

THE ABS
CAPACITY
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POUR L'APA

Webinar on traceability of digital sequence information on genetic resources (DSI)

Global webinar

2nd November 2021, 1pm-3pm CET

Welcoming words of Hartmut Meyer – Team leader of the ABS Initiative

- The ABS Initiative announces the continuation of its activities on DSI in the context of the Norwegian – South African Environmental Cooperation Program
- First round of publications, webinars and the Global Dialogue on DSI brought together many governmental experts and negotiators, stakeholders from various sectors, representatives of indigenous peoples and local communities
- Support for an informed exchange on DSI during OEWG 3.1 in the context of the future post-2020 Global Biodiversity Framework
- A formal intersessional process asking for submissions on DSI and for further analyses of the policy approaches, options and modalities will prepare for OEWG 3.2
- As contribution to the informal intersessional process, the ABS Initiative will concentrate on remaining divergences in the DSI discussion, based on the analysis of the Co-Leads of the contact group on DSI of the OEWG
- Last reports of OEWG can be found here <https://www.cbd.int/meetings/WG2020-03>

Presentation of Hartmut Meyer – overview about the use of DSI, the current situation and options to realize traceability– limits and challenges of such systems

- First step: getting DSI from genetic resources
The access to genetic resources should include agreements on PIC and MAT
Based on these benefits can be shared with the providers
- However, the accessed sequences do not remain in the laboratory of the first user. It is rather common practice that the sequences are stored centrally in databanks and are available to everybody worldwide without conditions.
- Many sequences do not have country tag, the origin thus remains unclear
- PIC and MAT contracts cannot be uploaded in the DSI database– bypassing possible relevant conditions in the MAT
- DSI can be downloaded from open databases and new products can be developed without addressing possible requirements of the MAT

DSI – Third Party (Commercial) Use – Traceability

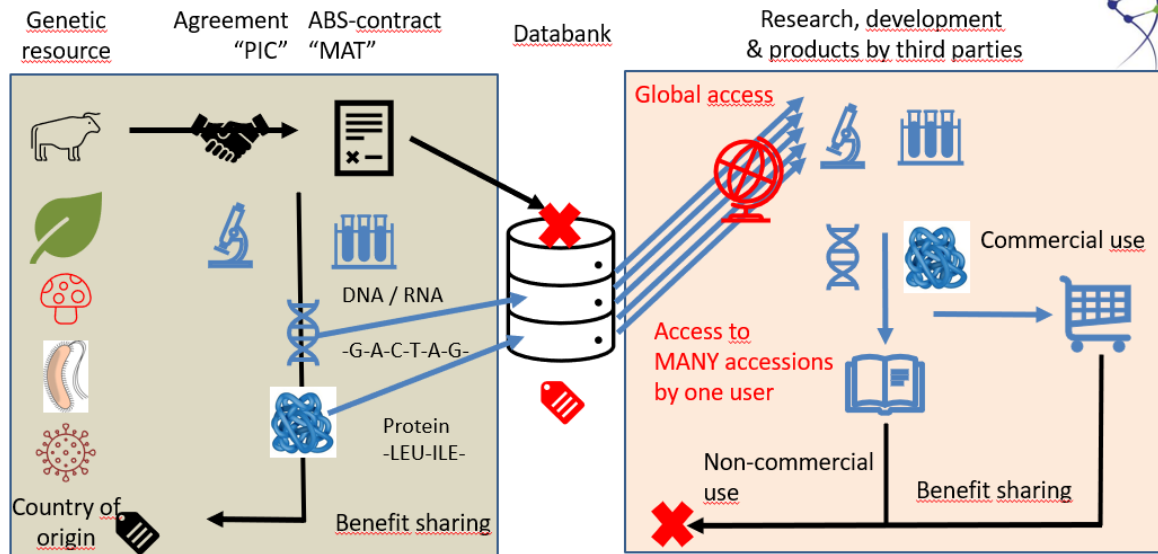


Figure 1 Hartmut Meyer

Views on DSI traceability in the post-2020 process

Outcome of the Ad Hoc Technical Expert Group (AHTEG) on DSI

- Traceability could be relevant depending on the approach to benefit sharing followed, and the related monitoring and compliance requirements. For example, in the case of a multilateral approach to benefit-sharing, traceability of digital sequence information and monitoring of its use along the value chain may not be required.

