THE ABS CAPACITY DEVELOPMENT INITIATIVE

National ABS Approaches to DSI: Perspectives, Options and Limits

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Contents

Acronyms

ABS	Access and Benefit-sharing
CNA	Competent National Authority
CBD	Convention on Biological Diversity
COP	Conference of the Parties
DSI	Digital Sequence Information
GR	Genetic Resources
GSD	Genetic Sequence Data
INSDC	International Nucleotide Sequence Database Collaboration
IPLCs	Indigenous Peoples and Local Communities
IPR	Intellectual Property Rights
IRCC	Internationally Recognized Certificate of Compliance
PIC	Prior informed consent
MAT	Mutually agreed terms
MTA	Material Transfer Agreement
NP	Nagoya Protocol
NSD	Nucleotide Sequence Data

Executive summary

Three scenarios employing national ABS regimes to regulate DSI use and description bilaterally are assessed against a set of desirable characteristics of an ABS system (based on Sirakaya 2020) [12]. The **advantages and disadvantages** of each scenario are analyzed from **the perspectives of providers, users, and databanks**, delineating potential **limits** of bilateral DSI regulation.

Scenario 1 assumes that there is no ABS regulation in place in the country of origin of the genetic resource (GR) from which the DSI was described. All terms and conditions, rights and duties are negotiated case-by-case using private contract law.

In Scenario 2, established ABS legislation in the country of origin requires PIC and MAT for the description, deposit and use of DSI, and prescribes third-party users' obligations. Countries that are Party to the Nagoya Protocol are obliged to monitor and enforce users' compliance with providers' legislation.

Scenario 3 provides open access to GR and DSI, under terms and conditions. This regime aims to control results rather than processes. No PIC is required for access to GR, or for the description, deposit and use of DSI. Instead, the outcomes of R&D (e.g. a publication, an IPR, or a product) have to be reported in an ABS online registration system in the country of origin of the resource. Monetary benefit sharing obligations arise only when a final product from DSI use is being commercialized. The current Brazilian ABS system is akin to scenario 3.

The above scenarios are evaluated against Sirakaya's characteristics of an effective ABS system: legal certainty; sustainable use; transaction costs; cost effectiveness; predictability; fairness and equity; transparency.

Taking the different **perspectives** of **providers, users, and databanks,** the study provides an extensive discussion of the various implications. In summary, these can be depicted as follows:

Scenario 1: Absence of ABS regulation

Perspectives Characteristics	Providers	Users	Databanks
• **Legal certainty**	**none**	**none**	**none**
• Sustainable use	lowest	lowest	lowest
• Cost-effectiveness	lowest	lowest	lowest
• Transaction costs	highest	highest	rather high
• Predictability	none	lowest	lowest
• Fairness and equity	lowest	lowest	lowest
• Transparency	lowest	lowest	lowest
Remarks	Monitoring compliance may lead to high technical/ administrative burden and costs, which are likely to outweigh benefits.	Proving compliance may lead to high technical/ administrative burden and costs, which are likely to outweigh benefits.	Expectations that databanks will include private data access and use agreements may lead to high technical burden and costs.

Scenario 2: ABS regulation requiring PIC/MAT

Perspectives Characteristics	Providers	Users	Databanks
• **Legal certainty**	**intermediate**	**intermediate**	**intermediate**
• Sustainable use	low	low	low
• Cost-effectiveness	rather low	rather low	rather low
• Transaction costs	rather high	rather high	rather high
• Predictability	rather low	rather low	rather low
• Fairness and equity	low	rather low	rather low
• Transparency	rather low	rather low	rather low
Remarks	Technical complexity of monitoring DSI use may be beyond the capacity of most provider countries.	Legal uncertainty due to the complexity of different ABS rules in different countries.	Expectations on databanks to include IRCC (PIC/MAT) may lead to high technical burden and costs. Low predictability due to uncertainty about the legal implications of sharing DSI.

Scenario 3: Open access, under terms and conditions

Perspectives Characteristics	Providers	Users	Databanks
• **Legal certainty**	**highest**	**highest**	**high**
• Sustainable use	highest	rather high	highest
• Cost-effectiveness	highest	rather high	highest
• Transaction costs	lowest	rather low	lowest
• Predictability	rather high	highest	highest
• Fairness and equity	intermediate	intermediate	high
• Transparency	intermediate	highest	rather high
Remarks	Transparency is key, but depends on willingness of all stakeholders to comply. Low control over DSI use. High benefit sharing compliance costs and dependence on third parties. High cost of creating and maintaining an ABS online registration system is likely to outweigh the benefits for most provider countries.	Pre-set terms and conditions allow users to acknowledge their rights and obligations before deciding to start DSI use/description, clarifying costs and risks beforehand. Bulk DSI use will require more complex and burdensome compliance efforts, in which case benefit-sharing and compliance may increase transaction costs, reducing cost-effectiveness.	Instead of requiring PIC/MAT for DSI use/description, databanks would have to require the IRCC/certificate of registration prior to the depositing of the DSI – not as a condition of use, but as a condition for the deposit of the sequence. Political pressure to create such fields may lead to technical burden and costs for databanks, while users may be reluctant to accept this change.

Based on this analysis, the study concludes that none of the outlined scenarios is able to produce the full set of desirable characteristics of an effective ABS system. In each scenario, frequency of use elevates costs for providers (having to grant and monitor each use), users (having to comply with every single use) and databanks (being requested to acquire users' compliance, or to change and adapt), which would inevitably have a negative effect on sustainable use, to the detriment of all stakeholders.

A key issue is the difficulty involved in identifying the GR underpinning the DSI, and/or the country of origin of those GR. If this information is not available (for example, if it does not appear in a country tag), none of the scenarios work. Massive data mining, bulk data analyses, metagenomics etc. add to these challenges. Furthermore, none of the bilateral scenarios provides solutions for particular complications associated with DSI, notably the issue of transboundary occurrence.

Although some difficulties may be reduced in scenario 3, this comes with its own challenges: Not all GR providers may reach the technical and financial conditions necessary to implement and maintain a national ABS online system for registering the use of DSI. Likewise, not all users may be able to meet the conditions (IT and qualified staff) to register and track activities in various and diverse online systems. In addition, scenario 3 largely depends on the good faith among providers and users.

In summary, the study finds the feasibility of tracking and tracing DSI description and use under a purely bilateral approach to be extremely costly and entangled. Without DSI use, benefits will hardly be generated. Frequency of use should be fostered and not regarded as a transaction cost, as is the case in all three scenarios: "If the transactions are frequent, the parties will invest in a governance structure that decreases transaction costs and makes these transactions efficient" (Gehl Sampath 2005, in: Richerzhagen, C. 2011). This raises the question whether DSI description and use could perhaps be better addressed through a multilateral governance structure.

I. Introduction

The bilateral approach to access and benefit-sharing (ABS) under the Convention on Biological Diversity (CBD) and the Nagoya Protocol (NP) requires the identification of the legal provider of the genetic resources (GR) from whom users have to obtain prior informed consent (PIC) and mutually agreed terms (MAT), in order to access and utilize the GR and, in special cases, make them available to third party users through deposit in ex-situ collections.

Without any doubt, biological information – and genetic information as a subgroup – is an essential part of any organism: "[T]he idea that genetic material transmits information as genetic information is actually foundational to molecular biology, genetics and the omics and other developments to which it gave rise. (…) It is therefore reasonable to conclude that information is a component of genetic material and that the representation of this information using standard symbols such that it can be manipulated or reproduced by skilled persons will logically fall within the scope of instruments that address genetic material and genetic resources" (Oldham, P. 2020 [1]).

Genetic information is depicted as the sequence of nucleotides in DNA or RNA. Increasingly efficient DNA sequencing technologies have been developed since the late 1970s and now allow sequencing of large pieces of DNA within hours. Since the 1980s, electronic depositories for these sequences have been built up. Today, the International Nucleotide Sequence Database Collaboration (INSDC) is the largest institution for storing and making available millions of DNA, RNA and protein sequences – which many experts see as the core categories of "digital sequence information" (DSI).[1]

Opinions diverge as to whether or not genetic information of organisms – made available as DSI – is under national sovereignty and thus within the scope of the CBD and its NP. During the negotiations leading to the CBD/NP, the matter of whether and how biological and genetic information relates to ABS was not extensively discussed, and the negotiators never conclusively decided whether genetic information is in or out of scope.

By the time the 13th Conference of the Parties (COP) to the CBD took place in 2016, rapid advances in gene sequencing, editing and printing technologies, in parallel with vastly expanded data storage, retrieval and manipulation capacity due to the information revolution, led to intense discussions (initially under the Synthetic Biology agenda item) about the link between ABS and DSI (which was adopted as a placeholder term).

In 2018, after some initial exploratory work, all members of the CBD adopted Decision 14/20, which forms the basis of the current international discussions on regulating the use of DSI:

- Parties noted that, "**as there is a divergence of views among Parties** regarding benefit-sharing from the use of digital sequence information on genetic resources, **Parties commit to working towards resolving this divergence** through the process established in the present decision"
- Parties decided "to **establish a science and policy-based process** on digital sequence information on genetic resources"

A formal interpretation of legal texts (Spranger, T. M. 2017 [2]) does not appear well suited to resolve the divergences; more forward-looking approaches are necessary to find "a balance between the interest in open and free access to information on genetic resources and the interest in a fair and equitable sharing of benefits with countries and communities providing those genetic resources which do not necessarily benefit from the results of research and development activities" (Sollberger, K. 2018 [3]).

When discussing whether and how to regulate DSI under ABS measures, many Parties recommend or apply the existing bilateral approach stipulated by the CBD and the Nagoya Protocol. This means starting regulation through PIC and MAT given for access to the GR from which the DSI originates, as the use of DSI would otherwise "escape" the control of the provider. From the perspective of the provider, and considering current international practices regarding the use of DSI, the MAT needs to dictate conditions about the use of genetic information contained in the accessed GR at three levels:

1. Creation of DSI from the GR accessed and publication/ storage of such DSI
2. Use of DSI by the first user, the holder of PIC and MAT
3. Access to DSI published/stored, including benefit sharing obligations for subsequent users

The international discussions and studies triggered by COP Decision 20/14 shed light on the current practices of description and storage of, access to and use of DSI. The ability of the legal provider of the GR/DSI to exercise control over DSI use is challenged by several practices and rules:

1 In the absence of an internationally agreed definition of DSI, we determine that in the context of this study DSI includes at the minimum sequences of nucleotides in DNA and RNA as well as of amino acids in peptides and proteins.

- Government policies mandate publication of the results of publicly funded research, including DSI.
- Scientific journals require the publication of nucleic acid and amino acid sequences used in an academic study and the deposit of these sequences in international databanks.
- National and international databanks (including databanks under control of Parties to the Nagoya Protocol) do not offer technical options to upload MAT with DSI.
- Governments apply policies of open access without ABS-related conditions to DSI stored in the databanks they oversee.
- In general, users of databanks do not download single sequences for their R&D, rather they download large numbers of sequences which could have been generated from GR from various countries, giving rise to a potentially massive accumulation of highly variable bilateral benefit sharing conditions applying to the user, if MAT were to be uploaded with each entry of a gene sequence or other genetic data.

Although several countries intend to regulate DSI explicitly or implicitly through their national legal ABS frameworks, it seems that most MAT do not contain any conditions regarding DSI, and/or that the DSI conditions would not be implementable (see above list of challenges). Against this background, many Parties began to discuss alternative approaches to regulating benefit sharing when using DSI which is accessed in databanks. The recent Combined study on DSI in public and private databases and DSI traceability, requested by CBD Parties [4], sheds light on the current state of nucleic acid sequences stored in the databanks of the International Nucleotide Sequence Database Consortium (INSDC) in relation to possible regulations of DSI:

- Since 1982, the number of bases in GenBank has doubled every 18 months, with a current average of 3,700 new submissions per week.
- The April 2019 release of GenBank contained over 212 million nucleotide sequence data (NSD) entries consisting of over 321 billion bases.
- The 10-15 million INSDC users[2] are distributed across every country in the world
- Every country in the world has some NSD in the INSDC.
- The DSI country tag came into existence in 1998 and became a required field in 2011, but only 16% of all GenBank entries have a country of origin and over half of the country-tagged NSD come from four countries (USA, China, Canada and Japan).
- In 2018, over 40% of entries submitting NSD to the INSDC reported a country of origin
- Whole genome sequences are growing hyper-exponentially as sequencing costs fall and the throughput continuously grows.
- INSDC members provide open access, no login is required, and thus no personal information on the user base is available.
- A user or an automated programme can access the ftp site and download all or parts of GenBank as individual files directly onto computers or servers of public and private research entities.
- Downloads from the GenBank website amount to 1.3 Terabytes per month whereas ftp downloads amount to 53 Terabytes per month.
- There is no dedicated PIC/MAT metadata field in the INSDC submission form, while information on the Nagoya Protocol Internationally Recognized Certificate of Compliance (IRCC) is not available at present in the metadata, and is often very difficult if not impossible to infer from the associated publication.
- The authors found no evidence that DSI is available in the associated NSD entry in the INSDC with mutually agreed terms (MAT) documentation that could be associated with the country of origin of the GR or with benefit sharing obligations.

