



WILDSI

EXECUTIVE SUMMARY

**FINDING COMPROMISE ON
ABS & DSI IN THE CBD:**

REQUIREMENTS & POLICY IDEAS

**FROM A SCIENTIFIC
PERSPECTIVE**

EXECUTIVE SUMMARY

The 15th Conference of the Parties (COP) to the Convention on Biological Diversity (CBD) will meet next year to negotiate and define the Post-2020 Global Biodiversity Framework (GBF). A critical point of negotiation will be the issue of access and benefit-sharing (ABS) from “digital sequence information on genetic resources” (DSI). Outside the CBD, DSI is actively discussed in other international fora including the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), United Nations Convention on the Law of the Sea (UNCLOS), and World Health Organization (WHO) Pandemic Influenza Preparedness (PIP) Framework.

DSI is essential for life sciences research, including biodiversity, food security, and public health to name a few. The current model for DSI is “open-access” which not only enables scientific reproducibility and enforces scientific integrity, it enables global non-monetary benefit sharing, including scientific capacity building in developing countries precisely because everything is open, free, and reusable. Yet this very openness raises questions from some Parties about alleged lost opportunities for benefit-sharing. Tension builds because of the divergence between some Parties’ desire to maintain control over genetic resources (GR) and DSI, and the scientific community’s observation that the value of DSI can only be fully realized if the system is as open and comprehensive as possible.

The open-access system for DSI is incompatible with the individualized bilateral ABS system envisioned by the Nagoya Protocol (NP). There are five key reasons for this: 1) the scale, the sheer volume of DSI data and users exceeds current ABS capacities by orders of magnitude; 2) the technological integration of the dataset is highly automated for big data movement; 3) there are at least 800 databases involved in downstream analyses required for DSI to become meaningful; 4) DSI is used and published in a multilateral manner – multiple authors using on average 44 sequences from different countries in millions of publications; 5) because of sequence conservation caused by evolution, many sequences are highly repetitive and “ownership” will prove very complex.

Furthermore, a benefit-sharing based solely on country of origin of the DSI, would primarily benefit just four countries since over half of DSI identifying the country of origin comes from the USA, China, Canada, and Japan. While low- and middle-income countries do not contribute the majority of DSI, their scientists access the information with the same access opportunities

as researchers from other countries. In fact, DSI is sourced from many different legal jurisdictions including the treaties listed above as well as from jurisdictions without ABS (so-called free access and Observer states) and, of course, from human beings and old biological material (around 25% of the database). And ALL of this DSI is mixed together in one single large infrastructure. The situation is complicated.

Policymakers need to know what the data tell us about DSI and address these challenges when considering options for DSI and ABS. The goal of the WiLDSI project is to provide scientific input on the DSI issue – based on data and our experience as users of DSI and GR. To ensure any future DSI system will be able to support scientific research, it should be evaluated against these **five requirements for successful science**:

1. Open access. Open availability of research data including DSI enables scientific reproducibility and integrity – a cornerstone of the scientific process. For the scientific community at this stage, it is critical to know that open access to DSI generated by scientists for scientists will continue to be guaranteed, that data will be publishable, available, linkable, downloadable, and can flow into the downstream databases and software we use every day.

2. Simplicity. Recognize the practical challenges created by the existing bilateral NP system and consider a new way of thinking about ABS. Paperwork and stamped documents are incompatible with the scale, technological platforms, and daily realities of scientific inquiry with DSI.

3. “Future-proof”. Any future system should be able to handle big data, high-throughput science, petabyte datasets, automated data processing, and a highly interconnected infrastructure of thousands of databases. DSI is simultaneously “hands-on” data that is manipulated and interacted with in hundreds of specialized software programs.

4. Legal certainty. Avoid cumbersome processes to ensure compliance is straightforward and use rights are clear. People usually do the right thing if there is a simple, straightforward path towards compliance that brings certainty.

5. Opt-in GR. Because scientists must have access to GR in order to generate DSI there is a high-risk for a two-tier GR/DSI system which would create impracticalities and additional bureaucracy.

The international scientific community would welcome a coherent solution covering both by an optional mechanism for Parties to opt-in the GR used to produce the DSI in the same system.

These five scientific requirements lay out the characteristics of an ideal DSI system but over the course of our research, three additional factors should be considered: the amount of time until any benefits materialize; whether ABS and biodiversity/sustainable use can be better connected and incentivized; the opportunity and need for an overarching “universal DSI” solution compatible with other ABS systems.

Before assessing the possibilities for monetary benefit-sharing, the value and the non-monetary benefits of open DSI provided by option 0, the status quo must be accounted for. **Option 0** offers over 15 million users worldwide free access to DSI. DSI itself costs significant financial resources to generate, annotate, analyse, and publish and these research and infrastructure costs are carried by a small number of countries. While option 0 is ideal for scientists because it requires no compromise and no additional bureaucracy or costs, the political landscape makes it clear that new ideas that both enable option 0 and provide monetary benefit-sharing are called for. Each of the options represent compromise of varying degree but preserve some form of open access to DSI. On the following page the **five policy options** are summarized briefly and a comparative table of the options is presented.

