



International Exchange on Digital Sequence Information (DSI)

8th to 9th November 2022, The Hague, The Netherlands

Funded by Directorate-General Environment of the European Commission and hosted by the Government of the Netherlands

Organized by GeoMedia GmbH on behalf of the European Commission

REPORT

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¹ Disclaimer: This report was prepared for the use and benefit of the participants of the DSI Exchange in The Hague, Netherlands, 8 to 9 November 2022, 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 EU Commission, GeoMedia GmbH, or any cooperation partners of the organizers. The EU Commission and GeoMedia GmbH do not assume any liability for the accuracy or completeness of the report.

Short overview and outcomes

The International Exchange on Digital Sequence Information (DSI) was funded and organized by the Directorate-General Environment of the European Commission, hosted by the Government of the Netherlands and held at *NH Atlantic* in The Hague, Netherlands, from 8 to 9 November 2022.

At a time where negotiations on benefit-sharing from DSI on genetic resources are approaching a critical moment (the 15th Meeting of the Conference of the Parties of the Convention on Biological Diversity (CBD) had been confirmed to finally take place in Montreal, 7-19 December 2022), it was crucial to gather inputs for negotiators from public and private sector users, as well as other relevant stakeholders.

The overall **objective** of the 'DSI Exchange' was to promote a deeper mutual understanding of perspectives among global academic and commercial DSI users of different sectors, and elaborate key messages for negotiators. Besides DSI users from the public and private sectors covering more than 20 countries from all world regions a small number of renowned DSI experts and representatives of Indigenous Peoples and Local Communities (IPLC) were invited to support the Exchange by contributing knowledge and perspectives. Few representatives of the European Commission and EU Member States also attended to contribute to the discussion from a policy-maker's perspective. The Secretariat of the Convention of the SCBD attended the meeting as observer.

The Exchange provided an opportunity for academic and commercial users of DSI to be updated on the state of international discussions and studies related to various fora, to share and exchange different users' perceptions, interests and concerns, and to brainstorm ideas about a way forward.

The meeting was convened by the European Commission and hosted by the Government of The Netherlands. The Exchange started by informing participants about the status of the formal and informal discussions on DSI, identifying the core issues in the discussion in the CBD and other fora. Participants were then invited to discuss and reflect on the following topics:

- Benefit-sharing from the use of DSI
- (Open) Access to and use of DSI
- Capacity building / Technology transfer

On each of these topics, key messages were extracted by the participants for consideration by negotiators when discussing and adopting the COP decision on DSI in December 2022:

Benefit-Sharing

- Context: Users may deal with many countries (50 and more) => Learning from the past:
 - Experience of heterogeneity vs. countries having single interests
 - Holistic approach regarding genetic resources, DSI, derivatives and associated traditional knowledge
 - Needs to be simple
- There is willingness to pay for
 - 100% legal certainty of any use
 - Open, public, interconnected ecosystem for everyone (North <-> South)
 - o Simple, pragmatic and affordable mechanism
 - Alignment across all UN fora
- There is willingness to support
 - CBD objectives 1 (conservation) and 2 (sustainable use)
 - Capacity building and technology transfer
 - Infrastructure (from databases and molecular laboratories to enabling environments for R&D)
 - IPLCs as custodians of biodiversity

- Modalities need to be compatible with criteria 1-4 by the OEWG at its 3rd meeting in Geneva in March 2022
 - International standardisation
 - Redistribution based on needs of stakeholders and biodiversity conservation, not of countries of origin
 - Broad and simple scope as basis for benefit generation

(Open) Access to, and use of DSI

- Open access is key, but not necessarily free (however: no paywall as this modality would disrupt interoperability among databases and infrastructures)
- Responsible behaviour (provenance of data) increase information to increase transparency
- R&D with commercial vs. non-commercial outcome, which may change over time
 - Benefit-sharing with commercialisation: distinction between commercial and noncommercial R&D irrelevant
 - Benefit-sharing at access: Distinction between commercial and non-commercial R&D VERY challenging at this stage, triggering point for BS would not be clear leading to legal uncertainty.
- Legal certainty for all stakeholders (including users, IPLCs, and others)!
- NO COMBINATION of benefit-sharing at access point and commercialisation.
- Design Principles
 - Before COP 15: What can we learn from ABS as a whole? => align expectations
 - o After COP 15: What is it that we would like to achieve?
- No 'track & trace' all along the value chain, because of tracking and tracing impracticalities. However, it is possible to take measures to improve transparency.

Capacity building and technology transfer

- Capacity building and technology transfer are essential and central to ensure EQUAL ability to generate, access and use DSI by scientists and other stake- und rights- holders in all countries => fairness & equity
- Key component of non-monetary Benefit-sharing is more value/importance than monetary Benefit-sharing as such
- Cover infrastructure, skills and knowledge plus policy framework for technology transfer
- Need for monitoring with meaningful indicators in the GBF to ensure visibility and sustainability of the system, e.g. regarding HR retention and facilitated procedures
- Involve all relevant stake- and rights- holders, incl. government departments such as public health, agriculture, research and education
- Bottom up and needs-based approach, but coordinated top-down (e.g. build platform for exchange)
- Partnerships: public non-public / developed developing countries / South-South

Key CBD negotiators from around the world were gathering from 10 to 11 November at the same venue for a separate, but a thematically related event – the 'DSI Retreat' –, which was organised by the ABS Capacity Development Initiative in the context of the South Africa & Norway Strategic Partnership. Using this opportunity, the afternoon of the 9th of November was devoted to a joint meeting of the participants of both events. Participants of the DSI Exchange presented their key messages to negotiators. Both the negotiators and the stakeholders engaged in a lively discussion, which continued during a joint dinner hosted by the Government of the Netherlands.

