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AD HOC TECHNICAL EXPERT GROUP ON
DIGITAL SEQUENCE INFORMATION ON
GENETIC RESOURCES
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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

Note by the Executive Secretary

1. At its fourteenth meeting, the Conference of the Parties to the Convention on Biological Diversity requested the Executive Secretary to commission a peer-reviewed 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, taking into account the submissions provided in paragraph 9 (decision 14/20, para. 11 (e)).

2. Accordingly, and with financial support from Norway and the European Union, the Executive Secretary commissioned a research team to carry out the study.

3. A draft of the study was made available online for peer review from 29 October to 29 November 2019.[1] The comments received in response have been made available online.[2] The research team revised the study in the light of the comments received and prepared, in consultation with the Secretariat, the final version as presented herein. Any views expressed in the study are those of the authors or the sources cited in the study and do not necessarily reflect the views of the Secretariat of the Convention.

4. It should also be noted that this study is distinct but complementary to three other studies the Executive Secretary was requested to prepare pursuant to decision 14/20, paragraph 11(b), (c) and (d) and the synthesis of views prepared pursuant to decision 14/20, paragraph 11(a).

5. An executive summary of the study is presented below followed by an annex containing the entire study. The study is presented in the form and language in which it was received by the Secretariat.

[1] See notification 2019-094 of 22 October 2019.

[2] See https://www.cbd.int/dsi-gr/2019-2020/studies/#tab=2.

EXECUTIVE SUMMARY

6. The present study serves the science- and policy-based process on "digital sequence information on genetic resources" (DSI), which was established by decision 14/20 at the fourteenth meeting of the Conference of the Parties to the Convention on Biological Diversity, in November 2018. It reports findings on how domestic measures address benefit-sharing arising from commercial and non-commercial use of DSI as well as the use of DSI for research and development. It also provides an overview of the types of domestic measures that address DSI, how they have been implemented, some of the challenges that countries face in developing and implementing measures related to DSI, and the decisions of some countries not to regulate access and benefit-sharing (ABS) for DSI at all.

7. Information for this study was obtained from various sources, including the ABS Clearing-House (ABSCH), literature and website reviews, interviews, and responses to a survey circulated by the Secretariat of the Convention. The authors sought information regarding measures for all 196 Parties to the Convention. The authors note that DSI, which is used herein as a placeholder term, is a sensitive and controversial topic in a number of jurisdictions, which made gathering data on measures addressing DSI particularly challenging. Moreover, a number of Parties to the Convention and to the Nagoya Protocol still do not have ABS legislation, let alone measures addressing DSI. Thus, this study should be considered a first glimpse of the dynamic and evolving landscape of measures addressing DSI in which relevant factual information is not always available for analysis. In many countries, ABS legislation, regulations, policies, etc., are still being developed and making their way through a time-consuming and challenging legislative process.

8. For this study, domestic measures are understood as comprising 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. While some countries have adopted explicit DSI-related language in measures, others have simply interpreted their existing ABS frameworks to cover DSI. A number of other countries assert that DSI falls outside the scope of the definition of genetic resources and is therefore not within the scope of the Convention or the Nagoya Protocol. As such, they do not intend to introduce measures on DSI in their domestic ABS frameworks.

9. Domestic measures address DSI benefit-sharing arising from commercial and non-commercial uses through both access provisions and benefit-sharing provisions, and the implications of addressing DSI at the domestic level vary depending on which of these foci are chosen and how DSI is addressed. A total of 16 countries and one subnational jurisdiction were identified as having domestic measures (legal, administrative and policy measures) in place addressing DSI, and one country addresses DSI by implementing measures (PIC, MAT or permits) in the absence of domestic measures. In addition, 18 countries without domestic DSI measures indicated that they are in the process of developing, or have plans to introduce, such measures.

10. The authors identified five main approaches to addressing DSI in domestic measures:

(a) Some countries address DSI only in conjunction with the utilization of a "physical"[3] genetic resource. In other words, when access to a "physical" genetic resource is granted, some countries include conditions on the use of DSI that could originate from that physical sample as part of PIC and MAT;

(b) Other countries have domestic measures in place that seem to suggest that PIC and MAT would be required to access DSI independently of access to a "physical" genetic resource;

[3] As the study will show, some countries consider DSI to be included within the scope of the definition of a genetic resource, notwithstanding the CBD definition of genetic resources as genetic "material". Therefore, to avoid confusion and accurately reflect the various domestic perspectives, the word "physical" will be used in quotation marks to indicate lack of consensus on this issue.

(c) In another group of countries, even though there are no access requirements for DSI, benefit-sharing is required from its utilization. In other words, benefit-sharing obligations are triggered by utilization rather than access;

(d) Some countries also may address DSI in relation to benefit-sharing and research and development through other measures – directly or indirectly – such as compliance-related measures, and monitoring mechanisms;

(e) Some countries seeking to promote unrestricted access to and use of DSI for commercial and non-commercial research intentionally choose not to adopt domestic measures that would regulate access to DSI or require benefits to be shared from its use. Thus, the lack of ABS obligations for DSI in those countries can be seen, in effect, as an intentional "non-measure."

11. The implementation of ABS systems in practice involves various tools, such as permits, mutually agreed terms (MAT) and material transfer agreements (MTAs). There is evidence of both permits and contractual terms being used to address the use of DSI and benefit-sharing arising from its use, sometimes even in the absence of formal domestic ABS measures.

12. Independently of how and whether DSI is addressed in domestic measures, it is worth noting that every Party has the right to include provisions in MAT on the use of DSI even when their domestic measures do not cover or address DSI. This may involve including relevant benefit-sharing obligations in contracts, such as the sharing of data and research results, but also through clauses intended to restrict the type of sequencing done and the subsequent use of those sequences.

13. Although contracts might facilitate relevant restrictions being passed on to third parties in some cases, there are nevertheless clear limitations to taking a bilateral approach to dealing with DSI through contracts, particularly when DSI is published in publicly accessible databases. Lawsuits for breach of contract or alternate dispute resolution mechanisms could conceivably address some of these issues, including through the removal of DSI from databases.

14. Most countries that are addressing DSI expect benefit-sharing arising from its use. Some countries anticipate monetary benefit-sharing arising from joint intellectual property rights or monetary payments. However, no countries reported having received monetary benefits to date.

15. As required by the Nagoya Protocol, a number of countries have compliance measures in their ABS framework addressing the utilization of "physical" genetic resources. These compliance measures may be pertinent to DSI which results from the utilization of a "physical" genetic resource and is the subject of obligations found in MAT.

16. Most Parties to the Convention and to the Nagoya Protocol do not have measures on DSI. Some countries intentionally choose to omit DSI from domestic benefit-sharing measures because they do not believe that it falls within the scope of the Convention and Nagoya Protocol, and/or see lack of regulation as a way to facilitate scientific advancement through open access to DSI. Such countries typically regard open access as a form of non-monetary benefit-sharing.

17. Several countries that are not yet regulating, nor definitively planning to regulate, DSI are considering whether to do so in the future. This existing lack of regulation is, in some cases, due to the ongoing negotiations on the issue at the international level. For others, internal agreement on a position on DSI is still being developed. In some countries, it also reflects a currently limited capacity to develop and implement relevant measures. Thus, for several countries, the lack of domestic measures addressing DSI may be only a temporary state of affairs.

18. The annexes to this study include a table outlining the presence of measures addressing DSI by Parties to the Convention and to the Nagoya Protocol, a literature search, and five case studies exemplifying ways in which the use of DSI and benefit-sharing is being addressed at the domestic or institutional level.

Annex

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

20 January 2020

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Contents

List of Acronyms

ABS	Access and Benefit-Sharing
ABSCH	Nagoya Protocol Access and Benefit-Sharing Clearing-House
ABS-MS	Access and Benefit-Sharing Monitoring System
AHTEG	Ad Hoc Technical Expert Group
BfN	German Federal Agency for Nature Conservation (Bundesamt für Naturschutz)
BOLD	Barcode of Life Data System
CBD	Convention on Biological Diversity
CETAF	Consortium of European Taxonomic Facilities
COP	Conference of the Parties
COP-MOP	Conference of the Parties serving as Meeting of the Parties
CONAGEBIO	National Commission for the Management of Biodiversity
CTLGH	Centre for Tropical Livestock Genetics and Health
CNA	Competent National Authority
DNA	Deoxyribonucleic acid
DSI	"Digital Sequence Information on Genetic Resources"
DSMZ	Leibniz Institute DSMZ-German Collection of Microorganisms and Cell Cultures
EU	European Union
GEF	Global Environment Facility
GMBSM	Global Multilateral Benefit-Sharing Mechanism
GTLE	Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches
GIZ	Deutsche Gesellschaft für Internationale Zusammenarbeit
GSD	Genetic Sequence Data
ILRI	International Livestock Research Institute
IRCC	Internationally Recognised Certificate of Compliance
IP	Intellectual Property
IPLC	Indigenous Peoples and Local Communities
IUCN	International Union for the Conservation of Nature
MAT	Mutually Agreed Terms
MENA	Middle East and North Africa
MET	Ministry of Environment and Tourism (MET)
MTA	Material Transfer Agreement
NBA	National Biodiversity Authority (India)
NBC	National Biopiracy Commission (Peru)
NBRI	National Botanical Research Institute
NBSAP	National Biodiversity Strategy and Action Plan
NEMA	National Environmental Management Authority
NFP	National Focal Point
PIC	Prior Informed Consent
Qld	Queensland
RNA	Ribonucleic acid
UNDP	United Nations Development Programme
PCT	Patent Cooperation Treaty
WIPO	World Intellectual Property Organization

1. INTRODUCTION

1.1 Purpose of the Study

In November 2018 during the fourteenth meeting of the Conference of the Parties (COP) to the Convention on Biological Diversity (CBD) in Sharm El-Sheikh, Egypt, the COP adopted Decision 14/20 relating to the issue of "digital sequence information on genetic resources" (DSI).[19] The decision included the establishment of a science and policy-based process on DSI and the establishment of an extended Ad Hoc Technical Expert Group (AHTEG). The work of the AHTEG will be informed, in part, by four peer-reviewed studies on DSI, of which this study is one.[20] This study aims to provide information 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 for consideration by the AHTEG.[21]

1.2 Objectives of the Study

Given that information and analysis is generally lacking on how countries are regulating the use of DSI,[22] this study aims to provide a broad overview of the extent to which countries are addressing benefit-sharing from commercial and non-commercial use of, and research and development on, DSI, and the measures they are employing in this regard. The goals of the study are to:

- describe which types of domestic measures have been adopted and how these address benefit-sharing arising from commercial and non-commercial use of DSI and the use of DSI for research and development;
- give an indication of how widespread such measures are and how these measures have been implemented (if at all);
- identify the monetary or non-monetary nature of any benefits being shared or expected to be shared pursuant to the measures; and
- summarize some of the challenges with developing and implementing such domestic measures in relation to DSI.

1.3 Use of Terms

The following section explains the approach to the use of various terms taken by the authors of this study, while bearing in mind that the authors have not attempted to define terms where they have not been defined by a Party.

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[19] *Decision 14/20. Digital sequence information on genetic resources*, UN Doc. CBD/COP/DEC/14/20. (Decision 14/20). The acronym DSI is used in quotation marks throughout this study to reflect the placeholder nature of the term, which is still under discussion in the COP.

[20] Decision 14/20, para 11(b) – (e).

[21] It has long been recognized that the boundary between commercial and non-commercial use based on the generally defined stages of R&D is blurry, and that commercial potential (an aspect of the distinction between commercial and non-commercial research) can be difficult to assess, particularly in early-stage research. As such, this study does not focus on establishing distinctions between non-commercial and commercial research using DSI. See e.g., L. Glowka, *A Guide to Designing Legal Frameworks to Determine Access to Genetic Resource*s (IUCN, 1998), p. 28; M. Walloe Tvedt & O. Rukundo, Functionality of an ABS Protocol (Fridtjof Nansen Institute, 2010), p. 12; C. von Kries & G. Winter, Defining commercial and non-commercial research and development under the Nagoya Protocol and in other contexts, in E. Chege Kamau, G. Winter, P-T. Stoll, eds, *Research and Development on Genetic Resources: Public Domain Approaches in Implementing the Nagoya Protocol* (Routledge, 2015).

[22] The literature search in Annex G reflects the paucity of analysis of existing international policies and regulations that address DSI. Most works dealing with regulation and management of DSI focus on conceptual approaches and instruments, such as global commons, open access, bounded openness, a global multilateral regime, and contractual approaches, including material transfer agreements.

1.3.1 DSI

We note that there is a lack of clarity regarding the scope and concept of DSI and the most appropriate terminology to describe the relevant subject matter covered by the phrase.[23] In its preamble, COP Decision 14/20 notes that, despite its use in negotiations, "the term 'digital sequence information' may not be the most appropriate term and that it is used as a placeholder until an alternative term is agreed upon." This study does not attempt to define DSI, instead it takes an inclusive approach to identifying measures that might address the range of possible DSI subject matter identified in the report of the first meeting of the Ad Hoc Technical Expert Group on Digital Sequence Information on Genetic Resources.[24] Although it has taken on a prominent role in policy debates, the term "digital sequence information" or DSI is used in this study purely as a placeholder, as we recognize that at some later time the concept may be clarified.[25]

1.3.2 Domestic measures

Taking into account the text of Article 15(7) of the CBD as well as Articles 5, 6, 15 and 17 of the Protocol, the authors of this study have interpreted the term "domestic measures" as comprising 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. In this study, the authors use the term 'implementing measures' to mean contractual arrangements such as prior informed consent (PIC), mutually agreed terms (MAT), or material transfer agreements (MTAs). Although these predominantly depend on and implement aspects of ABS domestic measures such as legislation, they can also exist and be employed independently of such domestic measures.[26]

As noted in the first assessment and review of the effectiveness of the Protocol, many Parties are still in the process of establishing ABS legislative, administrative and policy measures and institutional arrangements. For many Parties, this process is time-consuming, resource intensive, and challenging.

1.3.3 Use of DSI

COP Decision 14/20 calls for this study to address both commercial and non-commercial use of DSI. Use of DSI was not defined by the decision. The authors of this study have adopted a broad understanding of the word "use", which might potentially include the production, analysis, sharing, publication, and patenting of DSI, and other forms of commercial and non-commercial use.

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[23] See Laird, S., and Wynberg, R. *Fact Finding and Scoping Study on Digital Sequence Information in the Context of the Convention on Biological Diversity and Nagoya Protocol*, January 2018, UN Doc. CBD/DSI/AHTEG/2018/1/3.

[24] *Report of the Ad Hoc Technical Working Group on Digital Sequence Information on Genetic Resources*, 20 February 2018, UN Doc. CBD/SBSTTA/22/INF/4; CBD/DSI/AHTEG/2018/1/4. DSI may refer to: Nucleic acid sequence reads and the associated data; Information on the sequence assembly, its annotation and genetic mapping. This information may describe whole genomes, individual genes or fragments thereof, barcodes, organelle genomes or single nucleotide polymorphisms; Information on gene expression; Data on macromolecules and cellular metabolites; Information on ecological relationships, and abiotic factors of the environment; Function, such as behavioural data; Structure, including morphological data and phenotype; Information related to taxonomy; Modalities of use. The report also noted that there was consensus that "the term 'digital sequence information' (DSI) is not the appropriate term to refer to [types of information on genetic resources that may be relevant to the three objectives of the CBD and objectives of the Nagoya Protocol]".

[25] It should be noted that this study does not address digital sequence information on human genetic resources. Parties to the CBD reaffirmed that human genetic resources are not included within the framework of the Convention in Decision II/11, paragraph 2.

[26] We note that some countries addressing DSI appear to consider, in this context, MAT, access permits, and MTAs to be forms of domestic measures as well, particularly in the absence of formal legislation regarding DSI.

1.4 Methodology and Sources of Information

Information on domestic measures addressing DSI was gathered by the authors from May to August 2019. An important source of information was the ABS Clearing-House (ABSCH), which lists national ABS measures and Internationally Recognized Certificates of Compliance (IRCC). CBD Party profiles on the CBD's website were also scanned for relevant information. The study authors conducted interviews with 44 individuals in 28 countries in order to better understand domestic laws, regulations, policies, and practices relating to DSI and benefit-sharing.[27] The interviewees included national focal points (NFP), competent national authorities (CNA) and other government personnel in selected countries, as well as academic researchers, staff of collections of genetic resources, industry representatives, members of intergovernmental and non-governmental organizations, and legal and policy consultants.

A survey on domestic measures was developed by the study authors and circulated by notification 2019-054 in English, French, and Spanish[28] to all CBD and ABS national focal points. Thirty-six Parties responded to this survey.[29]

Further information on domestic measures was obtained through a review of submissions made by Parties and other stakeholders pursuant to paragraph 9 of decision 14/20,[30] a literature search[31] , and searches of domestic ABS websites and the World Intellectual Property Organization (WIPO) Lex database.

Obtaining information on domestic ABS measures can be challenging, for example, because not all countries include this information in the ABSCH. For example, MAT are often treated as confidential, meaning that information on DSI included in these documents generally are not publicly accessible, irrespective of whether they are commercially sensitive or not. Nevertheless, some non-commercial MAT, and MTAs, which include clauses on DSI, were obtained through the ABSCH and other sources.

Keeping these limitations in mind, this study should be considered a first glimpse of the dynamic and evolving landscape of measures addressing DSI in which relevant factual information is not always available for analysis.

2. STUDY OVERVIEW

There currently is no international consensus on how or even whether domestic measures should address the use of DSI and benefit-sharing arising from its use. Nevertheless, as countries have become more aware of the many advances in biotechnology and related technologies, which may allow for the use of DSI with or without access to the underlying genetic material, a number of Parties have begun exploring, and in some cases adopting, measures addressing the issue.[32]

[27] For the list of interviewees, see Annex H. "Interview" includes both semi-structured and unstructured communications by phone, email and other forms of electronic communication, and in person. Information from interviews are identified in this study as "[interviewer], [interviewee], [Descriptor, if anonymous], date of interview. The study authors selected for interviews, within the time constraints of the study, persons believed to have information about actual and potential domestic measures that might address DSI.

[28] The survey was also circulated informally in Portuguese and Arabic to Portuguese and Arabic-speaking NFPs.

[29] The English version of the survey instrument is provided in Annex I.

[30] Information from submissions made pursuant to this decision are identified in this study as "[party name], Submission under Decision 14/20." A separate synthesis of the views and information contained in those submissions is being prepared by the CBD Secretariat. All submissions are available at: https://www.cbd.int/abs/dsi-gr/2019-2020/submissions.shtml.

[31] See Annex G.

[32] It should be noted that the ABS legislation of some countries, such as Brazil and Mozambique, encompassed DSI well before some of the more recent biotechnological advances involving uses of DSI emerged.

As listed in Annex A, 16 countries[33] and one sub-national jurisdiction were identified as having domestic measures (legal, administrative and policy measures) in place addressing DSI, and one country[34] addresses DSI through implementing measures (PIC) in the absence of domestic measures. In addition, 18 countries[35] without domestic DSI measures indicated that they have plans to introduce such measures in the future.

The authors identified five main approaches to addressing DSI in domestic measures:

1) Some jurisdictions address DSI only in conjunction with the utilization of a physical genetic resource.[36] In other words, when access to a genetic resource is granted, conditions on the use of DSI that could originate from that genetic resource may be included as part of PIC and MAT.

2) Other countries have domestic measures in place that suggest that, in addition to DSI being regulated in conjunction with "physical" genetic resources, PIC and MAT would be required to access DSI independently of access to a "physical" genetic resource.[37]

3) In another group of countries, there may be no access requirements for DSI separate from access to a "physical" genetic resource, nevertheless, benefit-sharing is required from its utilization. In other words, benefit-sharing obligations are triggered by DSI utilization rather than access, and often are captured by obligations in MAT.[38]

4) Some countries also may address DSI in relation to benefit-sharing and research and development through other measures, such as compliance-related measures and monitoring mechanisms.[39]

5) Finally, some countries seeking to promote unrestricted access to and use of DSI for commercial and non-commercial research may intentionally choose not to adopt domestic measures that would regulate access to DSI or require benefits to be shared from its use.[40] As such, the lack of ABS obligations for DSI in such countries can be seen as, in effect, an intentional "non-measure."[41]

In addition, some countries do not fit neatly into one of the above categories, either because they combine elements of more than one category or the study authors were unable to obtain sufficient information to definitively place them in a particular category.[42]

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

[34] Bahrain.

[35] These are Burundi, Cameroon, Ecuador, Ethiopia, Gambia, Guinea, Guinea-Bissau, Iraq, Libya, Madagascar, Bahrain, Palau, Philippines, Rwanda, Senegal, Sudan, Togo, and Uganda.

[36] Namibia, Australia (Queensland), Panama. See section 3.2.1.

[37] Bhutan, Colombia, Kenya, and Peru. See section 3.2.2.

[38] Brazil, India, Malawi. See section 3.2.3.

[39] See section 3.3.

[40] Australia, the European Union, and Japan are exemplary. A full listing of such countries is not available. Countries taking this "non-measures approach are not included in the tally of countries with domestic measures addressing DSI.

[41] See section 5.1.

[42] Bolivia, China, Costa Rica, Malaysia, Mozambique, Bahrain, South Africa, and Uganda. See Section 3.2.4.

