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

As requested by decision 14/20 (paragraph 11 (e)) from the Fourteenth Conference of the Parties to the Convention on Biological Diversity

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List of Acronyms

ABS	Access and Benefit-Sharing
ABS-CH	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)
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
GSD	Genetic sequence data
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)
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

EXECUTIVE SUMMARY

This study serves the science and policy-based process on "digital sequence information on genetic resources" ("DSI"), which was established by COP Decision 14/20 at the Fourteenth Conference of the Parties (COP) to the Convention on Biological Diversity (CBD) 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, and some of the challenges countries face in developing and implementing measures relating to "DSI".

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. The authors sought information regarding measures for all 196 CBD Parties. 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 CBD and Nagoya Protocol Parties still do not have ABS legislation, let alone measures addressing "DSI". 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.

For this study, domestic measures are understood as comprising formal access and benefit-sharing (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". Domestic measures address benefit-sharing arising from commercial and non-commercial uses of "DSI" on genetic resources through both access provisions and benefit-sharing provisions. The implications of addressing "DSI" at the domestic level will depend largely on where "DSI" is addressed in the relevant measures.

A total of 15 countries and one sub-national jurisdiction were identified as having domestic measures (legal, administrative and policy measures) in place addressing "DSI", and one country addresses "DSI" through 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.

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

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

- 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.

The implementation of the ABS system 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 ABS measures.

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 can 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. 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.

Those 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.

As required by the Nagoya Protocol, a number of countries have compliance measures in their ABS framework. Whilst these measures focus mostly on the utilization of physical samples of genetic resources, some countries with compliance regimes acknowledge that "DSI" can result from utilization of physical genetic resources and thus may be the subject of obligations found in MAT covered by compliance measures.

Most CBD and Nagoya Protocol Parties do not have measures on "DSI". Some countries intentionally choose to omit domestic measures on "DSI" and benefit-sharing in order to promote open access to "DSI" to facilitate scientific advancement. Such countries typically regard open access as a form of non-monetary benefit-sharing. This might be described as an intentional "non-measure," i.e. an absence of measures designed to promote an open access policy objective.

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 lack of clarity 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 limited capacity to implement relevant measures, which highlights the need for capacity building on, among other things, how "DSI" is used and can be monitored. Thus for several countries, the lack of domestic measures addressing "DSI" may be only a temporary state of affairs.

The annexes to this study include a table outlining the presence of measures addressing "DSI" by Parties to the CBD and 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.

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").[1] 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.[2] 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.[3]

1.2 Objectives of the Study

Given that information and analysis is generally lacking on how countries are regulating the use of "DSI",[4] this study aims to provide a broad overview of the extent to which countries are addressing benefit-sharing from, 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] *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.

[2] Decision 14/20, para 11(b) – (e).

[3] 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 Resources* (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),

[4] The literature review 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 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.

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.[5] 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.[6] 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.

1.3.2 Domestic measures

Taking into account the text of Articles 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.[7]

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 and challenging.

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[5] 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.

[6] *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]".

[7] 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".

1.3.3 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".

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). The CBD Party profiles on the CBD's website were also scanned for relevant information. The study authors conducted interviews with 43 individuals in 28 countries in order to better understand domestic laws, regulations, policies, and practices relating to "DSI" and benefit-sharing.[8] 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[9] to all CBD and ABS national focal points. Thirty-six Parties responded to this survey.

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,[10] a literature search (see Annex G), 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. 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.

[8] 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.

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

[10] 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.

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.[11]

As listed in Annex A, 15 countries[12] and one sub-national jurisdiction were identified as having domestic measures (legal, administrative and policy measures) in place addressing "DSI", and one country[13] addresses "DSI" through implementing measures (PIC) in the absence of domestic measures.[14] In addition, 18 countries[15] without domestic "DSI" measures indicated that they have plans to introduce such measures in the future.

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

1) Some jurisdictions address "DSI" only in conjunction with the utilization of a physical genetic resource.[16] 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 PIC and MAT would be required to access "DSI" independently of access to a physical genetic resource.[17]

3) 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, and often captured by obligations in MAT.[18]

[11] 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.

[12] Bhutan, Bolivia, Brazil, China, Colombia, Costa Rica, India, Kenya, Malawi, Malaysia, Mozambique, Namibia, Peru, South Africa, Uganda, and Queensland, Australia. This list may be under-inclusive. For example, the study authors received a communication from the NFP in Panama indicating that the country does interpret "genetic resources" in ABS legislation as covering "DSI", contrary to their survey response but consistent with their survey answer that benefit sharing for "DSI" is required.

[13] Oman.

