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Policy Brief

DSI in Marine Microbiome Research

– Implications for policy, research and innovation

1. Executive Summary and Key Messages

Marine microbiomes—the vast communities of microorganisms in our oceans –provide an added value for the **Digital Sequence Information** (DSI) genetic sequence data sourced from biodiversity. The use of DSI is transforming research and raising new policy challenge, particularly regarding how benefits from its use should be shared. Currently, global policy (via the UN Convention on Biological Diversity, CBD) is converging on a multilateral mechanism to share benefits from DSI, including a proposed global fund (the "Cali Fund") for contributions from DSI users.

A webinar was organized by research project "BlueTools" (GA-101081957) in collaboration with project "BlueRemediomics" (GA-101082304) about "ABS, DSI and open science; implications for microbiome and biocatalysis innovation", featuring speakers from national and European institutions as well as researchers from the public and private sectors. Over 200 worldwide attendees had the chance to share their experience on different aspects related to DSI, such as definition of DSI, development of benefit-sharing regulations and the possible impact on research, innovation and open science. This policy brief integrates conclusions from the EU-funded project **BlueTools**` webinar and international sources to inform stakeholders on the governance of DSI, with the aim of reconciling open science objectives with principles of equity and benefit-sharing.

Key messages and recommendations include:

DSI, research, innovation and open science:
Digital sequence information is now integral to microbiome research. International consensus is forming around a multilateral DSI benefit-sharing mechanism that preserves open access to data while ensuring fairness.

The EU and its Member States could actively promote this mechanism, while at the same time ensuring it doesn't undermine the open science data ecosystems that drive innovation. European engagement in DSI policy must align conservation goals with innovation, supporting capacity building for biodiversity-rich countries, strengthening compliance support within the EU and promoting awareness among researchers and industry.

2. Benefit Sharing from the Use of Digital Sequence Information (DSI)

2.1 What is DSI, State of the Art in Benefit Sharing, Conflicts and Technical Impediments

Although there is not an international or common definition of **"Digital Sequence Information"** (DSI), this term is generally used as a placeholder to refer digital data derived from genetic resources – most commonly, nucleotide sequence data (DNA/RNA sequences) stored in databases, but also associated data like amino acid sequences or digital genomic descriptors. DSI has become central to microbiome research, where data is publicly shared to accelerate discovery. However, this raises a crucial question: **if researchers can use a digital sequence of a genetic resource without accessing the physical material, should benefit-sharing obligations still apply and if so, how[1]?**

During a webinar organized by research project "BlueTools" (GA-101081957) in collaboration with project "BlueRemediomics" (GA-101082304) about "ABS, DSI and open science; implications for microbiome and biocatalysis innovation", a survey was conducted among the >200 workshop attendees, with a total of 57 worldwide participants (among others, Spain, France, Germany, UK, Netherlands, Belgium, Norway, Croatia, Austria, Switzerland, India, Japan, China, Indonesia, South Africa,…); 72,8% of the participants work in public research organizations, including high education institutions, 16% in private research organizations and 9,1% are affiliated to governmental institutions; 21% of the polled reported having requested access to genetic resources in their own country, 31% from a different country, whilst 48% had never requested access to genetic resources; 24,3% of the applicants indicated having received assistance from a National Focal Point, 11% from their own organization, 13,5% through online resources (e.g. infographics, webpages, webinars, etc.) and 5,4% have received assistance from colleagues who have requested this access before.

Global Policy Response

The principle of fair and equitable benefit-sharing from the use of DSI was already recognized at COP15, both in the Kunming-Montreal Global Biodiversity Framework and in Decision 15/9 on DSI. At COP16, the CBD adopted a landmark decision (CBD/ COP/16/2) to **establish a global fund, called the "Cali Fund" , for fair and equitable benefit sharing from DSI**. This fund will collect contributions from users of DSI and allocate benefits broadly (e.g. to conservation projects, global capacity-building), without tracing every sequence back to its country of origin in individual negotiations. **Benefit sharing includes monetary contributions** from commercial users of DSI, based on use and ability to pay, **and non-monetary benefits** to support global capacity. According to the COP16 draft, companies above a certain size threshold are expected to contribute ~1% of profits or 0.1% of revenue derived from DSI-utilizing activities. These indicative rates and thresholds will be finalized at COP17. Importantly, **public research institutions, universities, and open-access sequence databases are not required to pay** into the fund, acknowledging that fundamental research and data infrastructure should remain unhindered. The Cali Fund starts as a voluntary mechanism, but **COP16 also "invites countries to incentivise contributions"** from users in their jurisdictions, through national policies to ensure companies pay into the system[2].