Participants of the Exchange expressed that they were motivated to take forward what they had learned from the meeting and to integrate it into their work. In general, stakeholders participating in the Exchange noted that the event was successful in providing an open environment to discuss this controversial issue and a unique opportunity to discuss directly with negotiators.

Official Opening of the Exchange

Mery Ciacci of the Directorate-General Environment of the European Commission opened the meeting by thanking the Government of The Netherlands for hosting the DSI Exchange. She pointed to the approaching of the final round of the negotiations towards the adoption of the post-2020 Global Biodiversity Framework in December 2022 and the critical role of DSI in those negotiations. She highlighted the importance of gathering inputs and views from stakeholders from both the private the and public sectors, and called for their constructive engagement into the discussion, as any CBD COP decision on DSI will affect their daily activities. She further pointed to the importance of DSI-based R&D as basis for the future development of humankind, thus requiring practical solutions that are adequate for researchers, IPLCs and administrators. Finally, she thanked the Governments of Norway and South Africa for the joint organisations of the afternoon session on the next day, providing the users (commercial and public R&D) with an opportunity to present key messages to and discuss with negotiators.

<u>Kim van Seeters</u> of the Dutch Ministry of Agriculture, Nature and Food Quality briefly thanked the organisers for the opportunity to host the meeting.

Technical Introduction

<u>Kathrin Heidbrink</u>, facilitator of the event, provided an overview of the agenda and reminded participants that the meeting takes place under the Chatham House Rule². A quick sociogram gave an overview about who is in the room: mainly public Researcher and members of Industry, few IPLCs and policy makers.

Setting the Scene

With a view to setting the scene, <u>Timothy Hodges</u>, co-facilitator of the event, highlighted the unique opportunity the DSI Exchange is offering to the participants: to communicate key messages to negotiators and thus constructively influence the possible outcome of CBD COP 15. He expressed his expectation that, despite not necessarily everyone having the same views on all aspects, participants will be able to identify key points for consideration by negotiators. He reminded participants that, 30 years ago, the CBD started with joint visions and optimism, while today different views about implementation continue to exist. While the Nagoya Protocol is a given, technological progress requires those involved in treaty making to find an acceptable solution for DSI. He further reminded participants that the CBD provides a relevant forum for IPLCs and their world views. Therefore, any solution for DSI requires an integrated, interconnected and holistic view of the problem. Closing his input Mr. Hodges pointed to the conflict between defending negotiation positions and responding to broader global responsibilities by reiterating that it is not about DSI requiring a solution, but rather what can DSI contribute to resource mobilisation for addressing climate change and the biodiversity crisis.

Briefing on the DSI process thus far

<u>Charlotte Germain-Aubrey</u> of the Secretariat of the Convention on Biological Diversity gave a short overview on the formal DSI process since COP 14 in 2018, starting with so-called archetypes for potential policy options and a range of established criteria to assess those different options. She presented the outcomes of an assessment matrix exercise of the different policy options carried out by the members of the Informal Advisory Group3. The scoring reveals that there is broad support for enhanced technical and scientific collaboration and capacity-building, and preference for the policy option on a standard MAT in a bilateral system only as part of a hybrid solution, and for policy options based on a multilateral approach unless they impose a fee at access to DSI.

² When a meeting, or part thereof, is held under the Chatham House Rule, participants are free to use the information received, but neither the identity nor the affiliation of the speaker(s), nor that of any other participant, may be revealed.

<u>Suhel al-Janabi</u> of GeoMedia provided an overview of the informal dialogue formats and exchange meetings, including physical and later virtual formats in the context of the COVID-19 pandemic. He highlighted the roles of the 1st Global DSI Dialogue (Nov. 2019) in identifying the original set of archetypes for a DSI solution, and the 2nd Global DSI Dialogue (July/August 2021) on identifying key areas of convergence and divergence. Technical issues were discussed since 2020 in many different webinars, leading to the exchanges which took place in on the island of Vilm and in Bellagio: The 1st Vilm meeting (Nov. 2021) identified implications of the policy options on practical work with DSI, in particular on open access, while the Bellagio meeting (May 2022) discussed the implications of different policy options on the applicability for other treaties. An emerging key message is that any solution based on the bilateral option is impracticable, and the 2nd Vilm meeting (Sep. 2022) identified the preference of the private sector for a multilateral system for benefit-sharing from the use of DSI.

Taking stock: Where are we in the DSI discussion?

After these inputs participants had the opportunity to discuss where there is progress and where important questions are still open.