The current DSI context as described by workshops, webinars and studies conducted as part of the science- and policy-based process agreed at COP 14 therefore has four major features:

- DSI is published online in databases and electronic publications
- mostly with no country tag
- mostly free to access and download
- with no MAT attached to DSI

This poses concrete limitations and challenges to Parties seeking to regulate the sharing of benefits arising from the use of DSI through bilateral PIC and MAT agreed at the time of access to the GR from which the DSI originates. The potential use of a massive number of DSI entries by a single user challenges the logic of bilateral ABS measures and the monitoring and compliance mechanism foreseen by the Nagoya Protocol. In view of these limitations, what are the options to bilaterally regulate DSI use without losing track, trust and benefits?

2 These data only represent usage of GenBank not all of NCBI and its associated tools and platforms or EMBL-EBI and DDBJ and their other databases and tools. Those numbers are estimated at 100 times more users globally for each of the three INSDC databases suggesting perhaps more than 500 million users worldwide.

II. Methods and Scenarios

Bearing in mind the challenges and questions identified above, the present study takes the **perspectives** of providers, users and databanks to look at three different bilateral approaches to ABS national measures (**scenarios**) that could be used to regulate DSI, examines their impact (**advantages and disadvantages**), and discusses the **limits** of these different bilateral approaches to DSI.

A. PERSPECTIVES: Impact of Bilateral Strategies from the Perspective of Providers, Users and Databanks

Use of DSI typically occurs in two distinct phases:

DSI phase 1: GR accessed under PIC and MAT: access to GR, sequencing to create DSI, use of DSI by the first user, uploading of DSI into a database (hosted by a national or foreign institution, which is important for determining the applicable law during DSI phase 2), bearing in mind that major DSI databases do not provide an option to upload MAT with DSI.

DSI phase 2: Use starting at the databank: accessing DSI from a databank (which in most cases is not under the legal regime of the country providing the original GR), use without any benefit sharing obligations, use of ten thousand or more separate DSI items, which would make adherence to ABS contracts (if uploaded) quite difficult if not impossible.

Regarding DSI phase 2, according to the WilDSI[3] White Paper *Finding Compromise on ABS & DSI in the CBD: Requirements & Policy Ideas from a Scientific Perspective* (Scholz, A. & Hillebrand, U. 2020 [5a]):

"Under the Nagoya Protocol (NP), DSI can conceptually be addressed by Parties through Mutually Agreed Terms (MAT) as the outcome of utilization of a GR, but there are significant technical, legal, practical, and regulatory challenges if DSI were to be handled by all Parties and all users in a bilateral manner over the long-term. This is because DSI is accessed and used at a different scale and complexity than GR. (…)

The open-access system for DSI is incompatible with the individualized bilateral ABS system envisioned by the 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 establishing 'ownership' will prove very complex."

Furthermore, benefit-sharing based solely on the recorded 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" (Scholz, A. & Hillebrand, U. 2020 [5a]).

Nevertheless, *Three open access scenarios for DSI in the framework of the CBD: A discussion paper for the European DSI scientific stakeholder workshop* (Scholz, A. & Hillebrand, U. 2020 [5b]) adds the following: "If Parties to the CBD/NP were to exclusively rely on IRCCs for the utilization of genetic resources as well as DSI generation, production, and usage, it would create a technological basis for improved 'connectivity' and transparency between digital data and genetic resources. Parties could adopt standardized/simplified terms and conditions (similar to open-source software licenses) that would make downstream user compliance more efficient."

Bearing in mind the challenges of the present DSI landscape and the diversity of policy options under discussion, the present study describes three representative ABS implementation scenarios and then analyses the advantages and disadvantages, from the perspectives of providers, users, and databanks, of each scenario for possible bilateral approaches to regulating DSI (phases 1 and 2).

3 WiLDSI (Wissenschaftsbasierte Lösungsansätze für Digitale Sequenzinformation (DSI) / Science-based approaches for Digital Sequence Information) is a project funded by the German Federal Ministry of Education and Research (BMBF) and implemented by the Leibniz Institute DSMZ and the Leibniz Institute IPK Gatersleben
https://www.dsmz.de/collection/nagoya-protocol/digital-sequence-information

B. OPTIONS: National Implementation Scenarios

The following three scenarios are simplified ABS regimes categorized according to requirements regarding access, description, deposit, and third-party use of DSI, particularly the requirement, or not, of PIC and MAT for the abovementioned activities. The proposed scenarios describe some of the possible nuances to be observed in practice, but do not exhaust the options for the regulation of ABS and DSI, nor do they describe all the possible models that could be implemented within each ABS regime scenario.

Although genetic resources ownership varies according to national circumstances, possibly belonging to private persons or to the owner of the land from which it was obtained, the present study aims to reduce complexities by adopting the assumption that "the material ownership of GR belongs to the States and that they have sole competence to decide under what conditions access to 'their' GR can be granted and resulting benefits shared" (Pauchard, N. 2017 [6]).

The three national implementation scenarios that will be analysed here are: 1) Absence of ABS regulation, 2) ABS regulation requiring PIC/MAT, and 3) Open access, under terms and conditions.

Scenario 1: Absence of ABS regulation

In this scenario, there is no specific ABS legislation in place, and no requirements to obtain PIC/MAT to describe, deposit and use DSI (phases 1 and 2), as well as no approved models for ABS agreements or ABS contractual clauses available for providers and users. All clauses of contracts, terms and conditions for access to GR, including regarding DSI description, deposit, use and third-party users' obligations, are to be negotiated on a case-by-case basis, according to private contracts law legislation. Similarly, all rights and duties, including benefit-sharing, monitoring and compliance obligations applicable to DSI, are set in private contract negotiations, without parameters pre-set by any ABS law.

The above scenario could also be applied to other national circumstances, such as NP/CBD non-parties, or in cases where the entities providing GR/DSI (collections, botanical gardens, etc.) have operational procedures that require contractual arrangements (Material Transfer Agreements, MTAs) defining utilization arrangements, third party transfers, etc., as well as to NP parties that do have ABS legislation but would waive PIC requirements (such as in the EU or UK, for instance).

An "Absence of ABS regulation" regime is here considered to be "based on two categories of instruments to achieve its objectives. First, in order to conserve biodiversity and encourage sustainable utilization of biological and genetic resources, CBD States Parties are invited to develop and implement plans, strategies, or programmes. Second, regarding equitable sharing of the benefits, private law contracts are the core instrument. They formalize the arrangements concluded between a GR supplier State and a particular user by stipulating which GRs are used, for which purposes, and how any corresponding benefits could be shared" (Pauchard, N. 2017 [6]).

This scenario will allow discussion of the limitations of the use of private contract law to regulate the description, deposit, use, rights, and obligations related to the DSI (phases 1 and 2).

Scenario 2: ABS regulation requiring PIC/MAT

This scenario describes the national environment of a Party to the Nagoya Protocol with established national ABS legislation requiring PIC and MAT for the description, deposit and use of DSI while also foreseeing third-party users' obligations. In this study, the scenario is described as stated by Pauchard (2017 [6]): "States Parties to the NP are required to adopt clear national ABS legislation. Provider countries have to put procedures into place to regulate access to GR situated on their territory".

Access to the genetic resource, as well as the description, deposit and subsequent use of DSI are "granted through an access permit whose deliverance is conditioned by the obtaining of the Prior Informed Consent (PIC) of the Competent National Authority (CNA, the official body entitled to regulate ABS according to the corresponding national legislation)" (Pauchard, N. 2017 [6]).

In some national systems, ABS legislation only allows the CNA to oversee and approve the MAT, which in turn define DSI description and use. Similarly, there are national circumstances in which access/utilization approval is regarded as a matter of permit issuance, rather than a PIC process.

For the present analysis and discussion, however, this study will assume that in this scenario issuing a permit and/or obtaining PIC are treated as the same administrative instrument that authorizes access, description, and use of DSI (phases 1 and 2). To simplify terminology, such an administrative process that authorises DSI description and use (phases 1 and 2) will be referred to as PIC for description and use of DSI.

Although there are national situations in which PIC must be obtained from additional providers (indigenous people, local communities, individual breeders, etc.), in this proposed scenario, DSI description and use are exclusively subject to the CNA's PIC. Once a PIC is granted, user and provider have to agree on terms and conditions by signing the MAT, in line with the requirements of the relevant ABS legislation.

Although it might be required by national ABS measure, "MAT constitutes a bilateral private law contract that establishes the conditions of access, uses of the resource and the sharing of benefits (commercial or non-commercial research purposes, amount of monetary benefits to be shared, payment terms, etc.). As a user country, a State Party has to ensure that GRs used through R&D programs on their territory were obtained in accordance with the provisions of the providers' ABS legislation. If that is not the case, they must take compliance measures" (Pauchard, N. 2017).

That said, if all DSI description and use are covered by PIC and MAT, user countries that are Parties to the Nagoya Protocol would have to apply user measures to certify that DSI-related activities conducted by their nationals comply with the terms and conditions agreed in the MAT, since in this scenario, the biological information described in the DSI is considered a component of the genetic resource.

As a result, actions in fulfilment of obligations pertaining to the description and subsequent use of DSI, including third-party use from databanks (DSI phase 2) and product commercialization, if covered by PIC/MAT, would have to be observed in and enforced by a user country that is a Party to the Nagoya Protocol.

In this regard, all countries, including developing countries and countries in transition, would similarly be required to enforce and monitor DSI description and use, since "every country around the world – both developed and developing countries – has users that use the INSDC and the NSD that it makes publicly available" (*Combined study on DSI*, requested by CBD Parties).

Scenario 3: Open access, under terms and conditions

The third national implementation environment scenario is a bilateral ABS regime which provides open access[4] to and use of DSI, under terms and conditions. There are examples of bilateral ABS regimes which have "open access, under terms and conditions", such as the current Brazilian ABS system, as described in Novion, H. & Brina, L. (2019 [7]) and Brazil's Position on DSI (2019 [8]), as well as of multilateral options, such as the "Bounded Openness" model as proposed in M. R. Muller (2015 [9]).

4 Open access to a genetic resource to describe and deposit DSI for subsequent use under terms and conditions.

The third scenario aims to achieve some of the desired outcomes of an ABS system as described in the Report of the WiLDSI Workshop: *Digital Sequence Information, Open Access, and Sustainable Benefit Sharing: Scientific Input to International Policy Decisions* (WiLDSI 2020 [10]). An ABS system "should potentially be:

- Compatible with existing free, open access INSDC
- Administratively nimble or invisible for scientists
- Integrated and NOT a stand-alone system (e.g., blockchain)[5]
- Income-generating in a painless way without explicit public sector funds
- Clear in legal scope and compatible with CBD/NP and other legal mechanisms
- Satisfy the demands of the developing world
- Stop being 'DSI' and become something else."

The third scenario could be described as an ABS regime with **regulation of results and not of processes**, moving away from the control of access activities to the control of the outcomes of access and of the economic exploitation of products arising from research and development. This regime **does not require PIC for access to GR, or for description, deposit and use of DSI (phases 1 and 2)**. Instead, results from access and use activities would be declared ex-post, through a 'one-stop-shop' ex-post electronic registration system (ABS online registration system), to be developed and managed by the ABS CNA in the country of origin of the GR from which the DSI was described. It is a model based in the **regularization of users' activities through the registration of outcomes**.

This model provides open access to and streamlined use of DSI (including DSI phase 2), subject to terms and conditions. The use of DSI obtained from a databank will have to be reported in the ABS registration system only when a scientific paper or a DSI description is to be published, an IPR to be obtained, or a product to be manufactured. Similarly, only marketable final products arising from DSI (including if obtained from a databank) will have monetary benefit sharing obligations.

