

From extractive to blessing:
Inverting psychedelic biotech
through adoption of
the Nagoya protocol and
Free, Prior, Informed Consent (FPIC)

Los Angeles Medicinal Plant Society
Symposium 2021

Dr. Joseph Peter Barsuglia



My Background

Past:

- Research / Clinical Psychologist Crossroads Ibogaine Clinic 2015-2017, ibogaine + 5-MeO
- Psychotherapist - Phase 2 Trials MAPS MDMA-Assisted Therapy for PTSD 2016-2019
- Co-founder w/ Partner Tricia Eastman, International Retreat Leader for Psychedelic Journeys
- Personal healing with iboga, heart for Gabon, Bwiti initiate in lineages Fang and Missoko

Present:

- Advisor, Journey Colab - developing Mescaline + 5-MeO through FDA
- Advisor, Lionheart Ventures - due diligence, ethical adherence and reciprocity
- Advisor, non-profits VETS (Veteran's Exploring Treatment Solutions) and Mission Within

Future:

- HU Azores - Institute for Sacred Science, Integration, and Ancestral Wisdom

MINDCURE Announces
Manufacturing of Synthetic
Ibogaine to be Used in
Company's Clinical Research

Mr. Wonderful
thinks
psychedelics are
the new wave of
medicine and this
Shark Tank
investor is betting
big.

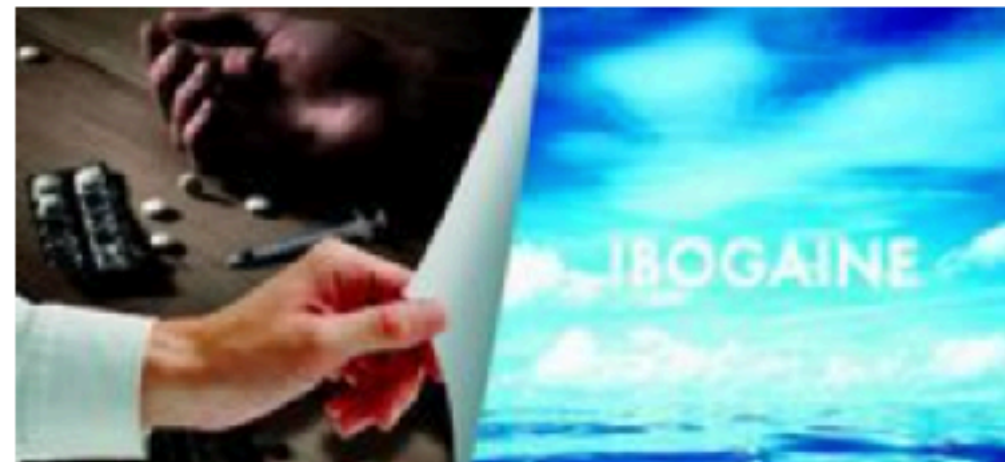


THE WALL STREET JOURNAL.

Psychedelics-Drug Startup Raises \$24 Million Ahead of IPO

Drugmaker is pursuing trials of hallucinogen's efficacy for treating
addiction, other mental-health conditions

Ibogaine Partners Franchise



Make Money by Saving Lives with a Drug & Alcohol
Miracle Cure Opportunity!



Start your business!



TIME

SUBSCRIBE

HEALTH • MENTAL HEALTH

Inside Ibogaine, One of the Most Promising and Perilous
Psychedelics for Addiction



MindMed



atai

LIFE SCIENCES



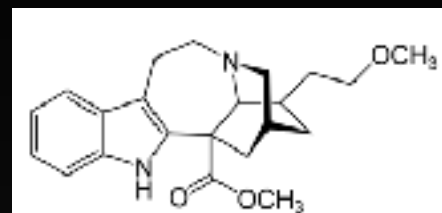
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IBOGAINE

GILGAMESH

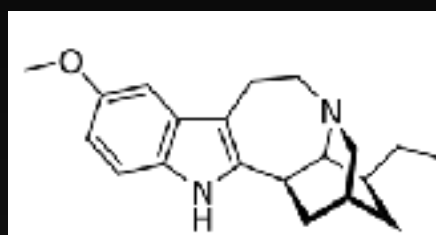
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MINDCURE

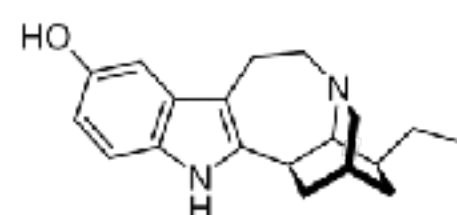
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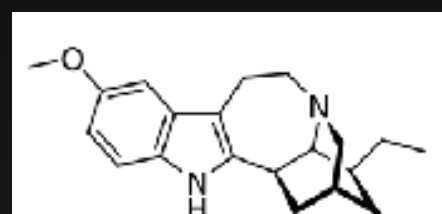
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Ibogaine