To improve traceability and transparency, Decision 16/2 addresses public and other databases that make DSI on genetic resources publicly available, encouraging their operators to request available metadata (including country of origin/source where known) and to notify users of the benefit-sharing expectations linked to commercial utilization that generates monetary gains. However, **open access to DSI will be maintained** – keeping the mechanism consistent with open-science principles (FAIR data, CARE principles for indigenous data, and the UNESCO Recommendation on Open Science).

In parallel, other international forums are aligning. The new **UNCLOS Agreement on Marine Biodiversity Beyond National Jurisdiction (BBNJ)**, from 2023, includes provisions for benefit sharing from marine genetic resources (including DSI from areas beyond national waters). This synergy ensures that DSI will have a **coherent global benefit-sharing approach**.

Interplay between DSI, Open Science and Researchers' needs.

Open access to genetic data is a cornerstone of modern biology: researchers publish sequence data in public repositories (like GenBank, EMBL-EBI's ENA, DDBJ) as a condition for journal publication. In the BlueTools webinar survey, 36% of the professionals consider that

1 C. Lawson *et al.*, "Challenging the existing order of knowledge sharing governance with digital sequence information on genetic resources". Journal of Intellectual Property Law and Practice, 19(4), 337-357, 2024. DOI: 10.1093/jiplp/jpad129
2 Klünker *et al.*, "Digital Sequence Information between Benefit-Sharing and Open Data", Journal of Law and the Biosciences, Vol 9(2), lsac035, 2022, https://doi.org/10.1093/jlb/lsac035

DSI is crucial for their work and 21,5% use it occasionally. Open Science accelerates discovery, but if new rules were to impose restrictions on access to data (e.g. paywalls, requirement to obtain consent before data use), it would undermine decades of progress in making scientific data a global public good[2]. For this reason, data which has been already published must remain freely accessible for science to advance. Moreover, **public databases should remain open, while playing a pivotal role in signposting**, e.g. by reminding users that "if datasets are for commercial purposes, benefit-sharing is required under CBD/BBNJ". Moreover, new metadata requirements must not compromise the efficiency and openness of data submission and access.

The emerging multilateral approach decouples data access from benefit obligations. Open science is preserved (no conditional access to data), and benefit-sharing is handled through downstream contributions. However, ensuring users comply with expected contributions is not straightforward, which is why **COP16 invites national measures to incentivise compliance**. Policymakers will need to translate this into action (potentially through domestic legislation or tax incentives).

Technical Impediments

Unlike physical samples, digital data can be copied endlessly and flows globally. **Tracking the origin of every sequence in a researcher's analysis is costly and technically very difficult**, as the origin of sequences is not always annotated in databases. Moreover, a single research project might analyse millions of sequences from hundreds of organisms: linking each to a benefit-sharing obligation would be unfeasible. **Nevertheless, databases will ask data submitters to include country of origin information where available, to provide transparency on sample origin to the extent possible.** Importantly, this is not a new policy created only in response to the recent (CBD/COP/16/2) decision: the INSDC began implementing a spatiotemporal metadata policy in 2021, explicitly to improve the scientific value, utility, traceability and FAIRness of sequence data. However, there are tens of millions of legacy sequences already in databases that will never have reliable origin metadata. Those sequences are considered part of the public domain and available for use without new conditions.

