

Study 4: Fact-finding Study on How Domestic Measures Address Benefit-sharing Arising from Commercial and Non-commercial Use of Digital Sequence Information on Genetic Resources and Address the Use of Digital Sequence Information on Genetic Resources for Research and Development

Professor Margo A. Bagley
Emory University School of Law

The Team

Margo
Bagley

Lead author

Elizabeth Karger, Manuel
Ruiz Muller, Frederic
Perron-Welch, and Siva
Thambisetty

Main authors

Lúcia de Souza, Tekau Frere, Christine
Frison, Fran Humphries, Nihaya Khalaf,
Charles Lawson, Jorge Cabrera Medaglia,
Hartmut Meyer, Prabha Nair, and Michelle
Rourke

Contributing authors

Methodology*

- Review of submissions on DSI
- ABSCH (IRCCs, Party profiles, implementation reports)
- Survey (36 NFP responses)- To all CBD and NP NFPs
- Interviews (44 in 28 countries) - NFPs, CNAs, other government personnel, academic researchers, consultants, etc.
- Literature search

“Domestic Measures”:

- Formal ABS legislative, administrative or policy measures, such as laws, regulations, decrees, proclamations, ordinances, policy statements, codes of conduct, guidelines, best practices/standards, and compliance measures.

* Variety of data collection

challenges

Study provides a “first glimpse of the dynamic and evolving landscape of measures addressing DSI in which relevant factual information is not always available for analysis.”

Key Findings

- **16 countries and one subnational jurisdiction¹ were identified as having domestic measures (legal, administrative and policy measures) in place addressing DSI**
- **one country² addresses DSI by ABS implementing measures (PIC, MAT or permits) in the absence of formal domestic measures.**
- **18 countries³ without domestic DSI measures indicated that they are in the process of developing, or have plans to introduce, such measures.**
- **No monetary benefit-sharing reported to date.**

1. Bhutan, Bolivia, Brazil, China, Colombia, Costa Rica, India, Kenya, Malawi, Malaysia, Mozambique, Namibia, Panama, Peru, South Africa, Uganda, and Queensland, Australia

2. Bahrain

3. Burundi, Cameroon, Ecuador, Ethiopia, Gambia, Guinea, Guinea-Bissau, Iraq, Libya, Madagascar, Bahrain, Palau, Philippines, Rwanda, Senegal, Sudan, Togo, and Uganda

Terminology used : Two approaches

Specific terminology used in definitions or operative provisions

- Genetic information
- Genetic heritage
- Intangible components
- Gene sequences
- Sequence information
- Information
- Information of genetic origin

Bhutan, Brazil, Malaysia, Malawi, Mozambique, Namibia, and Queensland, Australia.

Pending legislation - Cameroon and Ethiopia (“DSI”).

• Interpretation of existing terminology to include DSI

- Genetic resources
- Genetic material
- Biological resources
- Associated knowledge
- Research results
- Derivative

Colombia, South Africa, China, India, Panama

The five main approaches

1. DSI is only addressed in conjunction with utilization of “physical” genetic resources
2. PIC and MAT are required for DSI independent of access to a “physical” genetic resource
3. Benefit-sharing obligations arise from the use of DSI (but not access requirements)
4. Addressing DSI through compliance/monitoring mechanisms
5. Intentional non-measures to promote unrestricted access to and use of DSI

***Some countries do not fit neatly into any of these approaches**

Approach 1:

DSI is only addressed in conjunction with utilization of “physical” genetic resources

- Access provisions in ABS framework for genetic resources
- No access provisions for DSI per se
- Through permits/contracts - restrictions may be placed on production, use and further distribution of DSI
- Examples: Namibia, Costa Rica, Queensland (Australia)

Approach 2:

PIC and MAT are required for DSI independent of access to a “physical” genetic resource

- Definition of genetic resources or “access” includes (or is interpreted to cover) DSI (triggering PIC/MAT); access to physical material does not appear necessary for benefit-sharing obligations to apply
- Examples: Bhutan, Malaysia, Peru, Bolivia, China, Colombia, Kenya, Mozambique, Oman, Peru, Uganda (not all actively imposing requirements).