Participants broadly agreed that

- The current system for ABS does not deliver on the benefit-sharing obligation of the 3rd objective of the CBD, which is mainly because of its complexity;
- DSI based R&D is essential for innovation, and any modality to share benefits from DSI should not affect research or be too cumbersome to comply with;
- A future-proof solution is required, as science and technology continuously evolve and it would be undesirable to repeat the same discussions in a few years time;
- Any benefit-sharing from the use of DSI should not only be seen as a solution for DSI, but as
 an element and part of the solution towards mobilising resources for conservation and sustainable use, i.e. implementation of the other two objectives of the CBD;
- The specific modalities of any solution are still unclear; and
- Fairness and equity are required.

Policy makers pointed to the fact that the current bilateral ABS process would increase the burden in R&D for users of DSI, and that the criteria of the matrix are useful to assess the policy options tabled.

Industry representatives highlighted that the collective experience with the current ABS system demonstrates a lack of legal certainty and clarity, pointing out that the complexity of the system leads to a preference to work with resources outside of the system and to bypassing benefit-sharing obligations. Some underlined the need for a better understanding of technical issues such as 'track & trace' and associated limitations. ("track & trace not workable!"). Furthermore, a need was expressed to better understand how the different policy options might work practically, and to assess the respective financial implications, i.e. a cost-benefit analysis. It was also highlighted that exceptions for public health related R&D rarely exist in existing regulatory ABS frameworks thus not recognising the benefit-sharing dimension of, for example, the development of treatments (such as vaccines), including against tropical diseases. The fear was expressed that a DSI solution agreed upon by CBD COP 15 could add more complexity to the already existing ABS system, which calls for better mutual understanding between negotiators and stakeholders, including IPLCs.

Representatives of the public research sector highlighted that information of the origin (countries and IPLCs) of DSI needs to be in the databases in order to increase knowledge and information. They pointed out the need for guaranteeing that access to DSI databases is equal for developing and developed countries, which is not a reality at this point in time due to a capacity and technology gap. It was stressed that a hybrid approach (a multilateral combined with a bilateral approach) for access to DSI in databases does not address the concerns regarding 'track & trace' of the R&D community (namely, preserve open access and current way of working of research), whereas a multilateral approach might undermine the wish of some Parties to the CBD to protect national sovereignty over their

biological/genetic resources. The need for a future-proof solution was mentioned several times with a reference to the rapid technological development.

IPLC representatives acknowledged their respect for the work of researchers and pointed to the need for open science, highlighting that access to data for comparison of sequence data is important for IPLCs to understand nature not only in a spiritual but also in a scientific way. The Nagoya Protocol recognises customary law and provides the opportunity to negotiate MAT, but this is not a current reality. A multilateral system would ensure benefit-sharing from a multilateral body (i.e. out of the control of national governments) and distribute them for the conservation and sustainable use of biodiversity, including by providing IPLCs with direct access to such funds.

Users' exchanges

During the following sessions participants were asked to focus their discussions around three key topics: (1) Benefit-Sharing, (2) (Open) Access to and use of DSI, and (3) Capacity building and technology transfer with a view to develop few key messages to negotiators and policy makers.

1. Users' exchange: Benefit-Sharing

During a 'written discussion' (similar to the 'world café' methodology) participants were asked to answer and comment in writing to the following questions posted on four separate boards, followed by a plenary session for a joint discussion:

- Who should benefit for which purpose?
- How could monetary Benefit-sharing function? (modalities, mechanisms, ...)
- How could non-monetary Benefit-sharing function?
- What could/should be trigger points?

Question 1: Who should benefit for which purpose?

- Countries of origin of GR (sovereignty). -> How to claim? -> Such as biological collections.
- Entities in possession of GR. -> Derivatives? -> We need to define what "possession" refers to.
- Person or organization, including in-country scientists, who sequence GR and do R&D on DSI developing a product, i.e. the biodiversity and life science infrastructure as a whole.
- Database providers of DSI to keep open access.
- Actors who are involved in conservation of biodiversity incl. sustainable use such as governments, IPLCs (e.g. regarding traditional knowledge associated to GR), communities.
- What about other objectives than biodiversity conservation? E.g., public health, food security, biosecurity, R&D innovation.
- Why to ensure fairness & equity
- Allocated to reinforce functional of overall international database system and inclusiveness
- The whole ecosystem of provider & users should benefit.

Question 2: How could monetary Benefit-Sharing function? (modalities, mechanisms, ...)?

- No hybrid, because of necessity to keep country tag along entire complicated value chain.
- One time payment Multilateral system (e.g. ITPGRFA) -> should not hinder R&D innovation and capacity building
- Should avoid track and trace
- On commercialization requires tracks & trace
- Avoid stacking of obligations (requirement to be in harmony with other systems)
- It must be simple and provide legal certainty (e.g. upfront payment into ML fund) (must cover physical GR):
 - Payments by commercial and academic users (any who use GR/DSI).
 - O Who does money in and how does money get withdrawn?

