

# POLICY BRIEF

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## Why Defining the Scope of Access and Benefit Sharing Matters

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**Voices for BioJustice**

Working towards the equitable and  
sustainable use of biodiversity

## INTRODUCTION

“Access to genetic resources and the fair and equitable sharing of benefits” (ABS) has become, arguably, the most studied and reflected upon concept in the Convention on Biological Diversity (CBD) process since 1992. But despite all of this attention, it is still not clear what is included under the scope of ABS. In other words: what does ABS actually cover?

The scope of ABS has shifted and changed over the years. In what could be called a “Big Bang” effect, the definition and conceptualisation of ABS has continuously and indefinitely expanded, shifted, changed and opened up to new meanings since 1992. This has meant that efforts to implement ABS nationally and internationally have been challenging.

It might seem obvious that before a government can regulate an activity it needs to know what that activity is. For example, regulating logging and the timber industry requires a good idea of what that entails and at which points regulations are most effective. This might include, for example, management plans, harvesting practices, allowable cuts, taxes, and so on. For ABS, this kind of clarity has long been absent and continues to obscure regulations and practices at international, regional and national levels.

Samples for drug development, a raw plant ingredient used in a cosmetic product, herbal teas, or microorganisms that contribute to biotechnological processes: do all fall under ABS?

How about a product that is based on TK from centuries prior? Where do we draw the line, and what is in and what is out?



*The oil derived from the kernels of the fruit of the marula tree (Sclerocarya birrea), is highly valued in the cosmetics industry. Credit: iamphoto © 123rf.com*

## KEY POINTS

- The **scope of ABS has shifted and changed** over the years, expanding and opening to new meanings since its adoption by the CBD in 1992.
- The shifting of scope has made **implementation of ABS challenging**.
- Many **governments remain unclear** about what activities and products fall within the scope of ABS.
- Weak ABS implementation is due in part to a **lack of clarity about scope**, with governments struggling to grant permission when they are unclear about what is being regulated.
- Scope is an issue with immediate relevance and urgency due to the **potential inclusion of genetic sequence data or “digital sequence information” (DSI)** within ABS measures.
- Traditional knowledge (TK) has become a “satellite issue” in national ABS frameworks, but it **remains unclear in practice how TK is regulated**.
- The Nagoya Protocol defined the scope of ABS to include “utilisation”, “biotechnology” and “derivatives”, but **countries are still struggling to create national institutional and legal frameworks** which clarify what ABS means and covers in practice.
- **Clear scope is essential to dissipate legal and practical uncertainties, and can also facilitate research and development**, the precursor to both monetary and non-monetary benefit sharing.
- **Unclear scope makes for unclear policy and legal frameworks** and can impact negatively on academic research and important conservation research.
- Unclear scope can also have **unintended negative consequences** on those who are intended to benefit from ABS laws.
- International and national regulatory frameworks have **widely diverging interpretations of ABS scope**.

## ABS SCOPE CREEP OVER TIME

### Four distinct phases characterise the way ABS scope has changed over time:

1. Under the FAO International Undertaking (1983) a narrow interpretation of ABS limited scope to plant genetic resources.
2. Under the CBD (1992), and over the next decade or so, the scope of ABS expanded significantly, particularly through national actions and the development of ABS frameworks which included genetic resources, natural products, derivatives, the TK of indigenous peoples and even biological resources through biotrade.
3. The Nagoya Protocol (2010) sought, unsuccessfully, to limit the scope of ABS by defining it as the utilisation of genetic resources and derivatives in R&D, including through biotechnology, but maintaining TK as an essential part of the scope of ABS.
4. Finally, the relatively recent discussion on genetic sequence data - or “digital sequence information” (DSI), has brought new interest to the scope of ABS as countries debate whether or not DSI should fall within the scope of the Nagoya Protocol. This debate is also now spilling over into other policy fora, including ABS discussions under the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), the World Health Organisation (WHO), and the United Nations Convention on the Law of the Sea (UNCLOS).

## CONFUSION AROUND ABS SCOPE

A lot of confusion surrounds the activities and products covered by ABS, both at the international level and, often more so, at national level. The CBD addresses “genetic resources” and “biological resources”, but what does that mean in practice to local groups, researchers, indigenous peoples, companies, and governments?