Independently of how and whether DSI is addressed in domestic measures, it is worth noting that every Party with domestic measures in place to regulate access to genetic resources has the right to include provisions in MAT on the use of DSI even when their domestic measures do not cover or address DSI. This involves including relevant benefit-sharing obligations in contracts such as sharing data and research results, but also clauses intended to restrict the type of sequencing done and the subsequent use of those sequences.[43] Section 4 below provides more information on how countries have been addressing DSI as part of PIC and MAT established for access to a "physical" genetic resource as an aspect of the implementation of their domestic measures, and even where such domestic measures do not exist.

In the survey responses and submissions, no countries reported receiving direct monetary benefits from the use of DSI to date. Costa Rica and Japan are the only countries that report receiving benefits from the use of DSI and in both cases the benefits identified are the generalized benefits that open access to DSI provides. However, as the discussion below indicates, there is wide variability in how "benefits" from the use of DSI are perceived and understood.

For the remaining countries for which no existing measures relating to DSI and benefit-sharing were identified, stated reasons for the absence of DSI measures varied. Some countries and regions indicated in their survey responses and submissions to the CBD Secretariat that this is an intentional policy decision designed to facilitate open access to DSI for research and development.[44] For others, internal agreement on a position on DSI and benefit-sharing is still being developed.[45] A further group indicated that the absence of measures is due to capacity constraints,[46] which in some cases is combined with a desire to delay implementing national measures on DSI until such time as an international consensus on the topic is reached. Thus, for some countries, the lack of measures on DSI may be only a temporary state of affairs.[47]

3. DOMESTIC MEASURES ADDRESSING DSI

Countries with domestic measures addressing DSI and benefit-sharing situate these measures within their existing frameworks for regulating ABS, which may or may not include stand-alone ABS legislation. These frameworks may comprise:

- specific laws to implement ABS, or other general laws that regulate certain types of biodiversity, such as wildlife, wetlands or fisheries and which include ABS provisions;[48]
- implementing regulations designed to put ABS provisions into practice.[49] These regulations may address DSI in addition to or instead of the legislation; and,

[43] See case study in Annex D describing material transfer agreements addressing different types of sequencing.

[44] See discussion in 5.1. See, e.g., Government of Australia, *ARC Open Access Policy Version 2017.1 (2017); Government of Canada, Tri-Agency Open Access Policy on Publications (2015);* Japan Science and Technology Agency (JST), *Policy on Open Access to Research Publications and Research Data Management* (2017); European Union, *Commission Recommendation (EU) 2018/790 of 25 April 2018 on access to and preservation of scientific information*, C/2018/2375, OJ L 134, 31.5.2018, p. 12–18.

[45] In Belgium, for example, there is no agreed position between the competent regions (Flanders, Wallonia and Brussels) on how to address DSI and whether to implement measures relating thereto. There are internal discussions on how to deal with the issue of DSI in the CBD and other contexts (see for example the information provided by the regional focal points for Flanders and Wallonia during the DSI Info-session day organized on May 9, 2019 in Brussels. Information on that session may be found here http://www.biodiversity.be/4781/). CF, interview with Salima Kempenaer (Belgian Federal Public Services-DG Environment), 19.07.2019. However, no authority from Belgium intends to regulate DSI specifically and a draft federal law to implement the Nagoya Protocol does not cover DSI.

[46] Angola, the Philippines, Sierra Leone, Sao Tome and Principe, Botswana, Timor Leste, the Gambia, Cook Islands, Fiji, Republic of the Marshall Islands, Federated States of Micronesia, Nauru, Niue, Palau, Papua New Guinea, Samoa, Solomon Islands, Tonga, Tuvalu, Vanuatu and Libya, Bahrain, Iraq, Palestine, and Djibouti. See discussion in section 5.2.

[47] See section 5 *infra*.

[48] See for example, footnote 81 listing a variety of Kenyan environmental laws used to address ABS.

- other instruments, such as guidelines and policy statements.[50]

Countries use different terms to refer to DSI in domestic measures. In some countries the terms used do not explicitly mention DSI but have been interpreted to also cover this subject matter. The scope of domestic measures addressing DSI depends on the context and use of those terms within the national frameworks.

For some countries, this results in PIC and MAT being required to access DSI. For others there may be only a requirement for users to share benefits from utilization of DSI. In other cases, domestic measures only address DSI as part of MAT resulting from access to a "physical" genetic resource.

3.1 Terminology

Some jurisdictions stated that their measures explicitly cover DSI,[51] while other countries indicated that they interpret existing language in their ABS or other relevant legislation as including DSI, in some cases defining genetic resources more broadly than in the CBD or the Nagoya Protocol.[52] However, the distinction between explicit and interpretive coverage is not clear-cut in practice. The following provides an indication of the range of terms used by countries to refer to DSI in domestic measures.

Six countries use explicit DSI-related terminology in their ABS legislative, administrative, or policy measures.[53] Some of the terms used include genetic information,[54] genetic heritage,[55] intangible components,[56] gene sequences,[57] sequence information,[58] information,[59] and information of genetic origin.[60]

In some countries DSI is considered as part of the definition of a broader term, for example genetic resources,[61] genetic material,[62] biological resources,[63] associated knowledge,[64] research results,[65] or derivative.[66]

Such terminology may appear in definitional sections, operational text, or both. Some other countries indicated, principally through interviews, that they are considering or are in various stages of consultations with respect to the inclusion of explicit terminology in their domestic measures.[67]

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[49] See for example, Brazil and Malaysia.

[50] See for example, China and Malawi.

[51] Bhutan, Brazil, Malawi, Malaysia, Mozambique, Namibia, and Queensland, Australia. At least two countries, Cameroon and Ethiopia, include explicit language in their pending legislation. Interestingly, Ethiopia's draft legislation uses the term DSI. See Ethiopia, draft ABS proclamation, referred to in Ethiopia, Submission under Decision 14/20.

[52] China, Colombia, Costa Rica, India, Kenya, Bahrain, Panama, and South Africa.

[53] Bhutan, Brazil, Malaysia, Malawi, Mozambique, Namibia, plus the sub-national jurisdiction of Queensland, Australia.

[54] Bhutan, Namibia, and Malawi.

[55] Brazil.

[56] Namibia.

[57] Namibia.

[58] Queensland, Australia.

[59] Malaysia.

[60] Mozambique.

[61] Colombia, Panama, and South Africa.

[62] South Africa.

[63] China.

[64] India, see the case study in Annex F.

[65] Ibid.

[66] South Africa.

3.2 Approaches to Addressing DSI through Domestic Measures on Access and Benefit-sharing

Among countries with DSI measures, divergent approaches are being taken within and across regions,[68] and even within an individual country, as in the case of Australia.[69] We found evidence of jurisdictions explicitly incorporating DSI-related language into their ABS legislative, administrative, and policy measures,[70] or alternatively interpreting the language in their existing ABS measures to include DSI.[71] In addition, at least one country addresses DSI through ABS permitting and contractual practice, even in the absence of formal ABS measures.[72]

3.2.1 Regulating DSI in conjunction with utilization of "physical" genetic resources

The three countries described below only regulate DSI in conjunction with PIC/MAT relating to "physical" genetic resources. DSI per se, such as in a publicly accessible database, is not currently regulated by these countries.

Namibia

Namibia's ABS legislation requires users who intend to access biological and genetic resources and their intangible components, which include genetic information or gene sequences, found in *in situ* or *ex situ* conditions, to apply for an access permit for research leading to commercialization, scientific research with a commercial purpose, commercialization, or export.[73] While the reference to *ex situ* conditions suggests the requirements could apply to DSI in databases, the requirement is applied only to "physical" genetic resources. Thus, any restrictions in relation to DSI" are made only in conjunction with the granting of access to a "physical" genetic resource. In order to obtain a permit, PIC must be obtained, MAT must be established, and in the case of transfer and export, an MTA also is required.

Panama

The phrase "genetic resources" in Panama's ABS legislation is interpreted to cover DSI and provides the basis for DSI related clauses to be incorporated in PIC/MAT agreements on a case-by-case basis.[74] Currently, researchers are not allowed to upload DSI from Panamanian genetic resources to databases such as GenBank due to loss of control and unauthorized commercial use concerns. The Department of Biodiversity in the Ministry of Environment is also investigating the feasibility of using blockchain technology to track DSI utilization.

Queensland, Australia

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[67] Belarus, Submission under Decision 14/20; ST, interviews with Galina Mozgova and Elena Makeyeva, 19.06.2019. Pacific Island States, such as Palau, Samoa, Tuvalu, Vanuatu, Fiji, Republic of the Marshall Islands, Solomon Islands and the Federated States of Micronesia; TF, interview with Ofa Kaisamy, 27.05.2019. Panama, MB, interviews with Dario Luque and Jorge Garcia, 10.01.2020.

[68] For example, explicit and interpretative inclusion of DSI by several African countries and intentional non-measures to facilitate open access to DSI in Europe.

[69] In Australia, the national government has expressly stated that DSI does not fall within its ABS system. However, Queensland, a sub-national jurisdiction, has ABS legislation that covers biodiscovery research on genetic information and DSI has been included in model benefit-sharing clauses. This jurisdiction is considering whether DSI should be included explicitly in its legislation (see the Australian case study in Annex B).

[70] Bhutan, Bolivia, Brazil, Colombia, Costa Rica, India, Kenya, and Queensland, Australia.

[71] China, Malaysia, Mozambique, Namibia, Saudi Arabia, Panama, and South Africa.

[72] Bahrain. Also Namibia prior to adopting its current ABS legislation, see Annex D.

[73] Namibia, *Access to Biological and Genetic Resources and Associated Traditional Knowledge Act 2 of 2017*, Section 8, https://namiblii.org/akn/na/act/2017/2.

[74] MB, interviews with Dario Luque and Jorge Garcia, 10.01.2020.

In Queensland, the Biodiscovery Act 2004 applies to the taking and using of "native biological resources" on or in "State land or Queensland waters" for "biodiscovery", which means biodiscovery research or the commercialization of native biological material or a product of biodiscovery research. "Biodiscovery research" means "the analysis of molecular, biochemical or genetic information about native biological material for the purpose of commercializing the material." Queensland's model benefit-sharing agreement currently includes DSI within the scope of "product" in the context of a product of biodiscovery. However, only DSI derived from accessed physical biological materials is captured by the legislation and model agreement.[75] For more details, see the case study in Annex B.

3.2.2 Regulating access to DSI independent of utilization of "physical" genetic resources

In some countries with access requirements for genetic resources, the definition of genetic resources includes (or is interpreted to cover) DSI subject matter, indicating an assertion of sovereignty over DSI. Accessing DSI thus may be viewed as equivalent to accessing the "physical" genetic resource, triggering PIC and MAT requirements.[76] For example, a 2014 Chinese joint ministerial notice defines 'biological genetic resources' to include not only materials and derivatives containing biological genetic functions but also information and data generated from therefrom.[77] The following are countries where it seems that the current domestic measures in place require PIC and MAT for accessing DSI whether "physical" genetic resources are being accessed or not.

Bhutan

The *Access and Benefit-sharing Policy of Bhutan*[78] guides the implementation of the ABS provisions of the *Biodiversity Act of Bhutan 2003*. Section 6(k) of the Policy defines 'genetic resources' to include the "biochemical composition of genetic resources, genetic information and derivatives." In section 6(c), "access to genetic resources" is defined broadly and equated to "utilization of genetic resources from Bhutan irrespective of whether they are accessed *in situ* or *ex situ* for the purpose of conducting any research and/or development on the genetic and/or biochemical composition of genetic resources." Access to genetic resources further extends to "the conducting of any research and development on derivatives of biological or genetic resources from Bhutan," which suggests that contact with tangible genetic material may not be necessary for access and benefit-sharing obligations to apply.

Access to genetic resources is determined by a "Scoping" phase and an "Actualization" phase, with differing conditions set for each. An ABS agreement including PIC and MAT must be completed between users and the Bhutanese government as the provider of the genetic resources and must be evidenced by an actualization permit from the NFP.[79]

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[75] A review of the Queensland law in 2016 indicated that the definition of "native biological material" did not include DSI. However, the Queensland Government is considering extending the definition of "native biological material" to explicitly include data, information or sequences. The taking of native biological resources from State land or waters for biodiscovery requires a collection authority together with an approved biodiscovery plan and a benefit-sharing agreement (MAT). DSI thus may be addressed through access as a term or condition of the collection authority, as a term or condition of the benefit-sharing agreement or as a part of the compliance code for taking "native biological material." CL, anonymous interview (government official), 05.06.2019.

[76] In addition to the countries described in this section, the Annex A countries of Bolivia, Mozambique, and Uganda also have measures that include DSI (as genetic information, intangible components, or through interpretation) within the definition of genetic resources, making it potentially subject to PIC/MAT. However, it is not clear that active efforts are being made to impose access restrictions on DSI currently in these countries. Also, Bahrain, while not having domestic measure relating to DSI, did indicate in its survey response that it is addressing DSI through PIC and requires benefit-sharing from its use.

[77] Ministry of Ecology and the Environment of the People's Republic of China, *Notice on Strengthening the Management of Biogenetic Resources Utilization and Benefit Sharing in Foreign Cooperation and Exchange*, available at: http://www.mee.gov.cn/gkml/hbb/bwj/201411/t20141105_291155.htm (unofficial translation).

[78] Bhutan ABS Policy 2015, available at: https://absch.cbd.int/database/record/ABSCH-MSR-BT-240076.

[79] Ibid, Section 6(a).

Colombia

The scope of the ABS regime applied in Colombia under the provisions of the Andean Decision 391 of 1996 and Resolution 1348 of 2014, requires benefit-sharing arising out the use of DSI whether it is associated with access to a "physical" genetic resource or if it is used directly from a database. In other words, in Colombia the use of DSI is subject to benefit-sharing when it is for bioprospecting, industrial or commercial purposes, even if "physical" genetic resources are not being accessed.[80]

In the 1996 Andean Decision 391: *Common Regime on Access to Genetic Resources*, "access" means the obtaining and use of genetic resources. Under that definition, in Colombian measures, "access" and "use" have the same meaning, therefore, the use of a "physical" genetic resource or DSI (for bioprospecting, industrial or commercial purposes) is regulated through the access contract which also establishes benefit-sharing conditions. Entities seeking to use, for bioprospecting, industrial, or commercial purposes, DSI from an *in vivo* obtained sequence from a native Colombian species, must sign an access contract which contains benefit-sharing requirements.

Colombia has not yet signed DSI access contracts, nevertheless mechanisms currently in place to address access and benefit sharing have the potential and capability to cover the use of DSI, whether associated with a "physical" genetic resource or from a database.

Colombia also regulates the dissemination of DSI as nucleotide and chemical sequences related to a "physical" genetic resource, by a clause which establishes that if digital information is deposited in a public database, either national or international, the number of the contract and the Colombian origin of the information must be explicitly published, and a clause which establishes that if digital information is deposited in a public database, either national or international, the Ministry must be informed.[81]

Kenya

Kenya's ABS regulations define "access" as "obtaining, possessing and using genetic resources conserved, whether derived products and, where applicable, intangible components, for purposes of research, bio-prospecting, conservation, industrial application or commercial use." [82] "Intangible components" includes any information held by persons that is associated with genetic resources within the jurisdiction of Kenya. Although this phrase was initially intended to cover traditional knowledge, it is now also interpreted as covering DSI. Any person who intends to access genetic resources or intangible components in Kenya must apply for an access permit and pay the relevant fees.

This regulation requires "reasonable access" to Kenyan genetic resources to be guaranteed for all Kenyan citizens, including for intangible components, whether they are held locally or abroad. The user of the genetic resources also has reporting obligations under the regulation, e.g., providing regular reports to the relevant authority on the status of research, including discoveries from research involving genetic resources and/or intangible components.[83]

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[80] See Colombia, submission under Decision 14/20.

[81] Email communication from Colombian NFP.

[82] *Environmental Management and Co-Ordination (Conservation of Biological Diversity and Resources, Access To Genetic Resources And Benefit Sharing) Regulations, 2006*. Kenya has listed a number of national legislative and policy measures in the ABS Clearing-House as being ABS measures. These include: *Science, Technology and Innovation Act, 2013; Seeds and Plant Varieties Act; Kenya Agricultural and Livestock Research Act. No. 17 of 2013; Forest Conservation and Management Act, 2016 (FCM Act, 2016); Protection of Traditional Knowledge and Cultural Expressions Act, 2016; Constitution of Kenya 2010; Environmental Management and Co-ordination Act, 1999 (Cap 387); Wildlife Conservation and Management Act, 2013; Wildlife Conservation and Management Act, 2013; The Environmental Management and Co-ordination (Conservation of Biological Diversity and Resources, Access to Genetic Resources and Benefit Sharing) Regulations, 2006; Access and Benefit Sharing (ABS) Toolkit; Biological Authorization Procedures*.

[83] Ibid.

Peru

Like Colombia, Peru is a member of the Andean Community,[84] and has been working to implement Andean Decision 391, which establishes a common regime on access to genetic resources. Decision 391 defines genetic resources as including "intangible components," which is being interpreted as covering DSI although, as with Kenya, it was originally understood to refer more specifically to the traditional knowledge of indigenous peoples. Under this interpretation, DSI is subject to access and benefit-sharing requirements whether in conjunction with access to a physical genetic resource or not. Under the new ABS draft regulation under public consultation,[85] "genetic information" is explicitly mentioned and regulated bilaterally through ABS contracts.[86] Benefit sharing is expected to derive from access to and use of genetic information.

3.2.3 Requiring benefit-sharing (but not access) from the use of DSI per se

Some countries have established a benefit-sharing requirement for use of DSI independently from access being granted to a "physical" genetic resource.

Brazil

Brazil's provisional (2001) and current (2015) ABS laws interpret the phrase used in the CBD, "genetic resources", as the term "genetic heritage", which is found in Brazil's 1988 National Constitution.[87] "Genetic heritage" was further defined, in part, as "information of genetic origin", which includes DSI. Brazil has adopted an ABS system in which users comply with PIC and MAT by completing a simplified registration procedure, as opposed to the more common bilateral negotiations approach. Brazil's system addresses both access to and benefit-sharing from DSI.[88]

The 2015 legislation requires users of Brazilian genetic resources to register their use through the SisGen online system prior to one of several triggering activities, such as applying for patent rights, commercializing an intermediate or end product, or disclosing results or research in scientific circles. Moreover, if utilization does not produce something that can be economically exploited, benefit-sharing is not required. As DSI is treated the same way as tangible forms of genetic heritage, the SisGen registry has specific fields for the user to provide the origin of DSI obtained from an *in silico* source, specifically, the name of the database, the accession number from that database, and a link to the source of the information.

India

India has not articulated an official position addressing DSI. Nevertheless, as described in the case study in Annex F, India's use of the terms "research", "associated knowledge", and "transfer of research results" could be deemed to include DSI. Interpretations of these terms are providing evolving authority for the imposition of benefit-sharing obligations on DSI on a case-by-case basis, even if (as described in

[84] Andean Community Decision 391: Common Regime on Access to Genetic Resources (1996); See https://wipolex.wipo.int/es/text/223610. See also El Reglamento de Acceso a los Recursos Genéticos (D.S Nº 003-2009-MINAM).

[85] Ministerial Resolution 205-2019-MINAM (2019).

[86] "Genetic information" is defined as a sequence of nucleotides, including digitally stored sequences.

[87] Brazil, Federal Law No 13,123 of May 20, 2015, Art 2(I); Manuela da Silva and Danilo Ribeiro de Oliveira "The new Brazilian legislation on access to the biodiversity (Law 13,123/15 and Decree 8772/16)" (2018) 49(1) Braz J Microbiol 1: "According to the new definitions of [genetic heritage], access to [genetic heritage], and research, the Law includes activities … such as research related to molecular taxonomy, phylogeny, molecular epidemiology, and molecular ecology, *as well as the use of information from public genetic sequence databases, such as GenBank*." (emphasis added).

[88] Brazil does not require PIC to access DSI, just a simplified, after the fact, registration procedure in the event of commercialization. As such, the study authors chose to categorize the Brazilian system as one requiring benefit-sharing, but not access, for DSI.

the case study) it is obtained separately from a "physical" genetic resource, such as from a public database.[89]

Malawi

Malawi regulates access to and benefit-sharing arising from the utilization of biological resources in accordance with the Environmental Management Act (2017) and other sectoral legislation. Malawi's ABS regulations, which are intended to explicitly address DSI, are still under development. Nevertheless, based on provisions of the Act, Malawi has developed ABS guidelines which indicate that Malawi considers all activities involving the collection, export, and utilization of "physical biological resources, traditional knowledge associated with genetic resources, genetic information, or any forms of DNA/RNA sequences or sequence data in any format including in microbiological, digital or synthetic or in any other format associated with genetic resources, to trigger benefit-sharing obligations."[90]

3.2.4 Miscellaneous ABS-related approaches to addressing DSI

As indicated earlier, several countries with domestic measures addressing DSI in an access and benefit-sharing context do not fit neatly into one of the above categories, either because they clearly combine elements of more than one category or because the study authors were unable to obtain sufficient information to definitively place them in a particular category.

