First Global Dialogue on Digital Sequence Information on Genetic Resources

6 – 8 November 2019, Pretoria, South Africa

Organized by:
the ABS Capacity Development Initiative, the South African National Department of Environment, Forestry and Fisheries,
and the Norwegian Government.

REPORT

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[1] Disclaimer: This report was prepared for the use and benefit of the participants of the First Global Dialogue on Digital Sequence Information on Genetic Resources held in Pretoria, South Africa, from 6 – 8 November 2019, and it is provided for information purposes only. It contains a compilation of the participants' contributions and discussions. The report, however, does not purport to reproduce all debates and interventions in full and according to the Chatham House Rule, under which the dialogue was held, the information provided is not attributed to the source. The presenters are, with their explicit permission, identified in the report. The statements in this report do not represent the views or opinions of the GIZ, the Governments of South Africa and Norway, or the cooperation partners of the GIZ. The Secretariat of the ABS Initiative does not assume any liability for the accuracy or completeness of the report.

Short overview of the dialogue

The First Global Dialogue on Digital Sequence Information on Genetic Resources (DSI) was jointly organized by the ABS Capacity Development Initiative, the Norwegian Government and the South African Department of Environment, Forest and Fisheries. Norway and South Africa have entered into a strategic partnership on global dialogues on DSI as part of the bilateral cooperation between South Africa and Norway. The dialogue, which was held from 6 – 8 November 2019 in Pretoria, hosted 65 participants from 27 countries. In addition to the organizers and representatives from the host countries, the participants included people from various countries, which have been actively involved in the discussion on DSI and/or countries that have taken steps to deal with DSI at the national level, including policy makers, negotiators or government advisors. Other participants included practitioners involved in the generation, distribution and/or use of DSI as well as experts familiar with DSI and the related issues. All participants at the dialogue were treated as speaking from their own perspective and not as a representative of a specific country or organization.

The DSI Dialogue offered participants the opportunity to discuss the issue of DSI in an informal context and outside of the formal process leading up to the fifteenth Conference of the Parties (COP 15) in Kunming, China, at which time further decisions will be made on "how to address digital sequence information on genetic resources in the context of the post-2020 global biodiversity framework". The two-and-a-half-day meeting focused on the exchange of technical information as well as understanding the views, priorities and expectations of the other participants. The objective of this dialogue was to lead to the increased capacity of all actors to participate effectively in the discussions on DSI. Participants were particularly interested in understanding the concept of DSI and its use, the issue of benefit-sharing, technical issues relating to data, databases, traceability and open access, regulatory and non-regulatory options and the possible implications as well as capacity building.

The meeting was opened by the Government of South Africa, the Government of Norway and the ABS Capacity Development Initiative. The dialogue started by informing participants about the status and nature of the discussions on DSI, identifying the core issues in the discussion in the CBD and other fora. The "Introductory Guide on DSI" – a resource created by the ABS Initiative – was presented to participants.[2] Presentations were held on the production, distribution and use of DSI. The meeting also took into account processes and approaches in international fora, informing participants about developments in selected UN fora. Participants were then invited to discuss and reflect on possible options for DSI in the CBD. The dialogue further identified some options and described the linkages between the use of DSI and benefit-sharing, identifying areas where there is a need for increased knowledge and wider stakeholder engagement. Issues for discussion at the 2nd Global Dialogue were briefly identified.

Participants expressed that they were motivated to take forward what they had learned from the dialogue and to integrate it into their work. Some noted that the event was successful in providing an open environment to discuss this controversial issue. Others highlighted that they would have liked to see indigenous peoples and local communities (IPLCs), representatives from different industry and research sectors at the meeting. The dialogue was closed by the ABS Initiative, the Government of Norway and the Government of South Africa.

[2] „Digital Sequence Information on Genetic Resources (DSI) – An Introductory Guide for African Policymakers and Stakeholders" (August 2019) available at: http://www.abs-initiative.info/fileadmin/media/Knowledge_Center/Pulications/DSI/Introductory_Guide_-_DSI_-_ABS_Initiative_-_201908.pdf

Expectations of the participants

The dialogue started with a session aimed at understanding priorities and expectations of the participants. The participants were asked to reflect on the following three questions:

1) What needs to happen here so that you will be satisfied with the dialogue?
2) Which issues would you like to discuss during the 2.5 days?
3) What should not happen at this dialogue?

The key points are summarised in the table below:

What needs to happen here so that you will be satisfied with the dialogue?
• Better understanding of the current system • Increasing understanding of all perspectives • The dialogue should contribute to the DSI process • Open dialogue • Understanding the roadmap and purpose of both Global Dialogues • Pragmatism and compromise • Sharing of ideas • Perspectivisation (empathy and looking at things from the other people's perspectives) • Focus on opportunities • People get to know each other and talk to each other • Active listening • Closing the science-policy gap • "Take-home" messages • Thinking outside the box • Creative thinking • Understanding rationale and perspectives of others • "Win-win" outcomes • Hearing each other speak • Learn more about DSI as such • Open-minded participants • Finding different options as possible ways forward • Creating a common understanding of scope and terminology • Establishing a good, pragmatic solution to the issue of DSI, possibly based on economics of information
Which issues would you like to discuss during the 2.5 days?
• Impact on research • Concept of DSI • Specialised benefit-sharing mechanism • "How to avoid nightmares?" • Understanding of DSI life cycle • Understanding scientific practices • What is the real problem, what is an opportunity? What is the goal of regulating DSI? • The use of DSI in all the different angles • Simplifying DSI definitions • Data sharing • Future proofing • Benefit-sharing (including practical issues) • Capacity building along several dimensions (science, business, legal and policy) • Consequences of regulating DSI

- Understanding open (versus free) access
- Transparency and defining limits
- Understanding issues around retroactivity
- Pros and cons of regulating DSI, including examples
- Benefits related to 1st and 2nd CBD objective
- Impact of restricted access to DSI on public health
- Discuss and develop understanding of guidelines and rules on collections of material
- Activities undertaken with DSI
- Technical aspects (the way DSI is used across the value chain)
- Role and diversity of database models
- Traceability
- Linkages to traditional knowledge (TK)/IPLCs and how benefits may be shared with TK-holders

What should not happen at this dialogue?

- Negotiations
- Taboos and restrictions in discussions
- Dominance by a few individuals
- Dishonesty
- Personal attacks
- Being dogmatic
- Repeating negotiating positions or discussing political positions
- Blame and shame
- Taking things personally
- Preventing information from this dialogue to feed into global discussions
- Unstructured and unfocused discussions

Presentations

Scene-setting

Setting the scene: Status of the DSI discussions, including role in contributing to the three objectives of the CBD

Hartmut Meyer (ABS Initiative) presented the status of DSI discussions, including the role of DSI in contributing to the three objectives of the CBD. He informed participants that the issue of DSI arose due to the increasing speed and falling costs of sequencing, which have resulted in an enormous quantity of sequence data from biological molecules being produced and stored in publicly accessible databanks, which are used for research and development, including for commercial purposes. He noted that this happens largely without applying the concept of benefit-sharing of the CBD, which is a core issue for many Parties of the CBD and other actors, who are concerned that this will negatively impact on the third objective of the CBD and the objective of its Nagoya Protocol. Mr Meyer also noted that DSI does not have an internationally agreed meaning and has become a placeholder term, and that its concept and scope are not clear. Parties and expert meetings are still struggling with clarifying scope and definitions.