All **terms and conditions regarding access, use and benefit sharing are pre-set in law of the providing countries.** Moreover, the ABS regime **does not require** users who are willing to research, describe or use DSI (phases 1 and 2) to negotiate MAT. Research and development activities, regardless of intention and phase, are exempt from monetary benefit-sharing obligations. Classical MAT negotiation is substituted by the adherence to a standard contract for situations previously defined in law.

5 The third scenario of this study assumes that every country would establish its National Fund and Ex Post Electronic Registration System (ABS Registration System). These national structures could be integrated in a regional and global level, in order to increase global transparency, traceability and enforceability, as well as to amortize technical and finance costs related to such endeavour.

The third scenario therefore identifies a single event as triggering monetary BS obligations: the commercial exploitation of a final product obtained from access to/use of GR/DSI (including DSI phase 2). In this scenario, only the manufacturer of the final product, is required to share monetary benefits, regardless of who has previously carried out access activities or where the product was manufactured. Every new product requires a new notification in the ABS registration system, and the same final product derived through a new formula is considered to be a new product requiring notification and sharing of benefits for as long as the product is marketed in accordance with a fixed net revenue percentage established in law.

With pre-set benefit-sharing obligations detailed in law, MAT negotiations are replaced by a system of adherence, in which users abide by the known benefit-sharing obligations by registering a final product in the ABS online registration system. Every final product ready to be marketed, regardless of the platform from which the genetic resource "potential value" was obtained, if in-situ, ex-situ or in-silico, has to be reported prior to being marketed.

Products commercialized without being reported and without a valid certificate of compliance (issued electronically by the CNA's ABS registration system after notification is given), are considered to be in contravention of the law and may attract sanctions and fines.

Licensing, transferral or the granting of permission for any use of Intellectual Property Rights (IPR) **do not require monetary benefit-sharing**.[6] Benefit-sharing obligations related to IPRs come into being only when a final product (obtained from the use of the licensed IPR) is commercialized. In such a case, it is the manufacturer of the marketable product and not the IPR holder that has to register the final product obtained from the IPR and share monetary benefits.

The same would apply to marketed products developed from many IPR-protected forms of information. With or without IPR, it is the marketing of the product that requires monetary benefit-sharing and notification of the development of the product. The IPR holder, on the other hand, has to register the access activity that led to the IPR request (access/use of GR/DSI), before its claim is deposited. The IPR's registration number in the ABS electronic system (IPR's certificate of compliance) shall be declared by all subsequent users giving notification of products developed from this IPR. In this sense, in countries that request IPR disclosure of origin and ABS conformity, the certificate would be presented as such.

Since an IPR can be licensed to several companies developing different products, each company will have to share the benefits of exploiting the product derived from the IPR obtained from a use of DSI. Benefits arising from one IPR would be shared by several producers, thus expanding the benefit sharing collection base while exempting biotechnological innovation. Every product developed from a particular IPR, in turn, would have to be reported in the one-stop-shop ABS registration system with a declaration of that IPR (certificate of compliance) as the source of the biological information that allowed the product to be developed.

IPR obtention and registration in this scenario plays a different role in traceability and compliance. All **ABS activities that complete the registration process receive a certificate of compliance** from the same ABS online registration system.[7] In this scenario, the compliance procedure flow is simpler. If the user correctly declares the requested information and completes its registration in the ABS electronic system, the user's activities will be considered as being in compliance with the law, and a certificate of compliance will be electronically issued by the ABS Registration System.

All registered ABS activities and products are subject to the CNA's ex-post administrative verification process, which may point out errors to be corrected by users, or identify fraud and wrongdoing. The user does not need to wait for the completion of the verification process to publish a paper, describe and deposit DSI, claim an IPR, or commence with the commercialization of products arising from the use of DSI (phases 1 and 2).

In this scenario, activities involving DSI phases 1 or 2 would be subject to the same obligations, terms and conditions: to register any outcome arising from the activity's description and use, and to register its deposit (as result publication). Similarly, if a finished product arises from DSI use (phases 1 and 2), it would have to be registered in the ABS online registration system prior to the commercialization, and monetary benefits would have to be shared according to the pre-set parameters specified in law.

6 Regarding the benefit-sharing exemption for IPR obtention and licensing, it should be recalled that not all products using GR/DSI are protected by IPR; that many IPR are granted to non-commercial institutions which could neither develop a marketable product nor be able to share monetary benefits due to the obtention of an IPR; that the level of value creation at the point of IPR is not very high, and the value in many cases is still optional; and that IPR as such do not have a monetary value which could be the basis for benefit sharing requirements.

7 An example is the SisGen electronic system from Brazil (https://sisgen.gov.br/) that provides transparency and social accountancy through the publication (in Portuguese) of non-confidential information on users, research, development, products notification and benefit sharing. In its publicity site, also in Portuguese, the electronic system allows anyone to access what are the activities (R&D, product notification, shipment); who are the users (companies, research institutes etc.); and how the benefit is going to be shared (monetary or non-monetary) (https://sisgen.gov.br/paginas/publicidade.aspx).

C LIMITS: Impact of Bilateral Strategies According to Desirable Characteristics of an ABS System

According to Sirakaya (2019) [11], eleven ABS goals are to be fulfilled by the Parties through their national ABS frameworks. A subsequent survey (Sirakaya 2020) [12] conducted with provider countries, academic users, industrial users and users from collections identified the recommended characteristics of an ABS system. Based on that survey, an effective system should provide for:

- legal certainty
- sustainable use
- cost effectiveness
- low transaction costs
- predictable conditions
- fairness and equity
- transparency

The advantages and disadvantages of each scenario will be discussed against these recommended characteristics. The underlying aspects of national sovereignty over DSI as an intrinsic part of GR are discussed under each point. Bilateral strategies are also discussed against the background of existing policies and practices on open access to DSI and publication requirements for users.

III. Discussion and Analysis

According to Bagley et al. (2020) [13], "That DSI can result from the utilization of genetic material and that its use and relevant benefit-sharing obligations or other conditions of use may be addressed in MAT appears to be fairly uncontroversial. A significant divergence, however, seems to arise with respect to the question of whether PIC and MAT could and should be required for the utilization of DSI per se, particularly when it is obtained from databanks (e.g., the International Nucleotide Sequence Database Collaboration – INSDC)".

Policy options for access and benefit-sharing and digital sequence information on genetic resources have been presented and discussed in many international fora, and they diverge on the use of PIC in such cases. Under the CBD, the Secretariat of the Convention organized a global webinar series and online discussion forum to share information related to DSI, including policy options.[8] The ABS Capacity Development Initiative also offered a number of webinars on technical aspects related to DSI.[9]

The spectrum of options under debate is wide and includes multilateral and bilateral arrangements, requiring either PIC and MAT for DSI use, requiring only MAT, or having no requirements at all. Regardless of the possible options and bearing in mind the scenarios described above (section II.B. – Options), it would seem that there may be both advantages and disadvantages for providers, users, and databanks in adopting a bilateral approach to the current use of sequenced, digitally stored biological information.

With due regard for the key requirements for an effective ABS system (section II.C. – Limits), the impact on stakeholders of approaching DSI description and use through bilateral regulation is again discussed for three implementation scenarios outlined above:

Scenario 1: Absence of ABS regulation

Notwithstanding the limitations that apply to providers' ability to control DSI phase 2 use (DSI obtained from databanks), in this scenario, they would be expected to negotiate private law contracts to regulate access to GR, including the description, deposit, and use of DSI (phase 1), and third-party users' obligations (DSI phase 2). These contracts would be negotiated and monitored on a case-by-case basis, as not all stakeholders would agree to sign a MAT to use DSI.

8 CBD Webinar Series on Digital Sequence Information on Genetic Resources https://www.cbd.int/article/dsi-webinar-series-2020

9 https://www.abs-biotrade.info/event-reports/

DSI phase 1 description and use may be subject to private contracts, allowing for monetary benefits from the economic exploitation of products arising from DSI (described and used under these private contracts) to be shared with the provider country. Depending on the terms and conditions of such private contracts for DSI phase I description and use, they may provide users with an ongoing level of legal certainty and predictability.

Although private contracts may impose terms and conditions for access, description, and use of DSI phase 1 and for third-party users (DSI phase 2), the terms and conditions for DSI phase 1 **will not be sufficient to enforce compliance** on the part of users of DSI phase 2 as the "potential value" of the resource is already outside providers' control.

In such a situation, monetary benefit-sharing from the economic exploitation of products arising from DSI phase 2 use will depend on:

- the users' willingness to abide by the terms and conditions of the provider country private contracts (if the DSI phase 2 has its origin identified); and
- the DSI phase 2 users' countries to establish and enforce national measures that require such users to comply with the terms and conditions of the provider country's private contracts' (if the DSI phase 2 has its origin identified).

None of the cases seems to align with the practices commonly in place with regard to the use of DSI phase 2.

Bearing in mind that DSI phase 2 is published online, mostly with no country tag, no attached private contracts, and free access and downloading, a national scenario with the absence of ABS legislation will have, from the providers' perspective, the least legal certainty; the lowest sustainable use and cost-effectiveness; and reduced transparency, with a low level of fairness and equity. Transaction costs in this scenario, on the other hand, will be the highest for providers and users alike.

It would probably not have any practical consequence if users were obliged, when depositing the DSI phase 1 sequence in a databank (as an attachment, for example), by a DSI phase 1 contract to declare DSI phase 2 terms and conditions of use. This is because "even though depositors of sequences can present, while registering a DSI, that they have obtained PIC and MAT, databases do not require this information, are not willing to create a specific field for that kind of information nor will they do anything with it (communicate provider countries or third users of the DSI, for example)" (*Combined study on DSI*, requested by CBD Parties).

This situation reduces providers' capacity to trace DSI, reducing transparency and making proper track-and-trace of DSI phase 2 use from databanks unfeasible. Terms and conditions in private contracts pertaining to DSI phase 1 that apply to third-party users won't control or manage DSI phase 2 use. From the providers' perspective, therefore, DSI phase 2 control through DSI phase 1 contracts is unlikely to be practicable.

Having said that, in the scenario in which DSI phase 1 is subject to private contracts, providers may increase the value and conditions for monetary benefit-sharing arising from economic exploitation of products obtained from DSI phase 1 use, aiming to compensate for the potential erosion of benefit-sharing caused by the economic exploitation of products developed through DSI phase 2. In such a situation, the level of fairness and equity will be reduced, while users' transaction costs may increase due to unfair, unbalanced and asymmetrical contract negotiations.

From the point of view of **users** in this scenario, since there is a high level of discretion amongst public officials in charge of negotiations, "It is conceivable that a provider state may even waive authorisation and contracting requirements if a user is subject to well-developed compliance control by his/her home state" (Kamau, E., Fedder, B. & Winter, G. 2010 [14]). Moreover, users may propose that their own contract models are used if providers do not have their own models in place.

Even if private contracts could properly cover DSI phases 1 and 2, and users could obtain favourable conditions (waivers and "non-measures"), **risks** will always be present, since user parties may not recognize the authorization as valid, due to **insufficient documentation** of compliance (in the absence of an internationally recognized certificate of compliance or a PIC/MAT specified in an ABS law). Thus, legal certainty and transparency are reduced.

In this regard, DSI arising from GR obtained from countries without ABS legislation and a correspondent IRCC may increase the paperwork load for users, who may be required to provide additional information, validation and proof of due diligence to certify that the DSI in question was obtained properly, through a private contract, before it was made available for use. In this scenario, costs arising from the extra effort of users to prove compliance with providers' terms and conditions may outweigh the potential benefits arising from deregulation, waivers, and non-measures, thus elevating transaction costs and reducing sustainable use, transparency, legal certainty, and predictability for users.

Similarly, users may be overburdened by increased compliance costs due to the complexity and volume of information to be gathered, validated and reported on for proof of compliance in a no-ABS legislation context. In cases where users are using multiple DSIs from different national contexts and databanks, reporting on compliance with different private contracts (that may, depending

on the outcomes of the contract negotiations, have different terms and conditions for similar activities) will most likely be costly and complex, if not administratively unfeasible. This context will inevitably elevate transaction and financial costs while reducing sustainable use and cost-effectiveness, thus undermining users' ability to accurately predict costs, and therefore reducing their willingness to describe and use DSI under this scenario.