[14] Through survey responses and submissions made to the CBD Secretariat, a total of seven countries reported that they have existing "DSI" measures in the form of legal, administrative or policy measures. As compiled in Annex A, these seven self-reporting countries along with nine others the study authors identified through research, combine for a total of 16 countries with domestic "DSI" related measures plus one addressing "DSI" without domestic measures.

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

[16] Costa Rica, Namibia, Australia (Queensland). See section 3.2.1.

[17] Bhutan, Bolivia, China, Colombia, Kenya, Malaysia, Mozambique, Oman, Peru, Uganda. See section 3.2.2.

[18] Brazil, India, Malawi, South Africa. See section 3.2.3.

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.[19]

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 can 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. 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 a wide variation in how "benefits" from 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 to facilitate open access to "DSI" for research and development.[20] For others, internal agreement on a position on "DSI" and benefit-sharing is still being developed.[21] A further group indicated that the absence of measures is due to capacity constraints,[22] which in some cases, is combined with a desire to delay implementing national measures on "DSI" until

[19] See section 3.3.

[20] 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); Swiss National Science Foundation, *Research Policies: Open Access to Publications* and *Open Research Data* (implemented through the Funding Regulations of the SNSF and General Implementation Regulations for the Funding Regulations, 2016); 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.

[21] In Belgium, for example, there is no agreed position as yet between the competent regions (Flanders, Wallonia and Brussels) on how to address "DSI" and whether to implement measures relating thereto. However, the negotiation of a draft federal legislation on the implementation of the Nagoya Protocol that specifically addresses "DSI" is on-going. See "Projet de loi relatif à l'accès aux ressources génétiques et au partage juste et équitable des avantages découlant de leur utilization et modifiant la loi organique du 27 décembre 1990 créant des fonds budgétaires". This information was 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.

[22] 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, Oman, Iraq, Palestine, and Djibouti. See discussion in section 5.2.

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.[23]

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;[24]
- implementing regulations designed to put ABS provisions into practice.[25] These regulations may address "DSI" in addition to or instead of the legislation; and,
- other instruments, such as guidelines and policy statements.[26]

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 aspect. The scope of domestic measures with regards to "DSI" would depend on the context and use of those terms within the national frameworks.

For some countries as explained above, this would imply that PIC and MAT is required to access "DSI". For others there may be only a requirement to share benefits from utilization of "DSI" without having established PIC and MAT for access to the related genetic resource. In other cases, domestic measures would only address "DSI" as part of MAT resulting from access to a physical genetic resource. In addition, some countries have put in place compliance and monitoring measures addressing "DSI".

3.1 Terminology

Some jurisdictions stated that their measures explicitly cover "DSI",[27] while other countries indicated that they interpret existing language in their ABS or other relevant legislation as including "DSI".[28] 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.

Seven countries use explicit "DSI"-related terminology in their ABS legislative, administrative, or policy measures. Some of the terms used include genetic information,[29] genetic heritage,[30]

[23] See section 5 *infra*.
[24] See for example, footnote 53 listing a variety of Kenyan environmental laws used to address ABS.
[25] See for example, Brazil and Malaysia.
[26] See for example, China and Malawi.
[27] 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.
[28] Colombia, China, Costa Rica, India, Kenya, Oman, and South Africa.
[29] Bhutan, Namibia, and Malawi.
[30] Brazil.

intangible components,[31] gene sequences,[32] sequence information,[33] information,[34] and information of genetic origin.[35]

In some countries "DSI" is considered as part of the definition of a broader term, for example genetic resources,[36] genetic material,[37] biological resources,[38] associated knowledge,[39] research results,[40] or derivative.[41]

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 consultation with respect to the inclusion of explicit terminology in their domestic measures. [42]

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,[43] and even within an individual country, as in the case of Australia.[44] We found evidence of jurisdictions explicitly incorporating "DSI"-related language into their ABS legislative, administrative, and policy measures,[45] or alternatively interpreting the language in their existing ABS measures to include "DSI".[46] In addition, at least one country addresses "DSI" through ABS permitting and contractual practice, even in the absence of formal ABS measures.[47]

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

Costa Rica

The Biodiversity Law No. 7788 (1998) regulates access to Costa Rican genetic resources and biochemical resources and requires users to obtain genetic resource access permits in most cases.

[31] Namibia.
[32] Namibia.
[33] Queensland, Australia.
[34] Malaysia.
[35] Mozambique.
[36] Colombia, South Africa.
[37] South Africa.
[38] China.
[39] India, see the case study in Annex F.
[40] Ibid.
[41] South Africa.
[42] 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.
[43] For example, explicit and interpretative inclusion of "DSI" by several African countries and intentional non-measures to facilitate open access to "DSI" in Europe.
[44] 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).
[45] Bhutan, Bolivia, Brazil, Colombia, Costa Rica, India, Kenya, and Queensland, Australia.
[46] China, Malaysia, Mozambique, Namibia, Saudi Arabia, and South Africa.
[47] Oman. Also Namibia (prior to adopting its current ABS legislation), see Annex D.

