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CETAF Workshop on Access and Benefit Sharing

DSI: current discussions, expectations and regulatory approaches



What do I include in DSI?

- For the purposes of this talk:
 - ▷ Nucleotide sequence data + Proteins and amino acid sequences, information on gene expression etc + metabolites and other macromolecules - i.e. any biological molecule (Group 3 of the 2020 CBD AGTEG)
 - ▷ the most inclusive concept, since at least some countries are likely to use this
 - ▷ Downloaded from an external database (public or private)
- Discussion around DSI is mostly at an industry or organisational level
 - ▷ Presumably in scope: If it is a public database (e.g., INSDC)
 - ▷ Presumably out of scope: data held by ones' own (private) institutional database might not be treated as 'DSI', at least under the CBD
 - ▷ Current decision is pending (and discussed on CBD COP 17)

Where is DSI being discussed and how does it affect us?

- ▶ [National access laws](#) and regulations of some countries require bilateral benefit-sharing
- ▶ [CBD – COP Decision 16/2 \(2025\)](#) sets up a voluntary multilateral benefit-sharing system
- ▶ [BBNJ Agreement \(in force 2026\)](#) – International agreement, including benefit-sharing; likely to be implemented through legislation in Parties; EU and some EU MS already parties
- ▶ [WHO PABS](#) (Pathogen Access and Benefit Sharing) – being negotiated
- ▶ [ITPGRFA](#) – under discussion
- ▷ Focus of this presentation is on the first three and particularly CBD and BBNJ, as these will have an impact in the near future.

DSI-regulation on country level

- ▶ Covered in National Access Law of some countries and may entail
- ▷ **Requirements on metadata** to be uploaded following research on GR that produces sequence data (including ‘click-wrap’ agreements)
 - ▷ Some countries believe that DSI should be covered by the Nagoya Protocol
 - ▷ This is not the case for the European Union
- ▷ **Download and use of DSI without** Providing Country **permission** of the original GR may be an offence under that country’s domestic legislation, even if it is not under the user compliance legislation of the EU
 - ▷ To date limited legal action / ruling about this
 - ▷ Academic use of DSI may make our use transparent and visible for compliance checks
- ▷ Countries may have both bilateral requirements and benefit from the CBD Multilateral Mechanism (MLM)

CBD COP decision 16/2 on Digital Sequence Information

▶ CBD COP Decision – general approach

- ▶ **‘Soft law’ approach** similar to the voluntary Bonn Guidelines (which however led to the Nagoya Protocol, which is legally binding on Parties)
- ▶ Not a separate protocol
- ▶ **Not legally binding** on Parties, far less detail than the Bonn Guidelines
- ▶ **Covers** in principle globally to all DSI from GR accessed within all countries’ territories, including territorial waters, i.e. including from non-parties
- ▶ **Does not include a definition of what DSI is / is not**
- ▶ **Covers all biota** other than human DSI
- ▶ Has no temporal restriction, i.e. **all DSI is globally in scope**, whenever generated and whenever originating GR accessed
- ▶ Requires **all users of DSI** to **share benefits** (non-monetary or monetary)

CBD COP decision 16/2 on Digital Sequence Information

▶ CBD COP Decision – in detail

- ▷ Sets up a Multilateral Mechanism for monetary Benefit Sharing from the use of DSI
 - ▷ Focusses on monetary benefits sharing, sets up the ‘Cali Fund’ to manage these funds
 - ▷ Identifies requirement for non-monetary benefit sharing, which is expected from non-monetary research
 - ▷ Voluntary system, but may be implemented through national legislation in some countries)

CBD COP decision 16/2 on Digital Sequence Information

▶ CBD COP Decision – in detail

▷ What are ‘non-monetary benefits’ (nmBS) of DSI use?