Likewise, although "up-front payments are avoided by users because they are averse to risk" (Richerzhagen, C. 2011 [15]), users may be required to negotiate **unfavourable** upfront payments with providers trying to compensate the potential benefit-sharing erosion arising from the economic exploitation of products developed with the usage of DSI phase 2. Such payments may not be in line with the ethos of equity and justice associated with benefit-sharing. An upfront payment could be priced too high. Furthermore, not all users necessarily pursue monetary benefits from DSI use (non-commercial research is an example of this), and in such a situation, costs outweigh benefits, transaction costs are high, and equity and fairness are reduced.

In relation to **databanks**, there is already "legal uncertainty surrounding the impact of ABS on data in the collections, in contrast to the case of materials where material transfer agreements for ABS have been discussed and implemented for a long time" (Dedeurwaerdere, T. et al. [16]).

In this scenario, if DSI phase 2 is to be dealt with through private contracts (bearing in mind that the majority of stakeholders are not comfortable with this possibility), there will be an increased expectation (and enhanced political pressure) on databanks to adapt or create terms and conditions to include "data access and use agreements" to which DSI phase 2 users will have to agree to before accessing data.

In this regard, according to Third World Network – TWN submission on DSI to the CBD [17], "Data access and use agreements offer the potential to permit DSI to remain publicly accessible while protecting the interests of providing countries and IPLCs. Akin to the 'terms and conditions' that accompany an airplane or train ticket, or utilities such as water and sewer services, data access and use agreements can be used to set forth benefit sharing obligations connected to publicly-accessible DSI."

Beyond a shadow of doubt, an ABS regime with burdensome and bureaucratic conditions will compromise benefit generation itself (from new information to new products), thus undermining its main purpose, which should be to facilitate the generation of relevant scientific data and economic resources for biodiversity conservation.

In this context, "Hindering the public-funded sector from the ability to leverage their research base for commercial objectives, through the imposition of additional regulatory burdens such as ABS for DSI, could lead to catastrophic loss of interest in, and of vital funding streams for that research" (Chartered Institute of Patent Attorneys (CIPA), 2019 [18]). Sustainable use will therefore be reduced.

Moreover, we may recall Sirakayas' statement (2020): "The current perception regarding the operationalisation of ABS is that the national implementations bring complexities for both academic and industrial users of GR as well as collections which result in less willingness to access GR (Koester, 2012; Lassen, 2016; Overmann & Scholz, 2016; Watanabe, 2015). Users commonly list the lack of legal certainty, inconsistency in ABS systems, reputational risk and investment uncertainty as the main reasons for concern (UNCTAD, 2017). Less access would inevitably result in fewer benefits shared and this vicious cycle would jeopardise the success of the entirety of the ABS system".

Regarding the detrimental effects of having no ABS legislation, Sirakaya, A. (2020) states: "The overarching reason why ABS implementation is neither beneficial for the providers nor for the users is that the providers do not regulate based on unified ABS goals and therefore the implementation does not lead to achieving the objectives of the international ABS framework. This inevitably jeopardises access to GR as well as benefit-sharing and hence slows down scientific research, thereby damaging the trust between the provider and the user. By harmonising international ABS goals as a starting point in regulating ABS matters, the providers can address the core of the implementation problem: inconsistency" (Sirakaya, A. 2020). Consequently, trust, fairness and equity are low.

Scenario 2: ABS regulation requiring PIC/MAT

According to Richerzhagen, C. (2011), "The creation and the strengthening of institutional infrastructures can decrease transaction costs and facilitate access in the ABS process. It abolishes information deficiencies and administrative complexity. (…) Competent authorities are the key contact for users in provider countries. National focal points are important for the collection, provision, and dissemination of information, and they play an essential role in raising the level of awareness in user countries." Providers' transaction costs are reduced, predictability and sustainable use are enhanced.

In relation to DSI phase 1, MAT and PIC rules established in law with terms and conditions that provide for DSI description, deposit and use increase officials' confidence in granting PIC and MAT. In this sense, if there is legal certainty on DSI phase 1, providers' work will be more predictable and transparent, enabling description and sustainable use of DSI Phase 1 to be increased.

In this scenario, DSI phase 1 description and use may be subject to PIC and MAT, allowing for monetary benefits from the economic exploitation of products arising from DSI covered by such PIC/MAT to be shared with the provider country. At the same time, in comparison with scenario 1, PIC/MAT relating to DSI phase I description and use may, depending on their terms and conditions, grant users an increased level of legal protection, predictability and sustainable use.

On the other hand, if DSI is to be addressed in accordance with the Nagoya Protocol (a position on which there is not consensus), every sequence description and use (DSI Phase 1 and 2) would be subject to PIC/MAT, with possible consequences such as "high transaction and administrative costs, reduced access to genetic resources, reduced international collaboration and negative impacts on scientific research and public health" (Brink, M. & van Hintum, T. 2020 [19]). In this situation, predictability, legal certainty, and cost-effectiveness are low, while transaction costs are high.

Although ABS legislation may impose terms and conditions, through PIC and MAT, for access, description and use of DSI phase 1, **it may not be sufficient to compel users of DSI phase 2 to comply**, since the "potential value" of the resource is already outside providers' control. Additionally, as previously stated, databanks do not require PIC/MAT and are not willing to require compliance with such terms and conditions or communicate them to provider countries or third-party users of DSI (*Combined study on DSI*, requested by CBD Parties).

Terms and conditions in DSI phase 1 PIC/MAT that supposedly apply to third-party users **won't actually impede DSI phase 2 use without PIC and MAT**. From the providers' perspective, therefore, DSI phase 2 control through DSI phase 1 PIC/MATs is very limited.

In comparison to the first scenario (no ABS legislation in place), jurisdiction shopping may be reduced but not eliminated, since:

- Users "are tempted to source genetic resources from countries where there is no access and benefit sharing legislation to avoid the need for time-consuming bilateral negotiations and high costs. Such views are shared by both research organisations and industry, with industry having stronger opinions, most likely due to more experience with negotiating PIC and MAT" (Milieu Law & Policy Consulting, 2020 [20]).
- "A user will go to a country where he can predict what the permit process will require and what the outcome could be (De Bièvre, Poletti, & Thomann, 2014). Due to this, providing for a predictable legal framework is essential for the provider that would like to valorise its GR" (Sirakaya, A. 2020).

Regarding compliance for DSI phase 2 use, since the state cannot control or restrict DSI use through PIC, requiring PIC for the use of DSI phase 2 may prove to be ineffective or unfeasible. Providers cannot realistically restrict its use in the same way as they would with tangible samples in their territory or DSI described from GR covered by PIC and MAT.

Control of DSI phase 2 use depends on **third parties' cooperation and willingness** to comply in order for providers to realistically be able to track and trace the economic exploitation of products arising from DSI phase 2. Since this doesn't currently seem to be the case for the use of DSI phase 2, providers won't achieve the desired predictability, transparency, sustainable use, fairness, and equity in relation to DSI phase 2 use.

In this scenario, transaction costs related to the requirement of PIC and MAT for the description and use of DSI phases 1 and 2 are significantly increased. Bearing in mind that all over the world, there are thousands of DSI uses per day, there are significant technical and financial costs limiting providers' capacity to analyse and grant PIC and MAT and to subsequently monitor and track every DSI description and use. Even if PIC is standardized, providers' officials still need to check the information provided by users and negotiate MAT on a case-by-case basis, which is probably not feasible for DSI phase 2, given the nature of its use. For providers, achieving effective compliance may entail increased financial and transaction costs, which will be likely to outweigh the benefits.

Even if an electronic permitting system were in place to streamline the issuing of PIC and MAT, DSI phase 2 use would still have to be analysed on a case-by-case basis. Backlogs and delayed responses by officials would become a weakness and a threat to the functioning of the ABS system, compromising the predictability, cost-effectiveness and sustainable use expected to be delivered by an ABS legislation, and also increasing providers and users' transaction and financial costs.

Likewise, since most MATs take at least a year to negotiate and involve a plethora of legal documents (Laird, S. & Virnig, A. & Wynberg, R. 2018 [21]; Scholz, A. & Hillebrand, U. 2020a; and Milieu Law & Policy Consulting, 2020), in the scenario of case-by-case PIC/MAT negotiation, costs can outweigh the anticipated mutual benefits (Ten Kate, K. & Laird, S.A. 1999 [22]).

Although PIC and MAT are negotiated on a case-by-case basis, ABS legislation that regulates PIC and MAT for DSI description and use (DSI phase 1) may still help providers to achieve compliance, provided that:

- Activities and institutions subject to compliance rules are clearly defined in PIC/MAT.
- Rights and obligations standardized by law allow for efficient monitoring of PIC/MAT implementation, providing sufficient clarity and predictability for providers who seek to enforce compliance than would be provided by the monitoring of private contracts, each with its own agreed rights and obligations.
- ABS legislation that establishes standard contractual clauses with clear and realistic terms and conditions helps increase the level of predictability and user willingness to access and develop processes and products from DSI. Having well defined activities and institutions which are subject to compliance would also reduce the complexity and cost of providers' compliance monitoring activities, thereby increasing sustainability and cost-effectiveness.
- Certificates of compliance for DSI phase 1 support the monitoring of DSI phase 2 use. According to Richerzhagen, C. (2011), certificates of compliance function as a tracking system and discourage unapproved and illegal use of genetic resources. In this sense, DSI phase 1 deposited with an attached certificate of compliance may be more attractive for users willing to access DSI phase 2, due to improved legal certainty.

In this scenario, ABS legislation that provides IRCCs is likely to lead to increased sustainable use, transparency and predictability for utilizers of DSI, particularly for DSI phase 1, and for providers monitoring compliance. According to Scholz, A. & Hillebrand, U. (2020b), "if Parties to the CBD/NP were to exclusively rely on IRCCs for the utilization of genetic resources as well as DSI generation, production, and usage, it would create a technological basis for improved 'connectivity' and transparency between digital data and genetic resources."

Bearing in mind that DSI Phase 2 use may possibly not be restricted by PIC and MAT obtained for DSI phase 1, providers might increase their demands in terms of monetary value and conditions imposed for the economic exploitation of products obtained from DSI phase 1, in an attempt to compensate for potential benefit-sharing losses arising from the failure to benefit from economic exploitation of products developed with the use of DSI phase 2. If this distortion materializes, providers could anticipate benefits, with the fairness and equity of benefits increasing on their side while decreasing on the users' side.

DSI phase 2 use bounded by PIC/MAT conditions will inevitably lead to "high transaction and administrative costs, reduced access to genetic resources, reduced international collaboration and negative impacts on scientific research and public health" (Brink, M. & van Hintum, T. 2020).

Regarding the **users'** perspective, according to an online survey on DSI completed by 340 respondents who already work with DSI in Germany (Karger, E. 2018 [23]), "It cannot be ruled out that respondents have had positive experiences with the Nagoya Protocol. However, if they have had positive experiences, these were not reflected in any of the comments made. Some of the themes that emerged included:

- Uncertainty. This included uncertainty about the legal implications of sharing DSI, legal uncertainty due to the complexity of different ABS rules in different countries, and uncertainty about the future and how their work will be affected;
- Bureaucracy and strict regulation. Respondents who have experience with the Nagoya Protocol regard it as a bureaucratic burden which creates a major drain on their resources, including both time and money. Some respondents indicated that it was very complicated or difficult to get PIC and MAT. According to some respondents, this was largely due to a lack of the necessary administrative procedures and institutions in the countries providing genetic resources. There was also concern that it was difficult to obtain PIC and MAT due to very strict regulations in some countries; and
- Negative impacts on their work including having to stop research, loss of collaborations with other scientists and restrictions on the ability to share data with former collaborators."

Moreover, according to Karger's study, "respondents who were unable to get PIC and MAT for sequencing or who received PIC and MAT without permission to sequence reported various consequences of this. These included:

- termination of the project/abandonment of the research question;
- being unable to conduct the project according to plan;
- obtaining permits for sequencing at a later stage of the project;
- having limited scientific insight into the genetic resources;
- the material could not be used / the specimen became useless;
- sequences generated at the request of the provider country (by another government department) could not be used;
- the work was obsolete;
- wasted resources in terms of time spent negotiating contracts;
- wasted time and funding/wages for scientific work which ultimately could not be used;
- having to find alternatives;
- doing other research; and
- having no interest to continue working with the same partners and having plans to change countries/resources in future."