- Countries pay (to a common fund) and then decide whether or not to collect funds from their constituencies.
- Countries pay based on what? -> project based as per IPLC needs or for upskilling.
- Fund allocated to IPLCs/countries for local conservation projects by IPLCs and upskilling (using allocation to buy training and scholarships etc).
- Countries pay to a common fund -> not managed by GEF please!
- Could a voluntary system be adopted as a first step? -> It won't work and this will lead to more frustration.
 - o The solution must cover both physical GR and DSI, including all derivates of GR.
 - It must be future proof (no need to define "DSI" or predict technology advances).
 - A multilateral system avoids jurisdiction shopping.
- Incentives for countries to upload GR/DSI in international system
- De-linking benefit-sharing from access.
- Deciding on "how" the benefit-sharing mechanism will function implies a clear decision on "what" we want to function (align expectations!!!).
- Broad based, include contributions of countries, diversified, well defined criteria
- Reasonable and realistic, but also fair and equitable
- Only part of a solution for resource mobilisation. -> with correct expectations. -> What does "correct" mean? "Correct" for whom?
- Payment upfront into a multilateral fund provides for predictability of the costs to users and of predictability to revenue for countries.

Question 3: How could non-monetary Benefit-sharing function?

- General commitments of the users under the CBD and the Plant Treaty are enough. Need to adopt more concrete obligations, e.g., % international aid committed for technology transfer and capacity building.
- Need CBD governance structure to distribute non-monetary benefit
- Should not depend entire on funds collected through monetary Benefit-sharing mechanism. Technology transfer has to have its own mechanisms!!!
- Through open access.
- Through capacity building improvement and technology transfer.
- Infrastructure development for conservation of GR and DSI
- Research/innovation infrastructure and ecosystems -> No duplication of infrastructure of DSI.
- Based on needs, targeted to local context and perhaps individual ("need to be defined") initiatives (supported by the institution on a political match-making platform) rather than central decisions (seems to work better).
- Individual (long-term) partnerships including government-level partnerships -> yes! But how to fund this???
- Market structure that makes products and services necessary for genomics affordable.
- Model like EU-Horizon ->set infrastructure ->funding ->cooperation -> legal
- Modalities of sharing information must work for recipients.
- Respect for legal rights, including rights about territories, resources, environmental standards: enabling mechanism for maintenance costs. -> Sustainable use of biodiversity.
- Needs to be seen as benefits by recipients not just providers.

Question 4: What could/should be trigger points?

- Using any DSI/GR. -> You touch it you pay. -> "it": DSI or database? -> simple, predictable and trace and tracking is not needed (why?).
- Not a paywall, but terms of use (single global MAT).
- A compliance checkpoint. -> If patent application contains biological data (yes or no) then you should have been paying.

- In the AU-proposal the trigger point is when you buy a product.
- Trigger point: voluntary vs. mandatory
- On commercialization multilateral system!! -> also at access!
- Retrospective possible -> Enter into compliance (join the system).
- Compliance (for non-monetary) -> capacity building
- Biological data in scientific publications

Considering the emerging different views of the participants regarding the four questions the ensuing plenary discussion was structured to focus first on commonalities and then on differences:

Observations and clarification regarding commonalities:

- Unclear whether more biodiversity funding will come from multiple sources.
- Understanding of benefits: most biodiversity-based products are benefits for people as well as for biodiversity protection and conservation. A certain proportion of benefits generated from using biological resources should go into conservation.
- Non-monetary benefit-sharing should focus on technology transfer and capacity building –
 more clarification is necessary who receives the benefits: R&D regarding conservation and sustainable use as well as public health?
- Monetary benefit-sharing should focus on conservation and sustainable use
- Need to understand benefits broader: Only parts can go into conservation and sustainable use.
- Not much emphasis on bilateral Benefit-sharing

Observations and clarification regarding differences:

- On triggers either access or use (but not a combination of the two), more clarification needed. What is meant by compliance? As member of a system what do you gain or lose if e.g. legal certainty is unclear?
- Regarding purpose of benefit-sharing: the diversity of actors to benefit maybe need to differentiate between monetary and non-monetary benefits.
- Regarding non-monetary benefit-sharing: Substantive capacities for sequencing as well as use of databases are only in developed countries
- Definitions and modalities are still unclear and expectation still rather different -> resulting in differences: what does "realistic expectations" mean, as well as "equity" and "fairness"?

2. Users' exchange: (Open) Access to and use of DSI

The next session asked the participants to discuss in four groups the question "What are implications (e.g. legal certainty, technical, admin., ...) of different approaches, e.g. trigger points, on open access for R&D activities?" for commercial and non-commercial R&D.

