WIPO SEMINAR
Intellectual Property and Genetic Resources: New and Emerging Technologies

DSI under the CBD & NP

Convention on Biological Diversity

Mrs Lactitia Tshitwamulomoni, Deputy Director, Department of Environment, Forestry and Fisheries, South Africa

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WHERE WE HAVE COME FROM

The 3 Objectives of the CBD:

a) Conservation of Biological Diversity.

b) The sustainable use of the components of biological diversity.

c) The fair and equitable sharing of the benefits arising out of the utilization of genetic resources ~ **Objective of the Nagoya Protocol on ABS.**

"Genetic Resources" means genetic material of actual or potential value. **(CBD)**

"Genetic material" means any material of plant, animal, microbial or other origin containing functional units of heredity. **(CBD)**

"Biotechnology" means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use. **(CBD)**

"Utilization of Genetic Resources" means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology. **(NP)**

"Derivative" means a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity**.(NP)**

'DSI' is a placeholder term for the CBD & NP negotiations ~ **COP Decision**

WHERE WE HAVE COME FROM

- DSI plays a fundamental role in **environmental & biological research including taxonomy**.

- It is also considered as a critical tool in the conservation & sustainable use of **GRs for food & agriculture**.

- Countries rely on access to and exchange of DSI to deal with vital issues such as **human, animal and plant health, food security and the environment.**

WHERE WE HAVE COME FROM

- DSI formed part of the CBD Agenda in 2016 during CBD-COP13 & COP-MOP2, in the context of Access and Benefit Sharing (ABS).

Key issue 1): Differences in terminology in scientific circles reflect differences in the material referred to, which makes it difficult to harmonize terminology ~ **The term DSI has no agreed definition.**

2) **:** Uncertainties on whether DSI falls within the scope of the CBD and the NP.

WHERE WE HAVE COME FROM

Five peer-reviewed science-based Studies commissioned by the CBD Secretariat:

a) Fact-finding and scoping study to clarify terminology & concepts; and also assess the extent, terms & conditions of the use of DSI in the context of the CBD & the NP.

b) Study on the concept and scope of DSI & how DSI is currently used.

c) Study on the ongoing developments in the filed of traceability of DSI, including how traceability is addressed by databases, and how these could inform discussions on DSI.

d) Study on **public** and , to the extent possible, private databases of DSI, including the **terms and conditions on which access is granted or controlled**, the biological scope and the size of the databases, numbers of accessions and their origin, **governing policies**, and the providers and users of DSI.

e) Study on how domestic measures address benefit sharing arising from commercial and non-commercial use of DSI and address the use of DSI for research and development.

SOME AREAS OF COMMON UNDERSTANDING

- Parties to the CBD & the NP, have common understanding on:

a) The importance of DSI for the conservation & sustainable use of biodiversity.

b) Existence of well-established & functioning international framework supporting the open exchange of DSI, e.g INSDC.

- ✓ allows the swift compilation, comparison & re-analysis of genetic information from a variety of sources, across multiple databases & gene sequences~ **Avoiding unnecessary duplication of research.**
- ✓ necessary for international research collaborations, which not only allow the pooling of expertise & resources to resolve problems of global or regional relevance, but are also essential vehicles for capacity building, & the exchange of knowledge & expertise.

SOME AREAS OF COMMON UNDERSTANDING

c)The need for capacity building & technology transfer to use DSI to contribute to conservation & sustainable use by many developing countries.

d) The need to find a **balance terminology** that is **adaptive & dynamic enough** to accommodate scientific, technological, market & other changes, and at the same time, a **terminology that is clear & solid enough to provide legal certainty.**

e) DSI should continue to be used as a placeholder, as per the COP decision.

SOME OF THE ISSUES AT STAKE

- DSI is a product of utilisation of physical GR.
- It can be used as a substitute for the original GR in the R&D process.
- Availability of DSI on open database or other platform that is outside control of provider country of original GR ~ **Third parties can download and use DSI outside the modalities worked out in the Nagoya Protocol for sharing of benefits.**