According to the survey, "the respondents who were not permitted to share or publish their DSI reported various consequences of this, including:

- having to exclude certain resources from their research, i.e. they could not use the material;

- being unable to include the data in their results;
- the quality of the research being affected;
- having to stop their research;
- limitations on cooperation or collaboration with third parties;
- having no intention to work in the same country again; and
- it being unlikely that they get further funding for the research."

Even if PIC/MAT could properly cover DSI phases 1 and 2 and users could obtain predictable conditions for access/generation and use of DSI (phases 1 and 2), transaction costs would likely be prohibitive when compared to the possible benefits. This may occur because providers probably won't be able to respond in a timely manner to all PIC/MAT requests for DSI phases 1 and 2. In addition, users would have to bear additional costs associated with compliance with different provider countries, with different terms and conditions, but only for those cases where DSI phase 2 origin is identified (which is not generally the case). This also adds more complexity and uncertainty to the DSI context for users.

In relation to facilitating measures for **non-commercial research,** according to Laird, S. et al. (2020) [24], "Even streamlined approaches for non-commercial research required substantial investments of time, money, and capacity to receive permits or sign ABS agreements in countries with unclear legal and administrative structures."

Moreover, according to Sirakaya, "separation between basic and applied research is becoming increasingly complex. During the interviews, users in general repeatedly stated that complying with some ABS laws has proven to be especially difficult for non-commercial research and SMEs as the system is rather costly for them" (Sirakaya, A. 2019).

According to CIPA's DSI submission to the CBD, it is "practically impossible to divide commercial from non-commercial use of DSI. The gap between the academic and private sectors is not clear cut. A great many of the world's major academic institutions from a great many countries are some of the largest holders of patented technologies. These intellectual property estates are a vital source of income to support fundamental basic research that benefits all of humanity" (CIPA, 2019).

Finally, according to Karger, E. (May 2018), "PIC/MAT negotiation for non-commercial research use of DSI generates uncertainty about the legal implications of sharing DSI, arising from:

- legal uncertainty due to the complexity of different ABS rules in different countries, and uncertainty about the future and how their work will be affected;
- bureaucratic burden which creates a major drain on resources, including both time and money;
- lack of necessary administrative procedures and institutions in the countries providing genetic resources increases difficulties in obtaining PIC and MAT due to very strict regulations in some countries leading to negative impacts on their work including having to stop research, loss of collaborations with other scientists and restrictions on the ability to share data with former collaborators."

In relation to non-commercial research on DSI (phases 1 and 2), from the perspective of users, legal certainty, sustainable use, cost-effectiveness and predictability are low, while transaction costs are high.

Regarding legal certainty, sustainable use and predictability, if all providers establish their own national legislation, they will inevitably be distinct from each other, with different scopes, interpretations, procedures and obligations to fulfil. Regulating DSI description and use in ABS legislation is also not the norm for countries with ABS legislation (Bagley, M. et al. 2020). This will inevitably hinder transparency, sustainable use and predictability in contexts in which DSI is used in bulk.

In this regard, Brink and van Hintum recall that:

"Each country was allowed to have its own interpretations and to make its own procedures, which resulted in a complex situation, also due to the uncertainty on how to make access procedures, the costs, and the sometimes insufficient capacity of countries to do this properly. This complex situation sometimes discouraged potential users from seeking access to genetic resources. So, while domestic access and benefit-sharing policies were intended to support, rather than hinder, the sharing of [Plant Genetic Resources for Food and Agriculture] (Wynberg et al., 2012), this was often not the case. Adverse effects of CBD based domestic ABS regulations on biodiversity research and international collaboration have been reported by various authors (Jinnah and Jungcurt, 2009; Neumann et al., 2018; Prathapan et al., 2018). (…)

Users of genetic resources fear NP's negative consequences, such as high transaction and administrative costs, reduced access to genetic resources, reduced international collaboration and negative impacts on scientific research and public health (…) The volume of paperwork required will increase significantly, as well as the complexity related to Databank management and the associated costs. (…)

Access will decrease, affecting collaboration between databanks, which will be less eager to rationalize their own banks with other databanks, resulting in redundancies, since they cannot be sure of access to other collections in the future, generating further stress on the already limited capacity of the PGR community." (Brink, M. & van Hintum, T. 2020).

In this context, the level of legal certainty, transparency, sustainable use and predictability are reduced, while transaction costs are increased.

Regarding the identification of the origin of a DSI phase 2 deposited in databanks, the linkage of a DSI use to a provider's ABS legislative terms and conditions is not just limited to the databank's willingness to require this information before the deposit, but also involves the very complex nature of sequences and the DSI's distribution through jurisdictions and taxa.

Laird, S. and Wynberg, R. (2018) [25] note that "some are sceptical of the potential to monitor digital sequence information in any meaningful way, and express concern about what they describe as the additional management, bureaucracy and expense involved in adding layers of legal documents and information to databanks. (…) There are concerns about how effectively identification can work for sequence information, since sequences from the same species from the same habitat might differ due to natural mutations over very short periods of time, and sequences from different species and origins might be similar. An additional challenge for identifying digital sequence information is that it is not immediately recognizable as belonging to a particular source, particularly as it undergoes modification." The level of legal certainty and transparency is reduced, while transaction and financial costs may increase.

Likewise, traceability in the context of the utilization of bulk DSI from innumerable providers adds to complexity, with the result that predictability, legal certainty and cost-effectiveness are low, while the transaction costs are high.

Scholz, A. & Hillebrand, U. (2020b) comment on tracking DSI and linkage to the terms and conditions imposed be the country of origin: "[A] country tag alone would not explain to the user what the benefit sharing obligations are. If a country tag were to replace the IRCC, then there would need to be a reliable, legitimate website for each country explaining how DSI is handled and what the standard terms and conditions for the country are. In either scenario, the user would still need to keep track of which DSI was used." Thus, predictability, legal certainty and cost-effectiveness are low, while transaction costs are high.

In this regard, DSI imposes new challenges and costs on users willing to comply with ABS legislation. According to Milieu Law & Policy Consulting (2020) in their *Analysis of implications of compliance with the EU ABS Regulation for research organisations and private sector companies*, companies had to hire specialists, set up working groups and develop IT systems "to help with collecting the information related to the origin of genetic resources and/ or associated traditional knowledge, and to track and trace their use throughout the different research and development phases."

Moreover, Milieu Law & Policy Consulting (2020) state that the obligation that rests on companies to obtain PIC and MAT "is considered extremely complex and burdensome (…) even when successful, [they] have encountered several problems, delays and costs." Understanding which authority to contact, which is the Competent Authority, and what is the specific legal framework in the provider country, is reported as a major issue: "Contacting National Focal Points in the provider countries outside of the EU often proves to be a challenge."

According to their analysis, "It is not possible to apply the knowledge acquired in one third country to other PIC and MAT negotiations. Unrealistic demands from provider countries, such as very high margins for profit sharing or requirements for local use only of the resources, are also reported as key obstacles". Moreover, "the cumulative costs for obtaining the PIC and MAT vary greatly, depending on the provider country, the local support structure of the individual organisation, the perceived importance of the genetic resource" (ibid.).

Finally, "Scoping is the most 'complex, burdensome and expensive' element for complying" and "the essential reason for developing IT tools (…) in all of the research organisations and private sector companies interviewed, across all sectors" (ibid.). In this complex context, predictability, legal certainty and cost-effectiveness are reduced, while transaction, technical and financial costs increase.

Regarding **databanks**, and bearing in mind that not all stakeholders are comfortable with the possibility of DSI (phases 1 and 2) description and use being mediated by PIC/MAT, there would also be an increased expectation on databanks to adapt or create new fields in their DSI deposit registration system. Such origin identification fields would be required to allow the upload of PIC and MAT addressing DSI phase 1 (contract to describe, deposit and use) and DSI phase 2 (contract allowing third-party users, restricting use or requiring users of such DSI to negotiate with provider countries). Financial and technical costs would inevitably weigh on databanks that (voluntarily or otherwise) followed this course.

According to Scholz, A. & Hillebrand, U. (2020a), "For the NP, there is no global GR infrastructure that can report on the world's GR. Perhaps because of this, the lack of transparency on GR access and use has led to a lack of trust amongst Parties". Moreover, the authors state that "the INSDC and biological databases are scientific institutions that cannot be asked to 'police' DSI usage or benefit-sharing (…) They are well-positioned to play a constructive scientific role but the legal entity for benefit-sharing must remain completely separate. Indeed, given the political/ governance structures of the INSDC partners, INSDC is under no obligation to make any changes in response to requests from the CBD".

In this scenario, databanks can contribute to transparency and predictability, thus helping to build trust, ensure sustainable use and reduce transactions costs. At the same time databanks can collaborate to improve fairness and equity: "There is a core DSI infrastructure already in place and in widespread use. Evidence-based data from INSDC could be critical in transitioning away from long-held suspicions and mistrust, to informed and honest discussions that move the policy process forward in a productive manner. INSDC could, upon formal request and with sufficient funding, assist Parties with the transparency measures" (Scholz, A. & Hillebrand, U. 2020a).

Regardless of the DSI phase in question, in this scenario, if providers have to grant, users have to obtain, and all stakeholders have to implement PIC/MAT for DSI description and use. This means that transaction costs will inevitably increase, considerably reducing sustainable use, legal certainty and predictability to providers, users and databanks, while compromising trust, fairness and equity. Transparency and cost-effectiveness would also be jeopardized if countries had highly diverse terms and conditions that users had to abide with.

Scenario 3: Open access, under terms and conditions

An effective ABS model is expected to reduce transaction costs for providers and users alike. From the **providers'** perspective, DSI use, especially for DSI phase 2, is complex and costly to monitor, and enforcing compliance with national legislation is problematic. Moreover, depending on the terms and conditions for DSI description and use in the national ABS law, officials may struggle to identify DSI phase 2 use and its respective users, and they may not be able to enforce the observation of national legislation relating to benefit-sharing obligations resulting from DSI use.

In this regard, the third scenario provides increased legal certainty: users know beforehand what terms and conditions they are required to abide by. It allows for open access and use (DSI phases 1 and 2 description and use are not conditional upon any previous obligations); focuses on end-user measures (only activities with DSI that led to a concrete outcome – a publication, an IPR or a product – must register or notify in an electronic system); and has a single benefit-sharing point of incidence (only final product commercialization shares benefits). Compliance is therefore expected to be higher compared to previously discussed scenarios. This also contributes to a reduction in transaction costs for providers, since:

- activities and institutions subject to compliance are clearly defined;
- monitoring activities go from prior command and control, on a case-by-case basis, to bulk data mining, ABS online registration system monitoring, databases integration, and verification of users' ex-post results declarations; and
- activities' certificates of compliance are obtained through an ABS online registration system, which reduces transaction costs and increases social recognition and accountability. This increases social control and efficiency in the monitoring of activities, as every stakeholder (IPLCs, NGOs, academia, companies; public agencies, justice agencies) can access information that is not confidential. Governmental bodies can directly access information registered in the system, enhancing coordination and cooperation in compliance matters.

At the same time, there is a reduction in opportunity cost ensuing from government officials' time and resources being expended on permits, MAT analysis, negotiations, and case-by-case monitoring, enabling officials to focus on implementing other priority ABS activities. With no time consumed by PIC/MAT negotiations, pre-set conditions reduce transaction costs (Sirakaya, A. 2019); Richerzhagen, C. 2011). Also, the contractual commitment to adhere to pre-set conditions for benefit sharing consolidates bargaining power in favour of providers (Richerzhagen, C. 2011). Sustainable use, fairness and equity may also be increased for providers, and the predictability and transparency of their work may be enhanced. This scenario increases the cost-effectiveness of compliance and permit-granting activities in comparison with the previous scenarios.

Regarding facilitation of access and special measures for non-commercial research, since access and use are facilitated to all sectors and for all purposes, providers are not required to establish special/sectoral treatment (NP Articles 8A, B and C). In other words, providers will not have to implement different monitoring activities for different "types" of use, which makes monitoring of compliance also cheaper and easier.

With one single process analysis flow for all types of use, this scenario provides reduced transaction costs for monitoring, particularly when compared with scenarios where officials have to monitor each sectoral activity with different terms, conditions and monitoring flows (special measures and wavers to facilitate access in scenario 2), or the same activities with distinct terms and conditions (scenario 1). In the scenario 3, providers will have an improved sustainable use environment, which also increases the cost-effectiveness and predictability of their work.