There is also often confusion about the nature of the activity and its end use. For example, is the research being conducted for academic purposes or for commercial ends? Or, more commonly today, is it a blend of both, and difficult to disentangle?

Stakeholders tend to view ABS in many different ways. This is partly because the scope of ABS has become exceedingly broad and often unclear. Existing international and national frameworks offer very different interpretations of the scope of ABS including, to varying extents, the inclusion of biological materials, genetic resources, derived products, indigenous peoples’ knowledge, biotrade, and more recently DSI – a negotiated placeholder term for information derived from genetic resources.

ABS policy has provided a home for numerous orphaned ethical issues associated with biodiversity, TK, genetic resources, and advanced science and technology. It has been all things to all people and has resulted in invaluable dialogues convened over the last few decades. But its implementation has always lagged behind its promise, in part due to the ambiguity around what it actually regulates and covers. This is a pressing matter today as policy makers and others grapple with the implications of DSI for ABS.



*Traditional knowledge related to medicinal plants such as these may lead to the discovery of useful compounds.  
Credit: Morley Read © 123rf.com*

## THE WIDE INTERPRETATION OF SCOPE IN ABS LAWS AND REGULATIONS

Access and benefit-sharing policies, laws, strategies and other tools include the following broad range of categories within their scope and coverage:

- Biotrade
- Genetic resources
- Genetic heritage or patrimony
- Genetic information
- Biological resources
- Biochemicals
- Derivatives
- Derived products
- Traditional knowledge
- Knowledge, innovations and practices associated with genetic resources
- Microorganisms
- “Digital sequence information”

### WHAT IS THE “SCOPE” OF ABS IN EXISTING LAWS?

Scope means quite simply what is covered by ABS frameworks. This means the activities, actions and circumstances that are included under specific ABS legal and regulatory rules and principles and the subject matter or phenomenon they apply to.

Defining the scope of laws is usually one of the first steps in a policy process. But ABS has worked backwards in this regard. Although informed by a set of international principles in the CBD and its 2010 Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation, the specificities of what activities fall within its mandate are left largely to national legislation and regulation to define. Even though the Nagoya Protocol narrows the content of ABS by defining “utilisation”, “biotechnology” and “derivatives”, countries are still struggling to create national institutional and legal frameworks which clarify what ABS means and covers in practice.

Inclusion of the TK of indigenous people under the scope of ABS frameworks has added an extra layer of complexity to ABS, as has the notion of DSI as ABS subject matter.

### PHYSICAL MATERIAL, INFORMATION OR BOTH?

Access and benefit sharing under the CBD was conceived largely around the products and advances in biotechnology and the commercial use of genetic resources. Genetic resources used in biotechnology typically take the form of genetic sequence data and information held in databases, rather than physical material. However, from the outset the CBD created confusion by defining genetic resources as material, rather than information (or natural information). The Nagoya Protocol also focused on physical or “tangible” material, while science and technology were moving towards greater use of intangible genetic sequence data. The collection of biological samples, the use of TK, biotrade value chains – all are quite different from genetic sequences, and the information contained in physical samples. The distinction between physical materials and the genetic information contained within them has become a critical issue, as governments deliberate on the inclusion of DSI within ABS measures.

## COVERAGE AND SCOPE OF ABS UNDER THE NAGOYA PROTOCOL

<b>Article 2. Use of terms</b>	The terms defined in Article 2 of the Convention shall apply to this Protocol. In addition, for the purposes of this Protocol: (c) “Utilisation of genetic resources” means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention; (d) “Biotechnology” as defined in Article 2 of the Convention means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use; (e) “Derivative” means a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity.
<b>Article 3. Scope</b>	This Protocol shall apply to genetic resources within the scope of Article 15 of the Convention and to the benefits arising from the utilisation of such resources. This Protocol shall also apply to TK associated with genetic resources within the scope of the Convention and to the benefits arising from the utilisation of such knowledge.

## TRADITIONAL KNOWLEDGE: WITHIN OR OUTSIDE ABS?

Traditional knowledge has become in some ways a “satellite issue” in national ABS frameworks. Whilst TK is addressed in ABS laws and is acknowledged as critically important, it is still unclear how TK protection can be effectively regulated under ABS frameworks. To date, broad references to contracts, biocultural protocols, defensive protection, registers and so on have folded TK into ABS, but with mixed and often disappointing results in practice. Almost all countries with ABS laws or regulations refer (in more or less detail) to TK within their scope. These include, for example:

- the Biodiversity Law 7788 and its regulations in Costa Rica;
- Law 13,123 on the genetic heritage of Brazil; and
- the Biological Diversity Act and implementing regulations in India.