Costa Rica

Costa Rica's measures addressing DSI combine elements of the approaches in Sections 3.2.1 and 3.2.3. The Biodiversity Law No. 7788 (1998) regulates access to genetic and biochemical resources and requires users to negotiate PIC and MAT with the providers as a requirement to obtain an ABS permit in most cases. The national ABS authority (CONAGEBIO) has indicated that DSI is covered under the definition of "access to genetic resources" of the Biodiversity Law (the definition of access includes obtaining associated knowledge of the samples of biodiversity). In addition, according to Costa Rican legislation, it is a responsibility of the State to authorize the utilization of the genetic and biochemical properties, as they are declared public goods. Costa Rica considers that the analysis and use of DSI is a type of subsequent utilization of genetic or biochemical resources, therefore it must be regulated.

Costa Rica supports the facilitation of access to DSI for research. However, for commercial utilization, Costa Rica considers that monetary benefit sharing must be ensured, even if the DSI is obtained separately from a "physical" genetic resource. Moreover, CONAGEBIO has the power/authority to impose restrictions on the further dissemination/deposit of DSI in public databases, where the DSI results from access to genetic/biochemical resources obtained through its permitting system. This approach is further described in the case study in Annex C.

Malaysia

Malaysia defines biological resources to include "genetic resources" and "information relating to" genetic resources.[91] Its survey results indicate that its ABS legislation explicitly addresses DSI and that DSI also is addressed via PIC/MAT/MTAs and permits.

South Africa

The 2013 amendment to the *National Environmental Management: Biodiversity Act, 2004* contains a definition of genetic resources that includes any genetic material, or the genetic potential, characteristics

[89] See case study, Annex F.

[90] Malawi, African Union Submission under Decision 14/20.

[91] See Access to Biological Resources and Benefit-Sharing Act 2017.

or information of any species, whether gathered from the wild or accessed from any other source.[92] On this basis, South Africa requires benefit sharing from uses of DSI, and includes in permit templates and MAT, clauses that address third party transfer and utilization of DSI, whether stored in public or private databases. PIC may also be required; however, that determination is made on a case-by-case basis.[93] As such, South Africa's regime can be viewed as including elements of 3.2.2 and 3.2.3.

Bolivia, China, Mozambique, and Uganda also have domestic measures addressing DSI; however, as with Peru and Malaysia, the study authors were not able to obtain sufficient information to place these countries definitively in a particular category.

3.3 Other Domestic Measures Relating to DSI

The majority of measures addressing DSI identified in this study directly focus on access and benefit-sharing.[94] Nevertheless, countries also may address DSI in relation to benefit-sharing and research and development through other measures, such as compliance-related provisions, and monitoring mechanisms.

3.3.1 Compliance measures

Although all Parties to the Protocol are obligated to establish compliance measures under Articles 15 and 16, and monitoring measures under Article 17, they are still absent from many ABS systems. However, compliance measures currently exist in some countries, many of which are often regarded as "users" of genetic resources,[95] such as the European Union (EU) and its Member States, Switzerland, and Japan. Some countries also have measures in place to ensure compliance with their own domestic ABS legislation.

European Union

Checkpoints within the meaning of Article 17 of the Nagoya Protocol have been established in the European Union (EU), and monitoring of utilization to ensure compliance is conducted by the Competent Authorities under the EU Regulation 511/2014 (EU Regulation). To comply with the EU Regulations, users in the EU "shall exercise due diligence to ascertain that genetic resources and traditional knowledge associated with genetic resources which they utilise have been accessed in accordance with applicable access and benefit-sharing legislation or regulatory requirements, and that benefits are fairly and equitably shared upon mutually agreed terms, in accordance with any applicable legislation or regulatory requirements."[96] This obliges users of "physical" genetic resources to follow the rules of provider countries, and "[w]hen the information in their possession is insufficient or uncertainties about the

[92] South Africa, Submission under Decision 14/20.

[93] MB, Interview, Lacticia Tshitwamulomoni, NFP, 22.07.2019.

[94] See Annex A.

[95] See "Compliance with rules on access and benefit-sharing arising from the use of genetic resources and associated traditional knowledge," Summary of EU Regulation No. 511/2014, available at https://eur-lex.europa.eu/legal-content/en/LSU/?uri=CELEX:32014R0511 ("'User' countries need to take measures to ensure that genetic resources used in their country were accessed in accordance with the ABS rules of the provider country").

[96] Regulation (EU) No 511/2014 on Compliance Measures for Users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union (Hereafter EU Regulation) Article 4(1). It should be noted however that in the context of ABS implementation, although all users have to exercise due diligence, the legal standard does not require the same type of measures for all users, but 'leaves some flexibility to take specific measures that work best in their respective context and given their capacities.' See Commission Notice (2016/C 313/01). *Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union*. Official Journal of the European Union C 313, 27.8.2016, p. 1–19.

legality of access and utilisation persist, users shall obtain an access permit or its equivalent and establish mutually agreed terms, or discontinue utilisation."[97] The ABS law in Switzerland has largely been harmonized with the EU Regulation, and Swiss users of "physical" genetic resources have similar obligations to EU users.[98]

Both the EU and Switzerland regard the production and use of DSI as being captured by their compliance measures to the extent that the production and use of DSI is part of the utilization of a physical specimen of genetic material that is covered by PIC and MAT and which falls within the scope of their compliance measures. The non-binding EU Guidance Document, for example, notes that it is open to provider countries to attach conditions through domestic measures enforcing MAT to the generation and use of DSI for commercial and non-commercial research and development at the time of access to a genetic resource.[99] It states:

> *[T]he use or publication of such data might be covered by conditions set in the mutually agreed terms, which should be respected. In particular, those who accessed the genetic resources and obtain sequence data from them should respect the conditions of the agreement entered into, and inform subsequent actors about any rights and obligations attached to the data obtained and related to any further uses of it.*

The EU Guidance Document explains that users should respect any conditions agreed upon in MAT, including those that deal with 'DSI'". In this way, the compliance measures are only indirectly relevant for DSI. Compliance with MAT conditions is not regarded by the EU as bringing DSI within the scope of the EU compliance measures, meaning that there are no measures in the EU Regulation relating to the use of DSI per se, e.g., when accessed from a database without access to the underlying "physical" genetic resource.[100]

The compliance regime in the EU Regulation also includes mechanisms, such as registered collections and recognized best practices, which may assist users with meeting their due diligence obligations.[101] Becoming a registered collection requires compliance with Article 5(3) of the EU Regulation but is a voluntary action.[102] Users who have obtained genetic resources from registered collections are considered to have exercised due diligence under the EU regulation with respect to obtaining the relevant information.[103] Restrictions relating to genetic resources (e.g. MAT) found in the documentation

[97] EU Regulation, Art. 4(5).

[98] Switzerland, Ordinance of 11 December 2015 on the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, Art. 3. (Hereinafter NagO)

[99] EU Guidance Document [2.3.3].

[100] EU Guidance Document [3.1].

[101] The Consortium of European Taxonomic Facilities (CETAF), in response to Art 20 of the Nagoya Protocol and Arts 8 and 10 of EUR 511/2014, has developed a Code of Conduct, which gained recognition as a best practice by the European Commission (the only one so far). The focus of the Code of Conduct is on collections and ABS compliance, but it provides only limited guidance on data. For instance, it recommends that when users are supplying biological material to third parties, such as sequencing companies, that this should be done "only in compliance with the terms and conditions under which [the material was] acquired, and set conditions in a contract that prohibit independent utilization". See *CETAF Code of Conduct and Best Practice on Access and Benefit-Sharing*, Commission Decision C (2019) 3380 final, Annex, p 5, available at: https://ec.europa.eu/environment/nature/biodiversity/international/abs/pdf/CETAF%20Best%20Practice%20-%20Annex%20to%20Commission%20Decision%20C(2019)%203380%20final.pdf.

[102] EU Regulation Art. 5(3).

[103] EU Regulation Art. 4(7); Godt, C. and Burchardi, M. 2018. Strict Liability for "Registered Collections"? Assessing Regulation (EU) No 511/2014 in Feit, U., Greiber, T. and Karger, E. (eds) Second Meeting of the European Competent National Authorities Implementing the Nagoya Protocol and the Corresponding EU Regulation. BfN Skripten. Federal Agency for Nature Conservation, Bonn. Other due diligence obligations in Article 4 relating to keeping and transferring information as well as complying with the requirements in the relevant documentation remain with the user and are not supported by the registered collection.

provided by registered collections may cover use of and benefit-sharing for DSI.[104] For more details on how the only registered collection in the EU (the Leibniz Institute DSMZ-German Collection of Microorganisms and Cell Cultures (DSMZ)) has dealt with this, see the case study in Annex D. Switzerland similarly allows for the recognition of best practices and recognition of collections.[105]

Japan

Japan also has compliance measures for users of genetic resources, although they are contained in guidelines that are not legally binding.[106] Japan interprets DSI per se as not falling under the definition of genetic resources, meaning that it is not subject to Japan's compliance measures and monitoring procedures.[107] Japan's ABS Guidelines state explicitly that they "do not apply to the following and other genetic resources to which the Protocol does not apply… (1) Information concerning genetic resources, such as nucleic acid base sequences (excluding those that qualify as traditional knowledge associated with genetic resources)."[108] This is an example of an intentional "non-measure" on DSI[109]. Japan has indicated that the issue of DSI can be adequately addressed by MAT between the provider and the user entered into at the time of access to a genetic resource.

India and South Africa

India[110] and South Africa, are examples of countries which have adopted measures to ensure that utilization of domestic genetic resources and associated traditional knowledge in their jurisdiction is done in accordance with their ABS laws. In both countries, the processing of a domestic patent application may be suspended until such time as compliance with ABS laws has been verified, including for inventions involving DSI-related subject matter.[111] In South Africa, information on genetic resource origin is communicated to the domestic NFP, who then ascertains whether the necessary ABS obligations were met by the patent applicant.[112] This disclosure requirement may be viewed as facilitating compliance with the domestic ABS regime.

3.3.2 Monitoring domestic genetic resource utilization abroad

Some countries have systems in place or in development to monitor the utilization of their own genetic resources abroad. For example, the National Biopiracy Commission (NBC) in Peru has the express mandate to track and monitor patents which disclose or claim Peruvian biodiversity and resources. The NBC includes patents that refer to DNA sequences and other forms of DSI-related subject matter in its tracking mandate. Also in Costa Rica, the Technical Office periodically checks publications and such, to see if Costa Rican DSI is being disclosed/deposited outside of the country.[113]

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[104] In April 2018, the DSMZ became the first collection listed in the European Union's (EU) register of collections. The German CNA, the Federal Agency for Nature Conservation (Bundesamt für Naturschutz, BfN), is responsible for regularly verifying that DSMZ's collection continues to fulfil the criteria for a registered collection. EU Regulation Art 5(4).

[105] NagO, Arts 6 and 7.

[106] Japan, Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization, 18 May 2017, Chapter 2, online: https://absch.cbd.int/database/record/ABSCH-MSR-JP-238074 (Hereinafter Japan ABS Guidelines).

[107] Japan, Submission under Decision 14/20.

[108] Japan ABS Guidelines, Chapter 1, Art 3.1(1).

[109] See Section 5.1, infra.

[110] See case study, Annex F.

[111] South Africa, Patents Act, 1978 as amended by the Patents Amendment Act, 2005, section 30(3A) and (3B); India, Patents Act, 1970 as amended by The Patents (Amendment) Act 2005, section 25.1(j) and (k), 25.2(j) and (k), and 64.1(p) and (q).

[112] See Margo A. Bagley, *Toward an Effective Indigenous Knowledge Protection Regime: Case Study of South Africa*, p. 20, Paper No. 207, Centre for International Governance Innovation (2018) (citing interviews).

[113] See case study, Annex C.

Similarly, the Indian National Biodiversity Authority (NBA), which is the CNA in India, monitors patent applications for inventions all around the world for claims that cover Indian biological resources, including applications that include DSI stemming from Indian biological resources. According to Indian law, lodging these patent applications requires prior approval from the NBA, irrespective of whether the patent application is filed in India or elsewhere (see case study in Annex F).

Over 1068 total approvals relating to uses of biological resources and associated knowledge have so far been granted by the Indian NBA, including 729 approvals for filing IP applications in India and abroad.[114] It is not possible to disaggregate the publicly available data to analyse how many of these IP rights concern DSI or are linked directly to the access of a "physical" genetic resource and relevant bioprospecting permits from India. However, as described in the case study in Annex F, in 2019 the NBA exercised its regulatory authority when notified of a PCT patent application, which included the genetic sequence of an Indian strain of the protozoal parasite, *Plasmodium vivax,* for which no approval from the NBA had been granted.

In the future, it may become possible to capture some evidence of the generation and utilization of DSI through information technology measures such as the ABS-Monitoring System (ABS-MS) currently being developed by experts associated with the ABS Capacity Development Initiative (implemented by Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ)). The ABS-MS is a machine-learning tool connected to several databases containing information on biological resources of Indian origin. It dynamically captures the updates in the databases and locates published data on biological resources of Indian origin from patent documents and other published scientific literature. The ability to integrate data, including relating to DSI from major data sources coupled with scanning of complex documents to track the use of biological resources having Indian origin, should make it a useful tool for the Indian NBA to assist in the detection of non-compliance (i.e., utilization without seeking approval) with ABS regulatory requirements.

Several African countries working with GIZ are likely to implement such systems in due course. In Kenya, where development of a similar system is well underway, the tool is expected to include unique identifiers linked to the material or information accessed and utilized, including DNA and amino acid sequences, to enable automated monitoring when scientific studies or patent applications are published.

4. ADDRESSING DSI THROUGH ABS IMPLEMENTATION TOOLS

Independently of whether DSI is addressed in domestic ABS measures, every Party with domestic measures in place to regulate access to genetic resources can choose to include provisions as part of PIC and MAT on the use of DSI. Benefit-sharing obligations themselves can be included in various documents, including access permits, other permits, MTAs, and MAT, and the use of DSI also may be restricted or controlled through PIC provisions. The following provides more information on how countries have been addressing DSI through access permits, MAT, or MTAs established for access to a "physical" genetic resource.

Nine countries reported addressing DSI in PIC, permits, or their equivalent in survey responses or submissions under Decision 14/20,[115] with an additional nine[116] indicating they plan to use PIC to address DSI. It is unclear whether any of these would involve efforts to restrict access to DSI already in *ex situ* repositories such as databases, or instead relate only to use of DSI generated after the grant of access to a "physical" genetic resource. For example, Ethiopia noted that both permit templates and MAT

[114] http://nbaindia.org/content/683/61/1/approvals.html, updated as of July 25, 2019.

[115] Brazil, Colombia, Costa Rica, Kenya, Malawi, Malaysia, Namibia, Bahrain, and South Africa.

[116] Belarus, Burundi, Cameroon, Ethiopia, Guinea, Liberia, Sudan, Togo, and Uganda.

would be revised "to incorporate mandatory clauses" that address the conditions for use of genetic information resulting from the utilization of genetic resources in public or private databases.[117]

4.1 Permits

Permits often overlap with MAT and/or MTAs. This is because permits may be employed to show that a user has complied with various regulatory requirements, which may include PIC and MAT. The following are some examples of issued permits addressing DSI.

Costa Rica

Costa Rica granted an access permit in 2010 containing the following restriction:

> *"For the DNA (genetic material) extracted from the requested genetic resources the Technical Office of CONAGEBIO restricts the publication of complete/full genomic information on national and international databases, meaning that the entire genomes cannot become public, only the information related to molecular markers. Likewise, before publishing the sequences of DNA of the molecular markers developed or used for project purposes, the applicant shall inform the Technical Office in advance and later submit the accession number of the sequences." (Unofficial translation)*

The Technical Office of CONAGEBIO has also indicated that other restrictions related to the dissemination, deposit, or publication of genomes or gene sequences could be imposed in an access permit, the exact terms of which could vary on a case-by-case basis. For further information see the case study in Annex C.

Kenya

The ABSCH includes several Kenyan access permits containing conditions on DSI access and usage. Kenya has included explicit language relating to DSI in such permits, which have been listed as IRCCs in the ABSCH. For example, an access permit was granted to a Yale University researcher relating to Tsetse fly samples, in which specific mention was made of access to Deoxyribonucleic acid (DNA) and Ribonucleic acid (RNA). The permit included the following conditions:

> *"You shall ensure that there is reasonable access by all Kenyan citizens to all genetic resources and information collected whether such genetic resources and intangible components including digital sequencing are held locally or abroad . . .*
>
> *You shall ensure that the local community/s Traditional knowledge on the genetic resources including digital sequences and their uses are well-safeguarded.*
>
> *You shall furnish quarterly reports to NEMA on the status of the research, including all discoveries from research involving genetic resources and/or intangible components."*

This reflects the interpretation of the "intangible components" language used in the Kenya legislation described in section 3.2.2 above.

Namibia

In 2016, Namibia issued a research/collecting permit in accordance with general, non-specific ABS legislation to allow genome sequencing of biological samples that had been collected several years earlier. This permit includes various conditions, including restrictions on the commercialization of the specimens or their derivatives, an expiry date and a requirement to share the research results and any relevant publications.[118]

[117] Ethiopia, Submission under Decision 14/20.

[118] EK, Anonymous interview, 31.05.2019.

Peru

Peru has listed several IRCC's on the ABSCH. One issued in July 2019 contains the following language: "the applicant may not request patents or other intellectual property rights on the genetic material accessed or the *information derived* from access to said resources."[119]

4.2 Material Transfer Agreements (MTAs) and Mutually Agreed Terms (MAT)

MTAs are a type of contract used to govern the transfer of research material between institutions or individuals. MAT are contractual terms intended to govern benefit-sharing arrangements between providers and users of genetic resources. Sometimes these functions are separated in different contracts and in some cases, a single contract might serve both as a MTA and contain MAT on benefit-sharing. For an example of MTA provisions with MAT used by an international research consortium producing genomic information, see the case study in annex E.

Six countries and one sub-national jurisdiction[120] were identified as addressing benefit-sharing from the use of DSI with MTAs and/or MAT, either as tools to implement ABS legislation or, in the absence of such a framework, on a case-by-case informal basis.[121] These agreements span a broad spectrum of DSI utilization in research and development: from deriving sequences from tangible material, through to clauses on benefit-sharing and intellectual property (IP) rights. The following examples illustrate some of the approaches.

4.2.1 Mutually agreed terms

Some MAT require published DSI to be accompanied by restrictions formulated by the providing country, e.g., by Malawi. Moreover, South Africa has indicated that its guidelines specify that "the MAT and the permit templates contain mandatory clauses that address third party transfer terms and conditions which could include the utilization of DSI on genetic resources, whether stored in public or private databases."[122]

Malawi

Malawi includes in its current MAT a section addressing use of genetic information or any forms of DNA/RNA sequences or sequence data. Malawi's MAT specify that the publication of any DSI from Malawian genetic resources must be accompanied by the following statement:

> *"The government of Malawi has commercial rights or other further use rights in products or processes developed based on the research results or this DSI, and any use requires a contract of use with the Government of Malawi. Use of genetic information is also addressed in MATs and covers the 'use of genetic information or any forms of DNA/RNA sequences or sequence data in any format'. Malawi requires what may be called a certificate of acknowledgement of source and rights, to be included in digital publications akin to a 'standard online accept-condition'.*

This restriction makes the use of "digitized" information conditional upon accepting the contract of use requirement in the Malawian Regulation.

[119] Emphasis added. See https://absch.cbd.int/database/IRCC/ABSCH-IRCC-PE-246755/1.

[120] Brazil, Colombia, Malawi, Malaysia, Namibia, South Africa, and Queensland, Australia.

[121] An additional nine countries indicated having plans to address DSI with MTAs and/or MAT: Angola, Belarus, Cameroon, Ethiopia, Guinea, Liberia, Sudan, Togo, and Uganda.

[122] South Africa, Submission under Decision 14/20.

4.2.2 Material transfer agreements

The study authors found that MTAs had already been used by some countries[123] to address sequencing, the use of the resulting sequences, and benefit-sharing, prior to discussions on DSI in the CBD forum, which began in 2016. In some cases, MTAs addressing DSI also appear to have been used as an interim measure in the absence of formal ABS frameworks.

MTAs may be used to impose restrictions on the use of DSI, including implications for third party users of DSI generated through "physical" genetic resource utilization, or to address the potential for IP rights to cover inventions resulting from the utilization of material and the sequences derived from it. These clauses include preventing IP protection without further permission of the providing party, requirements for joint IP rights, and "defensive clauses," which require IP to be "appropriately protected" before data can be published (see case studies in Annexes D and E).

Namibia

Namibia first adopted its ABS legislation in 2017. Prior to that time, MTAs were used in conjunction with collection permits, including to restrict the type of sequencing conducted by users of genetic resources and to prohibit commercial use of the genetic material and resulting sequences. There is evidence of this as early as 2011. These MTAs also addressed benefit-sharing by requiring data and results to be shared with the institution providing the material. For more information, see the case study in Annex E. Namibia has indicated that it will continue to use MTAs in its ABS system, namely when material is transferred and/or exported from Namibia.[124]

Belarus

Belarus[125] approved a MTA dealing with the transfer of 1000 samples of Antarctic organisms from a collection, which provides, among other things, that the user shall conduct molecular analysis of 1000 samples of Antarctic organisms (fragments of tissues, bodies or thalli) using DNA-barcoding nucleotide sequence alignment.[126] These DNA-barcodes are to be imported into the Barcode of Life Data System (BOLD) database to supplement the reference library of Antarctic species DNA-barcodes. In other words, the purpose of the utilization of these genetic resources was to generate and publish sequences. The MTA restricts use of the genetic resources to non-commercial purposes and requires the user to obtain prior approval from the CNA before submitting an application for IP rights to an invention based on use of the genetic resources.