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). Because "DSI" is not considered to be within the definition of genetic resources, but instead is deemed to result from "access to genetic resources," no access permits are required for "DSI" beyond the obligation to require PIC and MAT for access to genetic resources. However, 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.

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.[48] 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.

Queensland, Australia

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.[49] For more details, see the case study in Annex B.

3.2.2 Regulating access to "DSI" alone

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

[48] 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.

[49] 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), 06.19.

physical genetic resource, triggering PIC and MAT requirements.[50] 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 tangible materials.[51] The following are some examples of 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*[52] 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 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 (s 6(a)) must be completed between users and the Bhutanese government as the provider of the genetic resources and must be evidenced by an actualization permit by the NFP.

Colombia

Under resolution 1348 (2014) which defines access and benefit-sharing activities in Colombia, "DSI" is considered as part of genetic resources and so can be regulated through contractual provisions in access contracts. As such, access to "DSI", even in public databases, requires an access and benefit-sharing contract.[53]

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." [54]

[50] 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, Oman, 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.

[51] 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.

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

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

[54] *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*

"Intangible components" includes any information held by persons that is associated with or regarding 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.[55]

Malaysia

Malaysia defines biological resources to include "genetic resources" and "information relating to" genetic resources.[56] Its survey results indicate that its ABS legislation explicitly addresses "DSI" and that "DSI" also is addressed via PIC/MAT/MTAs and permits.

Peru

Like Colombia, Peru is a member of the Andean Community, 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 to cover "DSI". This allows "DSI" to be subject to access and benefit-sharing requirements even independent of access to a physical genetic resource.[57]

3.2.3 Requiring benefit-sharing (but not access) from the use of "DSI" alone

Some countries have established a benefit-sharing requirement for utilization 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.[58] "Genetic heritage" was further defined, in part, as "information of genetic origin",

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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.

[55] Ibid.

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

[57] See https://wipolex.wipo.int/es/text/223610. See also El Reglamento de Acceso a los Recursos Genéticos (D.S Nº 003-2009-MINAM).

[58] 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

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".

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

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 provide evolving authority for the imposition of benefit-sharing obligations on "DSI" on a case-by-case basis, even if it is obtained separately from a physical genetic resource, such as from a public database.

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."[59]

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 or information of any species, whether gathered from the wild or accessed from any other source.[60] 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" on genetic resources, whether stored in public or private databases. PIC may also be required; however, that determination is made on a case-by-case basis.[61]

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molecular ecology, *as well as the use of information from public genetic sequence databases, such as GenBank*." (emphasis added).

[59] Malawi, African Union Submission under Decision 14/20.
[60] South Africa, Submission under Decision 14/20.
[61] MB, Interview, Lacticia Tshitwamulomoni, NFP, 22.07.2019.

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. 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, they are still absent from many ABS systems. However, some mechanisms currently exist in major countries that are net users of genetic resources, such as the member states of the European Union (EU) and Japan. Some countries also have measures in place to ensure compliance with their own domestic ABS legislation. The following provides some examples of Parties/countries addressing or acknowledging "DSI" in compliance measures.

European Union

Under the EU Regulation 511/2014 (EU Regulation), "[u]sers 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."[62]

For this reason, EU users of genetic resources must "seek, keep and transfer to subsequent users the [IRCC], as well as information on the content of the [MAT] relevant for subsequent users"[63] or, where there is no IRCC, the information listed in the EU Regulation.[64] This is to ensure that information relating to ABS is available throughout the value chain in the EU. This obliges users of genetic resources to follow the rules of provider countries, and appears significant in conjunction with the EU Regulation requirement that "[w]hen the information in their possession

[62] 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.

[63] EU Regulation, Art. 4(3)(a).