Regarding providers' expectation of benefits in an open access scenario, it has been noted that "maximizing open access to basic data sets is essential for the rapid translation of research results into knowledge, products and procedures to improve matters of general interest" (Dedeurwaerdere, T. et al. 2016). By allowing open use, this scenario creates better conditions for an increase in the availability of non-monetary and monetary benefits compared to the previous scenarios; "by facilitating access for non-commercial research, provider countries will reap non-mon-

etary benefits such as training, technology transfer and greater understanding of their biodiversity" (Schindel, D. & Du Plessis, P. 2014 [26]).

Finally, regarding monetary benefit-sharing, "since the DSI system itself is already complex and huge, benefit-sharing mechanisms that are simple, easy to understand, and scalable will likely return far greater value than technologically complex or bureaucratically demanding systems". (Scholz, A. & Hillebrand, U. 2020a).

Regarding the "scale problem" posed by DSI, since only concrete results and products arising from DSI use have to comply, all other research and product development that did not deliver hoped-for results will not need to be registered. One could therefore say that this model can handle the "scale problem", return meaningful benefits, and be "administratively nimble", as anticipated by Scholz and Hillebrand (2020a). In this case, cost-effectiveness related to benefit-sharing is high, while the transaction costs are low.

In contrast to the previous scenarios, in which a signed private contract or agreed PIC/MAT captures or anticipates monetary benefits, this scenario relies more on the willingness of third parties (users, databanks, Parties to the Nagoya Protocol, and relevant stakeholders) to implement the CBD and related objectives and obligations (measures for ensuring users' compliance, for example) to capture monetary benefits from the economic exploitation of products arising from the use of DSI (phases 1 and 2).

The same pattern emerges with compliance efforts. While this scenario decreases provider states' control over activities conducted on "their" DSI/GR, it requires an effective NP implementation on the national level, especially by user Parties, to achieve an efficient international compliance with the national legislation of provider states (extraterritoriality).

This scenario is also highly dependent on the cooperation of third parties (databanks, users, governments, civil society, CBD Secretariat, etc.) with respect to the information exchange required to track and trace economic exploitation of products arising from DSI and then capture its monetary benefits. If the cooperation and commitment to the objectives of the CBD on the part of stakeholders are not fully realized, the cost-effectiveness of this scenario can be reduced, and the costs of its implementation can outweigh the benefits.

Regarding the effectiveness of this scenario, there are "concerns about how effectively identification can work for sequence information, since sequences from the same species from the same habitat might differ due to natural mutations over very short periods of time, and sequences from different species and origins might be similar. An additional challenge for identifying digital sequence information is that it is not immediately recognizable as belonging to a particular source, particularly as it undergoes modification" (Laird, S.A. & Wynberg, R.P. 2018). Backward tracking may be costly or unfeasible.

In this regard, providers may face high costs associated with benefit sharing compliance, and these costs may also outweigh the benefits. The same product may use numerous DSIs from different providers or DSIs that are widely dispersed across multiple jurisdictions and taxa. In such situations, new challenges and costs arise:

- The technical and transaction costs of identifying the origin of a GR/DSI from a product where multiple DSI are involved are increased.
- The costs associated with negotiations over benefit sharing with other countries of origin for the same DSI may lead to jurisdiction shopping or the formation of provider cartels, reducing fairness and equity.
- Conflicts may arise between countries of origin/providers over the apportionment of benefits from DSIs that are identical, but widely dispersed across jurisdictions and taxa. The issue of what proportion of the total benefits should be channelled to each country where the DSI occurs would have to be addressed. This could result in reduced legal certainty and predictability for providers.
- Tracking, measuring and calculating the contributions of each nucleotide sequence to the commercial product would be complex and incur additional costs

In this scenario, providers will have to rely on the willingness of databanks to adapt existing fields or create new fields in their DSI deposit registration systems. This would be necessary for facilitating access to useful information for traceability and compliance, but databanks are typically not willing to create specific fields for such information (*Combined study on DSI*, requested by CBD Parties). Difficulties with the identification of the origin of a DSI and its traceability in this scenario may hinder the capacity to capture monetary benefits arising from economic exploitation of products obtained through the utilization of DSI (phases 1 and 2).

Furthermore, this scenario is likely to allow for DSI free riders, since effective compliance depends on user countries being a Parties to the NP, and, moreover, having the capacity to implement the measures expected of user countries. Since this scenario is highly dependent on users' good faith and corporations' social and environmental responsibility, there may be reduced fairness and equity for providers.

Since this scenario also depends to a significant degree on traceability and enforceability for the capturing of benefits, it requires an ABS online registration system that should be:

- able to register all activities and products ensuing from the use of DSI (phases 1 and 2);
- user-friendly, i.e. simple and easy to operate;
- integrable with other useful databases for traceability and compliance (data mining) and for facilitating user registration (downloading of useful information from other databases);
- capable of protecting users' sensitive data registered in the system (confidential information related to intellectual property rights, business plans and strategies, R&D results, companies' revenue information, etc.); and
- capable of monitoring, tracing and controlling highly complex and dynamic activities.

In this scenario, the ABS online registration system of provider countries will be highly dependent on information technology: To put such a system in place, providers may be required to make substantial upfront investments, as well as to bear ongoing costs for the system's protection and maintenance. Also, providers may not have the necessary funds to establish efficient electronic ex-post ABS systems. And, if the electronic system is unable to properly protect sensitive commercial information registered in it, users may not feel confident to declare their activities due to concerns over electronic invasions and the misappropriation of sensitive information.

The need to implement an ABS online registration system raises further concerns regarding confidence. Although Sirakaya (2019) noted that collection representatives had stated that "notification is enough for monitoring the utilization of genetic resources," ensuring that a system for DSI use is secure and efficient may increase financial and technical costs and may reduce cost-effectiveness and sustainable use on the providers' side. This may occur due to a lack of confidence on the part of users that a notification of use will serve as a valid document to certify lawfulness.

This potential lack of trust may have further impacts, such as the users being forced to request a formal permit, instead of a notification receipt. This is because, for some users, "the permit is the only way to ensure legal certainty and to be certain that their access will not be challenged in the future" (Sirakaya, A. 2019). On the other hand, providers may also not trust in the strength of a notification: "The majority of the stakeholders representing provider countries opted for requiring a permit for access, stating it as the only way to ensure benefit-sharing" (ibid.). Mistrust in the strength of a notification may also increase transaction costs, reducing sustainable use and predictability.

From the providers' perspective, this scenario certainly decreases control over DSI use, while at the same time requiring significant upfront investment in technology to implement an electronic ABS system for registering and monitoring activities. Providers may also have to accept ongoing costs for the system's protection and maintenance. This will not be technically and economically feasible for all provider countries that wish to bilaterally regulate DSI use. The costs of creation and maintenance are likely to outweigh the benefits.

Furthermore**, from the users' perspective**, "pre-set conditions reduce transaction costs" (ibid.) and also reduce reputational risk and investment uncertainty, resulting in greater willingness to generate and use DSI (phases 1 and 2).

Pre-set terms and conditions allow users to acknowledge their rights and obligations before deciding to commence with ABS activities, as costs and risks are clarified beforehand, which increases predictability. Open access and use of DSI (phases 1 and 2) under terms and conditions pre-set in ABS legislation also ensures transparency for users who are willing to use DSI. Similarly, regarding compliance obligations for users, this scenario is expected to reduce opportunity costs to which users are subject, as less time and resources are dedicated to permits/MAT analysis, negotiations, and reporting. Pre-set BS obligations increase the confidence of users in developing new products.

Clarity on who has monetary benefit-sharing obligations is enhanced by pre-set parameters in law. These also provide for greater legal certainty and predictability when investing in bio-innovation and new products from DSI use. Moreover, it is "easier to delay monetary benefit-sharing if and until commercialization happens rather than to tie benefit-sharing to access (…) [B]enefit-sharing mechanisms that are simple, easy to understand, and scalable will likely return far greater value than technologically complex or bureaucratically demanding systems" (Scholz, A. and Hillebrand, U. 2020a). This scenario may have a high level of cost-effectiveness and lower transaction costs.

Since the commercialization of final products arising from the use of DSI is the unique trigger event for monetary benefit-sharing, there will be monetary benefits arising from DSI (phases 1 and 2) use that won't have to be shared, such as the licensing of IPR obtained from DSI use. Regarding IPR, benefit-sharing obligations arise only when a final product (obtained from the use of the licensed intellectual property right) is commercialized. This fosters innovation and technological development from DSI (phases 1 and 2) use, and also increases users' willingness to describe and use DSI, thus ensuring a higher level of sustainable use, fairness and equity, while reducing costs related to research, development and innovation from DSI use.

Moreover, in this scenario, the concerns expressed by the Chartered Institute of Patent Attorneys (CIPA, 2019) regarding the difficulties in differentiating between commercial and non-commercial use of DSI are not relevant to this model. There is no need for this differentiation, since benefit sharing would apply solely to the commercialization of products derived from DSI use, regardless of who conducted the research and development activities and whether the initial activity was commercial or non-commercial. In this regard, from the users' perspective, transaction costs are low, while legal certainty, sustainable use, cost-effectiveness, predictability, transparency, fairness and equity are high.

Similarly, regarding users' transaction costs in this third scenario, a certificate of compliance for ABS activities is obtained through an ABS online registration system, which reduces the complexity of compliance obligations and could eventually increase the social recognition and accountability of users. This system may increase the value of brands that have registered their products by making the proof of their compliance with ABS obligations publicly available. Consumers can access the (non-confidential) publicly available information to make their own assessments of the users' activities. In this situation, transparency is high, and fairness and equity are even higher.

In relation to tracking and compliance, while users would have to keep track of which DSI is been used, compliance obligations (registration/notification) would be required only for DSI use that led to a concrete outcome and not for all the DSI used. With these reduced obligations regarding compliance and within a scenario in which "there is a quasi-free flow of resources for the purpose of R&D" (Muller, M.R. 2015), users may have a more sustainable DSI description and use environment, increasing cost-effectiveness with less transaction and compliance costs.

On the other hand, products arising from multiple DSI use from different origins ("scale problem") will require user product traceability and notification in many different national ABS electronic systems, which will inevitably elevate transaction costs to users willing to comply with each national legislation.

In this regard, information gathering may be more time-consuming, as well as the reporting of results as required for monetary benefit-sharing compliance for DSI Phase 1, and Phase 2, if users are willing to comply with ex-post notification. Depending on the nature of the DSI use, such as in metagenomic and in bulk data analysis from multiple species from distinct origins, DSI use notification could be unattainable or administratively burdensome.

Similarly, if all provider states were to implement ABS online registration systems, the information required in each national ABS form would inevitably vary from provider to provider. In this scenario, bulk DSI use will require more complex and burdensome compliance efforts. In this regard, cost-effectiveness is low, while transaction costs are high.

Besides the complexities associated with the identification of the DSI phase 2 origin, **benefit sharing compliance** may also increase costs when a single product has been developed from a large amount of DSI from different providers. These include:

- costs of backward tracking in order to identify the "rightful" holders of the sovereignty rights over the GR/DSI who can lay claim to the BS;
- costs arising from tracking of DSI utilization in the production chain for monitoring and compliance (many providers of the same DSI); and
- costs related to benefit sharing with many countries of origin.

In such a situation, users will be required to increase their expenditure to properly address their compliance obligations. Users may have to set up specialist teams and IT systems devoted to collecting the information required from each national DSI environment, managing its compliance terms and conditions for DSI description and use, and track-and-tracing their use throughout their product value chains. This scenario may therefore reduce cost-effectiveness and increase transaction costs, compromising sustainable use.

Databanks, on the other hand, may enjoy a more favourable environment, since, according to the DSI AHTEG Report [27], "access measures would be unnecessary in a bounded openness model and other multilateral approaches in which utilization or commercialization would trigger benefit-sharing".

In an open-access regime, there are no advance conditions for DSI use that must be complied with, other than users' ex-post obligations (the regularization of DSI activities through registration), and every DSI in a database is potentially open to use for DSI phases 1 and 2. Such a regime will reduce the role of databanks in compliance procedures for users of the biological information sequences digitally available in their databases.

Similarly, other stakeholders' expectations regarding the role of databanks in compliance procedures, like potential requests to adapt or create terms and conditions to include DSI compliance proof documents, may be reduced. Market/regulatory approval offices, on the other hand, unlike databanks, will play an enhanced role in DSI use compliance.