MTAs developed by research institutions

MTAs are also being employed by research institutions in European countries, such as Germany[127] and Belgium,[128] either as a type of voluntary code of conduct, or in response to requirements of provider countries. For example, the Centre for Tropical Livestock Genetics and Health (CTLGH), a strategic alliance of the International Livestock Research Institute (ILRI), the Roslin Institute at the University of Edinburgh, and Scotland's Rural College, uses MTAs in the context of a large project in its dairy genomics program, which involves blood samples from cattle in a number of African countries. The ILRI-developed MTA does not deal with DSI explicitly, but refers to research results in general. The

[123] Malawi, Malaysia, and South Africa.

[124] See Annex D.

[125] In Belarus, amendments to domestic legislation are pending. The legislation does not yet include benefit-sharing conditions for access and use of DSI but the authorities are examining the issue. ST, interviews with Elena Makeyeva and Galina Mozgova 19.06.2019.

[126] https://absch.cbd.int/database/IRCC/ABSCH-IRCC-BY-246531/1

[127] See Annex D.

[128] CF, anonymous interview, research institution, 09.05.2019.

purpose of the MTA is to set the legal obligations for the project partners governing the utilization of genetic resources and the handling of research results and data. The MTAs contain benefit-sharing clauses with regard to public access to the generated data and the production of open access publications. For more details, see the case study in Annex E.

4.3 Benefit-sharing Arrangements

For those countries with ABS measures in place, the types of benefits that can be shared generally include both monetary benefits, and non-monetary benefits, such as the sharing of results and data, sharing of publications, and knowledge transfer. In the survey responses and submissions, no countries reported receiving direct monetary benefits from the use of DSI to date. Some countries suggested various factors contributing to this lack of monetary benefits accruing from DSI. These included difficulties in tracking and obtaining evidence of the generation and utilization of DSI, limited technical and legal capacity to develop effective measures, the lack of a global multilateral benefit sharing mechanism (GMBSM), and the limitations of bilateral instruments applying to informational goods shared extensively across jurisdictions.[129]

Of the countries that responded to the survey and/or made submissions to the CBD Secretariat on DSI, 20 indicated that they expect to receive benefits from the use of DSI.[130] Two approaches are illustrated below.

Brazil

As mentioned in section 3.2.3 above, Brazil requires benefit-sharing from the use of DSI without the need for users to establish PIC and MAT for access to the related "physical" genetic resource. In addition to the access registration described above, users must complete a "notification on finished product or reproductive material derived from access to genetic heritage", which will specify benefit-sharing obligations as required by the domestic legislation, before economic exploitation activities in relation to a finished product or reproductive material take place. The legislation defines a finished product as one "apt to be used by the final consumer" which is derived from access to genetic heritage (including from an *in silico* source), or the genetic heritage has aggregated value, where heritage was one of the main elements that adds value to (or is material to) the product.

Users can choose between monetary and non-monetary benefit-sharing for economic exploitation of a finished product or reproductive material derived from access to genetic heritage or associated traditional knowledge. Non-monetary benefit-sharing can include projects for the conservation or sustainable use of biodiversity, technology transfer, placing a product in the public domain without protection by IP rights or technological constraints, free distribution of products in social interest programs, and more.

When monetary benefit-sharing is chosen, one percent (1%) of the annual net revenue (except in the case of reduction of up to 0.1% by sectoral agreement[131]) should be paid to the National Benefit-Sharing

[129] NFP Survey comments, including from Colombia, Costa Rica, Sudan, Togo, and Senegal.

[130] Angola, Brazil, Burundi, Cameroon, Central African Republic, Colombia, Costa Rica, Ethiopia, Guinea, Guinea-Bissau, Malaysia, Malawi, Nepal, Bahrain, Panama, Sierra Leone, South Africa, Sudan, Togo, and Uganda.

[131] Article 21 of the law 13.123/2015 provides:

"In order to ensure the competitiveness of the sector concerned, the Union may, at the request of the party concerned, in accordance with the Regulation, conclude a sectoral agreement enabling the amount of the monetary benefit-sharing to be reduced to up to 0.1% (one tenth percent) of the sector annual net income from the economic exploitation of the finished product or reproductive material derived from access to genetic heritage or associated traditional knowledge of unidentifiable origin." http://www.planalto.gov.br/ccivil_03/_ato2015-2018/2015/lei/l13123.htm (unofficial translation).

The decree 8.772/2016 further explains:

Fund. This Fund is expected to promote the conservation of biological diversity; recovery, creation and maintenance of *ex situ* collections of samples of genetic heritage; implementation and development of activities related to the sustainable use of biodiversity, conservation, and benefit-sharing; and fostering research and technological development of genetic heritage and associated traditional knowledge.

In the year and a half that the system has been in operation[132] almost 800 legal persons and more than 25,000 individuals have completed access registrations in SisGen. Moreover, over 47,000 access (research and technological development) activities have been registered, 16% (3,747) of which included declared commercial intention and were registered as technological development activities.[133] Of these, 449 activities specified *in silico* origin, of which 64 declared activities with a commercial intention. These 64 are the only ones relating to DSI for which benefit-sharing would be required. However, because no economic exploitation of a finished product or reproductive material arising from the utilization of DSI has been notified in the SisGen from those 64 benefit-sharing arrangements so far, no monetary benefits related to the use of DSI have been received to date.

India

As noted in section 3.2.3 above, India requires benefit-sharing for DSI, although the requirement is currently determined on a case-by-case basis. Benefit-sharing obligations in India are specified as a percentage of the user's commercial gains, so non-commercial use of a biological resource or associated knowledge would not ordinarily give rise to commercial gains.[134] However, there is no legal impediment to requiring "non-monetary" benefits from DSI, which may include the sharing of scientific information relevant to conservation and sustainable use of biological diversity including biological inventories and taxonomic studies.[135] Details on India's benefit-sharing rates are provided in the case study in Annex F.

4.4 DSI and Open Access

Publication of, and open access to, DSI as part of the 'utilization of genetic resources' often occurs irrespective of the bilateral benefits specified in MAT. The prevailing scientific model involves the publication of research results and underlying data, and many journals require sequences to be deposited

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Art. 55. "The benefit-sharing agreement between user and provider will be negotiated fairly and equitably between the parties, taking into account the parameters of clarity, loyalty, and transparency in the agreed clauses, which should indicate conditions, obligations, types, and duration of benefits of short, medium, and long term, without prejudice to other guidelines and criteria to be established by the CGen [The Genetic Heritage Management Council]."

Art. 56. "The purpose of the sectoral agreements is to guarantee the competitiveness of the productive sector in cases where the application of 1% of the annual net income obtained from the economic exploitation of finished product or reproductive material derived from access to genetic heritage or associated traditional knowledge of unidentifiable origin characterizes material damage or threat of material damage." http://www.planalto.gov.br/ccivil_03/_ato2015-2018/2016/decreto/D8772.htm (unofficial translation).

[132] The new law (13,123 / 2015) that repeals the Provisional Measure No. 2,186-16 / 2001 entered into force on November 7th, 2015 (https://www.mma.gov.br/informma/item/246-acesso-ao-patrim%C3%B4nio-gen%C3%A9tico-e-aos-conhecimentos-tradicionais-associados.html) The SisGen Platform was implemented and made available for users on November 6, 2017 https://www.mma.gov.br/patrimonio-genetico/conselho-de-gestao-do-patrimonio-genetico/sis-gen.

[133] Brazil, NFP survey response. Brazil also received 1500 finished product notifications during this time period.

[134] See Indo-German Biodiversity Programme / Access and Benefit Sharing Partnership project (2019) Access and Benefit Sharing Monitoring Tool. http://indo-germanbiodiversity.com/pdf/publication/publication07-06-2019-1559912567.pdf and material in Annex F.

[135] PN, interviews, with T. Narendran and K.P. Raghuram, 24.06.2019. See also Annex F.

and accession numbers to be supplied prior to the publication of associated research.[136] In addition, the mandatory publication or open data access requirements for publicly-funded projects in many countries[137] (e.g., in the EU, the U.S., and Australia), often make this necessary for researchers.

Some countries do explicitly consider open access to DSI as a form of non-monetary benefit-sharing. Both Japan and Costa Rica, the two countries which indicated in their survey responses that they had received benefits from the use of DSI, referred to open access as a form of non-monetary benefit-sharing.[138] Such countries view the sharing of DSI produced through the utilization of genetic resources as something to be encouraged as it is beneficial for all countries, especially in terms of uploading data to publicly accessible databases.[139] Some countries prefer this kind of non-monetary benefit-sharing to be the only form of benefit-sharing for DSI, stating that it is a global benefit that promotes biodiversity-based commercial and non-commercial research.

While a number of countries that identify as net providers of genetic resources, including Brazil and South Africa,[140] also recognize and value the diffuse societal benefits generated by open access to DSI, they reject the notion that direct monetary benefits should not also be required. As such, they are employing or are putting in place measures intended to result in the sharing of such benefits.[141]

5. THE ABSENCE OF DOMESTIC MEASURES RELATING TO DSI

As noted above, many countries do not address DSI in their legislative, administrative, or policy ABS measures. For some, this decision is based on the view that DSI falls outside the scope of the definition of "genetic resources" found in the CBD and the Protocol. For others, the on-going negotiations at international level or capacity constraints appear to be inhibiting the development of measures addressing DSI.

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[136] See, e.g., P.B. Giles, *How to Claim a Gene: Application of the Patent Disclosure Requirements to Genetic Sequences*, 27 GA. ST. UL REV. 695 (2010), and R. Blasiak, J.B. Jouffray, C.C. Wabnitz, and H. Österblom, *Scientists Should Disclose Origin in Marine Gene Patents*, TRENDS IN ECOLOGY & EVOLUTION (2019). It should be noted that this "prevailing scientific model" does not, generally speaking, have the force of law, or a decision of the COP. "Mandatory" publication of sequence data in an open access database, pursuant to an organizational policy may violate a legally binding ABS contract or national law of a provider and open the publisher of the data to legal action and liability. While large-scale change appears unlikely, it is conceivable that the "prevailing scientific model" could be modified to take into account legal realities associated with ABS obligations pursuant to the CBD/NP.

[137] For example, the German Research Foundation (GRF) will not fund projects (e.g. data mining and data analysis projects) that have restrictions on sequencing or on the use of sequences. Such projects cannot be funded with public money. German Research Foundation Peer Review Comments, available at https://www.cbd.int/abs/DSI-peer/2019/Study4/DFG.pdf.

[138] Costa Rica, NFP survey response, 2019: "it is considered that the information generated as a result of the investigations are part of the distribution of benefits that can be used by the scientific community, including the original provider. In addition, this type of research feeds open access databases, whose information is used repeatedly by the scientific community. The more information feeds these databases, the results obtained from their use will be more robust." (unofficial translation).

[139] Some interviewees also noted that setting up and maintaining such open databases is costly, a fact that should also be quantified when assessing whether benefit-sharing is taking place. CF, anonymous interview, ABS private consultant, 09.05.2019; CF, anonymous interview, research institution, 09.05.2019.

[140] South Africa, Submission under Decision 14/20: "there is no national benefit from such international work and it is very difficult to trace the benefits that are being generated without an internationally agreed standard." Innovative data sharing arrangements, where publicly available data is not treated as being in the public domain, are possible. The Global Initiative to Share All Influenza Data (GISAID) license for instance respects the ownership of data submissions by explicitly not permitting the removal – or waiving – of any potential pre-existing 'rights' to the data. Elbe and Buckland-Merrett *Data, Disease and Diplomacy: GISAID's Innovative Contribution to Global Health* (2017), http://sro.sussex.ac.uk/id/eprint/66197/1/Elbe_et_al-2017-Global_Challenges.pdf

[141] The literature review (Annex G) shows a growing number of references to the potential of a Global Multilateral Benefit Sharing Mechanism (under Article 10 of the Nagoya Protocol) to make benefit-sharing more fair and equitable.

5.1 Domestic "Non-Measures" on DSI for Research and Development

Many countries[142] consider that DSI falls outside the scope of the definition of "genetic resources" found in the CBD.[143] This view could be seen as having implications for the issue of how domestic measures address the use of DSI on genetic resources for research and development. In particular, countries seeking to promote unrestricted access to and use of DSI for commercial and non-commercial research may intentionally choose not to adopt domestic measures that would regulate access to DSI or require benefits to be shared from its use. As such, the lack of ABS obligations for DSI can be seen as, in effect, an intentional "non-measure" with the goal of facilitating the use of DSI for research and development. One example is Japan, which, as noted in Section 3.3.1, has promulgated ABS Guidelines which state that they do not apply to DSI subject matter.[144] In this regard, it should be noted that many such countries do not require PIC for access to their domestic "physical" genetic resources, and similarly, do not require PIC for access to DSI either.[145]

5.2 Capacity Issues and Measures Addressing DSI

A number of other countries[146] also do not address DSI in their legislative, administrative, or policy measures, not because they do not want to, but rather due to capacity limitations. For example, competing priorities and inadequate staffing may have prevented them from developing ABS measures at all or modifying existing measures to cover DSI. Other capacity-limiting issues identified include:

- a lack of understanding of the implications of including or not including DSI-related terms in ABS measures;
- a dearth of personnel with sufficient expertise in regulatory institutions for environment, science and technology to address the issue;
- a lack of financial resources for training, national consultations, and development of measures; and
- the need to understand the rapid technological advancement in the utilization of genetic resources and DSI and to develop flexible and adaptable legal frameworks.[147]

Capacity limitations have, for example, been identified as a major issue in the Pacific Islands region. Interviews with experts and national authorities from various Pacific Island States suggest that challenges with implementing ABS measures are faced by all of these countries, which is reflected by the general lack of ABS legislative and/or policy frameworks. To date, only Palau has adopted a legal ABS framework and DSI has not yet been included in national or regional discussions on ABS. However, it appears that these States take the view that DSI should not be de-coupled from genetic resources, even if there is a lack of capacity to regulate DSI at a national level. Research on several Middle East and North African (MENA) countries identified similar capacity limitations.

The study authors also gathered, from interviews and survey comments, that a few countries who would like to address DSI are hesitant to do so due to a lack of international consensus, suggesting that there is a desire for clarity and capacity-building around DSI subject matter at the international level before some

[142] Including Switzerland, the Czech Republic, Japan, the Netherlands, the UK, Canada, and Belgium.

[143] Such an interpretation would allow it to be subject to PIC under Article 6(1) of the Nagoya Protocol.

[144] Japan, Submission under Decision 14/20.

[145] See section 3.3, *supra*.

[146] Including Angola, the Philippines, Sierra Leone, Sao Tome and Principe, Botswana, Timor Leste, the Gambia, Cook Islands, Fiji, Republic of the Marshall Islands, Federated States of Micronesia, Nauru, Niue, Palau, Papua New Guinea, Samoa, Solomon Islands, Tonga, Tuvalu, Vanuatu and Libya, Bahrain, Iraq, Palestine, and Djibouti.

[147] These issues were identified in surveys, interviews, and research as affecting, to a greater or lesser degree, a wide swath of developing countries across sub-Saharan Africa, the Pacific Islands, Eurasia, and the Middle East and North Africa.

national measures will be effectively developed.[148] This may include capacity to further explore and assess the potential of a multilateral approach to address DSI overall or certain DSI issues.

6. CONCLUSIONS

This fact-finding study has shown that domestic measures that address benefit-sharing arising from commercial and non-commercial use of DSI, as well as the use of DSI for research and development, exist in several countries. These countries have taken differing approaches to addressing DSI, including through access and benefit-sharing provisions. In some cases, national laws, policies and other measures are based on explicit DSI related terminology, while in others, existing terms are interpreted to include DSI.

Adoption of DSI measures seems to rest upon either the view that DSI is a genetic resource and may be regulated as such or that, regardless of whether it is characterized as a genetic resource, DSI results from utilization and thus is subject to benefit-sharing obligations related to research and development activities. Submissions and interviews indicate that a number of countries, by contrast, do not view DSI as falling within the definition of a genetic resource and therefore treat DSI as not being within the scope of ABS. These countries have thus, in some cases, intentionally excluded DSI from their national measures, a practice referred to in this study as intentional "non-measures".

The implications of addressing DSI at the national level will depend on how DSI is regulated in the relevant measures. If the definition of genetic resources, for example, either explicitly refers to DSI or is treated as including DSI by interpretation, PIC and MAT may be required for DSI use. However, if the definition of genetic resources (or other definitions in a measure) is not understood to include DSI, and DSI is only regarded as within the ambit of ABS when it results from the utilization of a "physical" genetic resource, it might be assumed that only benefit-sharing obligations would apply, and these obligations would be based on MAT.

That DSI can result from the utilization of genetic material and that its use and relevant benefit-sharing obligations or other conditions of use may be addressed in MAT appears to be fairly uncontroversial. A significant divergence, however, seems to arise with respect to the question of whether PIC and MAT could and should be required for the utilization of DSI per se, particularly when it is obtained from databases (e.g., the International Nucleotide Sequence Database Collaboration – INSDC).

Survey results and interviews reveal that some countries that are not currently regulating DSI are considering whether and how to do so in their ABS frameworks. This suggests that DSI may, over time, become increasingly relevant for ABS transactions in general as new legal, regulatory, and policy measures on ABS are adopted at the domestic level.

Contracts seem to be the main tool used by countries and institutions to regulate conditions of use of DSI as well as benefit-sharing obligations resulting from its use. In at least one country, the use of these contracting tools appears to be filling the gap occasioned by a lack of formal ABS measures addressing DSI. While non-confidential data on MAT is limited, we found evidence that contracts are used to address DSI in the context of "utilization", including though clauses requiring benefit-sharing (sharing of data and research results) and clauses intended to restrict the type of sequencing done and the subsequent use of those sequences, i.e. conditions of use. Nevertheless, limitations concerning enforceability may arise

[148] Survey responses: Togo, Venezuela, Burundi, Ecuador; and Senegal.

using a bilateral approach as MAT will not bind third parties, who are not parties to the contract, who obtain DSI from publicly accessible databases in cases where no mechanism exists for contractual obligations to be passed on to third parties. Some interviewees report anecdotally that if restrictions cannot be passed on to data users, the potential to bypass benefit-sharing obligations may result in more countries amending their contractual clauses to prevent publication of DSI (which would be likely to conflict with other obligations of many researchers, e.g., to publish their results and data) or being reluctant to make their genetic resources available for research and development.

Some countries view DSI as falling outside the scope of the definition of genetic resources and for this reason, they do not have domestic ABS measures regulating DSI. Such countries are likely to continue to promote unrestricted access to DSI in line with their national priorities. Some countries that are supportive of domestic measures imposing access and/or benefit-sharing obligations for DSI have also made limited references to the possibility of addressing the complexities of DSI benefit-sharing through a potential GMBSM under Article 10 of the Nagoya Protocol. How a potential GMBSM would interact with the emerging panoply of domestic measures on DSI is unknown.

The literature search highlights, among other things, the limited production of interdisciplinary research on DSI related issues. Particularly limited is integrated policy, legal and economic analysis on how domestic measures address DSI and benefit-sharing, address DSI use in research and development, and how they may affect the objectives of the CBD and the Nagoya Protocol. This suggests a need for further research to better understand these linkages.