[64] EU Regulation, Art. 4(3)(b): where no internationally-recognised certificate of compliance is available, information and relevant documents on: (i) the date and place of access of genetic resources or of traditional knowledge associated with genetic resources; (ii) the description of the genetic resources or of traditional knowledge associated with genetic resources utilised; (iii) the source from which the genetic resources or traditional knowledge associated with genetic resources were directly obtained, as well as subsequent users of genetic resources or traditional knowledge associated with genetic resources; (iv) the presence or absence of rights and obligations relating to access and benefit-sharing including rights and obligations regarding subsequent applications and commercialisation; (v) access permits, where applicable; (vi) mutually agreed terms, including benefit-sharing arrangements, where applicable.

is insufficient or uncertainties about the legality of access and utilisation persist, users shall obtain an access permit or its equivalent and establish mutually agreed terms, or discontinue utilisation."[65]

The production and use of "DSI" may be captured by these compliance measures as part of utilization of physical genetic resources. The non-binding EU Guidance Document 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.[66] 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 must respect any conditions in MAT that deal with "DSI". At the same time, the EU has clearly stated[67] that it regards open access to "DSI" as a significant non-monetary benefit. As such, outside of the use of "DSI" under conditions prescribed by MAT, 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.[68]

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.[69] Becoming a registered collection requires compliance with Article 5(3) of the EU Regulation but is a voluntary action.[70] 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.[71] Restrictions relating to genetic

[65] EU Regulation, Art. 4(5).
[66] EU Guidance Document [2.3.3].
[67] European Union, Submission under Decision 14/20.
[68] EU Guidance Document [3.1].
[69] 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.
[70] EU Regulation Art. 5(3).
[71] 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.

resources (e.g. MAT) found in the documentation provided by registered collections may cover use of and benefit-sharing for "DSI".[72] For more details on how the only registered collection (the Leibniz Institute DSMZ-German Collection of Microorganisms and Cell Cultures (DSMZ)) has dealt with this, see the case study in Annex D.

India and South Africa

In India[73] and South Africa, the processing of a domestic patent application may be suspended until compliance with ABS laws has been verified, including for inventions involving "DSI"-related subject matter. In South Africa, information on genetic resource origin is communicated to the domestic ABS focal point, who then ascertains whether the necessary ABS obligations were met by the patent applicant.[74] In such cases, this disclosure requirement may be viewed as facilitating compliance with the domestic ABS regime.

Japan and Switzerland

These countries take an approach to compliance with MAT related to "DSI" that is significant. Japan and Switzerland both recognize that MAT concluded at the time of access to a genetic resource may cover benefit-sharing from utilization of "DSI", but allow the confidentiality of such negotiated terms to take precedence over obligations to monitor any compliance with such terms.[75] They acknowledge that commercial confidentiality prevents drawing insights from the utilization of "DSI" in MAT.

3.3.2 Monitoring 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, etc. to see if Costa Rican "DSI" is being disclosed/deposited outside of the country.[76]

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).

[72] 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).

[73] See case study, Annex F.

[74] 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).

[75] Japan, Submission under Decision 14/20, Switzerland, Submission under Decision 14/20.

[76] See case study, Annex C.

Over 1068 approvals have so far been granted by the Indian NBA, including 729 approvals for filing IP applications in India and abroad.[77] 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 tangible resource and relevant bioprospecting permits from India. However, as described in the case study, 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 virus, *Plasmodium vivax,* for which no approval from the NBA had been granted.

In the future, it may become possible to capture evidence of the generation and utilization of "DSI" through IT measures such as the ABS-Monitoring System (ABS-MS) currently being developed by experts associated with the ABS Capacity Development Initiative (implemented by 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 detect non-compliance (i.e., utilization without seeking approval) with ABS regulatory requirements.

Several African countries are likely to implement such systems in due course. In Kenya, where development of a similar system is well underway, the tool will 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,[78] with an additional nine[79] 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 would be revised "to incorporate mandatory clauses" that

[77] http://nbaindia.org/content/683/61/1/approvals.html, updated as of July 25, 2019.
[78] Brazil, Colombia, Costa Rica, Kenya, Malawi, Malaysia, Namibia, Oman, and South Africa.
[79] Belarus, Burundi, Cameroon, Ethiopia, Guinea, Liberia, Sudan, Togo, and Uganda.

address the conditions for use of genetic information resulting from the utilization of genetic resources in public or private databases.[80]

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.

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

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.[81]

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."[82]

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[83] 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.[84] These agreements span the entire 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 African 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."[85]

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*

[81] EK, Anonymous interview, 31.05.2019.
[82] Emphasis added. See https://absch.cbd.int/database/IRCC/ABSCH-IRCC-PE-246755/1.
[83] Brazil, Colombia, Malawi, Malaysia, Namibia, South Africa, and Queensland, Australia.
[84] 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.
[85] South Africa, Submission under Decision 14/20.

> *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 "digitalized" information conditional upon accepting the contract of use requirement in the Malawian Regulation.