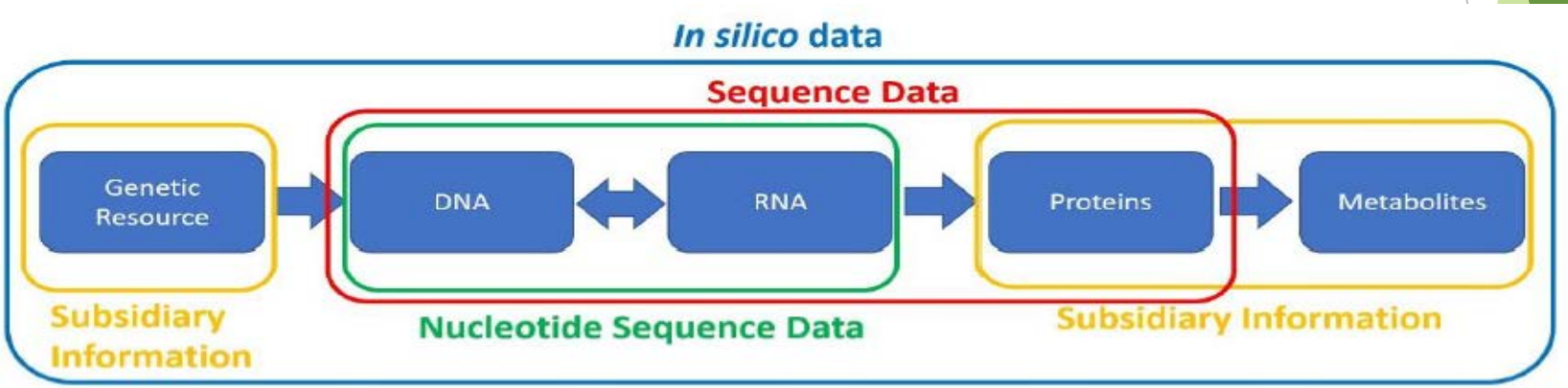
WHAT IS YET TO BE DECIDED

DSI concepts have different properties, different names, which are used by different stakeholders and found in different places.

- CBD & NP negotiators need to be able to understand what they are discussing (and know when they are talking about different concepts!)
  - ✓ Therefore it is necessary to understand the coverage of the DSI term.
- Responsibility of the AHTEG in March 2020 included developing "*options for operational terms and their implications to provide conceptual clarity on DSI and also identification of key areas for capacity-building*"
  - ✓ Identified three different 'groups' using rationale of degree of biological processing and the proximity to the underlying genetic resource.

WHAT IS YET TO BE DECIDED

- There are different concepts of DSI, more or less inclusive in scope
  - From the simple order of nucleotides in a strand of DNA
  - To the structure of proteins for which the DNA is coding
  - To the biochemical composition of molecules produced within cells (metabolites)



WHAT IS YET TO BE DECIDED

	Information related to a genetic resource			
	Genetic and biochemical information			Associated information
Group reference	Group 1	Group 2	Group 3	
High-level description of each group	DNA and RNA	Group 1 + proteins + epigenetic modifications	Group 2 + metabolites and other macromolecules	
Examples of granular subject matter	• Nucleic acid sequence reads; • Associated data to nucleic acid reads; • Non-coding nucleic acid sequences; • Genetic mapping (for example, genotyping, microsatellite analysis, SNPs, etc.); • Structural annotation.	• Amino acid sequences; • Information on gene expression; • Functional annotation; • Epigenetic modifications (for example, methylation patterns and acetylation); • Molecular structures of proteins; • Molecular interaction networks.	• Information on the biochemical composition of a genetic resource; • Macromolecules (other than DNA, RNA and proteins); • Cellular metabolites (molecular structures).	• Traditional knowledge associated with genetic resources • Information associated with digital sequence information Groups 1, 2 and 3 (for example, biotic and abiotic factors in the environment or associated with the organism) • Other types of information associated with a genetic resource or its utilization.

Report Of The Ad Hoc Technical Expert Group On Digital Sequence Information On Genetic Resources, 2020

WHAT IS YET TO BE DECIDED

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- The proposed groups are cumulative
- ✓ Group 2 includes all elements of Group 1, and Group 3 contains all elements of Groups 1 and 2
- AHTEG made distinction between *genetic and biochemical information* as included in Groups 1 to 3 and *associated information related to a genetic resource* (e.g. aTK, and other information: 'contextual', 'associated', or 'subsidiary information')

WHAT IS YET TO BE DECIDED

	Information related to a genetic resource			
	Genetic and biochemical information			Associated information
Group reference	Group 1	Group 2	Group 3	
High-level description of each group	DNA and RNA	Group 1 + proteins + epigenetic modifications	Group 2 + metabolites and other macromolecules	

- AHTEG agreed that **groups 1-3** could be considered as **DSI**, while associated information, including aTK, is not considered DSI.
- **But** recalled obligations to share benefits from the utilization of aTK under the NP and the CBD.
- Issue now back with the CBD & the NP negotiators to make use of this clarification on the scope DSI.

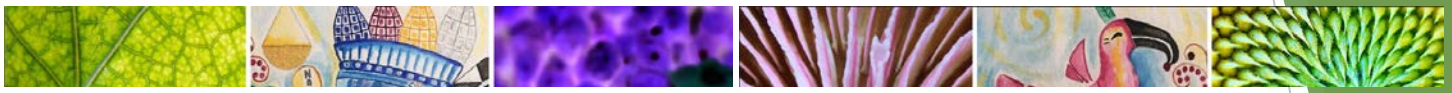
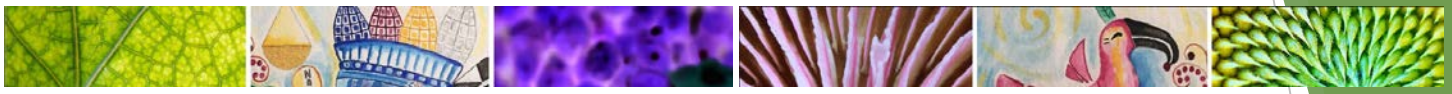