Discussions during Global DSI Dialogue and OEWG 3

- Traceability is necessary to share benefits to the providers of GR / DSI
- Traceability can be used in a bilateral approach of the Nagoya Protocol
- Current pattern of the use of DSI use makes tracking and tracing very difficult / ineffective
- Costs of traceability system might significantly exceed the benefits created / shared
- In multilateral approaches benefit sharing can work without traceability

Taukondjo Shikongo – Senior Officer for ABS at the CBD Secretariat in Montreal

Presenting the DSI process since 2018

Formal process

- AHTEG dealt with studies about concept and scope of DSI, traceability, databases and domestic policy measures at national level
- AHTEG were asked to develop options for operational terms
- AHTEG identified key areas for capacity building

Results of AHTEG

- Classification of distinct DSI in terms of concept and scope: Group 1 -4
- Group1 – narrow classification: covering DNA and RNA, only
- Group2 – intermediate classification: covering (DNA and RNA) + proteins
- Group3 – intermediate classification: covering (DNA, RNA and proteins) + metabolites
- Group4 – broad classification: covering (DNA, RNA, protein, metabolites) + traditional knowledge, ecological interactions, etc.

Informal process

Webinar Serie:

1. Understanding DSI: technical overview
2. Process and recent outcomes related to DSI under the CBD
3. Policy options for ABS and DSI
4. Criteria to consider policy options on DSI

The online forum open for everybody.

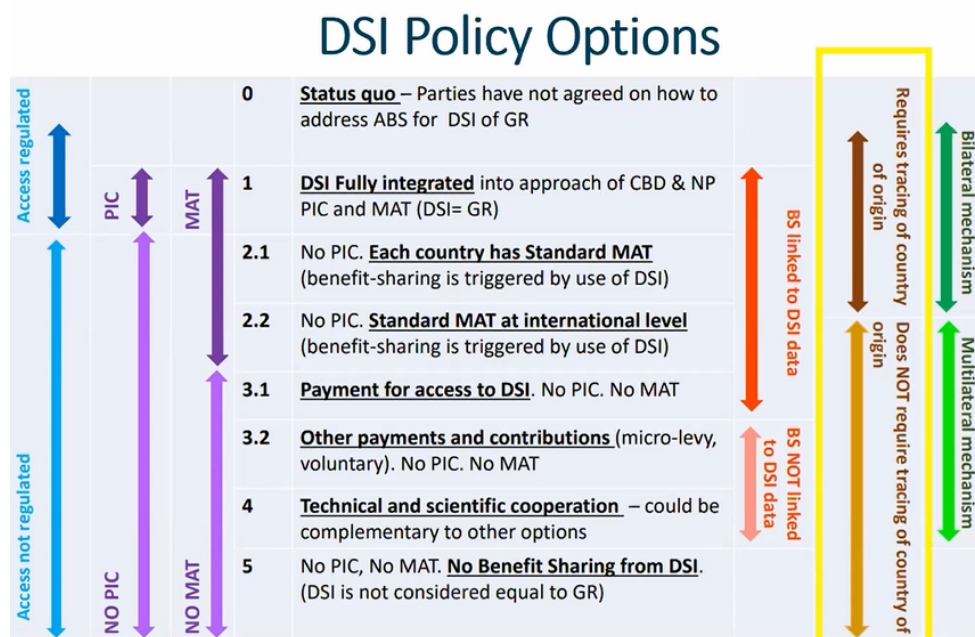


Figure 2 CBD Secretariat

Key criteria of policy options for DSI are:

1. Fair and equitable sharing of benefits from the use of DSI from GR
2. Open data
3. Contribution to conservation and sustainable use of biodiversity
4. Linking across biodiversity regimes and international fora
5. Financial feasibility of monetary benefit-sharing
6. Simplicity of solution (technical, legal)

1st part OEWG3 Aug/sept. 2021

- Goal: to strongly bring in the topic of DSI in the context of the post-2020 GBF and the recommendations to the COP
- This was discussed in plenary
- Contact group was established
- Co-leads were put in place and they developed a paper which became the basis of discussions of the parties involved: potential recommendation to COP, Co-leads provided a summary of areas of potential convergence and apparent divergence on DSI and Co-leads also provided a summary on the linkages DSI-GBF

The Contact Group called for submission of views and new information on policy approaches, options and modalities.

