



Regulations Surrounding Botanicals

by

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MSc

What are Genetic Resources?

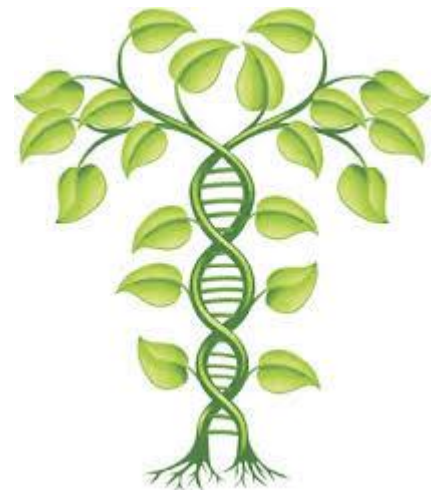
- All living organisms (plants, animals and microbes) carry genetic material potentially useful to humans
- These resources can be taken from the wild, domesticated or cultivated
- They are sourced from:
 - Natural environments (in situ)
 - Human-made collections (ex situ) (e.g. botanical gardens, genebanks, seed banks and microbial culture collections)

Why are Genetic Resources Important?

- They provide crucial information to better understand nature
- They can be used to develop a wide range of products and services for human benefit
- The way in which genetic resources are accessed and how the benefits arising from their use is shared can create incentives for:
 - The conservation and sustainable use of biodiversity
 - The creation of a fairer and more equitable economy to support sustainable development

What is Access and Benefit Sharing (ABS)?

- It refers to the way in which genetic resources may be accessed, and how the benefits that result from their use are shared between the people or countries using the resources (users) and the people or countries that provide them (providers)
- Based on the fundamental principles of prior informed consent (PIC) and mutually agreed terms (MAT).



What is prior informed consent?

- Permission given by the **Competent National Authority** of a provider country to a user prior to accessing genetic resources, in line with an appropriate national legal and institutional framework

What are mutually agreed terms?

- An agreement reached between the providers of genetic resources and users on the conditions of access and use and the benefits to be shared between both parties



National Focal Points (NFPs)

- Responsible for providing information on ABS, such as the requirements for gaining access to genetic resources

Competent National Authorities (CNAs)

- Established by governments and responsible for granting access to their genetic resources
- Represent providers on a local or national level



ABS Timeline



- 1992 The text of the Convention on Biological Diversity (CBD) is opened for signature at the Rio Earth Summit
- 1993 The CBD is ratified and comes into force
- 1998 A panel of experts is established to clarify principles and concepts related to ABS
- 2000 The Conference of the Parties establishes the Ad Hoc Open-ended Working Group on Access and Benefit-sharing.
- 2002 The Conference of the Parties adopts the Bonn Guidelines on ABS at the World Summit on Sustainable Development, States called for action to negotiate an international regime to promote the fair and equitable ABS
- 2004 The Working Group on ABS is given the mandate to negotiate an International Regime on ABS

2008 The Conference of the Parties establishes a clear process for the finalisation of the international regime on ABS and its adoption at its tenth meeting in October 2010

2010 **The Nagoya Protocol** on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization was adopted by the Conference of the Parties, at its tenth meeting, in Nagoya, Japan



Nagoya Protocol

**NAGOYA PROTOCOL
ON
ACCESS TO GENETIC RESOURCES
AND THE FAIR AND EQUITABLE
SHARING OF BENEFITS ARISING
FROM THEIR UTILIZATION
TO THE
CONVENTION ON
BIOLOGICAL DIVERSITY
TEXT AND ANNEX**



- International treaty to support the implementation of fair and equitable ABS
- Adopted in Nagoya, Japan on 29 October 2010
- In force from 12 October 2014
- International governance of bioactive diversity relevant for commercial and non-commercial sectors dealing with genetic resources
- Based on the fundamental principles PIC and MAT.

Why is the Nagoya Protocol Important?

**NAGOYA PROTOCOL
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TEXT AND ANNEX



- It will create greater legal certainty for users and providers of genetic resources
- It will help to ensure benefit-sharing, in particular when genetic resources leave the country providing the resource
- It establishes more predictable conditions for access

Active Parties

Albania

Belarus

Benin

Bhutan

Botswana

Burkina Faso

Burundi

Comoros

Côte d'Ivoire

Denmark

Egypt

Ethiopia

European Union

Fiji

Gabon

Gambia

Guatemala

Guinea

Guinea-Bissau

Guyana

Honduras

Hungary

India

Indonesia

Jordan

Kenya

Lao People's Democratic

Republic

Madagascar

Malawi

Mauritius

Mexico

Micronesia

(Federated States of)

Mongolia

Mozambique

Myanmar

Namibia

Panama

Peru

Rwanda

Samoa

Seychelles

South Africa (in 2011)

Spain

Sudan

Switzerland

Syrian Arab Republic

Tajikistan

Uganda

United Arab Emirates

Uruguay

Vanuatu

Vietnam



Core Elements of the Nagoya Protocol?