It may not be necessary for databanks to alter their DSI deposit conditions by creating specific fields for uploading data access and use agreements that DSI users must agree to before accessing information. Moreover, there is no longer any pressure on databanks to ensure the accuracy of stated origin and the legality of access.

Instead of functioning as compliance checkpoints in the due diligence process, databases will be free to do what they were meant to do, namely maximize open access to basic data. They will no longer have to bear financial and technical costs associated with DSI compliance requirements; legal certainty will probably increase both their cost-effectiveness and DSI phase 2 sustainable use.

A positive effect of such a scenario on DSI phase 2 use is that information indicating the country of origin in DSI deposits (the country tag) will probably increase, since there will be no ABS conditions/sanctions applying to the deposit of DSI without PIC/MAT. Consequently, the quality of the information provided in sequence deposits will be enhanced, and there will be an increase in the percentage of sequences with country tags in databanks. This scenario therefore promotes the sustainable use of DSI, increases transparency, contributes to traceability, and may provide for better quality information on DSI origin.

Reliable and freely accessible information is fundamental to scientific progress. Scientists need a user-friendly environment that allows for rapid publication, dissemination, and exchange of data among their peers. "Scientists do not make their data electronically available to others for various reasons, including insufficient time and lack of funding" (Tenopir, C. et al. 2011 [28]). In this regard, the third scenario allows for:

- a reduction in time spent on bureaucratic requirements, thus freeing more time for R&D and the sharing of data (the level of ensured sustainable use is high); and
- recognition of collections as potential beneficiaries of benefit-sharing, due to the role they play as promoters of conservation (ex-situ and in-silico). Databanks conserve relevant information on GR and make it widely available, thus contributing to the achievement of the three objectives of the CBD. The level of fairness and equity is high; the level of transparency is high.

This scenario is most likely to safeguard open access/open exchange and transfer of data, ensuring sustainable use and transparency, with high cost-effectiveness, and low transaction costs.

In regard to **transparency**, databanks would have a crucial duty, by contributing "with transparency and in transitioning away from long-held suspicions and mistrust, to informed and honest discussions that move the policy process forward in a productive manner" (Scholz, A. & Hillebrand, U. 2020a). Nevertheless, other stakeholders can contribute to tackling one of the core problems regarding DSI use. "The International Barcode for Life Initiative (iBOL), the Global Biodiversity Information Facility (GBIF), and similar initiatives, could play a critical role in determining the geographic dimensions of habitats and presence of species and hence, support the definition of the proportion of royalties to be shared among countries" (Muller, M.R. 2015).

An evident disadvantage of this scenario, from the perspective of databanks, relates to the fact that the deposit of a DSI is considered to be the publication of a result of access/utilization, and as such has to be electronically registered in the ex-post use registration system of the provider country. The provider will, in turn, issue the correspondent international certificate of compliance for the DSI to be deposited. Databanks may thus be required to create or adapt fields on the deposit forms to allow for the uploading of the IRCC relating to the DSI description or use (DSI phases 1 and 2).

In other words, instead of requiring PIC/MAT **for the description and use of DSI**, databanks would have to require the IRCC/certificate of registration **prior to the depositing of the DSI**, not as a condition for use, but as a condition for the deposit of the sequence. In this sense, there may be potential financial and technical costs for databanks, political pressure to create those fields, and reluctance on the part of users to accept and adapt to this change.

On the other hand, in this scenario, databanks would not have to verify the legality of the IRCC provided by the depositor, but only ensure that the depositing user has declared one. Compliance regarding the lawfulness of the IRCC provided would be the responsibility of the user's country, which would have to implement ABS user measures. Providers' and users' countries would be able to access the information in the databank's field, verify the IRCC information and, according to the Nagoya Protocol, affirm that DSI used within their jurisdiction (i.e. used by one of their nationals) has been deposited in accordance with the domestic ABS legislation or regulatory requirements of the providing Party.

Databank transparency is paramount for global compliance efforts in this scenario, since all countries have users of the infrastructure of databank's and benefit from the open access and exchange nature.

Summary overview: Stakeholder perspectives regarding ABS regulation scenarios

The overview below summarizes some of the pros and cons of each regulatory scenario from the perspective of each stakeholder.

Scenario 1: Absence of ABS regulation

Perspectives Characteristics	Providers	Users	Databanks
• **Legal certainty**	**none**	**none**	**none**
• Sustainable use	lowest	lowest	lowest
• Cost-effectiveness	lowest	lowest	lowest
• Transaction costs	highest	highest	rather high
• Predictability	none	lowest	lowest
• Fairness and equity	lowest	lowest	lowest
• Transparency	lowest	lowest	lowest
Remarks	Monitoring compliance may lead to high technical/ administrative burden and costs, which are likely to outweigh benefits.	Proving compliance may lead to high technical/ administrative burden and costs, which are likely to outweigh benefits.	Expectations that databanks will include private data access and use agreements may lead to high technical burden and costs.

Scenario 2: ABS regulation requiring PIC/MAT

Perspectives Characteristics	Providers	Users	Databanks
• **Legal certainty**	**intermediate**	**intermediate**	**intermediate**
• Sustainable use	low	low	low
• Cost-effectiveness	rather low	rather low	rather low
• Transaction costs	rather high	rather high	rather high
• Predictability	rather low	rather low	rather low
• Fairness and equity	low	rather low	rather low
• Transparency	rather low	rather low	rather low
Remarks	Technical complexity of monitoring DSI use may be beyond the capacity of most provider countries.	Legal uncertainty due to the complexity of different ABS rules in different countries.	Expectations on databanks to include IRCC (PIC/MAT) may lead to high technical burden and costs. Low predictability due to uncertainty about the legal implications of sharing DSI.

Scenario 3: Open access, under terms and conditions

Perspectives Characteristics	Providers	Users	Databanks
• **Legal certainty**	**highest**	**highest**	**high**
• Sustainable use	highest	rather high	highest
• Cost-effectiveness	highest	rather high	highest
• Transaction costs	lowest	rather low	lowest
• Predictability	rather high	highest	highest
• Fairness and equity	intermediate	intermediate	high
• Transparency	intermediate	highest	rather high
Remarks	Transparency is key, but depends on willingness of all stakeholders to comply. Low control over DSI use. High benefit sharing compliance costs and dependence on third parties. High cost of creating and maintaining an ABS online registration system is likely to outweigh the benefits for most provider countries.	Pre-set terms and conditions allow users to acknowledge their rights and obligations before deciding to start DSI use/description, clarifying costs and risks beforehand. Bulk DSI use will require more complex and burdensome compliance efforts, in which case benefit-sharing and compliance may increase transaction costs, reducing cost-effectiveness.	Instead of requiring PIC/MAT for DSI use/description, databanks would have to require the IRCC/ certificate of registration prior to the depositing of the DSI – not as a condition of use, but as a condition for the deposit of the sequence. Political pressure to create such fields may lead to technical burden and costs for databanks, while users may be reluctant to accept this change.

IV. Conclusion

The present study has suggested advantages and disadvantages for three scenarios of bilateral ABS/DSI regulation.

Some of the factors and impacts presented in this study are likely to see their cost and importance reduced as DSI-related techniques become cheaper and faster, while at the same time users' good faith and commitment to compliance, allied to environmental corporate social responsibility, are beginning to increase and become mainstream in biological information description and use.

An agreed solution for sharing benefits from the exploitation of products obtained by using DSI may be within sight when "there are increasing efforts to better link original physical material with digital sequence information, including metadata on the location of specimen collections. (…) Many in the database and research community support inclusion of the provenance of digital sequence information, which is important for science, and might also support benefit sharing" (Laird, S. A., & Wynberg, R. P. 2018). Legal certainty on DSI origin may increase with time, but there are many complex and challenging questions to be answered, since DSI is used and published in a multilateral manner and ownership identification is costly and entangled.

Although it may seem that scenario 3 has better prospects, not all genetic resource providers reach the technical and financial conditions necessary to implement and maintain a national ABS online system for registering the use of DSI (phases 1 and 2). To put such a system in place, providers may be required to make considerable upfront investments, as well as to support the ongoing cost of its protection and maintenance. Such an endeavour will not be technically and economically feasible for all provider countries that wish to bilaterally regulate DSI activities.

Likewise, not all users meet the conditions (available IT systems and qualified personnel) to register and track activities in various and diverse electronic registration systems. Users would have to complete a DSI use registration in each country, develop teams devoted exclusively to fact-finding, and comply with obligations in each of the systems, which would also be required if DSI were treated exclusively through PIC/MAT (scenario 2) or through private contract law legislation (scenario 1).

Furthermore, none of the bilateral scenarios provides solutions for particular instances of DSI, notably the issue of transboundary occurrence (where DSI is conserved through jurisdictions and taxa). Similarly, none of the scenarios would adequately address the difficulties associated with the identification of the genetic resource responsible for the DSI and/or the country of origin. According to the recent *Combined study on DSI*, requested by CBD Parties, although the DSI country tag came into existence in 1998 and became a required field in 2011, only 16% of all GenBank entries have a country of origin and, in 2018, just over 40% of the NSD submitted entries reported a country of origin.

If information about the provider of the genetic resource that underlies a DSI description is not available (for example, if it does not appear in a country tag), none of the scenarios provides a solution: bilaterally obtaining a private contract agreement (scenario 1); obtaining PIC/MAT (scenario 2); or obtaining a certificate of compliance through on-line outcome registration (scenario 3).

Only 40% of the DSI described in 2018 would be covered by these scenarios, but what about the other 60% from 2018, and the other 84% from GenBank? How could one bilaterally approach an agreement when it is not possible to identify who would be the second contracting party of the bilateral deal?

Finally, massive data mining, bulk data analyses, metagenomics and the like also increase the challenges associated with identifying the origin of every single DSI that is used.

Although some difficulties may be reduced in scenario 3, it largely depends on the good faith of users (who must be willing to declare the use of DSI). Such good faith may arise from pressure by another stakeholder, the consumers.

Indeed, the consumer is another potentially influential stakeholder with respect to the demand for ABS compliance from companies using DSI to develop products for the market. According to the Union for Ethical BioTrade's Biodiversity Barometer,[10] "Consumers' call for transparency on product ingredients and their origins is growing louder." Moreover, "as consumer interest in naturals continues to increase, so does biodiversity-based research and development. Complying with evolving rules on Nagoya Protocol and Access and Benefit Sharing (ABS) is an ever-growing imperative" (The Union for Ethical BioTrade, 2020 [29]).

Since the third scenario decreases providers' control over activities conducted on "national" DSI/GR, without shadow of doubt,

10 "Since 2009, [the Union for Ethical BioTrade] annually measures consumer awareness of biodiversity, and how this affects purchasing decisions. Eleven years of research, among 74,000 people from 16 countries, and among hundreds of leading companies, provides valuable insights that may guide companies and governments in their approaches towards people and biodiversity". http://www.biodiversitybarometer.org/#uebt-biodiversity-barometer-2020

compliance in the third scenario is the most dependent on DSI users' countries being Party to the Nagoya Protocol and, moreover, being able to implement measures that shall "provide that genetic resources utilized within its jurisdiction have been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the other Party" (Art. 15 of the Nagoya Protocol [30]).

Consumers can require ABS compliance from companies using DSI, thereby positively impacting corporate social and environmental responsibility to consolidate legal provenance as an asset for brands, which in turn contributes to global compliance with national laws. The road ahead is, however, still arduous. Not all countries have ratified the Nagoya Protocol or are demanding that their nationals comply with the laws of countries of origin. Many of these countries do not have legislation that controls the description and use of DSI, which makes it difficult for any of the scenarios presented in this paper to be effectively implemented.

Finally, the study has discussed the feasibility of tracking and tracing DSI phases 1 and 2 description and use under a purely bilateral approach, and has found it to be extremely costly and entangled. Besides this, the bulk use of DSI would entail frequent transaction costs arising from case-by-case compliance obligations, frequent private contract negotiations, frequent PIC/MAT obtention, or frequent registration online for every DSI use.

In all scenarios, frequency of use elevates costs for providers (having to grant and monitor each use), users (having to comply with every single use) and databanks (being requested to acquire users' compliance or to change and adapt), which would inevitably have a negative effect on sustainable use, to the detriment of all stakeholders.

Without use, benefits will hardly be generated. Frequency of use should be fostered and not seen as a transaction cost, as it is in all the three scenarios: "If the transactions are frequent, the parties will invest in a governance structure that decreases transaction costs and makes these transactions efficient (Gehl Sampath 2005, p. 69)" (Richerzhagen, C. 2011).