Peru has enacted a specific and stand-alone law for the protection of TK related to biological and genetic resources (Law 27811, on the Protection of Collective Knowledge of Indigenous Peoples, 2000). However, its implementation has been limited due to challenges relating to putting principles into practice when there are competing economic and political interests and developing laws that respond appropriately to indigenous peoples’ realities.

In South Africa, the Indigenous Knowledge Systems Act explicitly includes knowledge relating to biodiversity, but has a highly ambiguous scope, requiring any person who intends to use Indigenous Knowledge (IK) for commercial purposes to apply for a license and negotiate a benefit-sharing agreement. Significant implementation challenges arise from the fact that a parallel system is being set up to that envisaged under the Biodiversity Act for access and benefit sharing.

Clear scope is essential to dissipate legal and practical uncertainties and can also facilitate R&D, the precursor to both monetary and non-monetary benefit sharing. However, since its inception, legal uncertainties regarding scope have slowed commercial R&D investment in genetic resources. Of particular concern are the effects of stringent, costly and time-consuming ABS regulations on non-commercial, academic biodiversity research, including important conservation research. When scope is not clear, suspicions surround all forms of research, including academic research. Governments have also struggled to grant permission for research when they are unclear on what is being regulated, and what they can approve, with many fearing charges of abetting biopiracy.

## DIGITAL SEQUENCE INFORMATION AND ABS – WHAT DOES DSI MEAN?

In 2016 the CBD began work on genetic sequence data, commissioning studies and forming expert groups to explore ABS and what is termed “digital sequence information” or DSI. The term DSI itself is an indication of the confusion surrounding scope issues - it is a political, not scientific, term, amalgamating different policy concerns and priorities. Its meaning remains in dispute, and it is viewed as a placeholder that will allow those making future decisions and regulations to define the term at a later date (CBD/COP/14/WG.1/CRP.37, November 28, 2018). Recent studies commissioned by the CBD Secretariat have sought to respond to issues around scope, and what is included under this umbrella term, but a resolution is still in the future, and ABS measures hang uncertainly in the meantime in a no-man’s land, with some governments moving forward on their own, and others rejecting inclusion of DSI within ABS. No consensus has been reached on whether DSI is limited to DNA and RNA sequences or whether it also covers amino acid sequences or proteins and metabolites produced by biosynthetic enzymes. See recent CBD papers on this topic:

<https://www.cbd.int/abs/DSI-peer/Study-Traceability-databases.pdf>

[https://www.cbd.int/abs/DSI-peer/Study1\\_concept\\_scope.pdf](https://www.cbd.int/abs/DSI-peer/Study1_concept_scope.pdf)



*Clear scope is essential to dissipate legal and practical uncertainties and can also facilitate R&D*  
Photo Credits (left) Tatiana Shepeleva © 123rf.com; (right) Anna Ivanova © 123rf.com