With a view to simplify the discussion, the various policy options and potential approaches emerging from the formal and informal DSI process were summarized in line with the following three approaches:

- 'coupled' (access triggers benefit-sharing)
- 'de-coupled' (commercialisation triggers benefit-sharing)
- 'hybrid' (some combination of coupled & de-coupled)

Thus, focus was set on the trigger point for benefit-sharing regardless whether access to and use of DSI is taking place under a bilateral, multilateral or 'hybrid' system. However, participants felt the need to relate to these approaches by specifying whether bilateral, multilateral or a combination of these two would occur. The following table summarizes the key points put on cards by the participants in the matrix provided to visualise the outcomes of the discussions in the four groups:

Approaches	Commercial R&D	Both / no differentiation	Non-commercial R&D
'coupled' (access triggers benefit-sharing)	 Legal certainty* MA conditions are easier to negotiate Upfront legal certainty will foster R&D and collaborations and partnerships -> requires simple process e.g., multilateral system Freedom to operate on early stage Simpler for provider 	 Legal certainty* Simple, certain ONLY if multilateral standardized Difficult to accommodate date in bilateral system METRICS for non-monetary benefit-sharing Less benefits Harmful delays High administrative burden High costs -> disincentive Definition missing: "access", utilization and freedom to operate Two kinds of access Academic: free Commercial: paid May make start of research projects more difficult (depends on modalities) Simple and certain only if multilateral and standardized 	 If paywall, significant interoperability problems for automated databases exchanges <-> easy to understand if a single global use license Goes against national open access policy Greater price impact on noncommercial Non-monetary benefit-sharing: What with whom? "Match-making" tool to facilitate benefit sharing? Research funding must include funds for non-monetary benefit-sharing Institutional responsibility for individual researcher challenging to manage
'de-coupled' (commerciali- sation triggers benefit-shar- ing)	 Costs disproportionate to user Requires track & trace through R&D process -> disproportionate costs and effort Acts as disincentive to R&D if business uncertain -> loss of investment Price of benefit sharing uncertain No direct benefit from use of DSI. Single sequence rarely leads to direct product. A greater levy payment - due to value addition 	Less negative impact under a multilateral system Reduction of transaction costs Criteria need to be met across all options: predictability / how money is used / non-prohibitive fees No realized value of DSI (only access fee / value of sales)	 Maximizes open access Free Science as global public good; which is unaffordable ultimately to provider countries No impact, only discouraging for commercial collaboration
'hybrid' (some combination of 'coupled' & 'de-coupled')	 Complex / Confusing / Uncertain reduced use of DSI / stifling innovation Double payment? @Access point AND @commercialization? Competitive market will emerge 	 Complexity Track & trace or disclosure of origin May be simple global standard license 	

^{*}one group mentioned "legal certainty" for 'commercial R&D' only, one group for 'both'.

During the groups' presentations of the boards and the ensuing discussion the following points were reiterated or further clarified:

- 'Coupled approach' (access triggers benefit-sharing):
 - o Provides for legal certainty, but is it fair and equitable?
 - Access for academic research should be free and access for commercial purposes should be subject to payment.
 - However, it is difficult to separate commercial and non-commercial research at the point of access.

- Major difficulty to address the non-commercial / commercial continuum and actors involved.
- o It would conflict with (national) open access policies.
- o In operational terms, it would be simple only if standardized (multilateral approach or standard licence), but not if applied within a bilateral approach.
- Some operational ways, such as paywall, will create significant interoperability problems for databases exchanges.
- Lower potential to generate benefits and higher potential to generate administrative burden.
- 'Decoupled approach' (commercialisation triggers benefit-sharing)
 - Weak position of users when negotiating benefits under a bilateral approach, it may even lead to a stop of R&D.
 - o Disproportionate costs and efforts and benefits uncertain.
 - Higher administrative costs if under the bilateral approach (would require track and trace).
 - o Lower transaction costs and less negative impacts if under a multilateral approach.
 - Maximizes open access.
- 'Hybrid approach' (combination of the previous)
 - Has too many variables which are unknown.
 - Might provide for more flexibility but also for uncertainty.
 - Risk of double payments.

Other cross-cutting issues and inputs emerging from the discussion:

- Difficulty to define access: looking at DSI or e.g. downloading it. More legal certainty if access is understood as any touching of DSI.
- If individual researchers download DSI, how does the institution monitor it and what is the responsibility of the institution? Link to track & trace!
- Delivering benefits as non-commercial researcher:
 - What would be benefits? (Possible with e.g. some kind of partnership or collaboration)
 - o Funding institutions to provide additional funding for benefit-sharing. Funding policies need to absorb that matter.
- How are monetary benefits used? Really for CBD purposes? The user might have an interest in that. Some guidance for the usage of monetary benefits should exist!
- IPLC perspective: willing to decouple access from benefit-sharing, but then there needs to be a licence with substantive benefits. A multilateral system could provide a certain fixed percentage of benefits to megadiverse countries, the rest to all others. Still the problem remains to get benefits to certain actors/providers!
- All want to avoid track & trace, which option is possible? Need for clear criteria which resources and/or which use fall under which regime, so that costs for benefit-sharing are clear from the beginning.
- Industry wants open access, no additional burdens etc. At this point not sufficient information available to make an informed decision.

3. Users' exchange: Capacity building / Technology transfer

The third round of exchange addressed capacity building and technology transfer and was organised as a 'fish bowl' discussion. The guiding question was: "What should the outcome of capacity building and technology transfer be to make the system equitable and effective to meet the objectives of the CBD/GBF?"

With a view to focus the discussion participants were asked to reflect on four key aspects which should be addressed regarding capacity building and technology transfer:

- What should the outcome of CB be to make the system equitable and effective to meet the objectives of the CBD/GBF?
- How and by whom can/ should CB be implemented?
- In practical, concrete terms: What could capacity building consist of in any solution for DSI?
- What can partnerships and scientific collaboration deliver and what else is needed?