- Access
- Benefit-sharing
- Compliance
- Traditional knowledge



Domestic-level access measures should:

- Create legal certainty, clarity and transparency
- Provide fair and non-arbitrary rules and procedures
- Establish clear rules and procedures for prior informed consent and mutually agreed terms
- Provide for issuance of a permit or its equivalent when access is granted
- Create conditions to promote and encourage research contributing to biodiversity conservation and sustainable use
- Pay due regard to cases of present or imminent emergencies that threaten human, animal or plant health
- Consider the importance of genetic resources for food and agriculture and their special role for food security

Domestic-level benefit-sharing measures should:

- Provide for the fair and equitable sharing of benefits arising from the utilization of genetic resources, as well as subsequent applications and commercialization, with the contracting party providing the genetic resources
- Ensure that sharing of benefits is subject to mutually agreed terms. Benefits may be monetary (such as royalties) or non-monetary (such as sharing research results or technology transfer)



- To address benefit-sharing with respect to genetic resources occurring in:
 - Trans-boundary areas
 - Situations where prior informed consent cannot be obtained
- The need for and modalities of this mechanism are to be considered
- Benefits shared through this mechanism are to be used to support the conservation and sustainable use of biodiversity globally



Domestic-level Compliance Regulations should:

- Take measures to provide that genetic resources utilised within their jurisdiction have been accessed in accordance with prior informed consent, and that mutually agreed terms have been established
- Take measures to address situations of non-compliance
- Cooperate in cases of alleged violation of another Party's requirements



Domestic-level Traditional Knowledge measures should:

Aim to ensure that indigenous and local communities obtain a fair share of the benefits from the use of their:

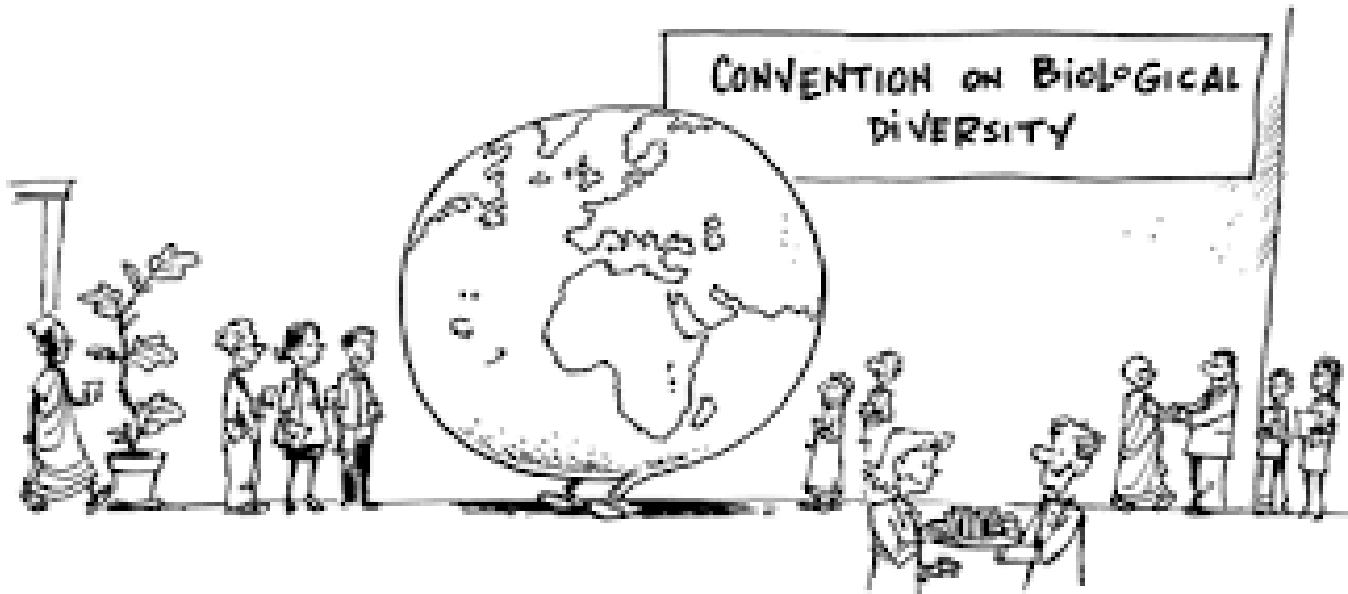
- Traditional knowledge associated with genetic resources
- Genetic resources, in cases where they have established rights to grant access to them, in accordance with national legislation