Mr Meyer highlighted that DSI is being discussed in various UN fora and that divergent positions on DSI have emerged over the past few years. Core areas of disagreement are, for example, on whether the definition of GR in the CBD covers DSI or not, whether DSI should fall under the ABS regime, and whether open access to DSI can be regarded as a sufficient form of benefit-sharing etc. Mr Meyer informed participants about different types of stakeholders involved in DSI and its different uses, noting that different types of sequences are used in a wide range of scientific disciplines, ranging from

basic research through to applied and commercial research. The use of DSI already plays a significant role in activities that can be connected to the three objectives of the CBD. Mr Meyer concluded with some selected examples of the use of DSI, e.g. the use of Ebola genome sequences to develop a drug.

Kristina Taboulchanas from the Secretariat of the CBD (SCBD) held a presentation on the status of discussions of DSI at the level of the CBD. DSI as an issue emerged initially during discussions on synthetic biology under the CBD. At COP 13 in Cancun, it became a cross-cutting issue relevant to discussions under the CBD as well as the Nagoya Protocol. The result were two decisions – one adopted by COP-13 (decision XIII/16) and one adopted by MOP-2 (decision NP-2/14) – that established a coordinated and non-duplicative process for work on this topic in 2017/18. COP 14 in Sharm El Sheikh recognized the importance of DSI for the three objectives of the CBD, that access to and use of DSI contributes to scientific research as well as to other non-commercial and commercial activities, and, that further capacity to access, use, generate and analyse DSI is needed in many countries. As there is a divergence of views among Parties regarding benefit-sharing from the use of DSI, Parties committed to working towards resolving this divergence through the process established until COP 15.

The process on DSI in 2019/20 includes studies and peer review on specific topics[3]. Ms Taboulchanas informed participants that the Meeting of an Ad Hoc Technical Expert Group on DSI (AHTEG) will take place on 17-20 March 2020 in Montreal, Canada to submit its outcomes for consideration by the third meeting of the Open-ended Working Group (OEWG) on the Post-2020 Global Biodiversity Framework. The OEWG on the Post-2020 Global Biodiversity Framework is requested to consider the outcomes of the AHTEG and to make recommendations to COP 15 on how to address DSI in the context of the Post-2020 Global Biodiversity Framework and submit the outcome of its deliberations for consideration by COP-MOP 4.

DSI: What are we talking about?

Three experts were invited to provide input on the concept of DSI, its production and use as well as its distribution through databases. Key aspects of the presentations are listed below.

Prof. Marcel Jaspars of the University of Aberdeen gave some insight into the concept of DSI.

- Prof. Jaspars provided an overview of the process of transcription, translation and biosynthesis, identifying the different types of sequences which can be generated from biological molecules. Sequence data may be generated from DNA, RNA and proteins.
- He pointed out various questions that need to be considered in the discussion on DSI: which types of sequences would be included under any terminology that replaces DSI; what length of sequences are still considered to be a 'sequence'; how are sequences to be treated which are similar and what level of variation is needed to be considered different; what is the status of modified DNA, RNA and protein sequences?
- He drew a distinction between data and information. Data are a means of communicating and facilitating exchanges about the material world, consisting of two parts: Data production (or

[3] 1) Concept and scope of DSI on GR and how it is used building on existing fact-finding study; 2) Ongoing developments in the field of traceability; 3) Public and private databases, including terms and conditions on which access is granted, scope and size of databases, number of accessions and their origins, governing policies, providers and users of databases; 4) How domestic measures address benefit-sharing arising from commercial and non-commercial use of DSI

material artefacts as research outputs that provides evidence of knowledge); dissemination and the ways and forms in which it is shared as information (knowledge, claims, models, theories, communities, and so on).

- DSI discussions to date have been about the representational form of the data or information and not the activity performed with that data.
- Regarding the definition of DSI: there can be a narrow and defined grouping (DNA, RNA) and intermediate (which also includes protein sequences) and a broad / inclusive group that contains everything (GR, DNA, RNA, proteins, etc.).

Dr. Christian Tiambo of the International Livestock Research Institute (IRLI) gave current examples of production and use of DSI.

- The Centre for Tropical Livestock Genetics and Health of ILRI develops and applies genomic and advanced reproductive technology to address tropical livestock development challenges.
- ILRI works with the providers with a strong focus on capacity building in the use of DSI; ABS may be as important for the samples as for the data (including DSI) generated. ILRI ensures (through MTAs and data sharing agreements) that any data associated with the sample is similarly covered to the samples.
- ILRI has a global access policy. Key messages on ILRI's global access policy and benefit-sharing:
  - Open access policy is a general rule for ILRI and the data they generate is generally made openly accessible to all. However, there are exceptions made to this policy, e.g. when countries do not allow data publication.
  - Respect for countries decisions on whether / when to make their DSI publicly available
  - Check that any public meta-data attached to DSI is not sensitive
  - Benefit-sharing terms are used for all countries, even if no ABS system exists

Dr Amber Scholz of the Leibniz Institute DSMZ - German Collection of Microorganisms and Cell Cultures GmbH presented on databanks and storage of DSI[4].

- Data is stored in publicly accessible databases, most of which are located in developed countries.
- Scientists put nucleotide sequence data (NSD) in a public database for everyone to see and use for three reasons:
  - Publishing: Journals will not publish your paper unless the data is in the International Nucleotide Sequence Database Collaboration (INSDC);
  - Funding: Grant agencies very often require it;
  - Ethics: Scientific reproducibility, integrity, data security.
- Scientists cannot publish without submitting their NSD to the INSDC. The INSDC is and will remain the core infrastructure for NSD.
- There are 10 – 15 million total users of INSDC. They live in every country in the world.
- Access policies for public NSD databases are overwhelmingly open access. NSD comes from the entire world, is used by the entire world, however, the use is dominated by around 15 countries.

[4] Three large databases are considered to be the main actors: The European Molecular Biology Laboratory- European Bioinformatic Institute (EMBL-EBI), the DNA DataBank of Japan (DDBJ) and GenBank, which is hosted by the National Center for Biotechnology Information (NCBI) in the USA. Together, these databases form the International Nucleotide Sequence Database Collaboration (INSDC). They have open access policies and exchange their data on a daily basis

Processes and approaches in international fora

Representatives from the secretariats of the World Health Organization (WHO), the UN Division for Ocean Affairs and the Law of the Sea (DOALAS), the Commission for Genetic Resources for Food and Agriculture (CGRFA), the International Treaty on Plant Genetic Resources for Food and Agriculture (IT-PGRFA) and the World Intellectual Property Organization (WIPO) gave inputs on the developments on DSI in their fora.

World Health Organization

Soumya Swaminathan informed participants via video recording that the World Health Assembly (WHA) of the WHO intends to broaden its engagement with the CBD in order to provide information on current pathogen sharing practices and arrangements, the implementation of ABS measures and the potential public health outcomes. She highlighted that WHO is consulting with internal bodies, including the PIP Framework, the HIV department, the Malaria departments, and others. The organization is engaging in broad outreach to ensure the collection of information and views from all relevant stakeholders on the topic, including from their member States. WHO has found that awareness raising about the Nagoya Protocol is needed. She stated that each country has an opportunity to include or exclude DSI in its respective ABS system and highlighted the need for the health implications to be taken into consideration, including as the result of potentially lengthy processes. In the past, there were 4 or 5 instances where laboratories were unable to share flu specimens in a timely manner as they were engaged in MAT negotiations which lasted between 5 to 8 months. It was noted that such situations could be critical in the case of an outbreak, pandemic or epidemic.

