2021; FAO, 2022; SCBD, 2022). The 70th World Health Assembly resolution requested the WHO Secretariat to study incorporating Genetic Sequence Data into the PIP Framework benefit-sharing mechanism (WHO, 2017). WHO research shows ABS legislation implementation has slowed seasonal influenza sample sharing within GISRS laboratories and WHO collaborating centers, while highlighting different functions of genetic sequence data versus physical samples and the irreplaceability of physical samples in certain contexts (WHO, 2019; SCBD, 2021; SCBD, 2022). As a focus across multiple international forums, multi-convention synergy is necessary for properly handling DSI issues. The BBNJ Agreement's adoption establishes international rules for DSI access and benefit-sharing of marine genetic resources beyond national jurisdiction, employing information exchange mechanisms, notification systems, and standardized batch identifiers to ensure DSI monitoring and transparency, establishing a dedicated fund for monetary benefits with sharing modalities to be determined by the Conference of Parties based on ABS Committee recommendations. Though its scope differs from CBD discussions, as the first international instrument directly addressing DSI access and benefit-sharing, its mechanism model will demonstrate effects for subsequent consultations under CBD, FAO, WHO, and other forums.

4. Strategies for Addressing DSI Access and Benefit-Sharing Issues

The aforementioned controversies represent only the tip of the iceberg among numerous DSI access and benefit-sharing disputes, with challenges persisting until the multilateral mechanism's final establishment. Some disputes, like scope and terminology, may remain unresolved long-term, as seen in the BBNJ Agreement precedent. In this context, China must accelerate the following efforts:

4.1 Strengthen Fundamental DSI Research

Effective DSI benefit-sharing mechanism implementation requires clear, stable, and legally certain scope and terminology, and proper handling of DSI utilization monitoring and open access disputes. While scientific advice cannot directly resolve interest conflicts, incorporating scientific knowledge into multilateral environmental agreements is crucial for ensuring unified terminology and effective implementation (Kobayashi et al., 2020). Therefore, fundamental DSI research remains essential. China must strengthen interdisciplinary research in law, economics, bioinformatics, and other fields to provide scientific support for DSI-related disciplines and industries and for national management measure for-

mulation, assess international consultation directions, clarify China's positions and strategies, and support participation in or coordination of DSI-related international forums. Additionally, pilot studies on DSI benefit-sharing multilateral mechanisms are necessary to provide practical foundations for subsequent consultations and domestic system construction.

4.2 Systematically Construct National Biological Resource Data Management Systems

As a crucial strategic resource, DSI requires timely and comprehensive national management measures. In 2014, the former Ministry of Environmental Protection and five other agencies issued the "Notice on Strengthening Management of Biological Genetic Resource Utilization and Benefit-Sharing in Foreign Cooperation and Exchange," classifying "information and data" as part of "biological genetic resources" to regulate increasingly active foreign cooperation and prevent resource loss (Ministry of Ecology and Environment, 2014). China has vigorously promoted secure and controllable open sharing of scientific data resources, with the "Scientific Data Management Measures" detailing data collection, submission, preservation, sharing, and utilization (Ministry of Science and Technology, 2018), and the "Biosecurity Law" stipulating catalog and list systems for important biological resource data. The "Data Security Law" clarifies and strengthens data security protection requirements through legislation, emphasizing both effective protection and lawful utilization. Given COP15.2 consensus on establishing a DSI access and benefit-sharing multilateral mechanism, China should timely formulate biological resource data management systems, systematically constructing key institutions for classification, submission, sharing, research, utilization, cross-border transmission, and benefit-sharing of biological resource data.

4.3 Continuously Enhance Biological Resource Data Infrastructure

China has established over 20 national scientific data centers for genomics, microbiology, and other fields, and hosts the World Data Centre for Microorganisms (WDCM), the most important physical resource data platform in global microbiology, continuously improving DSI databases and digital information platforms (Wu et al., 2021). In 2020, China launched the "Global Data Security Initiative," advocating development and security principles to promote data security and build a peaceful, secure, open, cooperative, and orderly digital economy. China should accelerate development of open, secure, shared, and reciprocal global infrastructure for biological resource data production and storage, establish industrial systems for data submission, analysis, research, and commercial application, and strengthen biological information data analysis and application capabilities. Additionally, China should launch China-led international cooperation programs on biological resource data, particularly with developing countries, to jointly build and share digital economy dividends. Relevant agencies could first issue international cooperation initiatives on biological re-

source data to steadily promote global sharing and exchange while ensuring data security, contributing China's solutions to global biological resource data governance.

4.4 Strengthen Domestic Multi-Convention Synergy and Implementation Effectiveness

As a hot topic across multiple international forums including CBD, FAO, WHO, and UNCLOS, DSI discussions in each forum influence others. COP15.2's package of outcomes incorporating DSI access and benefit-sharing has been followed by BBNJ Agreement inclusion, while WHO and WIPO intergovernmental consultations have conducted corresponding discussions. Outcomes from any forum provide reference value for others. As INSDC's second-largest user, CBD's largest user, and the world's largest provider (Rohden et al., 2020), and as a member of relevant international organizations or party to international instruments, China must continuously follow, participate in, or lead DSI discussions across forums. Since participation and implementation fall under different departmental responsibilities, China should fully utilize cross-departmental coordination mechanisms such as the China National Committee for Biodiversity Conservation to promote synergies in participating in DSI discussions across forums and coordinate responses to opportunities and challenges from DSI access and benefit-sharing.

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Note: Figure translations are in progress. See original paper for figures.