Informal Co-Chairs' Advisory Group (established by Co-Chairs, led by Co-Leads)

Co- chairs report to the working group

- Proposed analytic framework (multi-criteria analysis)
- Update of the co-leads' summary on the potential convergence and apparent divergence (divergences among the parties should be bridged before the COP)
- Recommendation for the further work

2nd part of the OEWG3 Jan 12-28, Geneva

Parties will have documents to consider:

- Co-leads' report on the work of the informal Co-Chairs' Advisory Group on DSI
- Compilation of submission on opinions and new views on options, approaches or modalities on DSI
- Pre-sessional document (expected on 1st December 2021 on the CBD website)

Fran Humphries, Law school at Queensland University of Technology, Australia

Marcel Jaspers, University of Aberdeen, UK

“Traceability Options for genetic resources and the associated sequence information to enable benefit sharing”

Overview of their publication

<https://www.frontiersin.org/articles/10.3389/fmars.2021.661313/full>

Example for a commercial product: Abyssine (Deepsane) (French cosmetic product)

- Complex situation: DSI material that is incorporated into a cosmetic product
- Original organism found in an area beyond natural jurisdiction, from a natural hydrothermal vent located in the East Pacific Sea in 1987
- DSI isolated from a bacterial strain HYD657 (2002 first publication) stored in a gene bank
- Its activity was discovered in 2002 and its chemical structure was defined in 2012

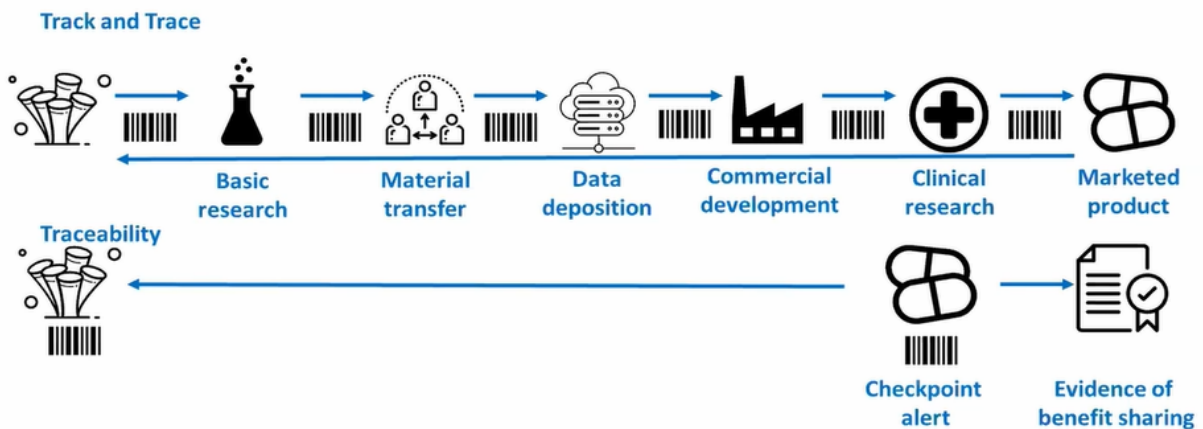


Figure 3 Comparing track & trace with traceability by Fran Humphries and Marcel Jaspers

- The idea of traceability is that a unique identifier is associated with DSI from the beginning, that it is handed on from user to user
- It shows how difficult it is to find a system which tracks and traces at every stage of a research and development process
- Often the sequence is traceable through the research process, but not during the commercial development
- Although it is in principle possible to trace back the sequence, it requires a lot of cooperation regarding the management of the data base

Options:

1) Track and trace identifier options

- Scientific identifier = e.g., accession numbers are identifiers that are already used by the INSDC and publications
- Administrative identifiers = created for the purpose of ABS monitoring and compliance, like identifiers in the ABS Clearing House
- None of these existing identifiers is fulfilling the goal of a permanent “attached ID”
- Identifiers have to be discussed at the national law level
- Blockchain is an often-discussed system to solve this problem
- But the provider country needs to have the technological capacity to interact with the blockchain infrastructure so that benefits can be shared with the provider
- In the Abyssine example, the user obtained identifiers. The accession numbers of the other sequences used in the analysis strain were also released under this ID. The ID was used in any subsequent use, hence the original genetic material can be traced back
- The French law excluded genetic material that was collected from outside its national territory before 2016. The law did not apply to the collection of Abyssine as this genetic resource had been collected before.

Opportunities: linking identifiers with existing compliance measures under national law e.g., reporting, checkpoints, indicating changes of use, and the provision of third-party transfer

Challenges:

- tracing information independently of the physical sample
- Gaps and variabilities in monitoring mechanisms

- Compliance burden is put on initial researchers and not on end-users
- Systems likely to be costly

2) Contractual/ licensing Traceability Option

- Tracking based on PIC and MAT
- Standardized Material Transfer Agreement (SMTA, respectively Standard Mutually Agreed Terms) attached to physical material or DSI or Creative Commons Licenses could be attached to DSI
- With machine-readable technology it is possible to incorporate contractual obligations to DSI

Opportunities:

- SMTAs can reduce compliance burden by providing standard terms and conditions
- SMTAs can be made machine readable aiding traceability
- Machine readable Creative Commons Licenses could be used for DSI

Challenges

- Countries have not (yet) agreed upon standard conditions for a multilateral system that are consistent across countries
- Third party transfer is often precluded, increasing burden on researchers to negotiate this on a case-by-case basis

3) End- User/End-product Traceability Option

- Does not require every process step to be traced
- Following the approach that Brazil has developed for its ABS law
- If the commercial utilization will occur the user will be obliged to notify the accession to the Clearing House with the identifier of the original material leading to the product and to commit to share the benefits using a central fund
- Goal keepers such as national funding agencies and academics journals could be established

Opportunities:

Lower impact on research - obligations for reporting and benefit sharing are only triggered once economic exploitation arises linking end user to provider through various databases (e.g., INSCD, Patent databases).

Challenges:

Resources and infrastructure required to link end-use to original data and/or sample

Higher reliance on good faith of end-user companies and accurate/public records of process steps and uses

4) Combined approaches to traceability

- A Material Transfer Agreement (MTA) / Mutually Agreed Terms (MAT) can lead to various options
- Imaginable is: user end/product /user registration (benefit sharing under national law), multilateral mechanism (e.g. for conservation), capacity building or and/or benefit sharing fund, subscription or tax models, open access/ no requirements

Opportunities

- Builds on good scientific practice and uses some existing databases/repositories,
- Flexibility for choosing possible options

Challenges

- Includes some of the challenges for traceability options above,
- Would need to be designed from scratch.

Carrot options for tracing DSI

- Capacity building for 'utilization' of DSI
- Market-based incentives (e.g. ABS certification)
- Scientific prestige economy incentives
- Private sector mechanisms (e.g. Global Compact)
- A lot of options depend on good will of the users and subsequent users

Conclusion

- Traceability for the DSI/CBD debate needs to be considered within the broader context - geographical, subject matter, activity and temporal scope of the various ABS frameworks,
- There is no one-size-fits-all approach to traceability mechanisms,
- Diverse approaches which suit local research and development environments can achieve similar traceability outcomes,
- Each country needs to consider the potential impact of systems developed on basic research, the practicality for achieving traceability objectives, and implications on resources,
- To be successful approaches should build on existing global infrastructure, or use procedures developed in other policy instruments.

Panel discussion

Moderation:

Lacticia Tshitwamulomoni and Gaute Voigt-Hanssen

Panelists:

Fabian Rohden, University of Lethbridge, Canada

Edward Hammond, Third World Network, USA

Christian Tiambo, International Livestock Research Institute, Kenya

Fran Humphries, Queensland University of Technology, Australia

Marcel Jaspers, University of Aberdeen, UK

To what extent is traceability relevant for DSI benefit sharing?