Key points raised included the need for a holistic approach with multiple actors involved and can be summarised as follows:

- Need for mechanisms for motivating young experts to stay in national and local companies
 thus also triggering more technology transfer,. i.e. prevent 'brain drain' e.g. by building programs in partnership with biotech companies offering young scientists interesting contacts;
 but challenging permit needs (including ABS-compliance) etc. requires assistance and structure from governments.
- Science cooperation needs to be long-term, incl. a sustainability model and an exit strategy for capacity building, i.e. more organized structures.
 - Outcome: Knowledge/skills/infrastructure managed and owned by national institutions.
 - For what?: Doing R&D on own GR, with access and use under the own system, while funding needs to be part of capacity building.
- Contexts which work best are universities industry collaborations with funding to bring young scientists into R&D projects where they are also able to build organisational skills to run/manage such R&D projects.
- Universities can 'glue' the system together: Possible spill overs in human health if focus is taken away from purely environmental needs.
- Setting up small R&D pilot projects to keep research in situ and contribute to larger projects.
- Create an enabling framework for international partnerships, as implementation at national level is burdensome (institutions need to be involved).
- Capacity building in the DSI sphere is on
 - o technical support and building human resources, and
 - o financial support for machines etc.
 - Countries provide different systems to realise both points in the context of development corporation programmes.
- Setting up a genomic platform to support universities.
- Setting up national depository collections for microbes.
- Identify the actual need for capacity building as countries are at very different stages. Get the baseline right. Get the right people involved. Every system has different needs:
 - Bottom-up versus top-down
 - o Sustainability, e.g., changes of focal points, differences between sectors and structures
- What is the relation of capacity building to DSI?
 - No direct relationship to GR and country of origin.
 - No need for access to a few genetic resources but access to a huge number of sequences.

- DSI metadata should be used to include IPLC issues and information. Need to develop specific IT standards for DSI metadata; this relates to 'track & trace'.
- Capacity building for IPLC researchers and IPLCs developing their own DSI systems.
- The global dimensions/controversies are based on different worldviews and values, don't forget this in the context of capacity building.
- Capacity building involving governments and the private sector is plagued with distrust.
- Capacity building will also depend on which benefit-sharing models will be decided upon. Will benefits reach IPLC researchers, IPLC is on the ground? Will they be players or recipients?
- Capacity building for DSI under the CBD goes through the ministries for the environment but the needs are much broader than just the environment, e.g. include agriculture, public health and research.
- A self-reporting system is needed (e.g., a match-making platform), thus improving visibility of capacity building.

Preparing for the 'Relay' session with negotiators: Key messages of users of DSI on the three topics discussed

Based on these outcomes the participants were asked to identify and agree about key messages to the negotiators and policymakers meeting at COP 15 to agree on a COP decision on DSI:

Benefit-sharing

- Context: Users may deal with many countries (50 and more) => Learning from the past:
 - o experience of heterogeneity vs. countries having single interests
 - Holistic approach regarding genetic resources, DSI, derivatives and associated traditional knowledge
 - Needs to be simple
- There is willingness to pay for
 - o 100% legal certainty of any use
 - Open, public, interconnected ecosystem for everyone (North <-> South)
 - o Simple, pragmatic and affordable mechanism
 - Alignment across all UN fora
- There is willingness to support
 - CBD objectives 1 (conservation) and 2 (sustainable use)
 - Capacity building and technology transfer
 - Infrastructure (from databases and molecular laboratories to enabling environments for R&D)
 - o IPLCs as custodians of biodiversity
- Modalities need to be compatible with criteria 1-4 by the OEWG at its 3rd meeting in Geneva in March 2022
 - International standardisation
 - Redistribution based on needs of stakeholders and conservation, not of countries of origin
 - o Broad and simple scope as basis for benefit generation

(Open) Access to, and use of DSI

- Open access is key, but not necessarily free (however: no paywall as this modality would disrupt interoperability among databases and infrastructures)
- Responsible behaviour (provenance of data) increase information to increase transparency
- R&D with commercial vs. non-commercial outcome, which may change over time
 - Benefit-sharing with commercialisation: distinction between commercial and noncommercial R&D irrelevant
 - Benefit-sharing at access: Distinction between commercial and non-commercial R&D VERY challenging at this stage, triggering point for BS would not be clear leading to legal uncertainty.
- Legal certainty for all stakeholders (including users, IPLCs, and others)!
- NO COMBINATION of benefit-sharing at access point and commercialisation.
- Design Principles
 - Before COP 15: What can we learn from ABS as a whole? => align expectations
 - After COP 15: What is it that we would like to achieve?
- No 'track & trace' all along the value chain because of tracking and tracing impracticalities. However, it is possible to take measures to improve transparency.