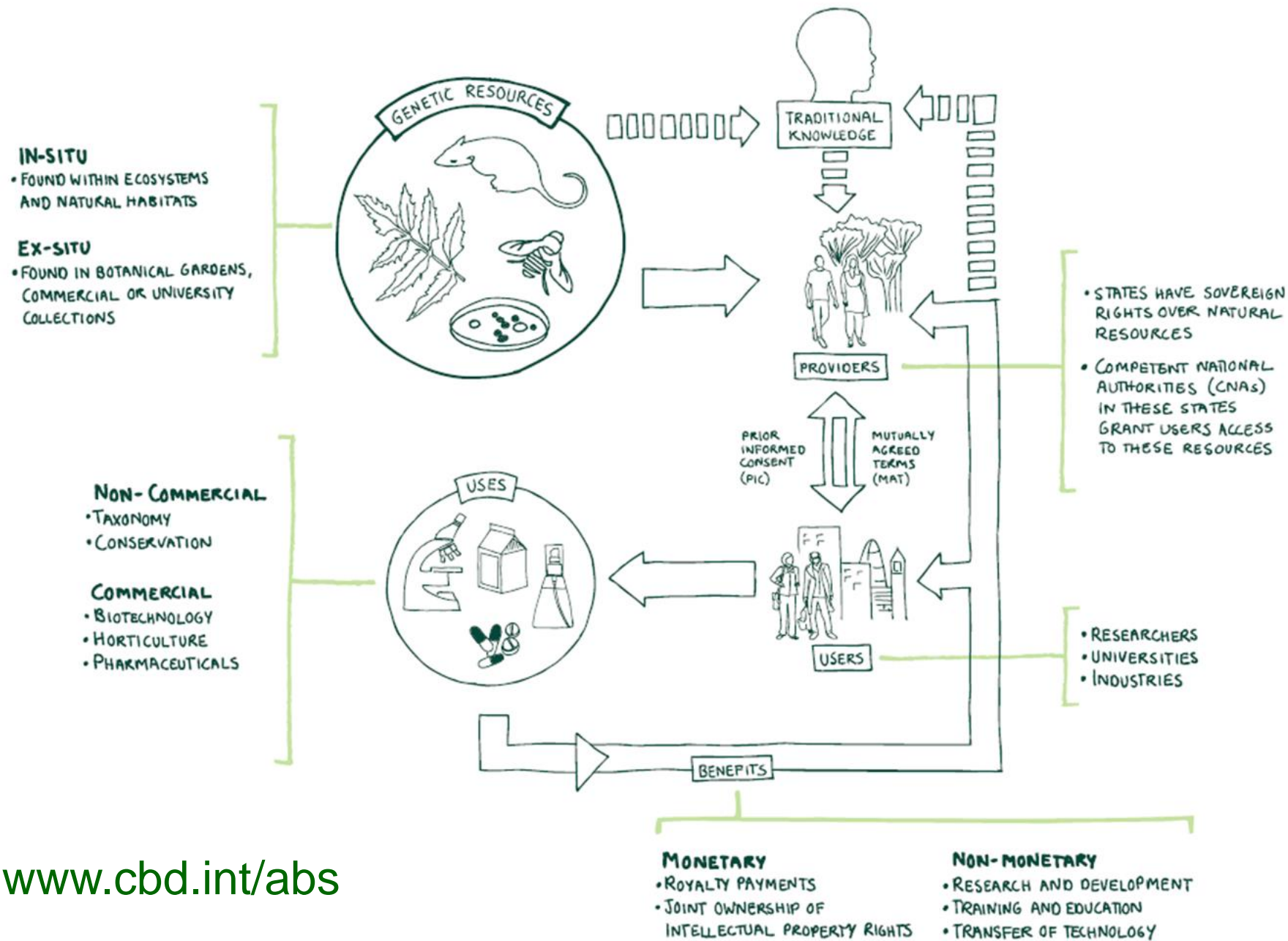


Supporting Mechanisms

- National Focal Points and Competent National Authorities: provide information, grant access and facilitate cooperation
- Access and Benefit-sharing Clearing-House: a web-based information exchange mechanism

<https://absch.cbd.int/>





www.cbd.int/abs

South Africa's Bioprospecting, Access and Benefit-Sharing Regulatory Framework

Guidelines for Providers,
Users and Regulators



- South Africa 3rd most flora/ fauna mega diverse country
- National Environmental Management Biodiversity Act 2004 (Act no 10, 2004)
- Bioprospecting, Access and Benefit Sharing (BABS) Regulations of 2008 (Amendments published 2014)
- Competent National Authority: Department of Environmental Affairs



environmental affairs

Department:
Environmental Affairs
REPUBLIC OF SOUTH AFRICA

- BABS application takes into account under Mutual Agreed Terms:
 - Access and Benefit Sharing
 - Traditional Knowledge Transfer
- Any indigenous species used for any purpose other than its intended purpose must have a permit.