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ANNEXES

Annex A: Table of CBD/NP Jurisdictions with Domestic Measures on DSI and Benefit-sharing

Jurisdiction	**Formal ABS measures addressing DSI (explicitly or by interpretation)**	**If so, what kinds of measures? (e.g., legislative, administrative, policy)**	**Are ABS implementing tools used to address DSI? (e.g., permits, MTAs, MATs, IRCCs)**	**Is benefit-sharing required for DSI?**	**Are there plans to revise or adopt new ABS measures in relation to DSI?**	**Notes on relevant legal information**
Queensland, Australia	Biodiscovery Act 2004 (Qld)	Legislation	MAT	Yes	Yes	Queensland's model benefit sharing agreement currently includes DSI within the scope of "product" (in the context of a product of biodiscovery) as "anything (physical or non-physical, for example, data including sequence information) in relation to which property rights (including Intellectual Property rights) which incorporates, is created, produced, extracted or derived from Native Biological Material."
Bahrain	None	N/A	PIC	Yes	Yes	Survey response notes that Bahrain is addressing DSI though PIC until adoption of framework law on ABS.
Bhutan	ABS Policy 2015	Policy	Not known	Yes	Not known	ABS Policy 2015 (https://absch.cbd.int/database/record/ABSCH-MSR-BT-240076) "Genetic resources means all material of plant, animal, microbial or other origin containing functional units of heredity and includes the biochemical composition of genetic resources, genetic information and derivatives."
Bolivia (Plurinational State of)	Decision 391 of the Andean Community on a Common Regimen on Access to Genetic Resources (1996); Supreme Decree 24676, national regulation to Decision 319 (1997)	Legislation, regulations	Not known	Not known	Not known	Supreme Decree 25676 defines "DNA" as "genetic material which contains determinant information on the hereditary transmittable characteristics for descendants."
Brazil	The Biodiversity Law, Law No. 13,123 /	Legislation	Registration,	Yes	No	The 2015 Biodiversity law defines genetic heritage (or patrimony) as "information of genetic origin, of

	2015		permits, MAT			plant, animal, microbial or other species, including substances resulting from the metabolism of living beings."
China	Notice on Strengthening the Use and Benefit Sharing Management of Biological Genetic Resources in Foreign Cooperation and Exchange (2014)	Ministerial notice	Not known	Not known	Not known	In 2014, the Ministry of Environmental Protection, together with the Ministry of Education, the Ministry of Science and Technology, the Ministry of Agriculture, the State Forestry Administration and the Chinese Academy of Sciences, issued a joint notice on strengthening management of access to genetic resources and benefit-sharing in international collaborative research and exchange programs. In the joint notice, "biological genetic resources" is defined as "flora and fauna, microbial species, and taxons below the rank of species of actual or potential value, their materials and derivatives containing biological genetic functions, and information data generated by them (excluding human genetic resources)." (unofficial translation)
Colombia	Decision 391, Resolution 1348(2014).	Legislation	Permits, PIC, MAT	Yes	Yes	Decision 391 of the Andean Community; Decree 1375 (2013) which regulates biological sampling; Decree 1376 (2013) which regulates collecting of wild species for non-commercial research; Decree (1384) which specifies activities covered under ABS - it defines functional units of heredity as including those that contain a code for a gene. Under resolution 1348 (2014) which defines "ABS" activities in Colombia, DSI is considered as part of genetic resources and so can be regulated through contractual provisions in access contracts.
Costa Rica	Biodiversity Law 7788 and its regulations	Legislation and regulations	Permits	Yes	No	The Biodiversity Law regulates the utilization of genetic and biochemical properties, as they are considered public goods. Costa Rica considers that the analysis and use of DSI is a type of subsequent utilization of genetic or biochemical resources, therefore it must be regulated. Furthermore, DSI is covered under the definition of "access to genetic resources" of the Biodiversity Law (the definition of

						access includes to obtain associated knowledge of the samples of biodiversity).
India	Yes, Biological Diversity Act, 2002	Legislation	Not known	Yes	No	Research is defined to cover all types of research with biotechnology. DSI regulation is seemingly handled on an ad hoc, case-by-case basis.
Kenya	the Environmental Management and Co-ordination (Conservation of Biological Diversity and Resources, Access to Genetic Resources and Benefit Sharing) Regulations	Regulations	Permits	Yes	Not known	ABS regulations define "access" as "obtaining, possessing and using genetic resources conserved, whether derived products and, where applicable, intangible components, for purposes of research, bio-prospecting, conservation, industrial application or commercial use". "Intangible components" includes any information held by persons that is associated with or regarding genetic resources within the jurisdiction of Kenya.
Country/ Region	**Formal ABS measures addressing DSI (explicitly or by interpretation)**	**If so, what kinds of measures? (e.g., legislative, administrative, policy)**	**Are ABS implementing tools used to address DSI? (e.g., permits, MTAs, MATs, IRCCs)**	**Is benefit-sharing required for DSI?**	**Are there plans to revise or adopt new ABS measures in relation to DSI?**	**Notes on relevant legal information**
Malawi	Environment Mgmt Act (Cap. 60:02 of the Laws of Malawi)	Legislation, regulations	Permits, MTA, MAT, PIC	Yes	Not known	ABS contracts indicate that any digital publication of sequence data from Malawian genetic resources must be accompanied with the following: "The government of Malawi has commercial rights or other further use rights in products or processes developed based on the research results or this DSI, and any use requires a contract of use with the Government of Malawi." Use of genetic information is also addressed in MATs.
Malaysia	Access to Biological Resources and Benefit Sharing Act 2017	Legislation	Permits, MTA, MAT, PIC	Yes	No	"biological resource" includes— (a) the genetic resources, organisms, microorganisms, derivatives and parts of the genetic resources, organisms, microorganisms or derivatives;

						(b) the populations and any other biotic component of an ecosystem with actual or potential use or value for humanity; and (c) any information relating to paragraphs (a) and (b); "derivative" includes a naturally occurring biochemical compound derived, developed or synthesized, from a biological resource or resulting from the genetic expression or metabolism of the biological or genetic resource, or part, tissue or extract, whether it contains functional units of heredity or otherwise, and information in relation to derivatives; "genetic resource" means any material of plant, animal, microorganism, fungi or other origin that contains functional units of heredity and that has actual or potential value for humanity. Transfer to third parties of results of research in relation to a biological resource or TK is restricted. Decree # 19/2007 on ABS available at: https://www.cbd.int/doc/measures/abs/msr-abs-mz-po.pdf article 1 defines access to the genetic resource: the activity carried out on genetic resources with the objective of isolating or identifying or using information of genetic origin or molecules and substances derived from the metabolism of living organisms and extracts obtained from these organisms.
Mozambique	Decree #19/2007 https://www.cbd.int/doc/measures/abs/msr-abs-mz-po.pdf; https://absch.cbd.int/countries/MZ	Legislation	Not known	Yes	Not known	art 1 (q) defines Genetic Resource: information of genetic origin contained in samples of all or part of plant, fungal, microbial or animal specimen in the form of molecules or substances derived from the metabolism of these living or dead organisms found in in situ conditions, including domesticated, or kept in *ex situ* conditions.
Namibia	Access to Biological and Genetic Resources and Associated Traditional Knowledge (No. 2 of 2017),	Legislation, regulations	Permits, MAT, MTAs	Yes	Not known	s.1 "access" means obtaining, collecting, possessing, acquiring, using, selling, either directly or indirectly, biological or genetic resources found in both in situ

	https://namiblii.org/akn/na/act/2017/2					or *ex situ* conditions under the control of the State, . . . derivatives, products including synthetic products, and where applicable, intangible components or associated traditional knowledge, for purposes regulated under this Act. "Intangible components" means all know-how, innovation or individual or collective practice, with a real or potential value, that is associated with the biological and genetic resource, its by-products or the biological and genetic resource that contains them, whether or not protected by intellectual property regimes. s8. Access permit (1) A person who intends to access biological and genetic resources in Namibia, found in both in situ or *ex situ* conditions . . .[including] intangible components, including genetic information or gene sequences, and associated traditional knowledge, must apply for an access permit in the prescribed form and manner prior to carrying out any (a) research leading to commercialisation; (b) scientific research with a commercial purpose; (c) commercialization, including industrial application and bioprospecting. The phrase "genetic resources" is being interpreted to include DSI and clauses governing DSI are being included in contracts on a case-by-case basis. International developments on DSI are expected to influence national efforts regarding the possibility of more focused DSI regulation.
Panama	Executive Decree No. 19 of March 26, 2019, on the Regulation of the Access and Control of the Use of Biological and Genetic Resources in the Republic of Panama and on the Establishment of Other Measures	Executive Decree	PIC/MAT	Yes	Yes	
Peru	Decision 391 of the Andean Community on a Common Regimen on Access to Genetic Resources (1996); Supreme Decree 003-009-MINAM (2009)	Legislation	Not known	Yes	Yes	Decision 391 of the Andean Community; Supreme Decree 003-2009-MINAM (2009); the Supreme Decree is under review currently. New draft regulation for ABS is under consultation. Includes specific references to DSI.
South Africa	National Environmental Management; Biodiversity Act	Legislation	PIC, MAT, MTAs	Yes	Yes	Definitions of "derivative," "genetic resource" and "genetic material" are all in the 2013 amendment to the National Environmental Management: Biodiversity Act, 2004 (Act No. 10 of 2004) and are interpreted as linked to DSI. PIC/MAT conditions are

						determined on a case-by-case-basis. Section 62. Access to the genetic resources of Uganda. (1) The Authority (meaning the National Environment Management Authority) shall, in consultation with the relevant lead agency, make regulations to prescribe measures for the sustainable management and utilisation of the genetic resources of Uganda for the benefit of the people of Uganda. (2) Without prejudice to the general effect of subsection (1), the regulations shall specify— (a) appropriate arrangements for access to the genetic resources of Uganda by non-citizens of Uganda, including the fees to be paid for access; (b) measures for regulating the export and import of genetic resources; (c) the sharing of benefits derived from genetic resources originating from Uganda". This language is being interpreted to provide the basis for addressing DSI as genetic resources are deemed to include DSI.
Uganda	National Environment Act No. 5 of 2019	Legislation	Not known	Yes	Yes	

Annex B: Case Study: Legislative, administrative and policy measures for ABS and DSI in Australia

Charles Lawson,[149*] Fran Humphries** and Michelle Rourke***

Introduction

Australia has signed and ratified the CBD and is a signatory to the Nagoya Protocol. The ABS laws in Australia are a matrix of Commonwealth, State and Territory laws, which regulate access to and benefit-sharing arising from the utilization of biological materials. This case study provides an overview of the Australian ABS landscape and how DSI could be addressed. It then focuses on Queensland's ABS legislation, which addresses DSI specifically.[150]

The Australian ABS landscape

As a federation, the power to make laws in Australia is shared between the Commonwealth and the various States and Territories. The Commonwealth's enumerated powers are set out in the *Constitution* and the Commonwealth Parliament makes laws for the Commonwealth and Territories. The States have their own parliaments and make their own laws according to their residual powers.[151] The Australian Capital Territory and Northern Territory also have their own parliaments and make some laws for their territories, including ABS laws.

In response to the provisions of the CBD, all Commonwealth, State and Territory governments have endorsed the *Nationally Consistent Approach for Access to and the utilization of Australia's Native Genetic and Biochemical Resources* (National Resource Management Ministerial Council 2002) that was reflected in the *National Strategy for the Conservation of Australia's Biological Diversity* (Department of the Environment, Sport and Territories 1996, Objective 2.8) so as to promote consistency in the regulation and management of access to genetic resources across Australia. The basic principles are that access to publicly-owned and managed biological materials should require prior permission, any benefits should be shared with the access providers, there should be certainty by providing a legal basis for access and benefit-sharing, and any regulation should facilitate continued access for non-commercial scientific research (National Resource Management Ministerial Council 2002, pp 5-7).

Australia provides an example of different ways of dealing with ABS (and potentially DSI) that are consistent with the CBD[152] using a mix of legislative, administrative and policy measures (see Table 1).[153] The Commonwealth, Queensland, Northern Territory, Western Australia and the Australian Capital

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[150] Noting that this phrase is a "place holder, without prejudice to future consideration of alternative terms": *Ad Hoc* Technical Expert Group on Digital Sequence Information on Genetic Resources 2018, [25] and Annex ([1]).

[151] The States include Queensland, New South Wales, Victoria, Tasmania, South Australia and Western Australia. The Territories are the Australian Capital Territory, Northern Territory, Ashmore and Cartier Islands, Australian Antarctic Territory, Christmas Island, Cocos (Keeling) Islands, Coral Sea Islands, Jervis Bay Territory, Norfolk Island and the Territory of Heard Island and McDonald Island.

[152] The CBD has been implemented in Australia (for an overview see Petherbridge 2004, pp 201-202 and 206-216).

[153] There is formal legislation by the Commonwealth under the *Environment Protection and Biodiversity Conservation Act 1999* (Cth), by Queensland under the *Biodiscovery Act 2004* (Qld), by the Northern Territory under the *Biological Resources Act 2006* (NT), by Western Australia under the *Biodiversity Conservation Act 2016* (WA), and by the Australian Capital Territory under the *Nature Conservation Act 2014* (ACT). The relevant laws might, as a generalization, be categorized as laws about collecting biological materials according to where they are located (tenures – such as "Commonwealth areas", national parks, nature reserves, and so on) or particular sorts of plants, animals, microbes, and so on (resources – such as native flora and fauna, protected species, threatened species, and so on). The Commonwealth's *Environment Protection and Biodiversity Conservation Act 1999* (Cth) also applies in the external territories and the Exclusive Economic Zone (except the coastal waters of the States and Territories).

Territory have dedicated ABS legislation. Victoria, New South Wales, South Australia and Tasmania do not have dedicated ABS laws but rely on general laws (mostly conservation and fisheries schemes) for accessing biological resources on State lands, waters and seas. Victoria and Tasmania also have a broadly applicable policy with an administrative framework to implement ABS via a coordinated approach.

The reach of all these ABS schemes and general laws is different, with significant areas not being covered by any ABS laws at all. Importantly, all of Australia's jurisdictions use access to physical materials as the trigger for ABS obligations. Utilization is determined as terms and conditions of either/both the access permission and/or the benefit-sharing agreement. Where the jurisdictions provide for access subject to permits, concessions, licenses, and so on, in ABS, conservation and fisheries legislation, there are generally powers to enable terms and conditions to be imposed. At least in theory, DSI could also be addressed through these kinds of regulatory measures and these might be a model for flexibility through the policy and administration approach (like Victoria) rather than just legislation. Other than Queensland, however, the Commonwealth, States and Territories have not engaged specifically with DSI in their ABS arrangements.

While each legislative scheme has enforcement and compliance provisions/codes with offences, penalties, record keeping, inspection, and so on, we are not aware of any compliance arrangements for ABS. Monitoring of utilization has been conducted through inquires and academic interest in compliance rather than compliance checks conducted by the authorities. We are also not aware of any administrative procedures following up on ABS permits and benefit-sharing agreements. Perhaps the most significant monitoring or compliance has been through institutional user concerns about risks to their reputation. There is also a strong research ethics culture in Australia and the soft regulation of research through research funding agreements (such as the governmental codes of ethical research).

Australia and DSI

The Commonwealth Department of the Environment is currently considering whether to become a Party to the Nagoya Protocol and, if so, how it would implement the relevant obligations. Nevertheless, the Commonwealth of Australia has consistently expressed its view that DSI does not fall within the scope for the CBD and Nagoya Protocol:

"Digital Sequence Information on genetic resources is not defined under the [CBD]. For the purposes of this submission Australia defines 'digital sequence information on genetic resources' as electronically held sequence information which represents the biological composition of 'genetic material' as defined under the [CBD]" (Australian Government 2018, p 2).

And:

"Australia continues to consider digital sequence information on genetic resources (or any term used, including but not limited to genetic sequence data or in silico) and the physical genetic resources and material ***as distinct entities****. Australia also considers digital sequence information on genetic resources (or any other such terminology) and 'derivatives' as defined under Article 2 of the Protocol as distinct entities" (Australian Government 2019, p 2).*

To consider DSI a "genetic resource" under the CBD and the Nagoya Protocol, the Commonwealth asserts, would require a renegotiation of the CBD and the Nagoya Protocol to redefine "genetic material" noting information does not contain "functional units of heredity" or genes. The Commonwealth's position, however, does not necessarily reflect Queensland's approach or affect Queensland's jurisdiction over its own land and resources.

Queensland's ABS legislation and DSI

Queensland's ABS scheme under the *Biodiscovery Act 2004* (Qld) applies to the taking and using of "native biological resources" on or in "State land or Queensland waters" for "biodiscovery" (s 3). "State land or Queensland waters" include only government held and controlled lands, waters and seas, and

expressly excludes private freehold lands and waters, and native title determinations granting rights of exclusive possession to certain lands, waters and seas (s 5 and schedule). The taking of minimal quantities of native biological resources by an educational institution or for non-commercial purposes is not regulated (ss 10 and 54). The taking of native biological resources for commercial purposes requires a collection authority together with an approved biodiscovery plan and a benefit-sharing agreement (ss 10, 11 and 17). Any monetary and non-monetary benefits are determined as terms and conditions of the benefit-sharing agreement (ss 34 and 35).

The *Biodiscovery Act 2004* (Qld) regulates the taking of native biological materials for research or commercialisation (s 10) and *does* address DSI. The relevant definitions are:

"biodiscovery" means "(a) biodiscovery research; or (b) the commercialisation of native biological material or a product of biodiscovery research" (s 5 and schedule).

"biodiscovery research" means "the ***analysis of molecular, biochemical or genetic information*** *about native biological material for the purpose of commercialising the material" (s 5 and schedule).*

"native biological material" means "(a) a native biological resource; or (b) a substance sourced, whether naturally or artificially, from a native biological resource; or (c) soil containing a native biological resource" (s 5 and schedule).

"native biological resource" means "(a) a non-human living organism or virus indigenous to Australia and sourced from State land or Queensland waters; or (b) a living or non-living sample of the organism or virus" (s 5 and schedule).

"sourced, from native biological material", means "(a) produced by, or extracted or otherwise ***derived from, the material****; or (b) synthesised from the material" (s 5 and schedule).*

It is apparent from these definitions that DSI is included, as sequences are derived and thus sourced from the biological materials. "Biodiscovery research" includes "the analysis of … genetic information" (s 5 and schedule). DSI could be addressed through access to the "native biological material" as a term or condition of the collection authority (ss 11, 14 and 17), as a term or condition of the benefit-sharing agreement (s 33) or as a part of the compliance code for taking "native biological material" (s 44).

Significantly, however, DSI is only covered that has been derived from the physical biological materials that are accessed. According to this statutory formulation, DSI not derived directly from the material is not a resource in its own right and is not covered by the scope of the legislation. A review of the Queensland law in 2016 indicated that the definition of "native biological material" did not include DSI and recommended that the definition be amended to include DSI (Queensland Government 2016, pp 77-78). In response, the Queensland Government is considering extending the definition of "native biological material" to include the data, information or sequences (Queensland Government 2018b, p 12). The Queensland Government response noted that the Commonwealth considers DSI to be a distinct entity from tangible physical genetic resources and materials and that DSI does not contain functional units of heredity or genes (Queensland Government 2018c, p 28).

Queensland's model benefit-sharing agreement currently includes DSI within the scope of "product" in the context of a product of biodiscovery, where intellectual property rights over data derived from native biological material are to be obtained. The definition provides:

"… anything (physical or non-physical, for example, ***data including sequence information****) in relation to which* ***property rights (including Intellectual Property rights) which incorporates, is created, produced, extracted or derived*** *from the Native Biological Material"* (Queensland Government 2018c, p 28).

The Queensland Government has recently introduced amendments to the *Biodiscovery Act 2004* (Qld) addressing traditional knowledge. The term "traditional knowledge" is not defined and will be developed

Table 1: Overview of ABS laws in Australia.

Jurisdiction		Commonwealth	Australian Capital Territory	New South Wales	Northern Territory	Queensland	South Australia	Tasmania	Victoria	Western Australia
ABS specific legislation	Lands (including waters)	✓	✓	-	✓	✓	-	-	-	✓
	Seas	✓	-	-	✓	✓	-	-	-	✓
ABS specific policy		✓	-	-	-	✓	-	✓	✓	-
ABS specific administration (permitting agency)		✓	✓	✓	✓	✓	✓	✓	✓	✓
Reach of ABS specific legislation	Public lands and waters	✓	✓	-	✓	✓	-	-	-	✓
	Private lands, waters and seas	-	-	-	✓	-	-	-	-	-
	Overlap with Indigenous lands, waters and seas	✓	✓	-	✓	✓	-	-	-	✓
	Overlapping with other schemes	✓	✓	-	✓	✓	-	-	-	✓
Reach of related non-ABS legislation	Lands and waters	✓	✓	✓	✓	✓	✓	✓	✓	✓
	Seas	✓	-	✓	✓	✓	✓	✓	✓	✓
Focus of ABS specific legislation and policy	Tenures (eg. area of land, water or sea)	✓	✓	-	✓	✓	-	✓	✓	✓
	Resources (eg. native plants)	-	-	-	-	-	-	-	-	-
Includes mention of DSI in ABS legislation		-	-	-	-	✓	-	-	-	-
Could include DSI derived from accessed physical materials		✓	✓	✓	✓	✓	✓	✓	✓	✓

in a proposed "traditional knowledge code of practice" at some time in the future. These amendments and proposed code do not obviously impact on DSI.

Conclusions

The Commonwealth considers DSI and physical genetic resources and material to be distinct entities and that DSI is not covered by the CBD and the Nagoya Protocol. Queensland has adopted a different approach to DSI, which only applies to commercial bioprospecting. The Queensland Government is considering extending the definition of "native biological material" to include the underlying data, information or sequences. The Queensland Government's current model benefit-sharing agreement expressly includes DSI within the scope of "product" in the context of biodiscovery. At present, only DSI and other information created, produced, extracted or derived from the accessed physical materials for commercial purposes is captured by Queensland's legislation. In Australia, the quintessential example where DSI is accessed from a database and used in isolation from the physical resource is not covered by any of Australia's ABS legislation, including Queensland's *Biodiscovery Act*. This means that access to DSI and its use to derive some benefit (such as manufacturing and selling a vaccine developed using only the DSI) is not the subject of any benefit-sharing obligations *unless* expressly negotiated in an access permit or benefit-sharing agreement when physical material is accessed. In short, DSI is *not* treated as a "genetic resource" as defined by the CBD in Australia's Commonwealth, State and Territory legislation, including in Queensland, but may be subject to benefit-sharing obligations, expressly recognised in Queensland, as arising from the utilization of a genetic resource in certain circumstances.

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Annex C: Case Study: CONAGEBIO (Costa Rica) permitting and contractual approach to control DSI benefit-sharing

Jorge Cabrera Medaglia[154]

Costa Rica's legal framework on ABS stems from the Biodiversity Law No. 7788 of April 30, 1998 (BL), published in the Official Gazette No. 101 of May 27, 1998. Presently, there is a 'General Access Procedure' (GAP) Decree N°31514-MINAE, of December 2003 that functions as one of the bylaws of the BL. Additionally, the regulations for access to genetic resources found in *ex situ* conditions were approved by Decree No. 33677-MINAE of 27 April 2007. These two decrees were recently amended by Decree No 41591-MINAE of May 2019. Finally, the decree 39341-MINAE establishing the procedures for the imposition of sanctions for illegal access was approved in 2015. The legislation and amendments are available on the ABSCH.