Ms Swaminathan informed participants that an interim report will be prepared on the results of their outreach in the coming months, which will be finalised later in 2020 and provided to the WHA. A report will also be provided to the COP. She noted the importance for WHO to discuss the issue at different levels and try to come up with potential solutions or mechanisms for timely exchange of pathogen specimens, especially of human pathogens, while ensuring that benefit-sharing takes place.

Division for Ocean Affairs and the Law of the Sea

Bart L. Smit Duijzentkunst, Legal Officer at the DOALOS United Nations Office of Legal Affairs, provided participants an overview of the status of BBNJ[5] negotiations on marine genetic resources via a voice recording of his presentation. Different formulations for the concept of DSI are on the table[6]. During the negotiations, several delegations emphasized that access and benefit-sharing were closely linked and should be considered together. Different views were expressed, however, on how this should be reflected in the agreement. Participants were further informed that provisions relating to scope as discussed under BBNJ process can be divided into geographical, material and temporal scope. Views differed on whether DSI may be regulated in the context of access or benefit-sharing. Views also differed on whether access referred to the collection of marine genetic resources in situ or also to access ex situ and in silico. These views were linked to different perspectives on whether or not to regulate access to marine genetic resources of areas beyond national jurisdiction and, if so, how. [7]

5 Biodiversity beyond national jurisdiction (BBNJ)

6 Digital sequence data (and information), Genetic sequence data (and information), Digital genetic sequence data and information, Digital sequence information of genetic resources, Marine genetic resources in silico

7 If in situ access were to be regulated, two models were generally put forward by those who support it: a notification-based model; and a licensing or permit-based model. Various terms and conditions for regulated in situ access were proposed, such as capacity-building; transfer of marine technology; and a requirement to deposit samples, data and related information in open source platforms.

Regarding the sharing of benefits, various proposals have been made to specify that the beneficiaries would be States Parties, in particular developing States and that the requirement to share benefits would fall on States Parties, including their nationals, that have accessed, collected or utilized marine genetic resources of areas beyond national jurisdiction. There was general support for the sharing of non-monetary benefits[8]. However, further discussions will be required on the sharing of monetary benefits. In terms of benefit-sharing modalities, further discussion will also be required on whether benefits should be shared on a voluntary or mandatory basis, which activities would trigger benefit-sharing, what types of benefits might be shared, as well as how and when benefits might be shared.

Commission on Genetic Resources for Food and Agriculture

The CGRFA established a new workstream on DSI in February 2017. In 2018, the CGFRA commissioned an Exploratory fact-finding scoping study on DSI on GRFA[9] to review the implications of the use of DSI for the conservation and sustainable use of GRFA, including exchange, access and the fair and equitable sharing of benefits arising from their use. The study states that DSI contributes to food security as a fundamental tool for characterization of GRFA, including breeding, enhancement and management. Further, DSI is an essential component for the characterization, conservation and sustainable use of GRFA; DSI underpins technology for the synthesis of DNA. Moreover, DSI makes it easier to get value from GR without possessing it or its DNA. DSI is extensively used in all subsectors of GRFA. With respect to storage, exchange and sharing of DSI, publicly accessible DSI includes content of about 1700 online databases with infrastructure mainly in developed countries. The amount of private DSI is unknown.

Mr Dan Leskien also shared insights on the role of DSI in research and product development. He informed participants that DSI is a component of nearly all research in biological sciences. Despite decreasing cost of DNA sequencing and synthesis, cost of electronic infrastructure and lack of capacity will make it difficult for some countries to benefit from the use of DSI. The next session will address: the innovation opportunities DSI on GRFA offers; the challenges associated with the capacity to access DSI and make use of it; and the implications of DSI for the conservation and sustainable use of GRFA as well as the sharing of benefits derived from GRFA. The Commission noted the importance of coordination with the ongoing processes under the CBD and its Nagoya Protocol and the Treaty.

International Treaty on Plant Genetic Resources for Food and Agriculture

A scoping study was conducted by E.W. Welch, M. Bagley, T. Kuiken and S. Louafi for the International Treaty, addressing technological, legal and benefit-sharing issues relating to synthetic biology. DSI was a relevant issue in the study. It was highlighted that some researchers have a decreased need to work with physical material and can simply work with sequences. It was also noted that it is very difficult to identify the source of the sequences once modified: databank institutions and sequencing companies may not be keeping or requesting information about the material source of the DSI. Also, patents often do not provide geographic and / or species origin information. In this context, it was noted that the potential for generating high-value products, and thus monetary and non-monetary benefits, through synthetic biology and other genomic technologies will probably grow. With respect to benefit-sharing, a significant portion of the value of DSI is in its aggregation in accessible databases.

8 These could include e.g. access to samples and sample collections; sharing of pre- and post-cruise information; transfer of technology and capacity-building; making available samples, data and related information on an open-access basis; as well as the publication of DSI, taking into account current international practice in the field.

9 J. A. Heinemann/D. S. Coray/D. S. Thaler

Mr Leskien also shed some light on the decisions of the Seventh Session of the Governing Body (GB-7) and the preparations for the Eighth Session of the Governing Body (GB-8). Among others, GB-7 clarified that the term DSI was taken from decision CBD COP XIII/16 and is subject to further discussion. The Governing Body also recognized that there is a multiplicity of terms in this area[10] and that further consideration would be needed regarding terminology. He highlighted that the question how to address DSI in the ongoing negotiations of a subscription system and standard material transfer agreement will be discussed at GB-8.

World Intellectual Property Organisation

Olga Begoña Venero Aguirre informed participants about developments in WIPO and its Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC). WIPO's mission is to lead the development of a balanced and effective international intellectual property system that enables innovation and creativity for the benefit of all. The Traditional Knowledge Division of WIPO is responsible for: facilitating text-based negotiations taking place in the WIPO IGC; for providing, upon request, technical assistance and capacity-building at local, national and regional levels; developing and making available various publications and materials and for maintaining practical databases; and working closely with other international organizations. In her presentation, Ms. Venero Aguirre referred to TK Division activities and resources such as the Guide on IP Issues in ABS Agreements and the WIPO Online Collection of ABS Contracts. She also informed participants about the existence of two WIPO standards relevant for DSI, i.e. WIPO Standard ST. 25 on Sequence Listings, which provides standardization of the presentation of nucleotide and amino acid sequence listings in international patent applications, and the move to the new WIPO Standard ST. 26.

Discussions

The following sections present the main discussion points from the following sessions: "DSI: What are we talking about", "Initiating the Dialogue" and "Widening the Dialogue". This part of the report does not purport to reproduce all debates and interventions in full. According to the Chatham House Rule under which the Dialogue was conducted, the information is not attributed to the source. The comments and observations made by individual participants have been arranged thematically and not according to the session in which the interventions were made.

Concept and terminology:

- Terminology, concept and scope of the concept (e.g. NSD, in silico) need further consideration.
- Sovereignty over DSI *per se* is not acknowledged by all actors. However, it is acknowledged that the use of DSI with a direct link to a physical sample could be regulated through MAT.
- Some regard a wide definition/understanding of genetic resources (which includes information and DSI) as going beyond sovereign rights and the CBD.
- Some actors prefer a restrictive definition, but this will bring them into conflict with other actors.
- There is fear among stakeholders, especially industry, of wide-reaching obligations associated with the adoption of broad concepts.