Eg. Rooibos – no permit needed for tea but permit needed for use of extract in a cosmetic
- Permit fees will benefit cultivation and indigenous knowledge
- 1 permit per a project
- Permits can contain multiple extracts



- Hoodia is a succulent plant indigenous to South Africa
- It has been used for centuries by indigenous San peoples to stave off hunger and thirst
- In 1996, the South African-based Council for Scientific and Industrial Research (CSIR) patented active compounds of Hoodia for potential commercialization of an appetite suppressant
- This led to a licensing agreement between CSIR and some large pharmaceutical companies to develop and commercialize a Hoodia-based product

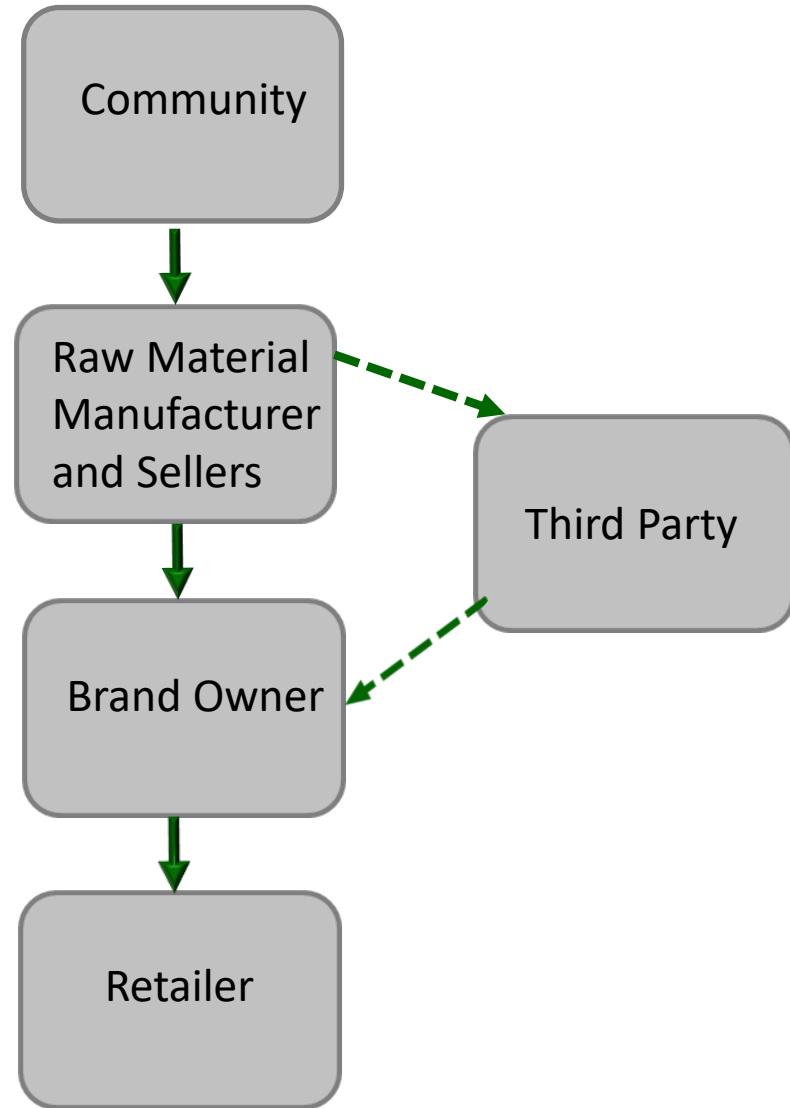


- Initial actions were taken without the consent of the San peoples which led to an outcry by NGOs and media attention
- As a result, a benefit-sharing agreement was signed with the San peoples

The agreement included:

- Monetary benefits:
- Milestone payments during product development
- Royalty payment in the case of commercialization
- Non-monetary benefits:
- Funds for development, education and training of the San community
- Funds to support projects and institutions working to improve research and protection of the San traditional knowledge and heritage

- Complex supply chain
- Who is 1 permit for a project?
- How do we know Traditional Knowledge? www.sanbi.org



Penalties for Offenders

First Offence:

5 million rand fine and/or 5 years imprisonment

Second Offence:

10 million rand fine and/or 10 years imprisonment





Imported material:

- Department of Environmental Affairs can audit you against the sourcing countries regulations
- Information is available on ABS Clearing House: <https://absch.cbd.int/>

Exported Material:

- Indigenous material is expected to comply with BABS Regulations independent of Nagoya Ratification

Time to Comply



As you can see this is law- you need to comply!

CTFA can assist with any queries:

technical@ctfa.co.za

011 795 4272

www.ctfa.co.za