- ▷ Proposed indicators for Kunming-Montreal Global Biodiversity Framework: R&D and publications – ([Nunez-Vega et al., 2025](#))
 - ▷ Will be of value as indicators, but not complete coverage of nmBS for DSI
- ▷ Early discussions implicit that what is developed from R&D would benefit everyone
- ▷ More recently, some countries want something that they can use and is a direct benefit for them
- ▷ Some nmBS of the NP could be applied to DSI, including access to research results (i.e. including data)
 - ▷ **But:** data and research results for some countries are not useful unless there is capacity to use them
- ▷ A ‘good’ nmBS-package should include
 - ▷ joint research and data and capacity building, linked to national priorities as in e.g. National Biodiversity Strategy and Action Plans

CBD COP decision 16/2 on Digital Sequence Information

▶ CBD COP Decision – in detail

▷ What are ‘non-monetary benefits’ (nmBS) of DSI use?

▷ Delivering nmBS from access and research on GR is facilitated when access takes place in-country

▷ often considerable interaction between researchers and local scientists / students / institutions

▷ leading to nmBS on a small but arguably very valuable way – but rarely recorded

▷ Delivering nmBS from R&D on DSI more challenging, because no direct engagement with countries

▷ Ensuring appropriate recording of shared benefits requires

▷ adequate administrative backbone, resources and funding (Clearing House Mechanism?)

▷ close collaboration with providers to document received benefits

▷ nmBS needs further elaboration for DSI

CBD COP decision 16/2 on Digital Sequence Information

- ▶ Databases managing DSI should (recommendation from COP 16/2)
 1. Inform DSI users accessing their databases for commercial activities and that generating monetary benefits from use of such information may require benefit-sharing through the MLM
 2. Inform those submitting data of the requirement to comply with applicable national and international ABS obligations
 3. Require full metadata where available, such as
 - ▷ country of origin of the GR from which DSI was derived
 - ▷ any other relevant metadata associated with the GR, including an indication of the presence or use of any associated Traditional Knowledge
 4. Require consistence with open access data principles, such as FAIR and CARE
 5. Request clarification from DSI submitters to indicate that uploaded DSI is not subject to any restrictions that prohibit its sharing or use

DSI in the Area Beyond National Jurisdiction Agreement

- ▶ Agreement under the United Nations Convention on the Law of the Sea (UNCLOS) on the Conservation and Sustainable Use of Marine Biological Diversity of Areas Beyond National Jurisdiction (ABNJ) – [the High Seas Treaty](#)
- ▶ **Entered into force 17 Jan 2026**
- ▶ **Establishes a legally binding instrument for the conservation and sustainable use of Biodiversity Beyond National Jurisdiction (BBNJ)**
- ▶ The EU and all European Countries have ratified or are in the process of ratification
- ▶ **Set legally binding** requirements on users of Marine Genetic Resources (MGR) and derived DSI
- ▶ Does not include a definition of DSI

DSI in the Area Beyond National Jurisdiction Agreement

- ▶ Scope and application of ABNJ agreement
- ▷ Its provisions apply to
 - ▷ **activities with respect to MGR and DSI** collected and generated **after** the entry into force of Agreement for the respective Party
 - ▷ **utilisation of MGR / DSI** collected or generated **before** entry into force, unless a Party makes an exception
- ▷ Many ABNJ elements need to be ensured through domestic legislation of Parties
 - ▷ Because of national implementation, obligations and responsibilities will differ in details based on respective enforced domestic legislation
 - ▷ Provisions for utilization of DSI thus will not be uniform across ABNJ-Parties although the main requirements of the agreement must be met

DSI in the Area Beyond National Jurisdiction Agreement

▶ Scope and application of ABNJ agreement

▷ **Pre-cruise Notifications**

- ▷ Must be applied for 6 months prior to cruise
- ▷ Requires identification of **all** Marine Genetic Resources (MGR) collected during a single voyage with the same single unique “BBNJ” standardized batch identifier (SBI)