4.2.2 Material transfer agreements

The study authors found that MTAs had already been used by some countries[86] 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.[87]

Belarus

Belarus[88] established a MTA dealing with the transfer of 1000 samples of Antarctic organisms from a collection, 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.[89] 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-

[86] Malawi, Malaysia, and South Africa.
[87] See Annex D.
[88] 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.
[89] https://absch.cbd.int/database/IRCC/ABSCH-IRCC-BY-246531/1

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[90] and Belgium,[91] 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 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. This lack of monetary benefits accruing to countries from "DSI" may be due, in part, to difficulties in tracking and obtaining evidence of the generation and utilization of "DSI" or to the limitations of bilateral instruments applying to informational goods shared extensively across jurisdictions.

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".[92] Two approaches are illustrated below.

Brazil

As mentioned in section 3.2.3 above, Brazil requires benefit-sharing from the use of "DSI" without having established 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.

[90] See Annex D.
[91] CF, anonymous interview, research institution, 09.05.2019.
[92] See Annex B.

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) should be paid to the National Benefit-Sharing Fund. This Fund aims 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 associated with genetic heritage and associated traditional knowledge.

These caveats thus limit the circumstances under which notification and subsequent benefit-sharing must be made. In the year and a half that the system has been in operation almost 800 legal persons and more than 25,000 individuals have completed access registration for over 47,000 access activities.[93] 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.

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.[94] 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.[95] 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.[96] The prevailing scientific model involves the publication of research results and underlying data, and many journals require sequences to be deposited and accession numbers to be supplied prior to the publication of

[93] Brazil, NFP survey response. Brazil also received 1500 finished product notifications during this time period.
[94] 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.
[95] PN, interviews, with T. Narendran and K.P. Raghuram, 24.06.2019. See also Annex F.
[96] For example, see Japan and Switzerland's Submissions under Decision 14/20 with respect to confidentiality of commercial information included in MAT, which prevents these State Parties from interrogating benefit-sharing provisions in MAT agreed in a bilateral manner with Provider countries. See *supra* Section 3.3.1.

associated research.[97] In addition, the mandatory publication or open data access requirements for publicly-funded projects in many nations (e.g., the EU, the U.S., and Australia), often make this necessary for researchers.

Some countries, particularly those who identify as net users of genetic resources, 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.[98] 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.[99] 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,[100] 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.[101]

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. We found that 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, capacity constraints appear to be inhibiting the development of measures addressing "DSI".

[97] 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).

[98] 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).

[99] 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.

[100] 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 be 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

[101] 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[102] consider that "DSI" falls outside the scope of the definition of "genetic resources" found in the CBD.[103] 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 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" to facilitate the use of "DSI" for research and development.

One such example is Japan, which notes that its ABS Guidelines "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)."[104]

In this regard, it should be noted that many of those countries do not require PIC for access to domestic genetic resources, and as a consequence they do not require PIC for access to "DSI" either. In such cases, countries have only adopted compliance measures, at most.[105]

5.2 Capacity Issues and Measures Addressing "DSI"

A number of other countries[106] 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;
- the dearth of personnel with sufficient expertise in regulatory institutions for environment, science and technology to address the issue;[107]
- the lack of financial resources for training, national consultations, and development of measures;[108] 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.[109]

[102] Switzerland, the Czech Republic, Japan, the Netherlands, the UK, Canada, and Belgium.
[103] Such an interpretation would allow it to be subject to PIC under Article 6(1) of the Nagoya Protocol.
[104] Japan, Submission under Decision 14/20.
[105] See section 3.3, *supra*.
[106] 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, Oman, Iraq, Palestine, and Djibouti.
[107] African Group, Malawi, and Nepal.
[108] Central African Republic, and Guinéa.
[109] South Africa.

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 need for clarity and capacity-building around "DSI" subject matter at the international level before some national measures will be effectively developed.[110] 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

Domestic measures address benefit-sharing arising from commercial and non-commercial use of "DSI" on genetic resources though access provisions as well as benefit-sharing provisions, based on explicit "DSI" related terminology or interpretations of terms to include "DSI". The jurisdictions with domestic measures addressing "DSI" for benefit-sharing appear to have adopted one of the following approaches. Some jurisdictions address "DSI" only in conjunction with the utilization of a physical genetic resource, while other countries have domestic measures in place that indicate PIC and MAT would be required to access "DSI" independently of access to a physical genetic resource. In another group of countries, even though there are no access requirements for "DSI" in place, benefit-sharing is required from its utilization. Also, 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. Furthermore, Parties also are employing permits, MAT, and MTAs to address "DSI" use even in the absence of formal ABS legislative regimes. In addition to these broad observations, the study yielded the following specific points and suggestions.

When countries refer to "DSI" in their national laws, policies and other measures, they do so in multiple ways, using various concepts, often through a broad interpretation of the scope of their existing ABS frameworks and practice. The implications of addressing "DSI" at the national level will depend largely on where "DSI" is addressed in the relevant measures. For example, if the definition of genetic resources either explicitly or by interpretation includes "DSI", PIC and MAT may be required at the outset of use, in addition to benefit-sharing obligations deriving from utilization.