[10] including, inter alia "genetic sequence data", "genetic sequence information", "genetic information", "dematerialized genetic resources", "in silico utilization", etc.

Open access:

Participants did not discuss definitions for "open access" or "free access" but some mentioned that "open access" does not mean access without any conditions. Access without any conditions might be best captured by the term "free access".

- Actors want open access to be safeguarded. There is a desire for sequences to be accessible for R&D, also among proponents of benefit-sharing.
- Scientists must publish DSI for reasons of transparency, checking, conditions in funding contracts etc.
- Open access is the predominant, but not the only model that exists among databanks.
- It was noted that it can be problematic for scientists when using data from different databanks that have different access requirements/rules.
- The open access policies adopted by databanks have developed independently of the CBD.
- There is a tension between open/free access (depending on the definition) and benefit-sharing.
- There is a need for open access to information on the one hand and a discussion on the allocation of benefits on the other hand.
- Open data is critical for progress (and for innovation).
- Barriers on access to DSI would have undesirable consequences.
- Broad access with few restrictions is considered to lead to societal benefits.
- Restrictions on data-sharing could have impacts on the Sustainable Development Goals (SDGs), for example, research on human health, crop diseases and animal nutrition.
- Open access is regarded by some as a key part of benefit-sharing.
- Collaboration and training are seen as benefit-sharing by some participants, but this is not necessarily recorded and recognized.
- Providers agree that significant benefits derive from open access to DSI.
- Access to DSI or data should not be used as a control or policing mechanism.
- It may be possible to make some adaptations to the existing open access system, but users of the system would have to know what agreements/rules are relevant for them. Best practice and standards can play an important role in this regard. Services could be made interoperable within the system but could be decoupled from access requirements.

Commercial and non-commercial use of DSI:

- Some are critical of the different treatment of private and public databases/data.
- Industry and the research community have common concerns about restricted access and potentially burdensome access and benefit-sharing rules. Scientists and industry are concerned about the unintended consequences of imposing such rules.
- It is impossible to say how many users of DSI there are at any one time because databanks do not require registration of users in general.
- Data is used by commercial users. Much more information on commercial use is needed in the context of discussing benefit-sharing options but this is difficult to obtain.
- The user landscape is complex. A lot of research starts with academic research that eventually goes into commercial research (and flows into products). The distinction between commercial use and academic use can be difficult to define. Some actors consider that this lack of clarity needs to be reconsidered in order to safeguard the integrity of the R&D process.
- Information creates value. The inputs and investment of users need to be taken into account in the R&D process.

Benefit-sharing:

When discussing benefit-sharing options for DSI, both bilateral and multilateral approaches were considered as well as the potential for decoupling access to data and benefit-sharing.

General

- Benefit-sharing plays a key role in incentivising sustainable use and conservation. Technology that is currently being developed allows people to bypass benefit-sharing provisions in the logic of the CBD and the Nagoya Protocol.
- Open access to DSI and monetary benefit-sharing are not mutually exclusive, e.g. as is the case in the patent system.
- There could be added-value for companies from benefit-sharing.
- Benefits are to be appropriately shared with provider countries and IPLCs.
- Both monetary and non-monetary benefit-sharing could be done better, as well as being measured and evaluated more effectively. Benefit-sharing could also be more tailored to conservation.
- Some organizations/institutes make sure benefit-sharing happens, but it is not well understood by many.
- Good benefit-sharing stories are important and there needs to be more transparency around benefit-sharing.
- Benefits arising from the commercial use of DSI should be captured by providers.
- If companies make profits from products based on DSI, a flow of benefits back to providers is possible on basis of MAT but simply relying on a "trickle down" effect to transform profits into societal benefits is problematic.
- Benefit-sharing needs to be accompanied by capacity building for the use of DSI in a technical and administrative sense.

With respect to multilateral approaches

- There are multilateral options for benefit-sharing, which could minimise transaction costs and yet provide resources necessary for conservation.
- Transaction costs can be reduced through multilateral systems. A multilateral system of access and benefit-sharing has been established by the ITPGRFA.
- Even for a multilateral system such as the Treaty, the use of many different pieces of material is problematic. More thinking needs to go into how to make a multilateral system work for benefit-sharing (stacking royalties is problematic).
- A multilateral system would not be concerned with the source of the DSI.
- Commercialisation could be a trigger for benefit-sharing within a multilateral system on DSI.
- In the BBNJ discussions, a prior notification system has been suggested by some actors.
- There is a tension between openness and benefit-sharing. What is needed is a system that leaves access open and polices stakeholder behaviour. A system that decouples benefit-sharing arising from the use of DSI with obligations to the initial provider of the resource could do this (multilateral mechanisms, specific agreements, etc).
- Solutions for benefit-sharing for the use of DSI have to be practical or users will avoid the system. There is a need to consider potential options, including decoupling access and benefit-sharing.
- If there had been more money shared through the Plant Treaty's multilateral system, there would be maybe more trust in such multilateral systems.

The ABS system:

- The original narratives on which ABS was based might not be applicable anymore. ABS was created under the assumption that one researcher goes to another country for one resource, undertakes R&D and develops a product. There will inevitably be more intermediate stages of value addition that need to be taken into account. The work of ABS is entering a higher degree of complexity. Nowadays, there are examples of one user sourcing genetic resources in 13 countries for a single project, ending up with 7 different contracts. Using multiple genetic resources or (sequenced) genetic information from a variety of countries could become a common practice. A key challenge is to find a way to manage these new types of uses.
- Many parties have not yet fully implemented ABS legislation, which results in challenges for users, e.g. researchers in the EU, to demonstrate compliance with provider country regulations.
- Key challenges relate to slow processes, lack of information and lack of clarity in various national ABS-related institutions.
- Frustration exists on the user side because access to tangible resources is often delayed or even impossible.
- The Nagoya Protocol system is not working for SMEs because it is too complex. There are many different types of companies from small to multinational companies. A system is needed that works for all actors.
- At different phases of the process, there may be new users due to commercialisation. This requires tracing.
- Transaction costs in ABS are too high. If transaction costs were lower, benefit-sharing would be higher and more straightforward.
- The scientific community and industry are concerned about having additional obligations. Extension of ABS to DSI could be more problematic for researchers.
- There are different views on ABS obligations with respect to DSI.
- DSI is considered to be an output of utilization and is thus regulated.
- Some suggest that DSI does not necessarily have to be viewed as something new or separate to the existing ABS system.
- Issues arise when DSI is obtained by third parties - what are their obligations? There is a lack of control. Some actors assume that if there was willingness to trace the data to its origin, this would be possible.
- The Nagoya Protocol has been in force since 2014 and it is a time of legal experimentation. Brazil, for example, has moved to a registration system. Other countries need to figure out which is the best legal framework for them at the country level.
- The question was asked as to how can value of biodiversity and the information in databases be captured. It was noted that contracts may not be the most effective tools.
- Consumers are supportive of responsible companies.
- There may be opportunities for benefit-sharing to be less focussed on bilateral transactions.
- There needs to be trust and access to justice before providers feel confident granting simplified access.

Data management/tracking and traceability:

- The value of the INSDC is linked with the availability of many millions of sequences.
- The existing public databases are not likely to put up a paywall.