Table 2. Options for terminology to describe DSI

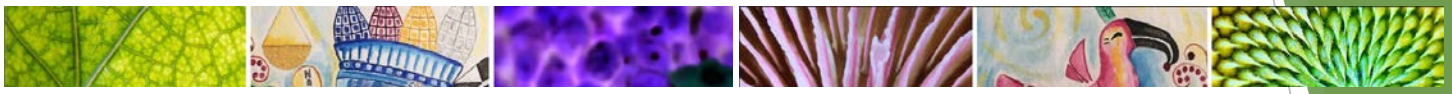
Group reference	Group 1	Group 2	Group 3	Associated information
Category/term	• Nucleotide sequence data (NSD); • Genomic sequence information; • Genomics information; • Nucleotide sequence information (NSI); • Genetic Resource Sequence Data (GRSD); • Digital sequence data (DSD); • Data on the genomic DNA (or RNA) of a sample genetic resource	• Genomic and proteomic sequence information; • Genomic and proteomic sequence information • Nucleotide sequence information (NSI); • Genetic information (GI); • Sequence data; • Nucleotide and amino acid sequence data (NASD); • Nucleotide and amino acid sequence and structural information (NASSI); • Nucleotide and amino acid sequence, structural and functional information (NASSFI); • Functional digital information of NSD; • Proteomic data; • Genomic and proteomic sequence information; • Data on the macromolecular composition of a sample genetic resource.	• Genomic, proteomic and metabolomic information; • Genetic and “omic” information; • Metabolomic data; • “Omic” information • Genomic, proteomic and metabolomic information; • Data on the biochemical and genetic composition of a sample genetic resource.	• Associated information; • Contextual Information; • Subsidiary Information.
Other terms were additionally discussed, including the following: digital sequence information, natural information, digital genetic resource information, digital genetic resource data and information, genetic resource data and information, genetic information, all data on a sample (genetic resource) and in silico.				

- **Issue now back with the CBD & the NP negotiators to make use of these options for terminology.**



WHAT IS YET TO BE DECIDED

- For each group, AHTEG discussed implications:
  - ✓ traceability;
  - ✓ use of DSI and technologies enabled by DSI in life sciences research and innovation processes;
  - ✓ INSDC on open exchange and use of DSI;
  - ✓ measures governing access, benefit-sharing and compliance.
- Discussions were preliminary
- Implications depend on benefit-sharing approach.
- Some potential implications not discussed in depth; could benefit from further information or consideration.

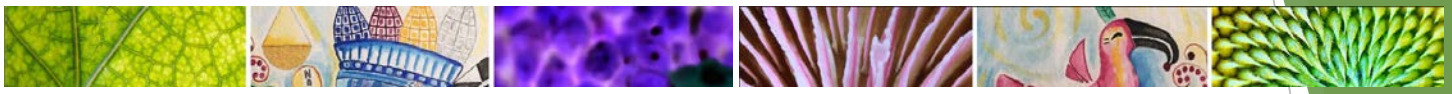


WHAT IS YET TO BE DECIDED

Capacity building discussed as form of non-monetary benefit sharing

Key areas:

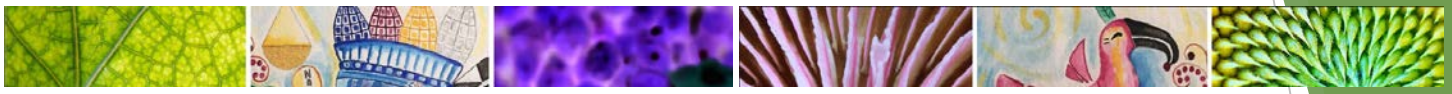
- General understanding of issues related to DSI including the economics of information
- Understanding the R&D steps along values chains based on GRs and DSI
- Analysis and processing of big data related to DSI
- Access and use of international databases
- Taxonomy, molecular biology applications for DNA/RNA extraction from genetic resources, PCR and/or sequencing, digital sequence information processing and uploading to databases, bioinformatics, database management.



WHAT IS YET TO BE DECIDED

- The OEWG on Post- 2020 Global Biodiversity Framework to consider the AHTEG recommendations in preparation for the upcoming CBD-COP15.

For more information on DSI :
https://www.cbd.int/dsi-gr/



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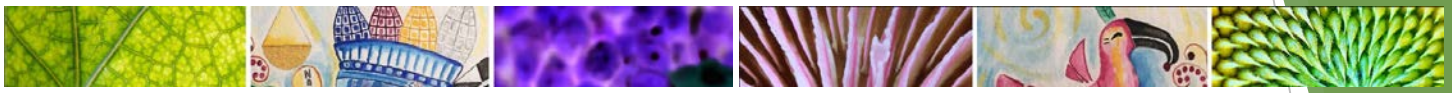

THANK YOU!