Another concern is **enforcement and monitoring of benefit sharing from the use of DSI**. How do we know when a company has used DSI and made a product or profit from it? How do we avoid duplicities with other benefit sharing mechanisms[3]? Patent offices could in the future become one such single-window, cross-mechanism checkpoint, similarly to the disclosure of origin or source in certain patent applications, contemplated in the 2024 WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge. This would require further legal development and consultation with patent authorities. At the moment, COP16 Decision 16/2 does not assign a formal role to patent offices; instead, it relies on the Cali Fund, invites Parties to adopt administrative, policy or legislative measures to incentivise contributions, and provides for receipts and annual certificates upon contribution to enhance reputation or for legal assurance when marketing products globally.

3 S. Sett, *et al.*, "Harmonize rules for digital sequence information benefit-sharing across UN frameworks". Nat Commun. Vol 15, p 8745, 2024. DOI: 10.1038/s41467-024-52994-z

2.2 Policy Recommendations for Benefit Sharing from the Use of DSI

To achieve a fair DSI benefit-sharing system without hindering science, EU and Member State policymakers should:

1. **Incentivize Industry Contributions.** Develop domestic policies or legislation that incentivise companies profiting from DSI to share benefits. This could include reporting requirements for large life-science companies on their DSI use, tax breaks or certificates of compliance for those who contribute.
2. **Ensure legal certainty and a clear license-to-operate** to ensure future investments in research and innovation projects by industry. Companies need assurance that contributions to, e.g., the Cali Fund fully satisfy their benefit- sharing obligations, without risk of overlapping (inter) national requirements or retroactive claims. The mechanism must be simple, predictable, and proportionate, avoiding complex tracking of DSI use or ambiguous definitions of "direct" and "indirect" benefit. Contribution rates must be meaningful and fair; applying them to a company's total revenue (particularly for diversified enterprises not primarily focused on biotechnology) risks imposing costs that are not economically viable and will hinder innovation.
3. **Protect Open Access Data.** Enshrine in policy that open access to scientific data is to be maintained. The EU's open science policies (such as Horizon Europe's open data requirements) should explicitly integrate with ABS/ DSI rules: researchers should not be asked to restrict data sharing. Support European and international data repositories in implementing the COP16 measures, like capturing metadata and displaying user notices, in a way consistent with the FAIR principles.
4. **Invest in Global Capacity and Technology Transfer.** Direct a significant portion of benefit sharing (both monetary and non-monetary) to capacity-building in developing countries, e.g. fund training programs, bioinformatics infrastructure, and research collaborations in countries that provide genetic resources to also become users of DSI for their own development.
5. **Engage Stakeholders in Policy Design.** Continue the dialogue with scientists, database curators, industry, and indigenous/local community representatives as DSI policies are implemented. The BlueTools/BlueRemediomics webinar itself is a model for such multistakeholder engagement.
6. **Harmonize with Other Regimes.** Ensure that **EU and national policies on DSI benefit-sharing are coherent with other international regimes**, such as the BBNJ agreement's provisions on access and benefit sharing of DSI derived from genetic resources in the high seas. A cohesive approach prevents loopholes and reduces confusion and duplicities.

By taking these steps, European policymakers will help establish a **solid benefit sharing system for the omics era** – one that continues to fuel open science while ensuring that benefits from utilizing the "digital genetic heritage" of our planet are shared fairly, supporting global biodiversity goals.

3. About the Authors

BlueTools is a research Project funded by Horizon Europe to advance functional metagenomics, microfluidics, microbial ecology, and synthetic biology. It will accelerate sampling/culturing of marine microorganisms, enhance bioinformatics pipelines, and demonstrate microbiome based products in a wide array of applications. BlueTools promotes a sustainable, and equitable exploration of marine genetic resources, works closely with sibling Project BlueRemediomics, and engages policy/stakeholder fora—such as the ABS/DSI webinar underpinning this brief.

Sources: This policy brief draws on discussions and insights from the BlueTools–BlueRemediomics ABS/DSI webinar (May 2025), the text of the **(CBD/COP/16/2) Decision on DSI**, the **German Research Foundation (DFG) statement on DSI**, and other relevant international documents, journal references and national case studies, as mentioned throughout. It is intended to inform European and national policymakers and stakeholders in navigating the complex but crucial interface of biodiversity policy, innovation and innovation.

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