- Provenance information in form of a country tag has been included in the DSI databases. This has been a binding requirement within the INSDC since 2011.
- Databanks do not allow the upload of MAT together with sequences and therefore the concept of securing benefit-sharing for DSI based on MAT is hypothetical.
- There is some duplication in the databanks, e.g. due to patent sequences acquiring new/additional accession numbers.
- Technical difficulties could exist in locating the exact source of DSI so that benefits can be shared with the initial provider of the genetic resource.
- It is challenging to ensure user compliance with any possible future benefit-sharing conditions on DSI use. Further, it would be extremely difficult to distinguish between commercial and non-commercial users. Specific traceability systems would be necessary.
- There is an ongoing trend of reducing transaction costs through new types of technology.
- Specific projects may be adopting their own technologies for data storage, but people are encouraged to use the public system. Blockchain, for example, does not have an interface to DSI databases and it makes it difficult to put the data into the system.
- Putting data into the system takes time and expertise. Interfaces support these processes.
- A centralised system that tracks samples from the outset could be a useful tool. It could provide the details on the legal requirements for the sample/data.
- Most users do not download complete records.
- Licensing terms on individual records are not difficult to make in a technical sense, but it is difficult to track and trace as well as make sure that the information is reliable and up to date.
- Validation of incoming data represents a significant effort. Data curators are not legal experts and there is no live update of licensing requirements, make a micro licensing tracking system enormously complex.
- There are some concerns about the potential environmental costs of tracing using blockchain.

Intellectual Property Rights:

- DSI is relevant for various types of intellectual property, including patent, copyright, trade secrets. IP holders have time-limited exclusive rights. There is a potential tension regarding the allocation of benefits.
- Considerable experience has been gathered in the patent system with DSI, which has been dealt with for decades, i.e. ever since gene patenting became standard practice. This experience shows that legal certainty with intangibles is possible and that legal standards can be developed which allow the exercise of rights and licensing.
- There is transparency in the patent system. Open access and monetary benefit-sharing are not mutually exclusive.
- Open access does not preclude monetary benefit-sharing. There are patented inventions that provide public non-monetary benefit-sharing.
- In the South African TK protection regime, knowledge is protected in perpetuity but any user who uses this knowledge needs to pay royalties for a specific time. This kind of approach could be instructive in the ABS context.
- The patent system functions with both endemic and widely available sequences.
- The starting point for different licensing arrangements needs to be taken into account. It is difficult to generalise.

- There are models on how to exercise copyright collectively to reduce of transaction costs.
- Regulatory IP frameworks at a national level probably have to coexist with global policy.

Willingness to change:

- There is a resistance to change, including in the scientific community.
- There has to be a willingness and flexibility on both sides – otherwise nothing will happen.
- Industry fears "bad change".
- There is a desire among providers to maintain control over genetic resources and receive benefits arising from the utilization of their genetic resources from. This could be problematic when potentially thinking of a multilateral system. It was suggested that if a multilateral approach is shown to work, it could make sense to consider it. The question was raised as to whether Parties would accept a multilateral system on DSI within their sovereignty.

General:

- Biodiversity is being lost because the holders of biodiversity do not get incentives out of it.
- It is crucial to address the ongoing biodiversity crisis.
- Most biodiversity exists in underdeveloped countries. People in these countries have other priorities, such as food, education etc. and are not concerned with the usefulness of biodiversity for science.
- Lack of trust between users and providers is a key challenge. Understanding the interests and needs of the stakeholders should be the starting point for the discussion about solutions.
- There is a misconception that indigenous knowledge holders do not contribute to DSI, but this is not accurate in many cases, especially when considering the other two objectives of the CBD.
- There is a need to find a balance between reducing transaction costs while recognizing the sovereign rights of states.
- It is necessary to understand how a system would work before moving forward.

Options for the CBD

In the session "Options for the CBD: Group reflections on elements and ideas for the Post-2020 Global Biodiversity Framework" small groups were formed to discuss the questions:

- What options do you think there are for the CBD?
- What needs to happen to make this possible?

Each group presented its views. The key points of these presentations are summarized in the Annex.

Reflecting on outcomes of the dialogue and way forward

Groups of stakeholder clusters were formed to reflect on what has been learned during the dialogue, especially about the views of others. It was noted that the dialogue had been open and not focused on questions of scope and definition, with a whole spectrum of possible ways of moving forward being identified. Some participants found it particularly encouraging to see the wide acceptance of the importance of open access, adding that there may be more acceptance of policy change if there is no compromise on open access to DSI for non-commercial research. It was noted that countries traditionally viewed as providers are also users of data, meaning that impacts on open access could have far-reaching consequences for scientists worldwide. At the same time, some participants pointed out that the idea of de-coupling access and benefit-sharing had not been well-digested. Individual comments

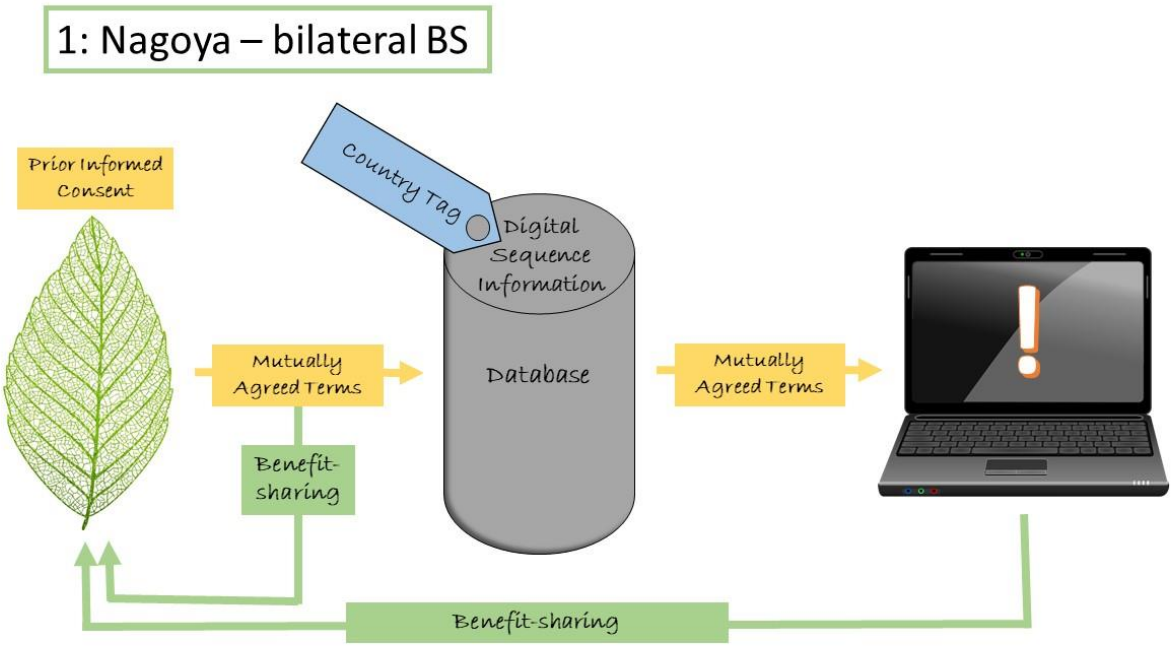
related to the need to think widely to find solutions for biodiversity loss, the importance of considering the link to intellectual property, the broad interest in finding a solution, the urgent need for a solution and the hope that databases will be supportive of implementation of any solution. Following on from the discussion about options, participants were invited to consider points for consideration with regard to analysing / evaluating any options on DSI.

These points for consideration are summarised below (grouped by the ABS Initiative).