Governance. In order to effectively and efficiently handle the technological and scientific complexity of DSI and the diversity of stakeholder interests engaged in this DSI issue, we recommend the creation of a public-private partnership (PPP) to govern the implementation of any future policy framework around DSI, including the five options described above. Compared to traditional governmental structures and purely public institutions, a PPP could offer a nimble legal structure that can directly engage with the private sector, which is expected to contribute a significant portion of monetary benefits. PPPs can bring together private entities, governments, varied international instruments, Observers, sub-national States, and a wide variety of stakeholders and respond in a timely, agile manner to emerging issues. A needs-based assessment at the beginning of the policy process could help to determine where funds are needed and for what purpose. A thorough assessment, including cost (for administration and technological requirements) and income generation estimates early on in the process is essential.

Concluding Thoughts. In past DSI discussions, a stark contrast has often been presented: *either* the status quo with an open-access model and extensive non-monetary benefit-sharing but zero monetary benefit-sharing *OR* a closed-access system with monetary benefit-sharing but dramatically reduced or zero non-monetary benefit-sharing and a loss of open-access. We are convinced that the debate between open access and monetary benefit-sharing is a false choice and that both principles can thrive if innovative ideas and open-mindedness are brought to the table.

The word “open” seems to stand in direct contradiction to an income-generating system. *However, open does not equal “free of any obligations”*; models can be deployed where DSI is visible to all, yet certain types of use or user may be subject to conditions. The questions here are how to generate income without closing off access or causing high transaction costs, and whether the priorities listed above can be reflected in a new system and the societal and non-monetary benefits can be maintained at their existing levels.

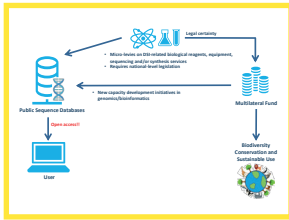
Parties will face challenging decisions at COP15 that require foresight – “How will our policies affect the scientific community that we expect to develop new vaccines, protect biodiversity for the next generation, innovate with new ideas that reduce waste and resources, enable sustainable development, and build up the bioeconomy?” While some Parties might hope to “control” DSI, this desire must be contrasted with the reality of how science actually works.

Benefit-sharing is most likely to materialise when free exchange can happen, when data flow easily, when new, unknown connections can be made between disparate pieces of data and information. Heavy-handed or bureaucratic attempts at monitoring/tracing/controlling this highly complex, dynamic ecosystem would not only require huge upfront investments, in our view, they are unlikely to produce meaningful new benefit-sharing but, instead, will lead us in the next decade or two to new levels of acrimony and frustration.

Instead, the debate around openness versus control should be contextualized in the broader question of how benefit-sharing can be more successful, more responsive, more situationally-aware than it has been to-date. It is our hope that this paper triggers further discussion and that scientific perspectives on this issue will be taken seriously and valued in the policy development process.

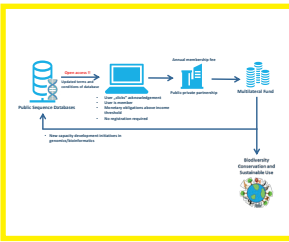
POLICY OPTIONS

Option 1: Micro-levy



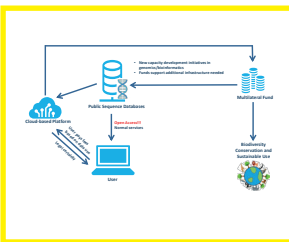
Option 1 separates access to DSI from monetary benefit-sharing and instead collects funds earlier in the R&D process by charging micro-levies on DSI-related charges. Micro-levies are small charges on high-volume purchases that should not impact the behavior of the purchasing customer. The DSI micro-levy could for instance be linked to aspects of DSI generation and be applied, for example, to DNA sequencing/synthesis services, laboratory reagents, or equipment. Option 1 is very simple, is likely to generate significant funding relatively quickly, and completely leaves the status quo open access system intact. However, micro-levies require national legislation to implement and can be unpopular domestically. Also, for some Parties, access and benefit-sharing might be perceived as too disconnected.

Option 2: Membership Fees



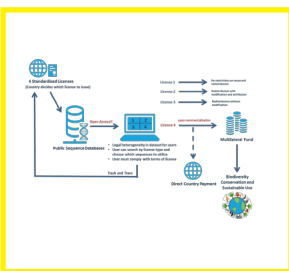
Option 2 would require annual “membership” fees for users of the global DSI dataset that have sales/income above a specified threshold. This would mean that academic (non-commercial) users would generally not pay a membership fee. Access to DSI is NOT behind a paywall – a financial barrier that precedes/prevents access. Instead, the conditions of use of the databases (e.g. INSDC) would remind users of potential monetary obligations and any monetary payments would be collected by a separate entity. Compliance could be supported by use of the patent disclosure system where DSI is already listed and disclosed. It would not be important to track and trace these sequences but rather it provides a yes/no check if DSI was used. Option 2 reflects benefit-sharing discussions under the IPTGRFA. Option 2 is a relatively simple, easy-to-understand system already discussed by other international fora, however compliance mechanisms are somewhat weak and negotiating the monetary obligation threshold would likely be contentious.