When conceived, the bilateral approach was expected to deliver cooperation, research, development, technology transfer and benefit sharing. "But ABS has calcified over the years around a bilateral transaction for physical samples that is marginal to contemporary research and development, and the dissonance between ABS and the scientific endeavor more broadly is only increasing. A new approach for ethically sharing the benefits of science and technology is sorely needed" (Laird, S. et al. 2020).

DSI description and use regularization could perhaps be better addressed through a multilateral governance structure, to be subsequently implemented on a national level. If such an approach seems to be too bold, we should bear in mind that "timidity does not help solve global issues. Bold thinking that moves outside the box or reconceptualises the box can assist with identifying effective workable solutions" (Oldham, P. 2020).

References

1. Oldham, Paul. 2020. Digital Sequence Information - Technical Aspects https://ec.europa.eu/environment/nature/biodiversity/international/abs/pdf/Final_Report_technical_aspects_of_DSI.pdf

2. Spranger, Tade Matthias. 2017. Expert opinion on the applicability of the Convention on Biological Diversity and the Nagoya Protocol to digital sequence information. https://www.bmbf.de/files/Legal_opinion_DSI_Prof_Spranger_EN_BF.PDF

3. Sollberger, Kaspar. 2018. Digital Sequence Information and the Nagoya Protocol. https://www.bafu.admin.ch/dam/bafu/en/dokumente/biotechnologie/rechtsgutachten/digitale-sequenzinformationen-nagoya-protokoll.pdf.download.pdf/20180407_Kurzgutachten%20Digitale%20Sequenzinformationen_Final.pdf

4. Combined study on DSI in public and private databases and DSI traceability. As requested by decision 14/20 (paragraph 11 (c) to (d)) from the fourteenth Conference of the Parties to the Convention on Biological Diversity Link: https://www.cbd.int/abs/DSI-peer/Study-Traceability-databases.pdf

5a. Scholz, Amber & Hillebrand, Upneet. (2020). Finding compromise on ABS & DSI in the CBD: Requirements and policy ideas from a scientific perspective. 10.13140/RG.2.2.35180.80001.

5b. Scholz, Amber & Hillebrand, Upneet. (2020). WiLDSI - Three open access scenarios for DSI in the framework of the CBD A discussion paper for the European DSI scientific stakeholder workshop Organized by the BMBF project "Science-based solutions for DSI" (WiLDSI) Co-hosted by the Horizon 2020 European Virus Archive project (EVA-GLOBAL) March 10-11, 2020, Brussels, Belgium

6. Pauchard, Nicolas. (2017). Access and Benefit Sharing under the Convention on Biological Diversity and Its Protocol: What Can Some Numbers Tell Us About the Effectiveness of the Regulatory Regime? Resources. 6. 11. 10.3390/resources6010011.

7. Novion, H. & Brina, L. (2019). National Implementation of Access and Benefit-sharing in Brazil. in: Proceedings of the International Workshop on Access and Benefit-sharing for Genetic Resources for Food and Agriculture. p.73 http://www.fao.org/fi/staticmedia/MeetingDocuments/AqGenRes/ITWG/2018/Inf8e.pdf

8. BRAZIL´S POSITION ON DSI (Notification 2019-012) 03 June 2019 https://www.cbd.int/abs/DSI-views/2019/Brazil-DSI.pdf

9. Muller, M.R. (2015). Genetic resources as natural information: Implications for the Convention on Biological Diversity and Nagoya protocol. 10.4324/9781315754451.

10. Report of the WiLDSI Workshop: Digital Sequence Information, Open Access, and Sustainable Benefit Sharing: Scientific Input to International Policy Decisions, (WiLDSI. 2020) https://www.dsmz.de/collection/nagoya-protocol/digital-sequence-information/dsi-workshop-january-2020

11. Sirakaya, A. (2019). Balanced Options for Access and Benefit-Sharing: Stakeholder Insights on Provider Country Legislation, Frontiers in Plant Science,10(October), 1–15. https://doi.org/10.3389/fpls.2019.01175

12. Sirakaya, A. (2020). "A balanced ABS system: Stakeholder perception on ABS goals." Sustainable Development. DOI: 10.1002/sd.2040

13. Bagley, Margo & Karger, Elizabeth & Muller, Manuel & Perron-Welch, Frederic & Thambisetty, Siva & de Souza, Lúcia & Frere, Tekau & Christine, Frison & Humphries, Fran & Lawson, Charles & Medaglia, Jorge & Meyer, Hartmut & Nair, Prabha & Rourke, Michelle. (2020). 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 address the use of digital sequence information on genetic resources for research and development. 10.13140/rg.2.2.34067.22561.

14. Kamau, Evanson & Fedder, Bevis & Winter, Gerd. (2010). The Nagoya Protocol on Access to Genetic Resources and Benefit Sharing: What Is New and What Are the Implications for Provider and User Countries and the Scientific Community?'. Law and Environment and Development Journal. 6. 246

15. Richerzhagen, Carmen. (2011). Effective governance of access and benefit-sharing under the Convention on Biological Diversity. Biodiversity and Conservation. 20. 2243-2261. 10.1007/s10531-011-0086-0.

16. Dedeurwaerdere, Tom et al. "Global scientific research commons under the Nagoya Protocol: Towards a collaborative economy model for the sharing of basic research assets." Environmental science & policy vol. 55 (2016): 1-10. doi:10.1016/j.envsci.2015.08.006

17. Comments of Third World Network on Digital Sequence Information. Reference: SCBD/NPU/DC/VN/KG/RKi/87804. 01 June 2019. https://www.cbd.int/abs/DSI-views/2019/TWN-DSI.pdf

18. Chartered Institute of Patent Attorneys submission on DSI to the CBD https://www.cbd.int/abs/DSI-views/2019/CIPA-DSI.pdf

19. Brink M and van Hintum T (2020) Genebank Operation in the Arena of Access and Benefit-Sharing Policies. Front. Plant Sci. 10:1712. doi: 10.3389/fpls.2019.01712

20. Milieu Law & Policy Consulting. 2020. Analysis of implications of compliance with the EU ABS Regulation for research organisations and private sector companies. https://ec.europa.eu/environment/nature/biodiversity/international/abs/pdf/ABS%20Regulation_Report%20on%20Compliance%20Implications%20for%20public%20and%20private%20sectors.pdf

21. Laird, Sarah & Virnig, Anne & Wynberg, Rachel. (2018). Access and Benefit-Sharing Agreements: Resources and Background Materials. Voices for Biojustice; University of Cape Town; The Darwin Initiative; People and Plants International; The ABS Capacity Development Initiative; The Christensen Fund.

22. Ten Kate, K. & Laird, S.A. (1999) The Commercial Use of Biodiversity: Access to Genetic Resources and Benefit-Sharing. Earthscan, UK.

23. Karger, Elizabeth. May 2018. "Study on the use of digital sequence information on genetic resources in Germany". In the project: Scientific and technical support on implementing the Nagoya Protocol - Part 1 "Digital sequence information and ABS" https://biodiv.de/fileadmin/user_upload/PDF/Projekte-aktuell/DSI-Study.pdf

24. Laird, Sarah & Wynberg, Rachel & Rourke, Michelle & Humphries, Fran & Muller, Manuel & Lawson, Charles. (2020). Rethink the expansion of access and benefit sharing. Science. 367. 1200. 10.1126/science.aba9609.

25. Laird, S. A., & Wynberg, R. P. (2018). 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, (November 2017), 1–77. Retrieved from www.cbd.int/abs/dsi-gr/ahteg.shtml#peerreview.

26. Schindel, David & Plessis, Pierre. (2014). Reap the benefits of the Nagoya Protocol. Nature. 515. 37. 10.1038/515037a.

27. Report of the Ad Hoc Technical Expert Group on Digital Sequence Information on Genetic Resources - AHTEG (2020). https://www.cbd.int/doc/c/ba60/7272/3260b5e396821d42bc21035a/dsi-ahteg-2020-01-07-en.pdf

28. Tenopir, Carol & Allard, Suzanne & Douglass, Kimberly & Aydinoglu, Arsev & Wu, Lei & Read, Eleanor & Manoff, Maribeth & Frame, Mike. (2011). Data Sharing by Scientists: Practices and Perceptions. PloS one. 6. e21101. 10.1371/journal.pone.0021101

29. The Union for Ethical BioTrade. (2020). UEBT Biodiversity Barometer 2020. http://www.biodiversitybarometer.org/#uebt-biodiversity-barometer-2020

30. 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: text and annex. (Secretariat of the Convention on Biological Diversity 2011) ISBN: 92-9225-306-9 https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf

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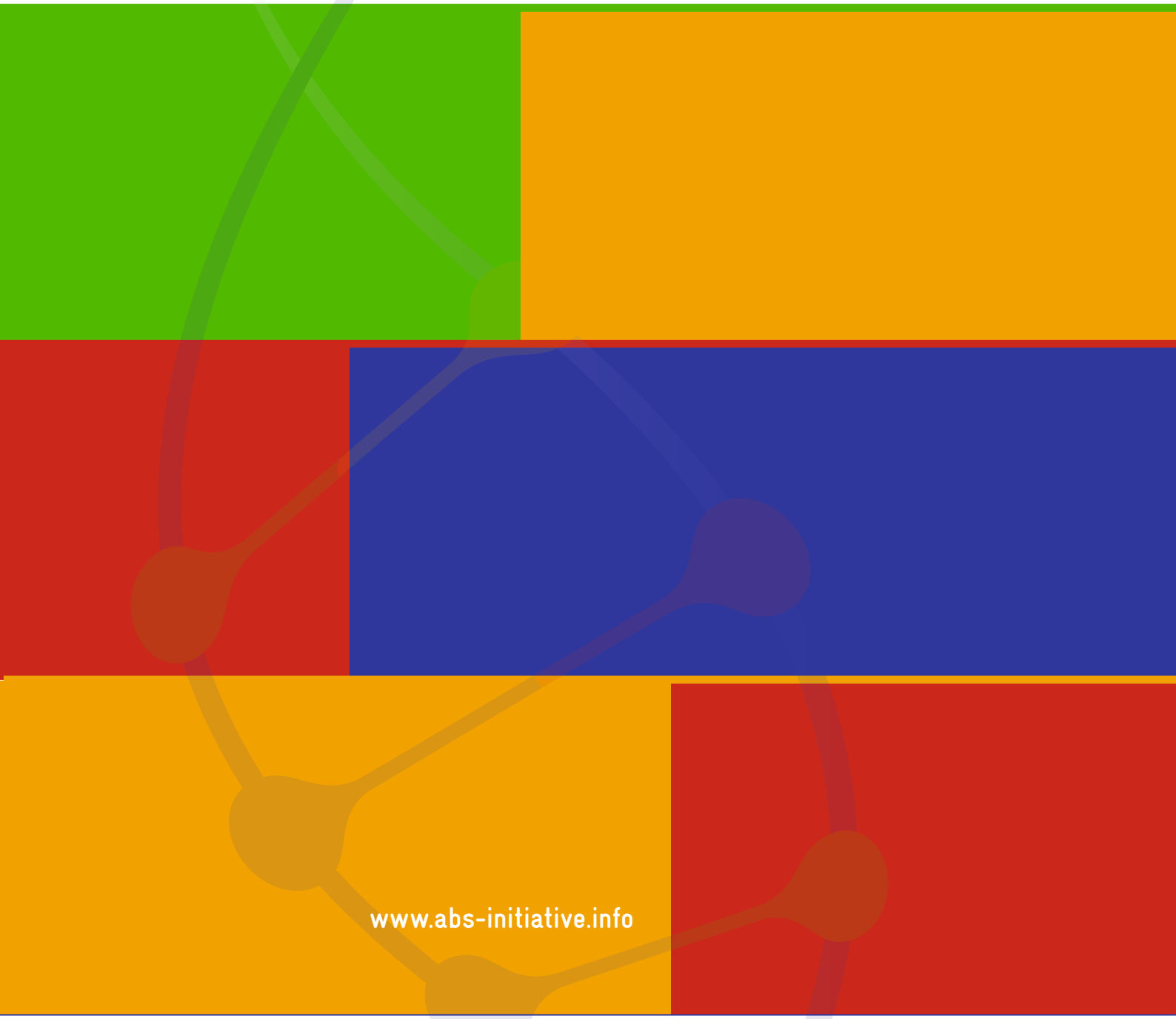

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