Capacity building and technology transfer

- Capacity building and technology transfer are essential and central to ensure EQUAL ability to generate, access and use DSI by scientists and other stake- und rights-holders in all countries => fairness & equity
- Key component of non-monetary Benefit-sharing is more value/importance than monetary Benefit-sharing as such
- Cover infrastructure, skills and knowledge plus policy framework for technology transfer
- Need for monitoring with meaningful indicators in the GBF to ensure visibility and sustainability of the system, e.g. regarding HR retention and facilitated procedures
- Involve all relevant stake- and rights-holders, incl. government departments such as public health, agriculture, research and education
- Bottom up and needs-based approach, but coordinated top-down (e.g. build platform for exchange)
- Partnerships: public non-public / developed developing countries / South-South

'Relay' of user messages to key negotiators

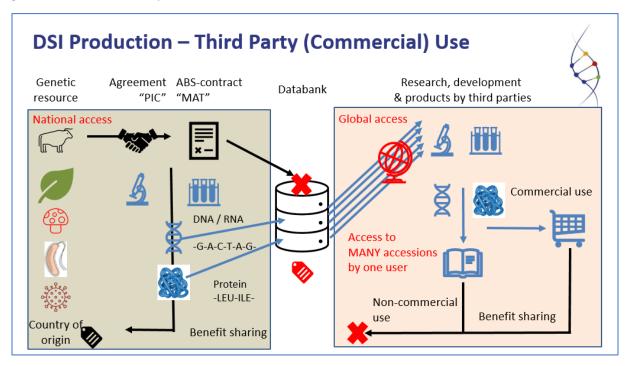
During the afternoon of the 2nd day of the DSI Exchange participants had the opportunity to present and discuss their messages with key negotiators and policy makers who were meeting from 10 to 11 November at the same venue (see separate report).

Opening of the Relay

Representatives of the sponsors, the host and the organisers of the DSI Exchange and the DSI Retreat briefly welcomed the new participants.

Working with DSI in practice

<u>Hartmut Meyer</u> of the ABS Initiative highlighted in his presentation the interlinkage between the utilisation of genetic resources and the use of DSI while pinpointing to the existing different access regimes for genetic resources (bilateral approach under the Nagoya Protocol on ABS) and the open access regime one DSI has been uploaded into the international databases.



<u>Charlotte Blom</u> of Novozymes (Denmark), an international industrial biotech company, active in many sectors, such as agriculture, bioenergy, oils & fats, starch & distilling, textile & leather as well as pulp and paper. R&D relies on an internal DSI database with sequences of internally sourced microbes and public DSI databases. She explained that R&D in the biotech sector starts with the screening of millions of sequences with a target activities leading based on available metadata to hundreds of potential target enzymes that are used as basis for protein engineering for tailoring the final enzyme(s). She concluded her presentation with the following points for consideration:

- Genetic resources (GR) and DSI are closely linked, but are used differently:
 - The frequency and number of samples/records accessed.
 - The need for fast access to sequences.
 - DSI used for 'deep learning tools, advanced prediction models, artificial intelligence etc.
 - Current and future research and innovation make use of big data sets.
- Final product often derived from many donor organisms and/or consist of blends:
 - o Protein engineering, e.g. using consensus analysis or shuffling.
 - Sequence redundancy –same sequence is found in multiple records.

- Legal certainty is important:
 - o For risk mitigation during product development (cost and rights of use).
 - o For global collaborations, incl. with academic partners.

<u>Halima Benbouza</u> of the National Council of Scientific Research and Technologies of Algeria highlighted the use of DSI for conservation and sustainable use of agricultural genetic resources, e.g. by verifying phenotypic (traditional) date palm varieties through genetic markers as basis for the identification date palm varieties based on their genetic make-up with commercial potential in harsh, climate change affected environments thus contributing to food security. She concluded her presentation with the following remarks:

- Scientific <u>capacity building</u> and technology transfer should be fully considered for any policy option.
- Open access to data bases is crucial for <u>research and innovation</u>, and should be considered with BS in a way that respond to the expectation of all based on <u>simplicity</u>, <u>transparency</u>, <u>fairness and equity</u>.
- Consensus definitions seems to be important to make sure that all stakeholders have the same understanding of the terms, concepts and principles.
- Increasing the 'technology gap' between provider countries and users of DSI, through different non-inclusive approaches and actions, will not resolve issues of global concern (challenges of health and food security worldwide).

The following question and answer session focussed on the use of DSI by Novozymes:

- 90% of R&D and new enzymes is based on existing DSI in both public and private databases, only 10% on newly accessed genetic resources.
- Use of DSI from public databases is essential as the internal/private database is not sufficient for machine learning etc.
- The internal database cannot be made publicly available. Data are relevant part of the business model! All DSI in the database are covered by MAT, unless the material originates form countries without PIC and MAT requirements or are old, i.e. collected in the 50s and 60s of the last century, which is the case for the majority of the material.
- Novozymes has an internal benefit-sharing policy. Quite some agreements failed in the past, too complicated to conclude and impossible to follow up.

A participant pointed out that the presentation by ABS Initiative on the DSI production did not reflect the flow-back of knowledge and information from access and use into the system.

Ms. Benbouza highlighted the need for comparative analyses by researchers in other countries who have access to sequencing and other techniques. Without access to the data developing country researchers cannot continue their work!

Discussion of users of DSI with negotiators / policy makers

The ensuing discussion between users of DSI and negotiators was structured according to the three topics discussed by the participants of the DSI Exchange before opening the discussion to other topics of interest.