Option 3: Cloud-based Fees



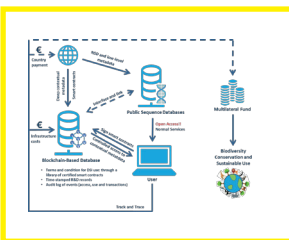
In option 3, a new cloud-based platform for DSI would be offered for users seeking legal certainty and “power user” services. This new system would be offered on top of the core DSI infrastructure. The cloud platform would offer advanced services (e.g. storage, analytics, sector-specific workbenches, etc.) for fees based on, for example, the amount of DSI use or storage or access to specialty features. The normal (status quo) open access to DSI via INSDC would remain in place but cloud portals would additionally offer users full legal certainty and advanced features that are otherwise cost-inefficient for users to build by themselves. A cloud-based system is scalable, responsive, and fees can be directly tied to usage. However new infrastructure costs are likely which would need to be recaptured and non-commercial users might pay proportionally more in this option than in others.

Option 4: Commons Licenses



In option 4, Parties could require DSI producers and users to associate a standardized license to any DSI placed in an open-access database. A small set of standardized licenses based on open-software commons licenses would be negotiated and direct users on their ABS obligations. Databases would need to allow licenses to be associated with DSI and users themselves would need to track and trace DSI used during utilization and adhere to the conditions in the license. Monetary benefits could be triggered at the point of access for certain users or at the time of commercialization. Alternatively, a commons license could require users to upload DSI to cloud-based infrastructures (option 3). Commons licenses are widely proven to work in the field of open-source software development and an entire ecosystem (bigger than ABS) runs on these licenses. However, this option requires the users to track and trace the use of their DSI which, would be challenging. Furthermore, negotiating standardized licenses at the international level might be challenging.

Option 5: Metadata & Blockchain



Option 5 uses blockchain technology not on DSI itself but rather on the associated legal and scientific metadata – a “hybrid blockchain” option. While the DSI itself would continue to be submitted to the core database infrastructure, certain scientific and legal metadata which would be put into a blockchain layer of records and access would be monitored and controlled, thus allowing the tracking of events of data access. Monetary benefits could be triggered at defined points in the R&D process if events are registered in the blockchain system. Option 5 requires significant upfront technological investment and costs, while generation of funds is unknown and likely to be long-term creating a possible imbalance in operating costs. Option 5 responds to calls for tracking and tracing and bilateralism, but has not yet been proven for use in ABS.

Table 1. Comparison of key aspects of the 5 policy options

Policy option	1. Micro-levy	2. Membership Fees	3. Cloud-based fees	4. Commons Licenses	5. Blockchain
<i>What DSI is affected?</i>	no effect	All non-human DSI; the whole dataset	All non-human DSI in the database imposing cloud-based fees	All DSI would be tagged with 1 of 4 licenses including retroactively on DSI already in the databases	DSI-associated metadata from Parties claiming sovereign rights
<i>Tracking/tracing required?</i>	No	No	No	Yes	Yes
<i>Jurisdiction shopping possible?</i>	Yes if unevenly implemented	No	No	Yes	Yes
<i>Changes to open access</i>	No. Fees are paid upstream in the DSI generation and research process.	For users below an income threshold, open access use is unchanged. For users above threshold, fees apply.	Status quo access option offered in parallel to a fee-based cloud option that offers legal certainty and advanced user services	Minimally. Licenses with conditions would be applied to all DSI.	Normal open access to DSI offered in parallel to blockchain on legal/scientific metadata
<i>Multilateral or bilateral</i>	Multilateral	Multilateral	Multilateral	Bilateral with multilateral opportunities to standardize licenses	Bilateral with multilateral opportunities to standardize (legal) conditions
<i>Who pays? When?</i>	"Consumers" of particular DSI-related products/services	Annual membership fee paid by users above an income threshold	User pays depending on data use (pay as you go)	Depends on intended use of DSI defined in license option(s)	Defined by the terms in the legal agreements
<i>Legal certainty</i>	Through receipt on payment of micro-levy on DSI products/services	Through membership annual payment	Through use of cloud platform	Established in 4 standardized licenses	Provided by a blockchain layer of records and access management system through identifiers, audit logs and smart contracts.
<i>Compliance</i>	Proof of payment of micro-levy	Monitoring activity likely needed	Monitoring activity likely needed	Monitoring activity likely needed	Through registering transactions in blockchain, smart contracts
<i>Who receives funds?</i>	Multilateral fund for biodiversity and infrastructure	Multilateral fund for biodiversity and infrastructure	Multilateral fund for biodiversity and infrastructure	Individual Parties (depending on contracts)	Individual Parties (depending on contracts) or a multilateral fund for biodiversity and infrastructure
<i>How long until funds accumulate?</i>	Short-mid-term	Short-mid-term	Mid-term	Long-term	Long-term
<i>Opt-in GR possible?</i>	Yes	Yes	No	Yes	Maybe
<i>Simplicity</i>	Simple	Simple	Complex	Simple	Complex