The Biodiversity Law states that all research or bioprospecting programs on the genetic or biochemical material of biodiversity that are to be carried out in Costa Rican territory require an access permit, unless they fall into one of the exceptions provided by Article 4 of the Biodiversity Law of 1998. These exceptions include: access to human genetic resources; the non-profit exchange of genetic and biochemical resources and the associated traditional knowledge of indigenous peoples and local communities; and research by Costa Rican public universities, which had one year (until 7 May 1999) to establish their own controls and regulations for research that involves non-profit access to biodiversity. If none of these exceptions apply, all sectors (pharmaceuticals, agriculture, plant protection, biotechnology, ornamental, herbal etc.) that wish to access genetic or biochemical components are subject to the Law and must follow its access procedures. The access regulations apply to genetic and biochemical resources on public or private lands, in terrestrial or marine environments, under *ex situ* or in situ conditions, and in indigenous territories.

The Biodiversity Law created the National Commission for the Management of Biodiversity (CONAGEBIO) as the Competent National Authority in Costa Rica, to propose policies regarding access to genetic and biochemical elements of biodiversity and related traditional knowledge that ensure proper scientific use and technology transfer and the fair and equitable sharing of benefits arising from access. The Commission reports to the Ministry of the Environment and Energy and it is the National Focal Point on ABS under the CBD. It acts through a Technical Office (TO) as the entity that processes, approves or rejects, and monitors, access-related activities.

Since 2004, Costa Rica has granted access to genetic and biochemical resources through more than 650 permits, and several ABS agreements have been negotiated with private companies, universities, farmers, and national and international research centres.[155] Two commercial permits have been granted by CONAGEBIO. One in 2016, to the cosmetics company Chanel, which developed "Blue Serum" using biochemical components of Costa Rican green coffee; and the second one to Lisanatura, a Costa Rican company, which produced a cough syrup using organic plants and which shares benefits with a rural cooperative. Most of these agreements have been concluded by the National Biodiversity Institute (INBio, a non-governmental organization) which has over 28 years of experience targeting the systematic search for secondary metabolites and products of commercial interest. INBio has implemented numerous projects involving processes for the extraction, isolation, fermentation, and characterization of compounds of interest in the pharmaceutical, agrochemical, and biotechnological industries.

[154] Professor, University of Costa Rica and International consultant on ABS. Participated in the drafting of the Biodiversity Law of Costa Rica and has served as a legal adviser for research institutions and other organizations seeking access permits in the country.

[155] CONAGEBIO, Costa Rican ABS Legal Framework, PowerPoint presentation prepared for a visit of a Delegation from Vietnam, dated August 2019

DSI in Access Permits and Contracts.

The Government of Costa Rica, through the TO, has indicated that DSI is covered under the BL's definition of access to genetic resources.[156] It also indicated that DSI for non-commercial research is facilitated (in practice it is unregulated; no PIC and MAT are required) but that benefit-sharing for commercial uses of DSI should be established, perhaps through the Global Multilateral Benefit-Sharing Mechanism (GMBSM) under discussion by the CBD COP. The specific criteria for the differentiation between commercial and non-commercial use is not clear.

The CONAGEBIO TO is also authorized to impose restrictions and prohibitions in permits on the further dissemination or deposit of genetic information in public databases to avoid the loss of control over DSI resulting from authorized access to genetic or biochemical resources. For example, granted permit No. PermitR-CM-089.2010-OT of 9 January 2010, contains the following restriction:[157]

> "*For the DNA (genetic material) extracted from the requested genetic resources the Technical Office of CONAGEBIO restricts the publication of complete/full genomic information on the national and international databases, meaning that the entire genomes cannot become public, only the information related to molecular markers. Likewise, before publishing the sequences of DNA of the molecular markers developed or used for project purposes, the applicant shall inform the TO in advance and later submit the accession number of the sequences".* (Unofficial translation)

The TO has also indicated that other restrictions related to the dissemination, deposit, or publication of genomes or gene sequences could be imposed in an access permit, the exact terms of which could vary on a case-by-case basis.[158] In addition, the TO periodically checks publications, etc. to see if Costa Rican DSI is being disclosed/deposited.

INBio's practices in relation to ABS contracts also illustrate how DSI related matters may be integrated and regulated under MAT in Costa Rica. For instance, in the ABS agreement between INBio, the University of Michigan (U-M), and Harvard University (one of the International Cooperative Biodiversity Groups), the following clauses were included in the research collaboration agreement (RCA) negotiated for the project "Discovery of Natural-product based Drugs and Bio-energetic Materials from Costa Rica Biota:"

> "*INBio will manage the data related to Samples, Isolates, Extracts, Fractions, and DNA pursuant to its activities under the Statement of Work using its databases; however, each of Harvard and U-M shall be permitted to maintain, in parallel with INBio, data sets that wholly or partially overlap the body of data that is managed by INBio*.
>
> *Harvard shall manage the information related to the Research in its databases and shall coordinate with U-M any information that needs to be transferred to NAPIS. Additionally, Harvard shall maintain information updated as long as there is work performed with the Materials.*
>
> *Data generated by the Parties in performance of Screens, such as structures and activities of Chemical Entities, will be deposited in ChemBank by U-M with prior notification to-, and written consent by-, INBio and Harvard. In case a third party has a commercial interest in such information, Harvard, U-M and INBio will require them to negotiate and enter into agreements with Harvard, U-M and INBio*".

[156] Costa Rica, survey response.

[157] On file with the author.

[158] Interviews cited in Cabrera Medaglia, Jorge, ABS in Costa Rica: legislation and practice, unpublished paper prepared for the University of Bremen, August 2019.

In such situations, INBio is the user of the genetic resources (acting here as an intermediary to Harvard and U-M) and the TO of CONAGEBIO as the CNA grants or denies the applications submitted by INBio. In accordance with the national legislation (BL and in situ decree of 2007) all access contracts like this one must be approved by CONAGEBIO. Moreover, the RCA was actually endorsed/approved as part of the permit granted by the TO of CONAGEBIO to INBio. The process of revision of the contracts is covered by a confidentiality agreement with the staff of CONAGEBIO.

Annex D: Case Study: Established practice of institutions involved in the collection, transfer and use of biological material/genetic resources: The role of MTAs in the production and publication of DSI – "The Future Okavango" case

Elizabeth Karger

Introduction

This case study[159] examines material transfer agreements (MTAs) used to deal with the cultivation, isolation, deposit, and production of gene and genome sequences (with a focus on the latter) from microbes sourced from Namibia for the non-commercial research project "The Future Okavango".[160] The beginning of the project pre-dates the entry into force of the Nagoya Protocol on 12 October 2014 and the adoption of the legislative ABS framework in Namibia in 2017. Nevertheless, the case demonstrates the established practice of two leading scientific institutions, namely the National Botanical Research Institute (NBRI)[161] in Namibia and the Leibniz Institute DSMZ-German Collection of Microorganisms and Cell Cultures (DSMZ)[162] in Germany, which is a registered collection under the EU Regulation.

"The Future Okavango" and the Material Transfer Agreements for the export of biological material from the Republic of Namibia for scientific purposes

During "The Future Okavango" project, scientists from the DSMZ collected soil samples in Namibia on several occasions between 2011-13 for the purpose of investigating the influence of land use on bacteria and soil fertility. At the time the sampling was conducted, there was no ABS legislative framework in Namibia and the NBRI was the Namibian authority responsible for signing MTAs dealing with the export of Namibian genetic resources for scientific or commercial purposes.[163] However under Namibia's new ABS legislation,[164] that responsibility is being shifted to a unit at the Ministry of Environment and Tourism (MET).

In order to export the soil samples from Namibia, and subsequently isolate microorganisms and characterize new isolates as part of "The Future Okavango", a number of steps were necessary, including obtaining permits to conduct the project and work in Namibia as well as a series of MTAs. The MTAs make specific reference to benefit-sharing and as such might be regarded as a combination of a MTA and mutually agreed terms (MAT). They will be referred to here only as MTAs.

The first MTA (MTA1), which was signed while the scientists were still in Namibia, provides that:

- the use of the material, progeny and any derivatives is **limited to non-commercial research**;

[159] For the purpose of the study, three interviews were conducted.

[160] The "Future Okavango" was a large interdisciplinary, multi-institutional project aimed at promoting sustainable resource use in the Okavango delta in the face of climate change and land use conflicts. The project ran for a period of 5 years from 2010 and 2015 and was funded by the German Federal Ministry of Education and Research (Bundesministerium für Bildung und Forschung, BMBF). As one part of the project, the DMSZ investigated the influence of bacteria on soil fertility in the context of different land uses with the aim of developing recommendations for land management. It was a follow up to the non-commercial research project "Biota Africa", which was also funded by BMBF and involved DSMZ.

[161] The NBRI is a subdivision of the Namibian Directorate of Agricultural Research Training of the Ministry of Agriculture, Water and Forestry.

[162] The DSMZ is a large collection of biological resources located in Braunschweig, Germany. It holds more than 50,000 items, including bacterial and fungal strains, human and animal cell lines, plant cell lines, plant viruses and antisera, and different types of bacterial genomic DNA. It is also a non-commercial research institute.

[163] http://www.nbri.org.na/sites/default/files/NBRI MTA Scientific Research 1-1.pdf and http://www.nbri.org.na/sites/default/files/NBRI MTA commercialization-1.pdf

[164] *Access to Biological and Genetic Resources and Associated Traditional Knowledge 2017, Act 2 of 2017*. See: https://namiblii.org/akn/na/act/2017/2.

- **benefit-sharing** is **required**, including the **sharing of research results** and **copies of papers** as well as the **acknowledgement of the NBRI as the source of the material**;
- **commercialization**[165] of the material, progeny and any derivatives is **prohibited** unless NBRI's permission is first granted in writing;
- **transfer** of the material, its progeny or derivatives to third parties is **prohibited** unless NBRI's permission is first granted in writing; and
- the material is provided without prejudice to any other requirements to obtain **prior informed consent (PIC) or share benefits**.

The schedule of MTA1 includes a list of the soil samples collected together with their unique identifiers and the purpose for which the samples are to be used. The schedule includes, for example, that sample "JO-2011/2-LN1", which was sieved soil from Mashare/Okavango region, was collected for **16S rRNA and mRNA analysis**[166] of the soil biota diversity. The 16S rRNA analyses were used for initial identification of the bacterial isolates.[167] Using the 16S rRNA gene sequences is considered to be a gold standard for the taxonomic identification of microbes and is a widely used method.[168] Microbes are invisible, making taxonomic identification through the use of sequences particularly important as there is no way of identifying them according to morphology as with plants and animals. DSMZ's catalogue, which shows the microbes, cell lines etc. available for purchase [169] indicates that the 16S rRNA sequences have since been published in GenBank. The GenBank accession numbers are also provided, which enables the direct linkage of the genetic resource to the sequences and vice versa[170]. The availability of the sequences in the database does not necessarily mean they will be used for commercial purposes or patented. 16S rRNA gene sequences, for example, are used for the purpose of identification, provide information on the distribution of microbes and do not contain functional information. They are not known to have any commercial value. Irrespective of the presence or lack of potential commercial value, once published in GenBank and other databases, use of the data by commercial actors cannot be excluded as the sequences are freely accessible. Neither the parties to the contract nor the competent national authorities will likely be able to monitor the use of the published data.

Once several bacteria of interest were isolated from the samples, purified and characterized, a second MTA (MTA2[171]) was negotiated with the NBRI to amend the conditions of MTA1 and allow deposit of the bacterial isolates into two public culture collections, [172] i.e. DSMZ and another collection in Belgium, [173] and to allow further transfer of the material from these collections to third parties for scientific purposes. The International Code of Nomenclature of Prokaryotes [174] (the Bacterial Code)

[165] Commercialization includes but is not limited to sale, filing a patent application, obtaining or transferring intellectual property rights or other tangible or intangible rights by sale, license or in any other manner, commencement of product development, conducting product development, conducting market research and seeking pre-market approval.

[166] These sequences have been subsequently published in GenBank.

[167] EK, anonymous interview, 31.05.2019.

[168] Keller, P.M., Hombach, M., Blomberg, G.V. 16S rNA-Gen-basierte Identifikation bakterielle Infektionen. BioSpektrum. 7(10). pp. 755-788.

[169] Link to catalogue: https://www.dsmz.de/catalogues/catalogue-microorganisms.html

[170] For example, https://www.dsmz.de/collection/catalogue/details/culture/DSM-29891 and https://www.ncbi.nlm.nih.gov/nuccore/KP638489. The metadata fields in the GenBank entry indicate the genetic source of the sequences.

[171] Available for download in the DSMZ's catalogue.

[172] Type strains of microbes must be deposited in at least two separate publicly accessible collections in two or more countries for valid strain description. These collections must be able to distribute these strains to third parties for scientific purposes.

[173] Belgium Co-ordinated Collections of Micro-organisms/Laboratorium voor Microbiologie, Universiteit Gent (BCCM/LMG).

[174] http://www.the-icsp.org/bacterial-code.

requires that microbes be deposited in two separate culture collections in two different countries when new species are identified and formally described. The new MTA was necessary for the DSMZ scientists to be able to publish their work and describe the new bacterial species identified in Namibia. The Bacterial Code also requires sequencing of the 16S rRNA gene in order to provide evidence of the taxonomic identity of the new organism. MTA2:

- **identifies** the relevant strain numbers, where the samples were collected and the sample number;
- provides that the strains may only be **made available to third parties under user agreements** that are (at least) as **restrictive** as the relevant conditions of the MTA;
- requires the collections to **notify NBRI** if these strains are made available to third parties;
- limits the use of the strains to **scientific purposes**; and
- **excludes** use for **commercial purposes – including genome sequencing**.

The restrictions on the use of the material and genome sequencing are found in **clause 9**, which provides:

> *"The **research of the strains** made available by the respective culture collections*[175] *to further users under this agreement (clause 8) shall be **limited to scientific purposes**. And **use for commercial purposes – including genome sequencing** – or any use for commercial applications **is excluded and requires prior written consent from the NBRI**". [emphasis added]*

In 2016 and in the context of a planned follow up project to The Future Okavango,[176] scientists at DSMZ together with partners in Namibia obtained permission from MET to conduct **full genome sequencing** of several of the strains for non-commercial purposes on the basis of a permit. This permit was obtained to avoid any potential legal uncertainty based on clause 9.[177] The permit, which is not publicly available in DSMZ's catalogue:

- **identifies** the phylum of strains (Acidobacteria) for which **full genome sequencing is permitted**;
- makes reference to the **previous MTAs** that apply to the strains; and
- provides that the specimen may only be used for the **purpose of the study**;
- requires **duplicates of publications or reports** to be made available to the MET; and
- **prohibits patenting or commercialization** of the specimens and their derivatives without the prior consent of MET.

DSMZ's internal measures - complying with the MTAs and the standards required of registered collections

In order to fall under the compliance measures of the EU Regulation, genetic resources must have been accessed **in-situ** on or after 12 October 2014 and must be collected from a Party to the Nagoya Protocol in which ABS legislative or regulatory requirements apply. Thus, the bacteria covered by the MTAs in the Okavango case actually fall outside the scope of the EU Regulation. Nevertheless, the information relating to the Namibian bacteria is displayed in the catalogue as part of a wider release of relevant information that took place during the process of becoming a registered collection. The DSMZ did this because compliance with domestic requirements in countries providing genetic resources is nonetheless necessary, despite these resources falling outside the scope of the EU Regulation. All documents relevant for Nagoya Protocol compliance, including PIC, MAT, Internationally Recognised Certificates of

[175] DSMZ and BCCM/LMG.

[176] *Whole-genome sequencing of Acidobacteria strains isolated from Namibia soils in Kavango East and Kavango West regions.*

[177] EK, anonymous interview, 31.05.2019.

Compliance (IRCC) and/or additional (depositor-originated) MTAs are provided in the DSMZ's catalogue. In the case of the Namibian bacterial strains, this means MTA1 and MTA2 are listed with the strains and available for download. The bacterial strains typically are ordered either online or by mail/fax through the DSMZ's catalogue and purchase of the strains is subject to DSMZ's distribution MTA[178] and "Terms and Conditions"[179], which describe the customer's obligations with respect to the material. These include:

- **commercial use** of the material **is prohibited** without further permission of DSMZ;
- for material to which **Nagoya Protocol obligations** apply, the **customer is required to adhere to the conditions** in the associated documents, **including PIC and/or MAT**, which are provided in the catalogue;
- **information** available in the catalogue has to be **downloaded and kept** for 20 years;
- **transfer** of the material to third parties **is prohibited** without further permission of DSMZ and in cases where transfer of the material is permitted, it must be **accompanied by these documents**. Furthermore, it indicates that transfer of the material **in absence of the PIC/MAT** is a **punishable offence** under German law; and
- notice that a **contract penalty** (1000 Euros) applies and additional **claims for additional damages** may arise in the case of intentional, culpable or unapproved commercial use of the material.

For the Namibian strains, the following notice is included in the catalogue:

> *"Documentation related to the Convention on Biological Diversity and the Nagoya Protocol.* ***Users must download, read, and adhere to the terms listed in the document(s) listed here.*** *Users are legally required to* ***maintain records*** *of these document(s) for 20 years after the last use of the resource.* ***Genome sequencing is not permitted on this strain without prior written approval*** *from the Namibian competent national authority, NBRI".*

Customers must agree to the DSMZ's terms and conditions and sign the DSMZ user MTA, which means they download and read the documents, in this case MTA1 and MTA2, as well as agreeing to comply with them. In cases of suspected non-compliance, the collection would inform the relevant competent authority, the German Federal Agency for Nature Conservation (Bundesamt für Naturschutz, BfN), and could take steps in private contract law.

Clarity of MTA terms

It could be argued that based on the wording of clause 9 in MTA2 (see above), two different and contradictory interpretations are possible. Genome sequencing is only mentioned in the context of commercial research and it could be argued that full genome sequencing is to be understood as commercial research and is therefore prohibited without further permission from NBRI[180]. This is the interpretation taken by DSMZ and reading all two MTAs and permit from MET together would seem to support this interpretation. However, genome sequencing is done regularly in the context of non-commercial research, which could realistically lead to scientists having an alternative understanding of the clause, i.e. that research for "scientific purposes" includes sequencing for non-commercial purposes, although the reference in the catalogue to the prohibition on genome sequencing might alert these customers to the relevant restriction. It is arguable that the "correct" interpretation of the clause is not

[178] https://www.dsmz.de/fileadmin/Bereiche/ChiefEditors/Forms/Neu16/Order_Form_DSMZ_E-Mail_Terms_Condition.pdf (see page 2).

[179] https://www.dsmz.de/terms.html.

[180] EK, Interview with Winter, Gerd, Universität Bremen,13.06.2019; EK, anonymous interview, 17.06.2019.

clear and in the case of a legal dispute, ultimately a judge would make the decision on which interpretation is correct. As customers usually order strains through the online catalogue, there is not necessarily any direct contact between DSMZ staff and customers to clarify the restrictions in place. Despite the apparent lack of clarity in the language used in MTA2, these clauses have been used as model clauses by other scientists and institutions[181].

DSMZ's Terms and Conditions

The DSMZ has taken a highly transparent and accountable approach to handling the bacteria obtained from Namibia. DSMZ's Terms and Conditions, user MTA, and public catalogue are the main instruments for ensuring that the customers comply with both the DSMZ's requirements and that the conditions in MTA1 and MTA2 are transferred to third parties. It is not possible to know whether the customers read the conditions of the documents, but in any case, before receiving the microbes, they will have signed that they have read them, will agree to them, and agree to store documents for 20 years.

The role of the collection is to support customers with the receipt of the relevant documentation but not to perform compliance checks. The collection does not have the legal mandate or resources to actively monitor the activities of its customers (thousands per year), who are located around the world. In order to discourage potential non-compliance, DSMZ uses the contract penalty mentioned above. These mechanisms were approved by the BfN as being sufficient for a registered collection.

Publication of DSI

No explicit mention is made of the publication of the sequences in the MTAs or MET permit. It is stated that the results and publications have to be shared with NBRI (MTA1/2) and MET (permit) and the Namibian authority is to be acknowledged as the source of the material. This implies that the provider of the genetic material has assumed that publication will occur. In any case, there are no explicit restrictions on the publication of the 16S rRNA gene sequence (MTA1/2) and full genome sequences (MTA3). To ensure traceability, the DSMZ refers to the sample numbers, the unique identifiers allocated to the strains, the permits issued by the Namibian government and the relevant MTAs in its publications[182].

Conclusion

This case study provides an example of measures adopted by leading institutions, including a registered collection in the EU, involved in the exchange and use of microbial biological resources to address the production and use of DSI. It highlights the constraints on the bilateral measures, such as MTAs when dealing with DSI. MTAs were the central measure for ensuring transparency, traceability and for handing on conditions and restrictions on the use of material, including restrictions on commercialization of the material and sequencing. More clarity in drafting the MTA would be necessary to ensure the wording of the relevant clause and restrictions are unambiguous and clearly understood by all actors. The restrictions in the MTAs make sense for identifiable actors who are in possession of the physical material and who are bound by the terms of these agreements. A significant challenge could arise from the publication of the sequences and use of these sequences by unknown third parties as the contracting parties cannot ensure that Namibia's restrictions on the commercial use of the sequences are adhered to.