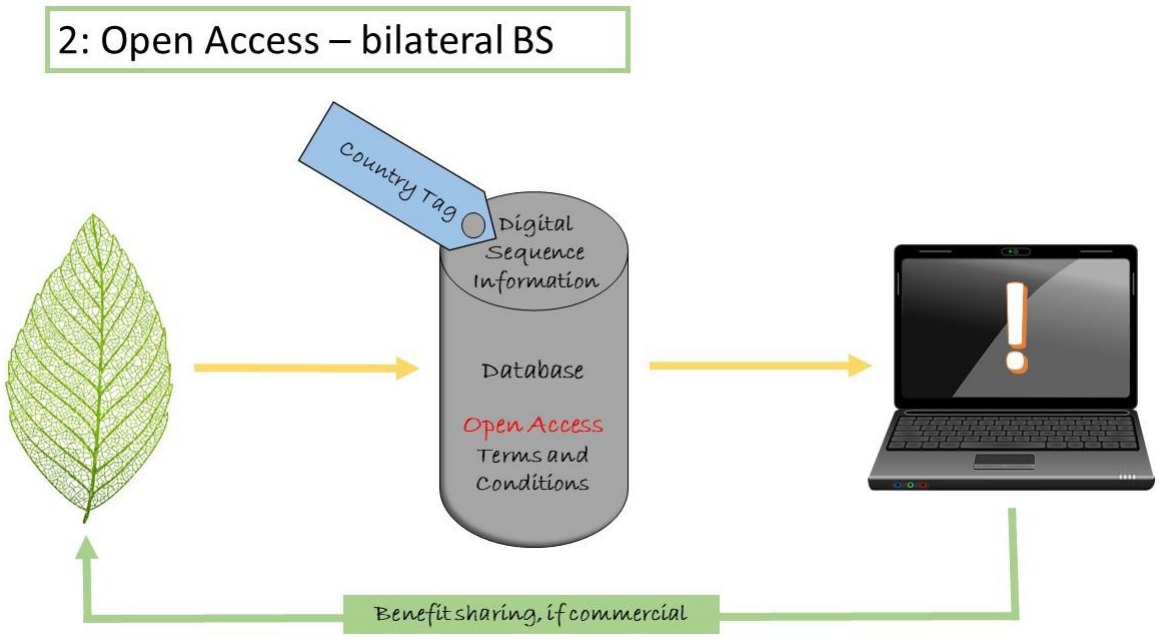
<table>
<tr><th>Deliverables</th><th>Governance aspects</th></tr>
<tr><td>• Alignment of incentives regarding CBD objectives
• Contribution to fight biodiversity loss
• Win-win-win gains (providers – users – environment)
• Global initiative delivering global benefits
• Potential to generate benefits
• Ability to quantify benefits (monetary / non-monetary)
• Ability to minimize biopiracy
• Enhance the ability to meet the SDGs</td><td>• Enforceability
• Voluntary or compulsory
• Fairness and equity
• Recognition of/link to provider of the (initial) genetic resource
• Legal certainty / predictability
• Ability to monitor
• Ability to build trust among partners/stakeholders
• Inclusiveness and recognition of the priorities of all stakeholders
• Transparency on storage and use of DSI
• Transparency in decision-making, distribution of funds etc.</td></tr>
<tr><th>Operational Aspects</th><th>Economic Aspects</th></tr>
<tr><td>• Feasible / doable / can be implemented
• Simplicity of the system
• Low level of complexity
• Effectiveness
• Flexibility / Adaptability
• Workable for different types of users
• Future proof (takes into account technological development)
• Ability to be implemented timely/quickly
• Not reinventing the wheel (i.e. not replicating existing systems but rather building on them)
• Compatibility with other/existing systems* legal frameworks, databases, funds, etc.</td><td>• Cost of setting up and maintaining the system
• Transaction costs
• Economics of information i.e. information spreads easily and is hard to control; asymmetry of information
• Incentives/ Incentives to participate</td></tr>
<tr><th>Potential impacts</th><th>Capacity</th></tr>
<tr><td rowspan="3">• Consequences for everyone (stakeholders affected directly/indirectly)
• Impact on R&D
• Not disruptive to open access
• No impediments to research
• No barriers to attaining the SDGs (DSI technology is applied in many SDG relevant sectors)</td><td>• Capacity development for the use of DSI (level playing field)
• Ability to use DSI globally</td></tr>
<tr><th>Other Aspects</th></tr>
<tr><td>• Realistic expectations
• Consideration of the environmental footprint
• Ease of access to justice*</td></tr>
</table>

*according to participants these points require further clarification

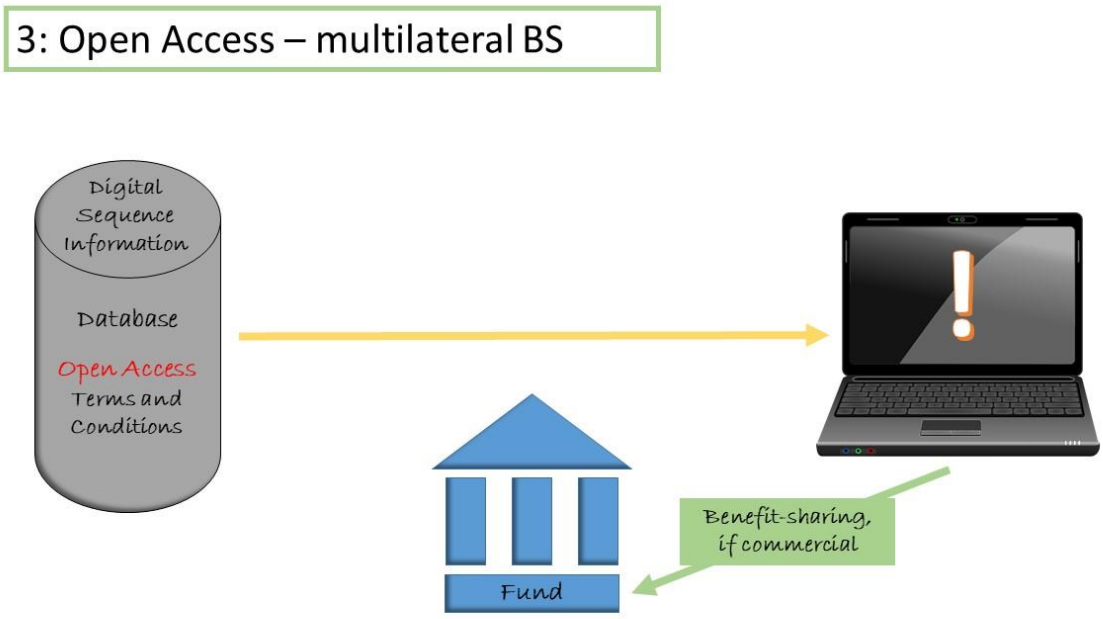
Several options synthesizing schemes discussed in the session on “Options for the CBD” were selected for further discussion. In the last session, participants discussed these synthesized options in the plenary, describing the linkages between the use of DSI and benefit-sharing.