Marcel Jaspers

- Recognition that benefits need to be shared is important.
- Still questionable how benefits are shared through a tracking and tracing system (T+T)
- How feasible and necessary is such a system?

Fabian Rohden

- Tracing itself is complicated. Carrot options can have a future regarding back tracing
- Tracking and tracing is impossible once you start changing the sequences
- The best system currently is run by INSDC
- Recommendation: to build a system based on the scientific system. As long as data is in a scientific database it is easier to obtain a good overview on processes and activities. Once data gets into private sector processes are becoming difficult to trace.

Edward Hammond

- T+T is inversely proportional to the degree to which a multilateral benefit sharing system is set. If there is a multilateral system with a clear formula for the total amount of benefit sharing, nobody has to rely too much on T+T
- Nevertheless, some monitoring will still be necessary, also within a multilateral system
- Country and origin tacks should be supported, particularly with view to INSDC
- Providers can better follow how their genetic resources are being used. It also builds confidence in a multilateral system

Fran Humphries

- With a multilateral fund access and benefit sharing can be seen separated
- It is a juristically complex discussion to have open access to DSI on the one side and to protect traditional knowledge associated with DSI on the other side

Christian Tiambo

- There is a need for benefit sharing
- It is important to further discuss traceability
- There is a need to consider the capacity of different stakeholders to use these systems
- It is important but it depends on the structure and the feasibility of traceability: is every country able to invest in an efficient traceability system?
- The good will of the commercial users to pay back benefits to the providers plays a key role. It will be always possible to bypass a T+T system
- The current benefit sharing system faces a lot of challenges. Thus it needs to be further discussed if further difficulties should be added to the processes
- It also requires further discussion on how capacity building would look like at a country level, a national level, regional level, at the level of scientists or in the communities?

Which elements of existing traceability systems could serve as models for genetic resources and DSI in context of benefit sharing?

Fran Humphries

- Machine readable elements are important
- Not necessarily rely on scientific identifiers because they serve to a range of purposes but not ABS
- It is difficult to create a whole new system that works scientifically and for ABS

Edward Hammond

- Systems that already exist in current data banks should be used to further develop these with view to benefit sharing

- GISAID has user agreements in its terms and conditions. This approach, hence could be an option and is common and acknowledged in the ecosystem of databanks
- a Mechanism need to be in place in which commercial users become responsible for benefit sharing

Fabian Rohden

- Making country tags mandatory would be helpful
- Open access helps transparency
- For the benefit sharing approach according to the CBD framework, the creation of an own ID system is recommended

Christian Tiambo

- A new system also must be adaptable for new situations
- Implementation of T+T should not complicate the scientific work

Marcel Jaspers

- The INSDC data base contains far more sequences than the sequences that are linked to genetic resources and ABS. we are talking about, based on genetic resources of provider countries
- Identifiers must be machine-readable
- In the near future, the users will for some applications no longer need DSI itself, they can create new proteins and the related DNA-sequences from scratch using the emerging knowledge about structures and functions of proteins. For the biotechnology industry, this a a great opportunity for the future

To what extend will technicalities of traceability will influence the discussion on benefit sharing options?

Edward Hammond

- A robust traceability system is technically possible. It needs to be discussed if we want one?
- The decision for either a bilateral or a multilateral system will have a bigger impact on a successfully applied benefits sharing system. Confidence under member states is important in the discussion. More important than T+T

Marcel Jaspers

- It is critical to build on the common good practice in science
- A lot of good data base norms have already been developed
- Required is a better cooperation between scientists explaining to them the benefits that could be achieved: less overlap, more knowledge about nature

Christian Tiambo

- Everything depends on the system that is put in place
- A common ground of negotiations is important, afterwards technical options can be discussed

Fabian Rohden

- Important to have a system that yield benefits

Fran Humphries

- Firstly, a consent is needed. Thereafter the discussion on technology can start