Keep digital sequence information a common good

Summary: The EU scientific community supports de-coupled multilateral options for access and benefit-sharing from digital sequence information.

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The political debate surrounding digital sequence information (DSI) on genetic resources under the Convention on Biological Diversity (CBD) has garnered immense interest and raised concern across the international scientific community. At the last CBD Conference of the Parties (COP 14), parties formally "agreed to resolve their differences" and, thus, with COP 15 set for October 2021, a decision on DSI and access and benefit-sharing (ABS) approaches.

Scientific perspectives on the evolving DSI policy discussions

Disrupting the flow of open DSI has the potential to not only severely hinder basic research and biodiversity conservation, but also innovation more broadly. This includes science and technology that addresses challenges in food security, health, biodiversity loss, and climate change worldwide, which could ultimately undermine progress on the Sustainable Development Goals (SDGs). What's at stake is best highlighted by the global SARS-CoV-2 pandemic: diagnostic kits within weeks of virus discovery, vaccines ten months later, and ongoing surveillance for variants, all possible thanks to rapid DNA sequencing and open DSI.

A number of initiatives have highlighted the concerns of the international scientific community and explained why DSI must remain openly accessible (see references). However, maintaining open access to DSI and benefit-sharing are not necessarily mutually exclusive and can even become reinforcing objectives. **Our recommendation to policymakers is to pursue multilateral options supplemented by international scientific cooperation:**

1. **Multilateral and decoupled.** Benefit-sharing for DSI must be multilateral rather than bilateral and decoupled from access to DSI. This significantly reduces the transaction costs that make bilateral options unworkable, maintains open access, and facilitates legal certainty. It is also an opportunity to redirect investment in regulatory compliance towards scientific capacity building. Additionally, opt-in mechanisms for genetic resources (GR) could be offered for countries wishing to simplify their current GR access procedures.
2. **Universal.** Biodiversity monitoring as well as many scientific questions can only be answered by analysing DSI from multiple countries or outside of national jurisdictions. From a scientific perspective, a "universal DSI solution" is needed which harmonizes ABS arrangements for DSI under the Convention on Biological Diversity and all other relevant international policy fora (terrestrial, marine, plant, pathogen, etc.). Coordination at the highest level is necessary to avoid excessive regulatory burden and create a level playing field for compliance.
3. **Existing infrastructure.** To be viable, policy options must synergize and work with the existing technical infrastructure (i.e., the International Nucleotide Sequence Database Collaboration, INSDC). Data must continue to flow and the amount and visibility of non-monetary benefit sharing needs to increase. The DSI "wheel" should not be re-invented.
4. **Biodiversity.** DSI policy must support biodiversity research and global biodiversity targets. DSI policy should incentivize rather than complicate the generation of

biodiversity data and directly support the goals of the post-2020 Global Biodiversity Framework (GBF) and the SDGs.

5. **Future-proof.** Because of the relentless pace with which DSI-based science evolves, any policy option for DSI must be sustainable, fit for purpose, and future-proof, meaning that it can evolve to meet technical requirements to 2050 and beyond.

The scientific community supports benefit-sharing from DSI

The ABS status quo can be improved to better align with the third objective of the CBD. Yet scientists are cautious after experiencing significant challenges in recent years during the implementation of the Nagoya Protocol (including EU Regulation 511/2014). The fragmented regulatory framework for ABS globally and the unresolved status of DSI creates legal uncertainty for scientists worldwide that needs to be resolved. However, we do not support benefit-sharing from DSI at all costs.

Bilateral mechanisms have enormous transaction costs and huge complexity

Any mechanism that requires an access permit or benefit-sharing arrangement to be negotiated on a bilateral basis for DSI, or which requires tracking and tracing, is unworkable on the basis of the transaction costs this would generate. The DSI data ecosystem is huge: composed of 1.5 billion sequences in the core DSI infrastructure, downloaded 34 million times per year, used by 10-15 million unique users, and connected to nearly 2,000 databases downstream of the INSDC that pull and push data in and out of the system. The dataset doubles in size roughly every two years and is linked to hundreds of thousands of publications that, on average, cite 44 sequences per publication. DSI use will continue to increase (exponentially) and touch new fields of research. Bilateral systems that require permission for *individual* sequences and transactions would be prohibitively complex for users and providers, ill-suited for generating knowledge, result in significant friction amongst databases, affect data interoperability, and have transaction costs that could paralyze the scientific ecosystem.

Bilateralism also creates competition between providers of DSI

Even simplified bilateral systems (e.g. standardized licenses where more than one option is available) will incentivize jurisdiction shopping where users preferentially use DSI from more favourable access jurisdictions and avoid less favourable conditions elsewhere. Any handling of DSI in subsets (free data vs. conditioned data) will create perverse incentives to avoid researching with some countries' DSI. This is an under-appreciated challenge given that the conserved nature of biodiversity means that for any given genetic material of interest, alternative sources are typically readily available. This means that ultimately our understanding of biological diversity in more restrictive countries would significantly decrease (in opposition to the GBF). From the scientific perspective, all options that include bilateral mechanisms for benefit sharing must be taken off the table during international discussions.

Multilateral options should prioritize maximal benefits with minimal transaction costs

From our viewpoint, multilateral options that establish de-coupled, globally standardized DSI access and benefit-sharing conditions must be prioritized. Critical for the scientific community will be to avoid point-of-service charges that create a "paywall" and thus cause significant data friction for users, disrupt thousands of downstream databases, and disadvantage scientists in low- and middle-income countries. Monetary benefit generation does not need to be linked to *access* to DSI at all. It can and should be de-coupled. Monetary benefits could

be collected, for example, via charges to ancillary services to DSI or downstream on bio-based commercial products.

DSI capacity-building should be an integral component of any multilateral option

Finally, DSI capacity-building must be integrated into multilateral options to maximize non-monetary benefit sharing. Such efforts must be practical, directly relate to the goals of the CBD and the GBF, and should attempt to "match-make" technical/scientific cooperation in a standardized, quantifiable manner, partnering with existing scientific bodies such as national academies for agenda-setting.

As the policy process evolves and decisions are made in the next few months, exchange between scientific and policy experts is essential to avoid unintended consequences.

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