Benefit-sharing

- Regarding the potential for resource mobilization, users mentioned that the scope of a solution for DSI needs to be broad to ensure simplicity, but that the scale of resource mobilisations was not discussed. Negotiators highlighted that realistic expectations are needed and that substantive benefit-sharing should come out of any solution.
- Regarding the functioning of a global benefit-sharing mechanism several views were expressed by negotiators:
 - o Benefits should go back to the providing country, where success can be monitored.
 - Redistribution should be based on country needs not country of origin, which might be difficult for some countries to accept.
 - Redistribution based on needs means to look into projects that address specific needs, e.g., to address the capacity gaps. Focus on needs does not require much 'track & trace'.
- Regarding the IPLC perspective users explained that
 - a broad scope should include DSI, associated traditional knowledge, derivatives and genetic resources.
 - the role and relevance of indigenous knowledge was not sufficiently discussed; focus was more on conservation and the importance of sustainable livelihoods.
- One negotiator warned that IPLCs' rights in developed countries about genetic resources and associated traditional knowledge might be undermined when establishing a multilateral benefit-sharing system.
- Regarding the question whether 'track& trace' would stifle R&D users mentioned that the Nagoya Protocol already creates significant difficulties for the utilisation of genetic resources and that applying the same to DSI would add layers of complexity, e.g. when comparing a created sequence with thousands of other sequences from a database. Costs involved would be extremely high and unaffordable for both researchers and many SMEs in the sector.

(Open) access to, and use of DSI

- Users highlighted in order to avoid a 'paywall' for access to DSI, a subscription system with e.g. a single global MAT would guarantee 'free' access to DSI.
- Users explained that information of the provenance of data could be used to assess the distribution key of benefits in a multilateral system rather than requiring users to track and trace the use through all R&D steps.
- One negotiator raised the point of ownership and the right to know who is accessing and using GR and DSI. Users responded that in case countries want to retain full control and prevent use of DSI from their genetic resources, then they should not load it up in public databases, e.g. by restrictions in the MAT for access to their genetic resources.
- Commercial users reiterated the need for private databases which constitute a huge investment for achieving a comparative advantage over competitors.

Capacity building / Technology transfer

- Regarding the scope and monitoring of capacity building there was broad agreement that capacity building is happening in many (long-term) research partnerships and sponsorship programmes for masters and PhD students. However, there are no reporting and monitoring requirements and methodologies.
 - Capacity building for DSI based R&D for public health, agriculture etc. will have significant impact at socio-economic level
 - o There is a need for regional approaches as national approaches alone will not work.
 - o Impact of capacity building will be diluted to be meaningless, if capacity building for improving IPLCs livelihoods will be included.
- Does track & trace stifle R&D? Participants mentioned that experience from NP already demonstrates difficulties with dealing with one GR, but with DSI layers of complexity is added, e.g., comparing a created sequence with thousands of other sequences. Cost involved with a new system would be extremely high – unaffordable for many SMEs in the sector.

General issues

Some negotiators argued that also private databases should be within the scope for a solution. Commercial users highlighted that the inclusion of private databases has not been discussed – this would require further thinking; focus is on open access to public databases.

Most stakeholders called for a solution that would not only apply to DSI, but more broadly to genetic resources as there is a need to address shortcomings and challenges of the current bilateral system, as well as not to have too many systems in place and to ensure legal certainty.

Regarding the difficulty to separate commercial and non-commercial research users responded that it would be best to have a system which does not require such differentiation, e.g. benefit-sharing triggered by commercialisation, i.e. when monetary benefits are generated. On the other hand, only some DSI based R&D leads to (successful) commercial products and the question remains how to assess the contribution of individual sequences.

Annex: Agenda of the meeting

Tuesday 8 November

09:00	Participants' Registration	
10:00	Opening of DSI Exchange	
	Official welcome and introduction	
	Setting the scene: Context	
11.00	Taking stock	
	Short input: Briefing on DSI process thus far	
	Plenary exchange: Where are we in the DSI discussion?	
12:30	Lunch	
14:00	Benefit sharing	
	Group and plenary discussions	
15:30	Coffee/tea	
16:00	(Open) ACCESS to and use of DSI	
	Group and plenary discussions	
17:45	End of session	
18:00	Reception by the Dutch Government	

Wednesday 9 November

09:00	Capacity building		
	Group and plenary discussions		
10:30	Coffee/tea		
11:00	Pulling the strings together		
	Review of results of previous sessions		
	Preparing for joint session with global negotiators in the afternoon		
12:30	Lunch		
14:00	Joint session with global negotiators		
	Welcome of negotiators		
14:15	Working with DSI in practice		
	Inputs / information for negotiators; Q&A		
15:15	Outcomes from DSI Exchange sessions		
	Presentation of key outcomes/messages to negotiators		
15:45	Coffee/tea		
16:15	Discussion between users and negotiators		
	Plenary discussion		
17:45	Closure		
	Closing remarks		
18:00	End of DSI Exchange sessions		
19:00	Joint Dinner for users and negotiators, hosted by the Dutch Government		