Approach 3:

Benefit-sharing obligations arise from the use of DSI (but no DSI access (PIC) requirements)

- No access to physical material required
- DSI in databases worldwide considered to be within scope of national measures
- No access provisions apply to DSI – data is open for use
- Benefit-sharing triggered by certain actions
- Examples: Brazil, India, Malawi, South Africa

Approach 4: Compliance and monitoring, related measures

- “Related” compliance measures
 - EU, Switzerland and Japan – DSI not part of compliance mechanisms
 - DSI may be addressed in MAT, which should be respected
 - Registered collection – case study on how dealing with DSI
 - Best practice
- Examples: India – monitoring patent applications worldwide (based on DSI from Indian species)

What does it mean when there are no domestic measures on DSI?

Two Primary Scenarios

1. No measures yet but either:
 - a) there is an intention to adopt measures in future (18 countries) (the lack of measures relates to capacity limitations)
 - b) waiting to see what will happen at the international level
2. Intentional non-measure – no intention to regulate

Approach 5:

“Non-measures”

- Promotes public access to DSI in open access databases
- No benefit-sharing obligations arise from use of DSI
- Deliberate policy decision to have no regulations on DSI access or benefit-sharing, etc.
- Example: Japan

Implementing Tools

Contracts

Sometimes used to address DSI in the absence of formal domestic measures

- Mutually Agreed Terms (MAT)/Material Transfer Agreements (MTAs)
- Parties have the right to include DSI provisions in MAT relating to “physical” genetic resources
- Can address benefit-sharing and/or use of DSI (publication, third party use, IPR)
- Some Parties note limitations to bilateral MAT approach – publication of DSI and uncontrolled use by third parties

Permits

- Allow access; generally show user has complied with requirements such as PIC/MAT
- May address benefit-sharing (data sharing, publication of results, etc.)
- May address use of DSI (data sharing, publication, IPR)

Benefit-sharing

- No direct monetary benefit-sharing reported so far
- Non-monetary benefit-sharing
 - Generalized benefits from open access to DSI (Costa Rica, Japan)
 - Public access to DSI/production of open access publications; facilitation of genomics research capacity building for African scientists (Africa, multi-country)

Implications of Differences in Approach:

Transaction costs and access

- Differences in approaches 2 (PIC/MAT required to access DSI) and 3 (no access requirements for DSI, only benefit-sharing) appear to have implications for transaction costs (bilateral model) and open access to DSI

Annexes (include among other things)

- Table of Jurisdictions with measures on DSI and benefit-sharing
- Five Case Studies (exemplifying ways DSI and benefit-sharing are being addressed)
 - Legislative, administrative and policy measures for ABS and DSI (Australia)
 - Permits and contracts for benefit-sharing (Costa Rica)
 - The role of MTAs in the production and publication of DSI (Namibia, Germany)
 - ABS contracts and MTAs on DSI use (Africa, multi-country)
 - Incorporation of DSI and DSI-related subject matter in existing terms (India)

Thank you for your
attention.

Questions?



Capacity issues – a lack of what?

- Understanding of the implications of including DSI in the ABS framework
- Understanding of technological developments
- Financial resources for training
- Financial resources for national consultations to develop measures
- Personnel/administrative capacity to operationalise national measures

Approach 3:

Brazil

Detailed survey response from Brazil

- New Registration system in place since 2017 (SisGen) – new approach: regulate benefit-sharing for genetic resources, not access
- Greatly reduces transaction costs (no need for bilateral case-by-case negotiation)
- Includes DSI: Genetic resources = “genetic heritage” and includes (“Information of genetic origin”) including in databases

Approach 3: Brazil cont.

- Registration is online & mandatory, but only **prior** to triggering activities (no need for access permission prior to research activities), such as
 - application for any intellectual property rights; commercialization of an intermediate product (by-products); notification of finished product or reproductive material developed as a result of the access.
- Notification and benefit-sharing required before economic exploitation of finished product
- Users can choose monetary (one percent (1%) of the annual net revenue paid into a National Benefit-sharing Fund) or non-monetary (specified activities) benefits

Approach 3:

Brazil cont.

- Registrations: 800 legal persons; 25,000 individuals
- **47,000** access activities registered (research and technological development)
- 449 *in silico*, 67 declared with commercial intention
- no finished DSI product or reproductive material notified in SisGen yet – no benefit-sharing arrangements or monetary benefits so far