## KEY INTERNATIONAL, REGIONAL AND NATIONAL ABS TOOLS AND FRAMEWORKS

International instruments	Scope of ABS
<b>FAO International Undertaking on Plant Genetic Resources (1983)</b>	The International Undertaking relates to the plant genetic resources of all species of economic and/or social interest, particularly for agriculture at present or in the future and has particular reference to food crops.
<b>Convention on Biological Diversity (CBD) (1992)</b>	ABS under the CBD relates to genetic resources (of plant, animal or microbial origin) being provided by a Contracting Party, which is a country of origin of such resources or by the Parties that have acquired the genetic resources in accordance with the CBD rules and principles.
<b>FAO International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) (2001)</b>	The International Treaty applies to all plant genetic resources for food and agriculture (PGRFA), but the multilateral ABS system it creates, applies only to PGRFA under the set list (Annex I) of the ITPGRFA and which are under administration and control of member states, in CGIAR ex situ centres and for use in agriculture.
<b>Bonn Guidelines on Access to Genetic Resources and Benefit Sharing (2004)</b>	The Bonn Guidelines include all genetic resources and associated TK, innovations and practices covered by the CBD and benefits arising from the commercial and other utilisation of such resources, excluding human genetic resources.
<b>Nagoya Protocol on Access to and Utilisation of Genetic Resources (2010)</b>	The Nagoya Protocol applies to genetic resources within the scope of Article 15 of the CBD and to the benefits arising from the utilisation of such resources. It also applies to TK associated with genetic resources within the scope of the CBD and to the benefits arising from the utilisation of such knowledge. Recently, discussions are centring on whether “DSI” should be part of the scope of ABS.
<b>World Health Organisation (WHO) Pandemic Influenza Preparedness Framework (2011)</b>	This Framework applies to the sharing of H5N1 and other influenza viruses with human pandemic potential and the sharing of benefits.
<b>United Nations Convention on the Law of the Sea (UNCLOS) (1994)</b>	A process is underway to identify the best policy options to regulate biodiversity (including marine genetic resources) beyond national jurisdictions (BBNJ) - i.e. the high seas or the deep seabed. ABS is included in these discussions, as is DSI. See Marine Genetic Resources in the UN BBNJ Process, at <a href="https://www.abdn.ac.uk/ncs/departments/chemistry/bbnj/#panel1104">https://www.abdn.ac.uk/ncs/departments/chemistry/bbnj/#panel1104</a>

## ABS SCOPE AND COVERAGE IN REGIONAL AND NATIONAL FRAMEWORKS

<p><b>Andean Community Decision 391 on ABS (1996)</b></p>	<p>Andean Community Decision 391 applies to all genetic resources of which member states are countries of origin for their derived products and intangible components, and those of migratory species. “Access” is defined as obtaining and using genetic resources in in situ or ex situ conditions, their derived products, or intangible components for research, biological prospecting, conservation, industrial or commercial applications, among others.</p>
<p><b>Biodiversity Law 7788 and regulations of Costa Rica (1998)</b></p>	<p>Law 7788 and its ABS provisions apply to elements of biodiversity which are under national sovereignty, including biochemicals, which are defined as any material of plants, animals and microorganisms which contain specific characteristics, special molecules or leads to design them.</p>
<p><b>The National Environmental Management: Biodiversity Act of South Africa (10 of 2004) and the 2008 Bioprospecting, Access and Benefit-Sharing Regulations</b></p>	<p>“Bioprospecting”, in relation to indigenous biological resources, means any research on, or development or application of, indigenous biological resources for commercial or industrial exploitation, and includes:</p> <ul style="list-style-type: none"> <li>• the systematic search, collection or gathering of such resources or making extractions from such resources for purposes of such research, development or application;</li> <li>• the utilisation for purposes of such research or development of any information regarding any traditional uses of indigenous biological resources by indigenous communities; or</li> <li>• research on, or the application, development or modification of, any such traditional uses, for commercial or industrial exploitation.</li> </ul> <p>“Indigenous biological resources” includes:</p> <ul style="list-style-type: none"> <li>• any indigenous biological resources whether gathered from the wild or accessed from any other source, including any animals, plants or other organisms of an indigenous species cultivated, bred or kept in captivity or cultivated or altered in any way by means of biotechnology;</li> <li>• any cultivar, variety, strain, derivative, hybrid or fertile version of any indigenous species or of any animals, plants or other organisms referred to above; and</li> <li>• any exotic animals, plants or other organisms, whether gathered from the wild or accessed from any other source which, through the use of biotechnology, have been altered with any genetic material or chemical compound found in any indigenous species or any animals, plants or other organisms.</li> </ul> <p>Amendments made in 2013 extend the definitions of “bioprospecting” and “commercialisation” to include “the trading in and exporting of indigenous biological resources to produce products”; and include “commercial exploitation” as a form of commercialisation. Prior to this amendment there was some ambiguity about whether biotrade was included within the ambit of the Biodiversity Act but the amendment clarified that biotrade now falls squarely within the regulatory framework, despite concerns that this approach is inappropriate and contrary to the intent of the Nagoya Protocol (Wynberg, 2017).</p>
<p><b>Federal Law No. 13,123 of 2015 (Brazilian ABS Law)</b></p>	<p>Under the new law, “access” is defined as research or technological development conducted on a sample of the genetic heritage of Brazil or associated TK. “Genetic heritage” includes information of genetic origin from plant, animal or microorganisms, including metabolic substances. This covers Brazilian native species as well as some non- native species.</p>