[181] EK, anonymous interview, 31.05.2019.

[182] Ibid.

Annex E: Case Study: Using clauses in ABS contracts and MTAs to regulate further uses of DSI from African (multi-country) livestock genetic resources

Hartmut Meyer

1 Project information

The Centre for Tropical Livestock Genetics and Health (CTLGH) is a strategic alliance of the International Livestock Research Institute (ILRI), the Roslin Institute at the University of Edinburgh, and Scotland's Rural College. CTLGH supports programs that improve livestock-based livelihoods in the tropics. In one of its projects, the dairy genomics program, it seeks to produce a collated set of sequence and genotype information on cattle breeds in Africa.[183] In the initial phase begun in 2017, raw genomic data of 25 African cattle breeds with sequence information on at least 10 individual animals per breed was targeted to be produced. This data is being generated, in part, through research on blood samples (genetic resources) accessed in various African countries. The raw genomic data will be archived in major public sequence databases (NCBI www.ncbi.nlm.nih.gov and EMBL-EBI www.ebi.ac.uk). It is intended that the raw data will be used by the African and the international research community in cattle genomics for the ultimate benefit of African livestock keepers, other livestock value chain actors and consumers. The program is funded by the Bill and Melinda Gates Foundation and the CGIAR Research Program on Livestock and Fish.

The access to genetic resources in this program initially took place in 13 African countries. Depending on the legal situation, ILRI entered into negotiations on PIC and MAT with the provider authorities as determined by national ABS regulations or agreed on specific MTAs with public institutions as owners of the genetic resources as per ILRI's institutional access and research policy.[184] DSI-related features of some of the agreements are described below.

2 Contractual agreements[185]

2.1 Material Transfer Agreement in the absence of legally binding ABS regulations

In six countries without ABS regulations in force at the time of access, MTAs were agreed upon by the providers (national universities and national agricultural research stations) in 2017 and 2018. The ILRI-developed MTA does not deal with DSI explicitly, but with research results in general. The purpose of the MTA is to set the legal obligations for the project partners governing the utilization of genetic resources and the handling of research results and data. The DSI-relevant clauses are:

> *4.1 ILRI is committed to global accessibility of its Publications, data, audiovisual materials and all information products as international public goods (IPGs) in line with CGIAR and ILRI open access policies.*[186]
>
> *4.2 ILRI acknowledges and accepts that all Intellectual Proprietary rights, including but not limited to patent rights in and to the Material and associated Data accompanying the material at the time of transfer ("Intellectual Property Rights") are and shall at all times remain vested in the provider absolutely. [emphasis by the author]*

[183] ILRI, Genomics Reference Resource for African Cattle: An Initiative of the Dairy Genomics Program of the Centre for Tropical Livestock Genetics and Health. ILRI Project Profile. (Nairobi: ILRI, 2016), available at: https://cgspace.cgiar.org/handle/10568/77173.

[184] ILRI, ILRI Research Contract Template 6: Materials Transfer Agreement, available at: https://cgspace.cgiar.org/handle/10568/80148.

[185] The analysed contractual agreements were made accessible to the author with the consent of the parties to the agreements.

[186] More information at: https://www.ilri.org/open.

4.3 ILRI undertakes not to assert or permit anyone else to assert or claim any right of ownership whatsoever in the Intellectual Property Rights, whether directly or indirectly.

The MTAs contain benefit-sharing clauses with regard to public access to the generated data and the production of open access publications. This is understood as public benefits arising from the research project, based on ILRI policies on open access and IP rights. According to the MTA, DSI produced through the research will be made publicly accessible in open access databases. Once in such databases, the partners of the MTA effectively have no control over the utilization of the DSI by third parties. This suggests that it will be very difficult to prevent others from asserting IP rights, specifically patents, on processes and products resulting from DSI utilization.

2.2 ABS contract based on legally binding national ABS regulations

In one country with ABS regulations in place at the time of access, a specific ABS contract was negotiated with the provider authority in 2018. The contract does not mention DSI explicitly but contains general clauses on research results that would include DSI. Such DSI-related clauses are:

Any Modifications[187] *generated shall be jointly owned by the Recipients except to the extent that such Intellectual Property Rights contain any of the Materials.*

In the event that Intellectual Property Rights arise from the study of the Materials by the Recipients and Provider, such Intellectual Property Rights will be jointly owned ("Joint IP") by the Recipients ("Joint Owners").

The Recipient(s)will conduct and manage any resulting outputs in a manner that ensures Global Access and rapid dissemination to people most in need in developing countries. Global Access commitments will survive the term of this Agreement. [emphasis by the author]

Any publication arising out of the study of the Materials for the Project shall be a joint publication by the Recipients and shall be published on an 'open access' basis. Publication shall only proceed after any identified new Intellectual Property has been appropriately protected. To this end, ILRI agrees to provide notice in writing to the Provider and (CNA), in not less than sixty (60) days before a Recipient files a copy of application for a patent or other intellectual property protection resulting from use of transferred Material by the Recipients. [emphasis by the author]

The contract includes the generation of public benefits through open access publication and public access to data. The strategy behind these clauses, which also cover DSI, seems to be that any possible IP rights are secured before open access to research results and data is made possible in order to preclude other users from securing IP rights. However, it remains unclear how this strategy would work in practice, especially in the context of projects and institutions which do not have commercial goals and are unlikely to produce patent-protected outputs. Moreover, it is not designed to prevent the patenting of non-obvious and lucrative products created by commercial entities from utilization of the open access DSI.

2.3 Negotiations on consortium agreement with 13 countries

ILRI also is undertaking negotiations on a consortium agreement with up to 13 countries, seven of which have an ABS framework in place. The providers are either the appointed governmental authorities or public research institutions. The purpose of this approach is to develop a common contract for all providers of genetic resources. Paragraph XI b. of this consortium agreement explicitly covers DSI when referring to "genomic information". The DSI-relevant paragraphs are:

[187] Substances created by a recipient that contain/incorporate/are derived from research specimen, progeny or unmodified derivatives.

XI Publications and Reports

a. Any publication arising out of the Project shall be published only on an 'open access' basis. Publication shall only proceed after any identified new Intellectual Property has been appropriately protected. To this end, the Users agree to provide notice of at least sixty (60) days in writing to the relevant Provider(s) before filing an application for a patent or other intellectual property protection resulting from use of transferred Genetic Resource.

b. The Users will ensure acknowledgement of all contributors to the Project with a list maintained on the data portal. Genomic information submitted to public sequence databases will be jointly attributed to the African partner involved in generating that sequence information and CTLGH.

...

XII Intellectual Property Management for Global Access & Benefit-sharing

a. It is here declared that the purpose of this project is to create knowledge and to transfer the intellectual property so harnessed to other parties, as long as such transfer shall be beneficial to environmental management, livelihoods, product development and industrialization, among other useful endeavours.

b. The Provider Countries shall be given first priority for accessing intellectual property assets developed as a result of this project.

c. The Users shall conduct and manage any resulting outputs as international public goods in a manner that that ensures Global Access and rapid dissemination to people most in need in developing countries. Global Access commitments will survive the term of this Agreement.

d. Neither the User nor the Provider shall apply for intellectual property protection over the research results or product, method, data or information or any innovation emanating from the use of the genetic resources thereof without consent of either party

…

The implications of these clauses are essentially the same as described in 2.1 and 2.2.

Several DSI-related conclusions can be drawn from these three contractual approaches. First, non-governmental entities are creating and using clauses which commit them to address DSI utilization in certain ways. These actions can be seen as a type of voluntary code of conduct. One such clause requires the source of DSI to be associated with sequence data in open access databases. Some clauses also call for global access to outputs of research and non-monetary benefit-sharing in the form of open access distribution of DSI. In addition, for this project in particular, the facilitation of capacity building of African researchers in the field of genomics could be regarded as an intrinsic benefit of the dairy genomics program. Against the background of the emerging DSI discussions, it is apparent that approaches developed to make DSI available in the context of an open access policy are in conflict with policies that seek to deal with DSI in the same way as with "physical" genetic resources. The intention to regulate DSI through legislation and contractual agreements while securing access to DSI will be a main issue in the forthcoming negotiations.

Annex F: Case Study: India as an example of incorporation of DSI and DSI-related subject matter as a matter of interpretation of existing legal terms

Prabha Nair

The Biological Diversity Act, 2002 (BDA) and the Rules and Guidelines enacted thereunder, provide for domestic measures dealing with access and benefit-sharing in India. Under the Act, regulated activities that would trigger benefit-sharing obligations are:

(i) *obtaining biological resources and associated knowledge*[188] for research[189], commercial utilization[190] and bio-survey and bio-utilization;[191]

(ii) *transfer of the results of research* over biological resources occurring in or obtained from India;[192]

(iii) *obtaining of IP rights in and/or outside India* for any invention *based on any research or information on a biological resource* obtained from India;[193] and

(iv) *third party transfer* of already accessed biological resources[194] under mutually agreed terms with National Biodiversity Authority (NBA).

Terminology

The definition of "biological resources"[195] under the Act primarily relates to tangible components while the term "associated knowledge" is undefined. The Access and Benefit-Sharing Guidelines issued in 2014 describes procedures for accessing biological resources and associated traditional knowledge for research[196] but do not confine the scope of regulatory jurisdiction to associated *traditional* knowledge alone. This leads to the interpretation that associated knowledge can include scientific knowledge too, and that DSI is scientific knowledge relating to biological resources. Research results may also cover DSI generated from accessed biological resources. The NBA regulates the 'transfer of research results'[197] which could include transfer of DSI with benefit-sharing obligations in respect of such transactions. In an interview, an NBA official shared the view that section 4 of the Act regulating transfer of results of

[188] Section 3, Biological Diversity Act, 2002

[189] Ibid Section 2(m) – "Research means study or systematic investigation of any biological resource or technological application, that uses biological systems, living organisms or derivatives thereof to make or modify products or processes for any use". The second part of this definition reflects the definition of biotechnology under the CBD and thus research could be interpreted to mean study or systematic investigation of a biological resource or through biotechnology.

[190] Ibid Section 2(f) –"Commercial Utilization means end uses of biological resources for commercial utilization such as drugs, industrial enzymes, food flavours, fragrance, cosmetics, emulsifiers, oleoresins, colours, extracts and genes used for improving crops and livestock through genetic intervention, but does not include conventional breeding or traditional practices in use in agriculture, horticulture, poultry, dairy farming, animal husbandry or bee keeping". In the broadest sense, one may argue that such end products when made using DSI can also constitute commercial utilization of the knowledge associated with biological resources.

[191] Ibid Section 2(d) – "Bio-survey and Bio-utilization means survey or collection of species, subspecies, genes, components and extracts of biological resources for any purpose and includes characterization, inventorization and bio-assay". This may also include sequencing activities.

[192] Ibid Section 4

[193] Ibid Section 6

[194] Ibid Section 20

[195] Section 2 (c) of the Act defines Biological Resources to mean "plants, animals and microorganisms or parts thereof, their genetic material and by-products (excluding value added products) with actual or potential use r value, but does not include human genetic material".

[196] Regulation 1, ABS Guidelines, 2014

[197] S 4 BDA.

research could restrict the transfer of DSI generated from a physical resource to a non-Indian person or entity.[198]

The 2014 Access and Benefit-Sharing Guidelines prescribe monetary benefit-sharing components in varying percentages in respect of each of the regulated activities. (See Table 1). However, the definition, scope, and extent of the regulated activities have not been subject to judicial interpretation and existing terms of the standard form ABS contracts for the regulated activities described above do not impose any conditions on the generation, use or transfer of DSI.

Intellectual Property Rights

Under the Biological Diversity Act, any person/entity, Indian or non-Indian, intending to obtain intellectual property (IP) rights in and/or outside India for *any invention based on any research or information on a biological resource* obtained from India should secure the prior approval of the NBA.[199] The emphasis hence is on the invention based on research or information on Indian biological resources and not on the inventor having direct access to the biological resources.[200] Since DSI may be treated as information on a biological resource, the NBA may regulate securing of IP rights based on DSI.[201] The NBA monitors the grant of patents in India and abroad by checking published patent applications and granted patents.[202]

Plasmodium vivax *and Oxford vaccine patent application*

In early 2019, the NBA invoked this regulatory power in respect of the Patent Cooperation Treaty (PCT) patent application PCT/GB2017/051391 [published Indian Application No. 201817042343] titled "vaccines" filed by Oxford University Innovation Ltd in the UK[203]. The invention describes the use of two known proteins derived from the nucleotide sequences of *Plasmodium vivax* (*P. vivax*) strains originating from different countries including India. Finding a reference to the sequence of *P. vivax* strain collected from Indian patients in a claim of the application (claim 5), the NBA directed the Indian Patent Office to stop further processing of the application and notified the applicant of the Biodiversity Act provisions. Following this correspondence, the applicant amended the Indian application by deleting all references to the Indian strain. According to the applicant, the nucleotide sequence of the Indian strain was obtained from a 2005 journal publication,[204] the inventor never accessed the Indian strain directly, and the reference to the Indian strain in the specification was just an example of one of the strains that

[198] Interviews were conducted with Dr. T. Narendran and Dr. K. P. Raghuram, Technical Officers of the NBA handling IP rights and Benefit-sharing. They each provided personal views on domestic ABS measures and DSI and their views should not be considered official positions throughout the case study. Both of them shared the view that India's position on regulation of access to DSI through domestic law is still under consideration. S.4 of the Act regulates transfer of research results on biological resources occurring in, or obtained from India to non-Indians, non-resident Indians, non-Indian entities and Indian entities with non-Indian participation in their share capital or management.

[199] S 6 BDA.

[200] This provision is limited to the process of obtaining patents in and outside India and plant variety protection outside India. The Indian Patents Act, 1970 does not explicitly mention the patentability of gene sequences. However, the Manual of Patent Office Practices and procedures, 2011, allows for genetically modified gene sequence/ amino acid sequence that contain claims directed to a gene sequence/ amino acid sequences, a method of expressing the sequence, an antibody against that protein/sequence, a kit containing such antibody/sequence. Section (8.03.07) d.7, Unity of Invention, The Manual of Patent Office Practices and procedures, 2011.

[201] Interview with Dr. T. Narendran, NBA.

[202] Section 18(3) of the *Biological Diversity Act* empowers NBA to oppose the grant of patents in other countries on biological resources obtained from India or knowledge associated with such biological resources which is derived from India. Under section 25 of the Indian Patent Act, 1970, any person may file a pre-grant opposition after publication of the patent application by the Indian Patent Office.

[203] The application principally claims virus-like particles (VLPs) for use as vaccines for the prevention of malaria.

[204] Lim et.al. "Plasmodium vivax: Recent world expansion and genetic identity to Plasmodium simium" in PNAS of October 2005.

could be used in the invention. However, because the patent application was not amended for other jurisdictions, the applicant continues to be in violation of the requirements of the Biodiversity Act in respect of obtaining IPRs.

Although not on DSI per se, the NBA has previously taken the position, in revocation proceedings before the European Patent Office for the Monsanto melon patent,[205] that access to the germplasm of a virus-resistant Indian melon, obtained from a United States Department of Agriculture depository, without approval from the NBA, would amount to a violation of India's Biological Diversity Act.[206] A similar position is also possible in the present case. The NBA may either decide that deletion of the reference in all patent applications would preclude the applicant from access and benefit-sharing obligations or that the inventor should have first secured the approval for access to the sequence for carrying out research and subsequently the patent applicant should have obtained permission for making a patent application.

Analysis

The *P. vivax* case indicates that the Indian National Biodiversity Authority is inclined to consider DSI and DSI-related subject matter broadly as falling under its benefit-sharing and IPR monitoring rules. However, it is also India's position that it is beneficial to make research results in the form of DSI or DSI-related data available through open access databases.[207] At the moment, there are no measures in place to actively seek information on the use of *ex situ* sequence information related to Indian genetic resources. However, a computerized tool called the ABS-Monitoring System (ABS-MS) was launched in India on the International Day for Biological Diversity 2019, and is expected to aid the NBA with tracking the use of Indian biological resources in patent applications and research.

[205] EP1962578 – 'Closterovirus-Resistant Melon Plants' granted by EPO on 4th May 2011.

[206] https://www.ip-watch.org/weblog/wp-content/uploads/2016/01/National-Biodiversity-Authority-India.pdf

[207] India, Submission under Decision 14/20.

Table 1

Benefit-Sharing Percentage for Regulated Activities[208]

S.No	Regulated activity	Provision	Form in BD Rules	Who is regulated	From whom should prior approval be procured?	Monetary benefit-sharing applicable
1	Non-commercial research or research for emergency purpose outside India by Indian Researchers/ Government Institutions Research	Reg 13 of ABS Guidelines Section 3	Form I	Only Non-Indian and non-Indian entities covered under section 3(2)	NBA	BS NOT applicable. Upfront payment for research on biological resources with high economic value
3	Bio-survey & bio-utilization for research	S 3	Form B	Only Indians/Indian government institutions	NBA	BS NOT applicable
4	Bio-survey & bio-utilization for commercial utilization	S 3	Form I	Only Non-Indian & non-Indian entities covered under section 3(2)	NBA	BS NOT applicable. Upfront payment for research on biological resources with high economic value
5	Transfer of research results to a person under section 3(2)	S 4	Form II	Both Non-Indian & non-Indian entities covered under section 3(2) & Indian & Indian entities	NBA	BS 3%-5% of the monetary consideration
6	Obtaining IPR	S 6	Form III	Both Non-Indian & non-Indian entities covered under section 3(2) & Indian & Indian entities	NBA	BS- If applicant commercializes 0.2-1.0% on the annual gross ex-factory sale less government taxes. When commercialised by third party– 2%-5% of the fee received and 2%-5% of royalty
7	Transfer of BR/AK accessed to third party	S 20	Form IV	Both Non-Indian & non-Indian entities covered under section 3(2)	NBA	2%-5% of any amount and/or royalty received from the transferee
		S 7	Form I of the concerned SBB Rules	Only Indian and Indian entities	SBB	Same as above

On Annual Gross ex-factory sale of the product minus government taxes – 0.1% for companies up to Rs.100,000,000 ($1,449,072.00 USD); 0.2% for companies between Rs. 100,000,000 ($1,448,988.74 USD) to 300,000,000 ($4,256,966.47 USD); 0.3% for companies above Rs. 300,000,000 ($4,256,966.47 USD)

[208] Based on ABS Guidelines 2014. The NBA has published a draft ABS Guidelines with revised benefit-sharing percentages for consultation, so these percentages are subject to further. (BS- benefit-sharing)

Table 2

Benefit-Sharing Percentage for Commercial Utilization based on purchase price of biological resources (BR)

Person/ entity to share benefits	Context	Competent Authority	Monetary benefit-sharing component (% of purchase price)
Trader	Direct purchase of BR from local people without prior bs negotiation	NBA/SBB	1.0 – 3.0
Manufacturer	Direct purchase of BR from local people without prior bs negotiation	NBA/SBB	3.0 – 5.0
Subsequent trader	Purchase from the first trader who directly purchased the resources from local people without bs negotiation	NBA/SBB	1.0 - 3.0 (upon proof of bs with immediate seller, percentage corresponding to the difference due)
Subsequent manufacturer	Purchase from the first trader who directly purchased the resources from local people without bs negotiation	NBA/SBB	3.0 – 5.0 (upon proof of bs with immediate seller, percentage corresponding to the difference due)
Applicant	Purchase from trader who has negotiated prior bs with local people	NBA/SBB	Not less than 3%
	Purchase from manufacturer who has negotiated prior bs with local people	NBA/SBB	Not less than 5%

Annex G: Literature Search

Methodology

Papers in this literature search have been selected according to the following criteria: they relate and refer, primarily, to the placeholder DSI (and competing concepts) in the context of access to genetic resources and the fair and equitable sharing of benefits (ABS) principles of the Convention on Biological Diversity (CBD), the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization and other international agreements. Most texts are freely accessible on the internet or available as books, journals or book sections. Works are presented in chronological order to reflect historical context. Finally, the review includes commissioned studies, submissions by a wide range of actors and conceptual works relevant to DSI regulatory/institutional frameworks.

Introduction

There has been limited production of policy, legal and institutional research specifically concerning the development and use of domestic DSI measures and international initiatives dealing with DSI and its relation to ABS *strictu sensu*. However, there are some texts and papers which, to some extent, describe and reflect upon "DSI." Most of these works offer more general legal policy and economic analysis of DSI and ABS. This search compiles selected texts chronologically under three broad sections: studies commissioned by relevant conventions and international bodies; institutional initiatives which describe management and use principles for DSI; and documents reflecting on conceptual frameworks to address DSI from a policy, institutional and regulatory perspective. Documents which refer to competing concepts such as genetic information, natural information, digitally integrated genetic sequences data, genetic sequence data, etc. are also included as they refer to the same phenomenon and existing concerns.