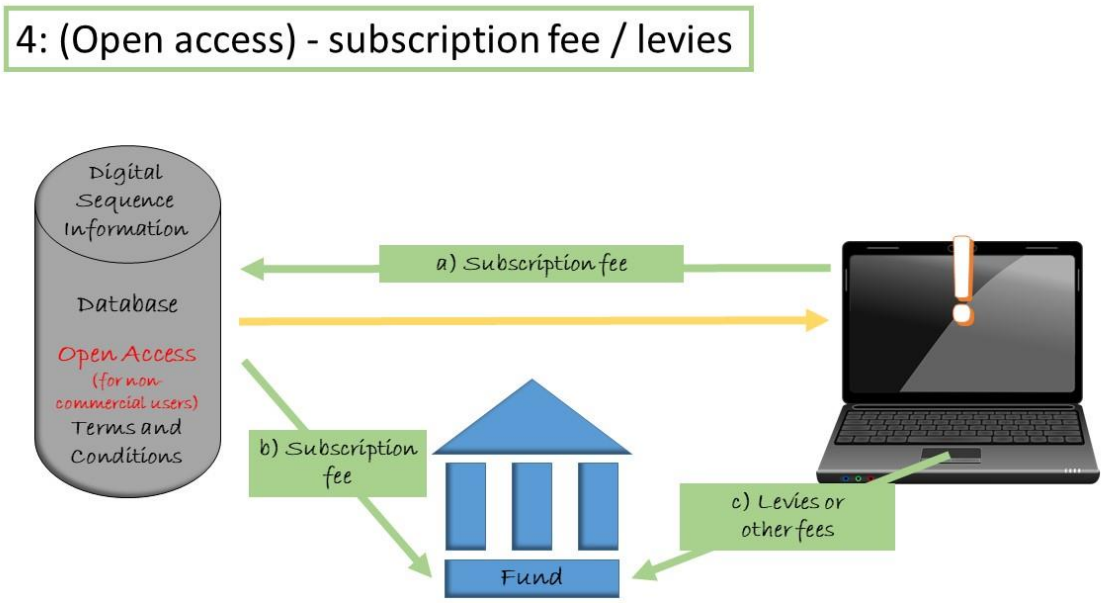
Option 1: “Nagoya –bilateral” describes the current model, which could regulate benefit-sharing for the use of DSI through the ABS contract (MAT) signed by the provider and first user. The MAT would need to contain specific third-party provisions for the use of DSI and associated benefit-sharing obligations, which would need to be binding on users of DSI. Option 1 requires a country tag connected to the uploaded DSI. Such country tags are meanwhile (since 2011) obligatory in certain DSI databases. However, it was underlined that the current templates used by DSI databases do not allow for parallel uploading of DSI and the respective MAT.



Option 2: "Open Access – bilateral" describes a model in which benefit-sharing in the case of commercial use of DSI is not regulated through MAT but through terms and conditions defined by a specific "regime". This model requires a country tag to be connected to uploaded DSI in order to enable the user of DSI to direct the benefit-sharing back to the country of origin. This model guarantees open access to DSI. The user is informed of the benefit-sharing obligations in case of commercial applications through the terms and conditions of the database.

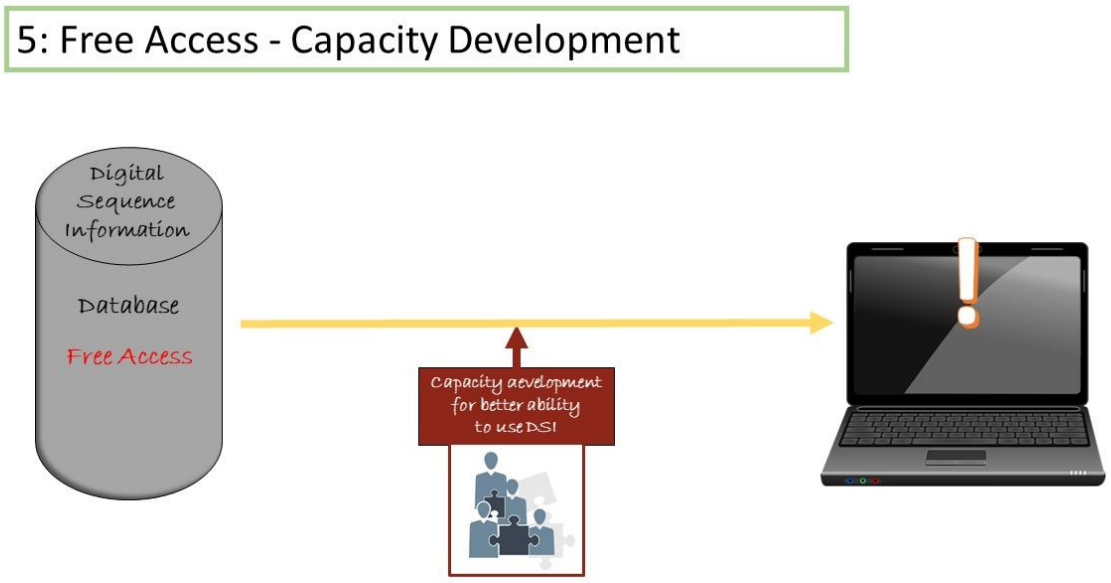


Option 3: Open Access – multilateral describes a model in which benefit-sharing in the case of commercial use of DSI is not regulated through MAT but through terms and conditions defined by a specific "regime". This model does not require a country tag connected to uploaded DSI as it foresees benefit-sharing into a multilateral fund. It was noted that the benefits should be brought back to developing countries through appropriate mechanisms. This model guarantees open access to DSI. The user is informed on the benefit sharing obligations in case of commercial applications through the terms and conditions of the database.



Option 4: (Open Access) – Subscription fee / levies describes a model in which benefit-sharing is realised through certain upfront payments not linked to specific products or related to value-creation. This model does not require a country tag connected to uploaded DSI but foresees that benefits are paid into a multilateral fund. Benefits should be brought back to developing countries through appropriate mechanisms. This approach guarantees open access to DSI. Among the different approaches that were discussed under this option, participants suggested differentiated fees (e.g. based on the use, turnover, etc.) that users would need to pay when accessing DSI. Participants also underlined that open access for non-commercial users must not be restricted unduly. The user is informed of the benefit sharing obligations through the terms and conditions of the database. Another approach suggested levies on e.g. equipment that is essential for the use of DSI (e.g. DNA sequencing or DNA synthesising machinery).

It was suggested that subscription fees in general would put benefit-sharing burden on scientists and could potentially lead to a high level of dissatisfaction. A subscription option could potentially have unintended consequences for scientists in developing countries if they need to pay for access to sequences.



Option 5 Free Access – Capacity Development describes a model in which no specific benefit-sharing obligations for users of DSI exist. It was noted that the benefits created through the commercial use of DSI will trickle down into society. Instead, capacity development for the users of DSI, specifically in developing countries, was suggested. It was noted that the costs for such capacity development should be covered by various sources and not only by the commercial users of DSI. This model offers free access to DSI.

Discussion points:

General considerations:

- All stakeholders will have a strong interest in knowing how their interests are reflected in any option/solution.
- For some participants, option 5 is the current default situation, which is unlikely to satisfy CBD Parties that are demanding that benefits arising from the use of DSI be shared fairly and equitably.
- Any option should consider the implications for traditional knowledge associated with genetic resources arising from the use of DSI.
- There is much public investment in database infrastructure and tools, meaning that although there is no direct cost to the user of these databases, access to data is not free in the sense that there is no cost and that the governance/cost of databases needs to be taken into account.
- Many options exist for the disbursement of benefits from fund to beneficiary, one option is the use of existing biodiversity-related funds as the GEF.
- Options may not necessarily be mutually exclusive, i.e. could potentially complement one another.
- Options may need to take account of both material and data.
- The models are presented in a simplistic way. The reality of access to and use of DSI is far more complex than portrayed.
- Capacity development for the use of DSI is a cross-cutting issue (across options).
- Databases can potentially address the existing redundancy in their systems.