However, if the definition of genetic resources (or other definitions in a measure) does not include "DSI" but "DSI" is regarded as resulting from utilization of a physical sample of genetic

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

resources, it can be assumed that only benefit-sharing obligations would apply. There seems to be an agreement that countries may require benefit-sharing from "DSI" generated from access to physical material if this is foreseen in the MAT. Where countries tend to differ is on whether PIC and MAT can or should apply to "DSI", as a category of genetic resources or per se, and on whether "DSI" in databases is subject to benefit-sharing as well.

Survey results and interviews reveal that many countries which are not regulating "DSI" at present are considering whether and how to do so in their ABS policy frameworks, including through contractual means. Contracts seem to be a preferred tool which countries and institutions are deploying to regulate conditions for utilization of "DSI" generated from access to a physical material. In certain circumstances, 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 is limited, we found evidence that contracts are beginning to be used as a measure to address "DSI"-related subject matter in the context of "utilization" of physical biological samples. This involves including relevant benefit-sharing obligations 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.

Nevertheless, it is clear that there are limitations to taking this approach. Contract clauses, if not carefully drafted, might not be able to address the needs of both the scientists (sequencing and publication) and the concerns of the provider (prevention of commercial use and commercialization without consent and benefit-sharing) at the same time. Moreover, assessing contract compliance appears likely to be significantly more challenging with "DSI" than with physical genetic resources. Furthermore, such contracts will not bind third parties obtaining "DSI" from publicly accessible databases which do not require benefit-sharing for data access. The Parties should consider further investigating whether: (1) if restrictions cannot be passed on to data users, this may result in other provider countries amending their contractual clauses to prevent publication of "DSI", possibly conflicting with the obligations of researchers to publish their results and data. (2) if users of genetic resources demand that "DSI" be published, and benefit-sharing is bypassed, some provider countries may become increasingly reluctant to make their genetic resources available for research and development.

A variety of limitations in the capacity of domestic policymakers to fully understand and address "DSI" complexities has emerged as an issue for many countries, particularly in developing nations, and this appears to be one of the reasons why more "DSI" related measures are not in place. Capacity building to develop national approaches to addressing "DSI" may require understanding how "DSI" is used in research and development, how information management and exchange occurs in practice, how the economics of information can assist in understanding policy and regulatory options, and the risks attendant in over-regulating informational resource flows such as "DSI" and affecting research in general. Capacity-building efforts may be usefully directed towards the role of checkpoints, monitoring contract compliance, tracking genetic resources and "DSI" and the "DSI"/IP interface.

Multiple perceptions also exist with regards to benefit-sharing and how this relates to "DSI". Open access approaches facilitating utilization of "DSI" have been highlighted as an important dimension of discussions and as a source of diffuse societal benefits. However, some countries

have raised concerns about how sovereignty over "DSI" may be impacted through open access approaches. For instance, once "DSI" is published or uploaded onto open access databases, it becomes freely accessible and certain countries sense a loss of both control and the potential for benefit-sharing. Moreover, countries who seek to prevent users from bypassing their benefit-sharing requirements, may be unsure how best to operationalize and verify compliance with those requirements for "DSI".

For "DSI", the notion of utilization of genetic resources is further complicated as many Parties classify the generation, access to, and publication of "DSI" as a non-monetary benefit per se while many aspects of the commercial biotechnological use of genetic resources necessitate the production of "DSI". The status as a non-monetary benefit depends on the conditions of access in a space where public information and proprietary interests can be combined in a myriad of ways. For some countries open-access databases may, in effect, transform what they classify as sovereign genetic resources into public domain data. The fact that most patent applications that protect commercially developed products or derivatives produced through biotechnology will require disclosure of sequence information is considered by some as an additional challenge to the classification of open publication of "DSI" per se as a non-monetary benefit.

Some limited references have been made to the GMBSM in surveys and interviews and there are ongoing and parallel discussions in the COP/MOP regarding its potential to address certain "DSI" issues within a broader global framework. A future GMBSM that includes "DSI" would certainly have impacts on national approaches, frameworks and measures.

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 regarding how domestic measures address "DSI" and benefit-sharing as well as "DSI" use for research and development their potential effects on the objectives of the CBD, and the Nagoya Protocol at the national level. This may be an issue for future consideration in capacity building programs and funding.