1. Studies commissioned by relevant conventions, organizations and governments

WHO Secretariat (2006), Implementation of the Nagoya Protocol and Pathogen Sharing: Public Health Implications. Available at, https://www.who.int/influenza/Nagoya_Full_Study_English.pdf

Welch, E., Bagley, M., Kuiken, T., Louafi, S. Potential Implications of New Synthetic Biology and Genomic Research Trajectories on the International Treaty for Plant Genetic Resources for Food and Agriculture. Scoping report commissioned by the Secretariat of the International Treaty on Plant Genetic Resources for Food and Agriculture, October 2017. Available at, http://www.fao.org/fileadmin/user_upload/faoweb/plant-treaty/GB7/gb7_90.pdf

Laird, S., and Wynberg, R. Fact Finding and Scoping Study on Digital Sequence Information in the Context of the Convention on Biological Diversity and Nagoya Protocol, Document CBD/DSI/AHTEG/2018/1/3, January 2018. Available at, https://www.cbd.int/doc/c/b39f/4faf/7668900e8539215e7c7710fe/dsi-ahteg-2018-01-03-en.pdf

Karger, E. (2018), Study on the Use of Digital Sequence Information on Genetic Resources in Germany. Scientific and Technical Support in Implementing the Nagoya Protocol. Part 1. DSI. Available at, http://www.biodiv.de/fileadmin/user_upload/PDF/Projekte-aktuell/DSI-Study.pdf

Sollberger, K. (2018), Digital Sequence Information and the Nagoya Protocol. Legal Expert Brief on Behalf of the Swiss Federal Office for the Environment (FOEN). (https://www.bafu.admin.ch/bafu/en/home/topics/biotechnology/law/rechtsgutachten.html).

Heinemann, J., Coray, D., and Thaler, D. (2018), Exploratory Fact Finding Study Scoping Study on "Digital Sequence Information" on Genetic Resources for Food and Agriculture. Commission on Genetic Resources for Food and Agriculture. Background Study Paper No. 68, FAO. Available at, http://www.fao.org/3/CA2359EN/ca2359en.pdf

Perron-Welch, F. (2019), Synthetic Biology and its Potential Implications for BioTrade and Access and Benefit-Sharing, UN Doc. UNCTAD/DITC/TED/INF/2019/12. Available at, https://unctad.org/en/PublicationsLibrary/ditctedinf2019d12_en.pdf

2. International and institutional initiatives addressing DSI

CBD/SBSTTA/22/INF/2/Add.2 CBD/DSI/AHTEG/2018/1/2/Add.2* 26 January 2018. Synthesis of Views and Information on the Potential Implications of the Use of Digital Sequence Information on Genetic Resources for the Three Objectives of the Convention and the Objective of the Nagoya Protocol. Digital Sequence Information in Relevant Ongoing International Processes. Available at, https://www.cbd.int/doc/c/657a/ea3c/76bead7f804634fea1ca0066/dsi-ahteg-2018-01-02-add2-en.pdf

CBD/SBSTTA/22/INF/2/Add.2 CBD/DSI/AHTEG/2018/1/2/Add.2* 26 January 2018. Synthesis of Views and Information on the Potential Implications of the Use of Digital Sequence Information on Genetic Resources for the Three Objectives of the Convention and the Objective of the Nagoya Protocol. Case Studies and Examples on the Use of Digital Sequence Information in Relation to the Objectives of the Convention and the Nagoya Protocol. Available at, https://www.cbd.int/doc/c/7a1d/3057/f5fa0ecb0734a54aadd82c01/dsi-ahteg-2018-01-02-add1-en.pdf

CBD/SBSTTA/22/INF/4 CBD/DSI/AHTEG/2018/1/4* 20 February 2018. Report of the Ad Hoc Technical Working Group on Digital Sequence Information. Available at, https://www.cbd.int/doc/c/7ea1/36b3/7ccf849897a4c7abe49502b2/sbstta-22-inf-04-en.pdf

3. General legal, policy and economic works on DSI

Vogel H.J (2007), From the Tragedy of the Commons to the Tragedy of the Common Place: Analysis and Synthesis through the Lens of Economic Theory. In: McMannis, C. (ed.) Biodiversity and the Law. Intellectual Property, Biotechnology and Traditional Knowledge. Earthscan, London, Sterling, pp. 92-115

Vogel H.J (2008), Nothing in Bioprospecting Makes Sense Except in the Light of Economics. In: Sunderland, N., Graham, P., Isaacs, P., McKenna, B. (eds.) Toward Humane Technologies: Biotechnology, New Media and Ethics. Rotterdam: Sense Publishers Series, 2008. pp. 65-74

Schei, J., and Walloe Tvedt, M. (2010), "Genetic Resources" in the CBD: The Wording, the Past, the Present and the Future. Fridtjof Nansen Institute (FNI Report), Oslo, Norway. Available as UNEP/CBD/WG-ABS/9/INF/1 at https://www.cbd.int/doc/meetings/abs/abswg-09/information/abswg-09-inf-01-en.pdf

Kamau, E., Winter, G., Stoll, T. (eds.) (2015), Research and Development of Genetic Resources: Public Domain Approaches in Implementing the Nagoya Protocol. Routledge by Earthscan. London.

Winands-Kalkuhl, S., and Holm-Muller, K. (2015), Bilateral v. Multilateral? On the Economics and Politics of a Global Mechanism for Genetic Resources Use. Journal of Natural Resources Policy Research 7(4):305-322.

Scott, D., and Berry, D. Genetic Resources in the Age of The Nagoya Protocol and Gene/Genome Synthesis. Report and Analysis of an Interdisciplinary Workshop. Sainsbury Laboratory University of Cambridge. October 2016. Available at, https://www.researchgate.net/publication/324201093_Genetic_resources_in_the_age_of_the_Nagoya_Protocol_and_genegenome_synthesis

Bagley, M. (2017), Towering Wave or Tempest in a Teapot? Synthetic Biology, Access and Benefit-Sharing, and Economic Development. In: Frankel, S., and Gervais, D. (eds.) Intellectual Property and the Regulation of the Internet. Wellington, Victoria University Press. pp. 85-111

Overmann, J., and Scholz, A. Microbial Research Under the Nagoya Protocol: Facts and Fiction. In: Trends in Microbiology. February 2017, Vol. 25, No. 2.

Bagley, M. (2018), De-Materializing Genetic Resources: Synthetic Biology, Intellectual Property and the ABS By-pass. In: McManis, C., and Ong, B. Routledge Handbook on Biodiversity and the Law.

Lawson, C., F. Humphries and M. Rourke, 'The Future of Information under the CBD, Nagoya Protocol, Plant Treaty and PIP Framework' (2019) 22(3-4) Journal of World Intellectual Property, pp 103-119.

4. Conceptual approaches to regulate and manage DSI

Common pools and global commons

Dedeurwaerdere, T., Louafi, S., and Brogiatto, A. Governing Global Scientific Research Commons under the Nagoya Protocol. In: Morgera, E., Buck, M., Tsioumani,E. (eds.)(2012), The Nagoya Protocol in Perspective: Implications for International Law. Martinus Nijhoff Publishers, Leiden/Boston. Available at https://www.researchgate.net/publication/236035006_
Governing_Global_Scientific_Research_commons_under_the_Nagoya_Protocol

Kamau, E., and Winter, G. (eds.) (2013), Common Pools of Genetic Resources: Equity and Innovation in International Biodiversity. Routledge, London. Earthscan from Routledge. Oxon & New York. pp. 219-236

Halewood, M., Lopez-Noriega, I., and Louafi, S. (eds.) (2013), Crop Genetic Resources as a Global Commons: Challenges in International Law and Governance. Bioversity International, Earthscan by Routledge. London.

Dedeurwaerdere, T., Melindi-Guidi, P., and Brogiatto, A. Global Scientific Research Commons under the Nagoya Protocol: Towards a Collaborative Economy Model for the Sharing of Basic Research Assets. Environmental Science and Policy. Volume 55, Part 1, January 2016, pp. 1-10. Available at, https://www.sciencedirect.com/science/article/pii/S1462901115300605

MTAs and contracts

Safrin, S. (2004), Hyperownership in a Time of Biotechnological Promise: The International Conflict to Control the Building Blocks of Life. In: American Journal of International Law. Volume 98, Issue 4, October 2004, pp. 641-685

Parry, B. From the Corporeal to the Informational: Exploring the Scope of Benefit-Sharing Agreements and their Applicability to Sequence Databases. In: Thiele, F., and Ashcroft, R.D. (eds) (2005), Bioethics in a Small World. Springer, Berlin, Germany. pp. 73-91. Available at, https://link.springer.com/chapter/10.1007/3-540-26951-7_7

Tvedt, M.W., Fauchald, O.K (2011), Implementing the Nagoya Protocol on ABS: A Hypothetical Case Study on Enforcing Benefit-Sharing in Norway. In: The Journal of World Intellectual Property. 14 (5), pp. 383–402. Available at http://www.fni.no/pdf/MWT-OKF-JWIP-2011.pdf

Andersen, R., and Winge, T. (2012), The Access and Benefit-Sharing Agreement on Teff Genetic Resources. Facts and Lessons. Fridtjof Nansen Institute, ABS Capacity Development Initiative for Africa. FNI Report 6/2012. Available at, http://www.fni.no/pdf/FNI-R0612.pdf

Walloe Twedt, M., Eijsink, V., Helene Stele, I., Strand, R., and Rosendal, K. The Missing Link in ABS: The Relationship Between Resource and Product. Environmental Policy and Law. 46/3-4 (2016)

Young, T., and Walloe Twedt, M. (2017), Drafting Successful Access and Benefit-Sharing Contracts. Legal Studies on Access and Benefit-Sharing, Vol. 2. Brill & Nijhof.

World Economic Forum (2018), Harnessing the Fourth Industrial Revolution for Life on Land: Towards an Inclusive Bio-economy. Fourth Industrial revolution for the Earth Series. Available at, http://www3.weforum.org/docs/WEF_Harnessing_4IR_Life_on_Land.pdf

Hammond, E. (2019), Ebola: Company Avoids Benefit-Sharing Obligation by Using Sequences. Briefing Paper 99. TWN. Available at, http://www.twn.my/title2/briefing_papers/No99.pdf

Open access

Lawson, C. & M. Rourke. Open Access DNA, RNA and Amino Acid Sequences: The Consequences and Solutions for the International Regulation of Access and Benefit-Sharing. (2016) 24(1) Journal of Law and Medicine, pp 96-118.

Smyth, S., de Beer, J., Phillips, P., MaCall, D. (2018), Governance of Digital Sequence Information and Impacts for Access and Benefit-Sharing. Center for the Study of Technology and Innovation Policy, University of Saskatchewan. Available at, https://www.researchgate.net/publication/324201093_Genetic_resources_in_the_age_of_the_Nagoya_Protocol_and_genegenome_synthesis

Deplazes-Zemp, A. A Global Biodiversity Fund to Implement Distributive Justice for Genetic Resources. In: Developing World Bioethics. 2019, Vol 19, Issue 2, Wiley & Sons.

Bounded openness

Angerer, K. (2011), Frog tales – on Poison Dart Frogs, Epibatidine, and the Sharing of Biodiversity Innovation. In: The European Journal of Social Science Research. 24, No. 3, pp. 353–369.

Vogel J.H et al. (2011), The Economics of Information, Studiously Ignored in the Nagoya Protocol on Access to Genetic Resources and Benefit-Sharing. 7/1 Law, Environment and Development Journal, pp. 54-55 Available at http://www.lead-journal.org/content/11052.pdf

Ruiz, M. (2015), Genetic Resources as Natural Information. Implications for the Convention on Biological Diversity. Earthscan from Routledge. London, New York.

Ruiz, M. (2018), Access to Genetic Resources and Benefit-Sharing 25 Years on: Progress and Challenges. Issue Paper No. 44. ICTSD, Geneva. https://www.ictsd.org/sites/default/files/research/access_to_genetic_resources_and_benefit_sharing_-_ruiz_final.pdf

Deplazes-Zemp, A. Genetic Resources: Analysis of a Multifaceted Concept. Biological Conservation 222:86-94, June 2018.

Findings from literature search

1. Increasingly, scholars and experts are paying more attention to the informational dimension of genetic resources from the point of view of policy, law and institutions.

2. There are limited references to analysis regarding specifically how national and international policies and regulations address DSI, but for a few and relatively recent reports.

3. Competing concepts with the placeholder DSI include genetic information, genetic sequences data, natural information, etc.

4. Papers referring to approaches to regulate and manage DSI and competing concepts focus on global commons, open access, contracts and MTAs, bounded openness, a GMBSM, among others.

5. Many references discuss the potential of a global approach, including through a GMBSM under the Nagoya Protocol to address the specificities of DSI.

6. An integrated and coherent conversation between economics and policy/law as they relate to the informational dimension of genetic resources seems missing and relegated to very few texts and fewer authors. The economics of information as applied to DSI and its policy repercussion has been neglected, surprisingly given the subject of interest: information.

Annex H: List of Interviewees

Name	Type of institution, sector, status, other	Country	Interview, e-mail communication, other	Date
(ST) Claudio Chiarolla	Eastern European Regional Project Specialist of the UNDP-GEF, Global ABS Project	Turkey	Video conference	11.06.2019
(TF) Ofa Kaisamy	Access Benefit Sharing Legal Adviser Secretariat of the Pacific Regional Environment Programme (SPREP)	N/A	E-mail communication	27.05.2019
(MB, FPW, NK) Fouad Bergigui	UNDP Regional Specialist for Africa	Turkey	Group phone interview	03.06.2019
(CL) Anonymous	Three government representatives	Australia	Interviews	05-06.2019
(CL) Anonymous	University professor	Australia	Interview	05-06.2019
(CL) Anonymous	Industry representative	Australia	Interview	05-05.2019
(MB) Edward Hammond	Third World Network	United States	Telephone	11.06.2019
(MB) Pierre Du Plessis	Consultant, African Union	U.K.	Personal conversation	12.06.2019
(ST)Elena Makeyeva	ABS NFP (Institute of Genetics and Cytology at the National Academy of Sciences)	Belarus	Video conference	19.06.2019
(ST) Galina Mosgova	ABS NFP	Belarus	Video conference	19.06.2019
(CF) Anonymous	Research institution	Belgium	In person interview	09.05.2019
(CF) Anonymous	Pharmaceutical industry	Belgium	In person interview	09.05.2019
(CF) Anonymous	Agrochemical industry	Belgium	In person interview	09.05.2019
(CF) Anonymous	Private consultant	Belgium	In person interview	09.05.2019
(CF) Salima Kempenaer	Government official	Belgium	In person interview	19.07.2019
(MR) Paula Rojas	ABS national authority, Ministry of the Environment	Colombia	E-mail communication	23.09.2019
(TF) Alex Hermann	Crown Law Department	Cook Islands	E-mail communication	06-08.2019
(JC) Maribel Alverez	CONAGEBIO (national ABS authority)	Costa Rica	E-mail communication	N/A
(JC) Marina Hernández	Ministry of the Environment	Dominican Republic	E-mail communication	N/A

(MR) Manuela Gonzalez	WWF	Ecuador	Phone interview	27.06.2019
(TK) Katy Soapi	Environment Unit of the Institute of Applied Science of the University of the South Pacific	Fiji	E-mail communication	06-08.2019
(MR) Klaus Angerer	University of Giessen	Germany	E-mail communication	27.05.2019
(EK) Anonymous	N/A	Germany	Telephone interview	31.05.2019
(EK) Gerd Winter	University of Bremen	Germany	Telephone interview	13.06.2019
(EK) Anonymous	N/A	Germany	Telephone interview	17.06.2019
(LdS) Gilherme da Costa	National Focal Point for ABS-NP	Guinea Bissau	E-mail communication	N/A
(PN) T. Narendran	National Biodiversity Authority	India	Survey response and personal phone call	24.06.2019
(PN) K.P Raghuran	National Biodiversity Authority	India	Survey response	24.06.2019
(MB) Frances Browne Seydou	National Focal Point	Liberia	E-mail communication	03.10.2019
(MB) Mphatso Kalemba	National Focal Point	Malawi	Personal interview	03.05.2019
(MB) Morten Walloe Tvedt	Fridtjof Nansen Institute	Norway	Personal interview	03-05.2019
(TF) Landisang Kotaro	Senior Researcher, House of Delegates	Palau	Interview	N/A
(MR/JC) Dario Luque (MB)	Biodiversity Department, Ministry of the Environment	Panama	E-mail communication; Personal Interview	07.10.2019 10.01.2020
(MB) Jorge Garcia	Biodiversity Department, Ministry of the Environment	Panama	Personal Interview	10.01.2020
(MR) Roger Becerra	National Agricultural Innovation Institute	Peru	Phone interview	03.08.2019
(LdS) Aline Castro	National Focal Point	Sao Tome and Principe	Phone interview	N/A
(MR) Marcel Jaspers	Marine Biodiscovery Centre	Scotland	E-mail communication	13.07.2019
(MB) Lacticia Tshitwamulomoni	National Focal Point	South Africa	Electronic communication	22.07.2019
(MB) Nada Babiker Hamza	National Focal Point	Sudan	E-mail communication	05.10.2019

(LdS) Marcal Gusmao	National Focal Point for ABS-NP	Timor Leste	E-mail communication	N/A
(MB) Christine Akello	Uganda National Environmental Management Authority	Uganda	E-mail communication	14.10.2019
(MR) Chris Lyal	National History Museum	United Kingdom	E-mail communication	15.07.2019

Annex I: Survey Instrument

Survey on Domestic Measures Addressing Benefit-Sharing from Digital Sequence Information on Genetic Resources

This **short** survey is part of a study commissioned by the Secretariat of the Convention on Biological Diversity (CBD) to report on how domestic measures address benefit-sharing arising from commercial and non-commercial use of digital sequence information on genetic resources (DSI) and address the use of DSI for research and development. In this study, the term 'digital sequence information' is used as a placeholder[209] in assessing the scope of domestic measures on benefit-sharing and the use of DSI at the national level. This survey is concerned with access and benefit sharing (ABS)-related measures adopted at the national level in accordance with the CBD and its Nagoya Protocol (NP).

In particular, we are seeking information on the following:

- whether a country has domestic ABS legislative, administrative or policy measures, and/or permits, material transfer agreements, mutually agreed terms dealing with ABS, **AND**

- whether these cover DSI, AND

- if so, how the use of DSI and benefit-sharing from its commercial and non-commercial use are addressed by these measures.

Please complete the survey and email it to secretariat@cbd.int as soon as possible and no later than JULY 1, 2019. Your responses are very important to us and your assistance with this very short survey will be greatly appreciated!

Survey

Please mark an "x" next to the best answer choice for each question and provide additional information, as needed, in the space provided.

1. **Name of country:**

2. **What best describes your position?**

   i. National focal point ___

   ii. Representative of the competent national authority ___

[209] The report of the CBD Ad Hoc Technical Expert Group on Digital Sequence Information on Genetic Resources noted that DSI could include, among others, "(a) The nucleic acid sequence reads and the associated data; (b) Information on the sequence assembly, its annotation and genetic mapping. This information may describe whole genomes, individual genes or fragments thereof, barcodes, organelle genomes or single nucleotide polymorphisms; (c) Information on gene expression; (d) Data on macromolecules and cellular metabolites; (e) Information on ecological relationships, and abiotic factors of the environment; (f) Function, such as behavioural data; (g) Structure, including morphological data and phenotype; (h) Information related to taxonomy; (i) Modalities of use."

iii. Other (please specify):

3. Does your country have domestic legislation addressing the ABS provisions of the CBD and/or the Nagoya Protocol?

i. Yes ___

ii. No ___

4. If, yes, do such ABS measures cover DSI?

i. Yes ___

ii. No ___

5. If yes, please LIST the ABS measures covering DSI, including their title, date of adoption, current status (in force, interim, voluntary etc.) and a brief explanation of the applicable provisions.

6. Are there plans to revise or adopt new ABS measures in relation to DSI?

i. Yes ___

ii. No ___

If "yes" please provide more information on your country's plans to address DSI:

7. Does your country's domestic legislation on access and benefit-sharing explicitly refer to DSI?

i. Yes ___

ii. No ___

If yes, please specify what terminology is used? (for example, genetic information, genetic heritage, genetic sequence data, intangible components, etc.):

8. Does your country address DSI in any of the following (mark "x" next to all that apply?)

i. Permits or their equivalent___

ii. Prior informed consent ___

iii. Mutually agreed terms (e.g. benefit-sharing contracts) ___

iv. Material transfer agreements ___

v. Other (please specify)

9. Is benefit-sharing arising from the commercial use of DSI required in your country?

i. Yes ___

ii. No ___

If yes, please specify the type of benefit-sharing expected:

10. Is benefit-sharing arising from the non-commercial use of DSI required?

i. Yes ___

ii. No ___

If yes, please specify the type of benefit-sharing expected:

11. Have any benefits related to the use of DSI been received so far?

i. Yes ___

ii. No ___

If yes, please specify the type (and if monetary, amount) of benefit-sharing received:

12. Have there been any challenges/difficulties associated with including DSI in your country's domestic measures dealing with access and/or benefit-sharing?

i. Yes ___

ii. No ___

iii. There may be in future ___

If yes, please specify what these challenges are or could be:

13. Is there anything else relating to DSI and your country's ABS system that would be helpful for us to know, or any of your answers you would like to clarify? If so, please use the space below to inform us:

14. Please provide the name of a contact person, their position and their contact details who we can contact, and who agrees to be contacted, if more information or clarification is needed regarding the answers to the question in this survey):

You have finished the survey. Thank you for your time!

_____