▷ **Standard Batch Identifier**

- ▷ Must also be applied to any DSI generated subsequently from respective MGR collected during the cruise
 - ▷ Multiple DSI records from multiple specimens and taxa will all have the same SBI
 - ▷ A single SBI may apply to DSI in multiple databases
 - ▷ Format of the SBI not yet set, and none will be issued in the near future
- ▷ MGR acquired in other ways (e.g. obtained not on scientific cruise or from fish markets selling specimens caught on the high seas) will not have an SBI so neither will any DSI

DSI in the Area Beyond National Jurisdiction Agreement

- ▶ Requirements for DSI falling under ABNJ in databases
- ▷ BBNJ-Parties need to ensure that DSI in databases under their jurisdiction can be identified as originating from ABNJ
 - ▷ “in accordance with current international practice”, and
 - ▷ “to the extent practicable”
 - ▷ **applies to all DSI(ABNJ)**, irrespective of when generated
 - ▷ Pre-Agreement DSI will lack an SBI, but requires (ideally standard) tag to allow positive ABNJ identification
- ▷ Geographic Scope
 - ▷ Both CBD and BBNJ ask for addition of geographical origin to DSI metadata
 - ▷ INSDC already asks for available geographical information, but currently does not distinguish between territorial waters and ABNJ

DSI in the Area Beyond National Jurisdiction Agreement

- ▶ Requirements for DSI falling under ABNJ in databases
- ▷ Biennial aggregate report on access to DSI linked to their SBI for collections and databases
 - ▷ DE has a reporting obligation (through the BfN)
- ▷ Access to DSI
 - ▷ The BBNJ Agreement does have a functional definition of Access
 - ▷ UK legislation defines “access to the samples for the purposes of their utilisation by another person”
 - ▷ Report is made by institutions to the Party, which forwards it to the ABS Committee

DSI in the Area Beyond National Jurisdiction Agreement

▶ Requirements for DSI falling under ABNJ in databases

▷ Reporting obligations

- ▷ Where ... practicable, [when] DSI(ABNJ) are subject to utilization ..., the following information, including the SBI, if available, be notified to the CHM as soon as such information becomes available:
 - a) Where the results of the utilization, such as publications, patents granted, if available and to the extent possible, and products developed, can be found;
 - b) Where available, details of the post-collection notification to the Clearing-House Mechanism related to the marine genetic resources that were the subject of utilization;
 - c) Where the original sample that is the subject of utilization is held;
 - d) The modalities envisaged for access to marine genetic resources and digital sequence information on marine genetic resources being utilized, and a data management plan for the same;
 - e) Once marketed, information, if available, on sales of relevant products and any further development
- ▷ Notification likely to be by the PI of the utilization project, reporting to the Party, which notifies the CHM

DSI in the Area Beyond National Jurisdiction Agreement

▶ Requirements for DSI falling under ABNJ in databases

▷ Benefit Sharing

▷ is not elaborated in the Agreement, but the following elements are mentioned:

- ▷ Access to DSI in accordance with current international practice;
- ▷ Open access to findable, accessible, interoperable and reusable (FAIR) scientific data in accordance with current international practice and open and responsible data governance;
- ▷ Capacity-building, including by financing research programmes, and partnership opportunities, particularly directly relevant and substantial ones, for scientists and researchers in research projects, as well as dedicated initiatives;

Summary – DSI under the CBD and BBNJ

▶ Under the CBD

- ▷ DSI is not considered to be covered by the Nagoya Protocol in the EU
- ▷ UK at least is not considering legislation
- ▷ Some provider countries are considering legislation, which may differ considerably between countries

▶ Under BBNJ

- ▷ ABNJ Parties are currently drawing up domestic legislation
- ▷ UK has the basic legislation <https://bills.parliament.uk/bills/4016>
 - ▷ Two more Statutory Instruments are expected, elaborating means of reporting and regulation
 - ▷ Guidance will also be produced
 - ▷ DSI is not defined, but a working definition may appear in the Guidance, so it is not fixed in legislation
- ▷ Currently EU MS are developing legislation separately, some including a definition of DSI



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