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 "any thing (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".
Bhutan	ABS Policy 2015	Policy	Not known	Yes	Not known	ABS Policy 2015 (https://absch.cbd.int/database/record/ABSCH-MSR-BT-240076) defines Genetic Resources as Genetic resources means all material of plant, animal, microbial or other origin containing functional units of heredity and include 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 transmitable characteristics for descendants."
Brazil	Law 13123, Biodiversity Law (2015) http://www.planalto.gov.br/ccivil_03/_ato2015-2018/2015/lei/l13123.htm ; Decree 8772 (2016), regulation of the Biodiversity Law	Legislation	Registration, permits, MAT	Yes	No	The Brazilian ABS framework refers to "access to the genetic patrimony" which is defined as "information of genetic origin, of plant, animal, microbial or other species, including substances resulting from the

	http://www.planalto.gov.br/ccivil_03/_ato2015-2018/2016/decreto/D8772.htm started on Nov 6, 2017 - Version 1 https://sisgen.gov.br					metabolism of living beings." Article 7, I of the Provisional Measure of 2001 defined genetic patrimony as: Information of genetic origin contained in samples of all or part of a plant, fungal, microbial or animal specimen in the form of molecules and substances derived from the metabolism of these living beings and of extracts obtained from these.
China	National regulations on the management of human genetic resources (2019)	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).”
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	“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 defined to cover all types of research with biotechnology. "DSI" regulation 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.
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	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 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 or ex situ conditions under the control of the State,. . .

	https://namiblii.org/akn/na/act/2017/2					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.
Oman	None	N/A	PIC			Survey notes that Oman is addressing "DSI" though PIC until adoption of framework law on ABS.
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 - 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 li in the 2013 amendment to the National Environmental Management: Biodiversity Act, 2004 (Act No. 10 of 2004) are interpreted as linked to "DSI". PIC/MAT conditions are determined on a case-by-case-basis.
Uganda	National Environment Act No. 5 of 2019	Legislation	Not known	Yes	Yes	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".

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

Charles Lawson,[111*] Fran Humphries** and Michelle Rourke***

Introduction

Australia has signed and ratified the CBD but is not a Party (or 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.[112]

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.[113] 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[114] using a mix of legislative, administrative and policy measures (see Table 1).[115] The Commonwealth, Queensland, Northern Territory, Western Australia and

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[112] 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]).

[113] 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.

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

[115] 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*

the Australian Capital 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:

(WA), and by the Australian Capital Territory under the *Nature Conservation Act 2014* (ACT). The relevant laws might, as a generalisation, be categorised 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).

"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).

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.

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		✓	✓	✓	✓	✓	✓	✓	✓	✓

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

Jorge Cabrera Medaglia

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) that functions as a by-law 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 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 article 4. 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 implies 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 components are subject to the Law and must follow its access procedures. The access regulations apply to genetic resources in public or private lands, 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 resources through more than 638 permits, and several ABS agreements have been negotiated with private companies, universities, farmers, national and international research centers.[116] Most of these agreements have been concluded by the National Biodiversity Institute (INBio, a parastatal 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.

[116] CONAGEBIO, Costa Rican ABS Legal Framework,, power point presentation, August, 2019

"DSI" in Access Permits and Contracts.

The Government of Costa Rica, through it's TO, has indicated that "DSI" is covered under the BL's definition of access to genetic resources.[117] It also indicated that "DSI" for non commercial research is unregulated (i.e. 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 legal ground for the differentiation between commercial and non-commercial use is not clear.

The CONAGBIO 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 January 9 2010, contains the following restriction:[118]

> "*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.[119] 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.*

[117] Costa Rica, survey response.
[118] On file with the author.
[119] Interviews cited in Cabrera Medaglia, Jorge, ABS in Costa Rica: legislation and practice, unpublished paper prepared for the University of Bremen, August 2019.

> *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*".

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[120] 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".[121] 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)[122] in Namibia and the Leibniz Institute DSMZ-German Collection of Microorganisms and Cell Cultures (DSMZ)[123] in Germany.

"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.[124] However under Namibia's new ABS legislation,[125] 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

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

[121] 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.

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

[123] 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.

[124] 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

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

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**;
- **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**[126] 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**[127] of the soil biota diversity. The 16S rRNA analyses were used for initial identification of the bacterial isolates.[128] 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.[129] 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 [130] 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[131]. 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

[126] To commercialise and commercialization shall include but are limited to sale, filing a patent application, obtaining or transferring intellectual property rights or other tangible or intangible rights by the sale license or in any other manner, commencement of product development, conducting product development, conducting market research and seeking pre-market approval.

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

[128] EK, anonymous interview, 31.05.2019.

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

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

[131] 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.