Next steps:

- More dialogue and exchange are required, not just at the DSI dialogue but in other countries and sectors to learn from other fora.
- It is important to have balanced representation, including from different regions, traditional knowledge holders, and various sectors, especially health.
- It is possible to learn from existing options and models, but any system needs to be tailored to the context.
- More forms of resource mobilisation, which go beyond ABS, are required in order to address the loss of biodiversity.
- Look into different possible models or approaches for dealing with DSI.

Annex

Options for the CBD: Group reflections on elements and ideas for the Post-2020 Global Biodiversity Framework – Presentations:

Group 1	• DSI is not in the scope but it is an output of utilization, so PIC and MAT will exist and there will be benefit-sharing. • There was no agreement on a definition of DSI. • Options discussed: Standard terms and conditions are created for databases, which provide two possibilities: (1) a complete decoupling of access and benefit-sharing. According to the standard terms and conditions, if you access DSI from the database, you agree that if you make a profit from using the DSI, some of this profit goes back to a multilateral system for distribution through an agreed (fair) mechanism; (2) semi-coupled model. If you make a product from DSI, you find out where the DSI came from and get MAT (not PIC) from the relevant rights holder.
Group 2	• Option 1: Maintain the status quo (current system), regulating DSI in MAT. • Option 2: Parties agree to regulate DSI as such, i.e. not through the current ABS system and not according to the rules applying to genetic resources. Option 2.1. DSI is considered to be a genetic resource, meaning the Nagoya Protocol applies: 2.1.a) Bilateral system applies to DSI; or 2.1.b) Would it be Article 10 Nagoya Protocol because you cannot grant PIC? This would be a difficult / onerous option? Option 2.2. If DSI is not under the definition of genetic resource– a new system is needed, which is not under the CBD because DSI is not a GR. A multilateral system would make sense. Parties could agree to form a new treaty.
Group 3	• DSI is a placeholder but more clarity on the term is needed. • There needs to be a cost-benefit analysis of any option. • There is a need to move away from the focus on controlling access to facilitating utilization/ open access for business. • Buy-in from US taxpayers (who fund GenBank) is key. • Terms and conditions or access policy is needed to maintain linkages. • Need to determine how to deal with third party use of DSI. • Consider multilateral approaches: look into different possible models or approaches, including a hybrid system that maintains the link between provider and initial users and moves into a multilateral system for subsequent use. • Agreeing on a definition: it is key to understand the concept and there is a need for more clarity. • More dialogue and exchange is needed, not just at the DSI dialogue but in other countries and sectors, including learning from other fora. • Case studies and pilots/testing would be constructive. It is really important to investigate modalities.
Group 4	• Need to map out options –bilateral, hybrid, multilateral • Identify guiding principles • Safeguard models for open access • Gain conceptual clarity • Keep stakeholders in the discussion, including economists – do we have everyone? • Keep options simple but do not oversimplify • Create incentives for options

	• Learn about what has worked or not worked in other systems – the private sector does not use the other system, why? • Look at different possible multilateral options– one size fits all, sectoral specific models, bounded openness, IP options (i.e. separate IP system over DSI) • Need examples of where it has worked and not worked, i.e. need an evidence-based approach • Develop pre-defined criteria to assess such a system, e.g. look at issues of complexity, transactions costs, fairness and equity, look at proof of effectiveness – assessment, e.g. blockchain *There was disagreement on the role of economics and how to refer to it – informational goods, economics of information*
Group 5	• Cut-off and triggers need to be identified • De-coupling –means different things to different people. It may mean decoupling of DSI from a physical resource or it may refer to the decoupling of access from benefit-sharing. • Need to look at options and elaborate different options to better understand what we are choosing • Options: Under CBD, not under CBD or under Nagoya Protocol? Question about whether it is automatically Nagoya Protocol or something new • The implications for enforcement should be considered • Benefit-sharing in any system should be considered as well as the no benefit-sharing option • Multilateral system, decoupling and bilateral – how is access addressed under these different options, including having no access rules? • Monetary, non-monetary benefit-sharing or both – many thought that there should be both • Trigger – no further conclusions, is it access or commercialization?

Group 6	• There is a need for a glossary of terms. This is not regarded as being easy to develop.
	• Scenario building:
	  ○ Bilateral/Nagoya Protocol – model
	  ○ Multilateral
	  ○ Hybrid – identified three different models: (1) shared system, physical resources are governed by the Nagoya Protocol and a multilateral system applies for DSI; (2) a multilateral system for everything; (3) users and providers have a choice of which system to use
	• Need case studies as they can enlighten us on various options
	• Can learn from existing options and existing models but any system needs to be tailored to the context
	• Need to identify areas of common understanding
	• Profile existing non-monetary benefit sharing by ex-situ collections (databases). What is the non-monetary benefit-sharing? For example, giving access to data - especially according to FAIR principles
	• Focus on concrete issues

Group 7	• Options 1: decoupled multilateral system for public data and a benefit-sharing obligation only exists upon market entry. Existing bilateral Nagoya Protocol obligations remain. We could start here. • Option 2: decoupled system for all. Could be a follow up option in future if Nagoya Protocol is not working. • Option 3: voluntary benefit-sharing upon market entry, stays Nagoya Protocol, e.g. a system like lion's share. Some research has shown that voluntary contributions can lead to funds getting more money as, transaction costs are low. However, there could be trust issues. • Option 4: mandatory tax or levy on all products or processes. E.g. levy on sequencing machines. Researchers will pay more, private sector may not pay.

	• Fund
	  ○ Governance issues, e.g. is it under CBD? Who holds it?
	  ○ Can statistics from INDSC assist in defining benefit-sharing? Who gets priority? Some countries e.g. have low use but provide high number of sequences. Use - biodiversity conservation, sustainable use, IPBES reports, member states capacity development

Group 8	• How to set up systems, governance, processes to capture and divide benefits with States providing DSI? • Possible to look to PIP Framework and look at lessons learned, including mistakes. • PIP – monetary benefits are paid by industry, but most pathogens are out. How to move forward? • Not just pharmaceutical sector – other sectors are relevant • The system should exclude academia – they should have open access • One suggestion – would it be possible for sectoral bodies to collect funds from their members to be distributed? There are many questions about how to get the information about who has access, what to do about non-members and how to identify them. • How to achieve buy-in into the system? • A GMBSM under Art. 10 may not be a good idea as it limits the discussion to Nagoya Protocol, but DSI is seen as a bigger issue and various fora are relevant. • How to allocate money received by a fund? IPBES – could identify global priorities for biodiversity, weighted in favor of communities, and for on the ground for sustainable use and conservation in hotspots (or where most needed). • To be cost effective – a fund could be incorporated in GEF infrastructure. • No agreement on possible triggers. The system should enable open exchange of data up to a certain point (similar to the idea of bounded openness). Data use is not tracked and traced and there is no regulation until users reach the point of commercialization. • Need to come to an agreement on governing DSI at COP 15 – if a multilateral system on DSI is established, TK could be included voluntarily. • Benefit-sharing going into this fund could be earmarked for certain sectors. • The system could also be used in the BBNJ context as it does not have an access mechanism. It may also be relevant for agricultural resources beyond the Plant Treaty. Regional and sectoral earmarks for benefit-sharing could be considered.