<p><b>Access to Biological and Genetic Resources and Associated Traditional Knowledge, Act no. 2 of 2017, Republic of Namibia</b></p>	<p>The Namibian Act regulates access to biological as well as genetic resources and the TK associated with these. It also regulates the innovations, practices and technologies associated with biological and genetic resources as well as TK. These resources are defined as follows:</p> <ul style="list-style-type: none"> <li>• Biological resources – organisms or parts thereof, populations or any other biotic component of ecosystems with actual or potential use or value for humanity</li> <li>• Genetic resources – any material of plant, animal, microbial or other origin containing or derived from functional units of heredity and which has actual or potential value</li> <li>• Associated TK – accumulated or individual knowledge, practices, innovation or technologies associated with biological or genetic resources which is created or developed over generations by local communities</li> <li>• Access – includes obtaining, collecting, possessing, acquiring, using and selling whether directly or indirectly</li> </ul> <p>The scope and coverage of this legislation is very broad, however, since the regulations for the implementation of this legislation are still being drafted, the operational implications for Namibia’s extensive biotrade activities are not yet clear.</p>
<p><b>Queensland Australia Biodiscovery Act 2004</b></p>	<p>The Biodiscovery Act seeks to facilitate access by biodiscovery entities (e.g. universities or research institutions) to minimal quantities of native biological resources on or in State land or Queensland waters (State native biological resources) for biodiscovery.</p> <p>“Biodiscovery” is defined broadly to include (a) biodiscovery research; or (b) the commercialisation of native biological material or a product of biodiscovery research.</p> <p>“Biodiscovery research” means the analysis of molecular, biochemical or genetic information about native biological material for the purpose of commercialising the material.</p>
<p><b>Draft Law on Access to Genetic Resources and Associated Traditional Knowledge and the Fair and Equitable Sharing of Benefits Arising from their Utilization, 2018, Cameroon.</b></p>	<p>The draft 2018 ABS Law, and draft implementing decree, are still under review within government, but in their current form they establish national patrimony and rights over <i>in situ</i> and <i>ex situ</i> genetic resources, derivatives of genetic resources, and genetic information (Article 5). They regulate access and utilization of genetic resources, defined as:</p> <p>Access - the collection or acquisition, including any transaction involving, genetic resources, derivatives, or associated traditional knowledge by a user (Article 7).</p> <p><i>Utilisation of genetic resources and associated traditional knowledge</i> - research on the properties of plants, animals, micro-organisms, and the associated traditional knowledge and derivatives, in order to enhance scientific knowledge or develop commercial products (Article 7).</p> <p>Definitions in Article 7 include those for bioprospecting, biopiracy, biotechnology, IPLC, MAT, associated TK, PIC, derivatives, TK holder, customary law, IPR, ABS permit, community biocultural protocol, biological resources, genetic resources, technology transfer, user, and utilisation of GR and TK.</p>

## WHAT SCOPE MEANS FOR ENACTING GOOD POLICY

Clarifying ABS scope is critical for policy implementation. A clear and circumscribed scope facilitates policy and regulatory options, implementation and enables legal certainty.

Elements central to a consideration of scope in ABS measures include:

- What is the underlying intention of the ABS measure and what kind of scope will best serve this aim?
- What are the advantages and disadvantages of narrowing or widening the scope? Which actors will be privileged or deprived by these measures?
- What can practically be regulated in a single framework? How similar or dissimilar are the products, activities and stakeholders associated with each regulatory framework? What are the advantages and disadvantages of customised approaches for different modes of utilisation vs harmonised expansive frameworks?
- What are the essential elements which need to be captured by ABS scope and the most efficient regulatory options following from that?
- What might be the most appropriate policy options through which ABS can best achieve economic development and social justice, positively impact biodiversity conservation, build capacity, and support R&D?
- Is ABS the best catchall to achieve conservation and equity for all activities, or might a collection of different measures better capture the range of uses now considered part of ABS?
- Which institutional body/ies within government will oversee these regulations? Do they have capacity and expertise in every field considered for regulation? Is the funding and institutional support to execute the laws adequate for effective implementation?



*Aloe ferox, native to South Africa, is widely used traditionally as well as in personal care and ethnobotanical products. Credit: Umberto Leporini © 123rf.com*

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