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[132]) was negotiated with the NBRI to amend the conditions of MTA1 and allow deposit of the bacterial isolates into two public culture collections,[133] i.e. DSMZ and another collection in Belgium,[134] and to allow further transfer of the material from these collections to third parties for scientific purposes. The International Code of Nomenclature of Prokaryotes[135] (the 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 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,[136] 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

[132] Available for download in the DSMZ's catalogue.
[133] 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.
[134] Belgium Co-ordinated Collections of Micro-organisms/Laboratorium voor Microbiologie, Universiteit Gent (BCCM/LMG).
[135] http://www.the-icsp.org/bacterial-code.
[136] *Whole-genome sequencing of Acidobacteria strains isolated from Namibia soils in Kavango East and Kavango West regions.*

permit. This permit was obtained to avoid any potential legal uncertainty based on clause 9.[137] 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 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[138] and "Terms and Conditions"[139], 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

[137] EK, anonymous interview, 31.05.2019.
[138] https://www.dsmz.de/fileadmin/Bereiche/ChiefEditors/Forms/Neu16/Order_Form_DSMZ_E-Mail_Terms_Condition.pdf (see page 2).
[139] https://www.dsmz.de/terms.html.

- 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 CNA 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[140]. This is the interpretation taken by DSMZ and reading all three MTAs 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 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 others scientists and institutions[141].

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.

[140]EK, Interview with Winter, Gerd, Universität Bremen,13.06.2019; EK, anonymous interview, 17.06.2019.
[141] EK, anonymous interview, 31.05.2019.

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 German Federal Agency for Nature Conservation (Bundesamt für Naturschutz, 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. It is stated that the results and publications have to be shared with NBRI (MTA1/2) and MET (MTA3) 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[142].

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.

[142] 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.[143] 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.[144] "DSI"-related features of some of the agreements are described below.

2 Contractual agreements[145]

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.*[146]

[143] 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.

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

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

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]

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 IPRs. 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 IPR, 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[147] 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

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

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

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:

> *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 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 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*[148] for research[149], commercial utilization[150] and bio-survey and bio-utilization;[151]

(ii) *transfer of the results of research* over biological resources occurring in or obtained from India;[152]

(iii) *obtaining of IPR in and/or outside India* for any invention *based on any research or information on a biological resource* obtained from India;[153] and

(iv) *third party transfer* of already accessed biological resources[154] under mutually agreed terms with National Biodiversity Authority (NBA).

Terminology

The definition of "biological resources"[155] 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[156] 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

[148] Section 3, *Biological Diversity Act, 2002*

[149] 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.

[150] 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.

[151] 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.

[152] Ibid Section 4

[153] Ibid Section 6

[154] Ibid Section 20

[155] 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".

[156] Regulation 1, ABS Guidelines, 2014

from accessed biological resources. The NBA regulates the 'transfer of research results'[157] 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 research could restrict the transfer of "DSI" generated from a physical resource to a non-Indian person or entity.[158]

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 rights (IPRs) 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.[159] 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.[160] Since "DSI" may be treated as information on a biological resource, the NBA may regulate securing of IPR based on "DSI".[161] The NBA monitors the grant of patents in India and abroad by checking published patent applications and granted patents.[162]

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[163]. The invention describes the use of two known proteins derived from the nucleotide sequences of

[157] S 4 BDA.

[158] 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.

[159] S 6 BDA.

[160] 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.

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

[162] 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.

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

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,[164] 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 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,[165] 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.[166] 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.[167] 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.

[164] Lim et.al. "Plasmodium vivax: Recent world expansion and genetic identity to Plasmodium simium" in PNAS of October 2005.
[165] EP1962578 – 'Closterovirus-Resistant Melon Plants' granted by EPO on 4th May 2011.
[166] https://www.ip-watch.org/weblog/wp-content/uploads/2016/01/National-Biodiversity-Authority-India.pdf
[167] India, Submission under Decision 14/20.

Table 1

Benefit-Sharing Percentage for Regulated Activities[168]

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	Reg 13 of ABS Guidelines				
	Research	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
			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
4	Bio-survey & bio-utilization for commercial utilization	S 3	Form I	Only Non-Indians & non-Indian entities covered under section 3(2)	NBA	On Annual Gross ex-factory sale of the product minus government taxes – 0.1% for companies up to Rs.100,000,000 ($1,419,072.00 USD); 0.2% for companies between Rs. 100,000,001 ($1,419,087.74 USD) to 300,000,000 ($4,256,966.17 USD); 0.3% for companies above Rs. 300,00,000 ($4,256,966.17 USD)
		S 7	Form I of the concerned SBB Rules	Only Indian and Indian entities	SBB	Same as above
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

[168] 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). (hyperlink no longer available).

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

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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	Costa Rica	E-mail	N/A

	ABS authority)		communication	
(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	Biodiversity Department, Ministry of the Environment	Panama	E-mail communication	07.10.2019
(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 Center	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

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