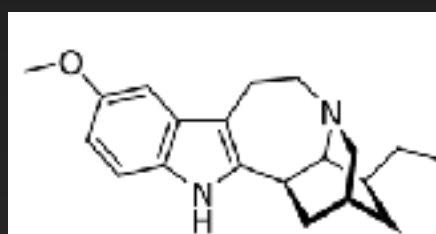


Noribogaine

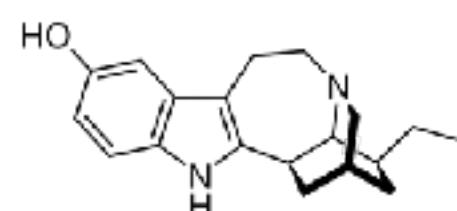


Ibogaine

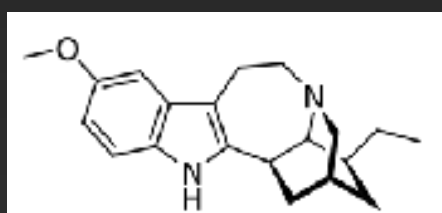
Novel
Ibogaine
Analog?



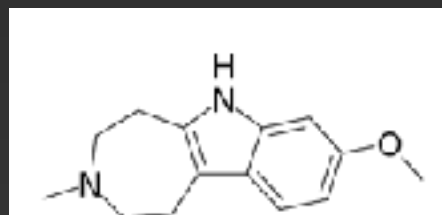
Ibogaine



Noribogaine



Ibogaine



Tabernathalog

Ibogaine biotech

Percent with reciprocity
to Gabon, adherence to
Nagoya Protocol or FPIC
= 0%





"Ibogaine has centuries of therapeutic history reinforcing its potential to heal pain."

- Kelsey Ramsden, President & CEO, MINDCURE.

"Ibogaine's therapeutic potential isn't a new concept."

- Ryan Hartwell, Chief Scientific Officer, MINDCURE.



Ibogaine is a naturally occurring psychoactive compound found in the root bark of the African shrub *Tabernanthe iboga*, as well as other plants in the Apocynaceae family. Although thought to be used for hundreds – if not thousands – of years in ceremonial and spiritual settings in African communities, the first Western reports of ibogaine use came from French and Belgian explorers in the 19th century.

**“It is no longer okay
for people to go into our forests
and to take our medicines,
patent them without our permission,
and use them without their teachings”**

~ Grandmother Bernadette Rebienot



Bwiti elder

Founding Member of the 13 Indigenous Grandmothers

Former President of the Association of Traditional Medicine Practitioners for Gabonese Health

As quoted in letter by Jyoti Ma - [Video link](#)

Compound to Nagoya Compliance

	<u>Clear traditional use & knowledge</u>	<u>Being Extracted and/or Patented</u>	<u>Prior Informed Consent? Or Nagoya compliance?</u>
Psilocybin	✓	✓	✗
5-MeO-DMT	✓	✓	✗
Iboga / Ibogaine	✓	✓	✗
DMT / Ayahuasca / Pharmahuasca	✓	✓	✗
Mescaline	✓	✓	✗ <div>journey colab</div>
Salvia Divinorum	✓	✓	✗

Ethical Initiatives in Psychedelic Community

1) “Statement on Open Science and Praxis With Psilocybin, MDMA, and Similar Substances”

Community-wide agreement signed by dozens of scientists, scholars, practitioners, research and service organizations, psychedelic societies, organizers, publishers, conferences, philanthropists and donors. Filed December 2017. Website - <https://files.csp.org/open.pdf>

The logo for the Council on Spiritual Practices, featuring the text "COUNCIL ON SPIRITUAL PRACTICES" in a blue serif font, enclosed within a thin blue rectangular border.

2) North Star Ethics Pledge

7 Ethical Principles developed from ~100 stakeholders in the psychedelic community
Developed 2020 - Website - <https://www.northstar.guide/ethicspledge>



A few issues with these initiatives:

- **Virtually zero % adherence to date for either initiative in psychedelic biotech**
- **Non-enforceable, no legal ramifications for failure to adhere**
- **Do not adequately address ecological concerns, indigenous people or knowledge**

extractive adjective

\ ik-'strak-tiv , 'ek-,strak- \

resulting in withdrawal of natural resources by taking without provision for replenishment



bless verb

\ 'bles \

1 *to confer prosperity or happiness

2 *to invoke divine care for

3 *to protect, preserve

4 *to endow, favor

5 to speak well of, approve

6 to praise or glorify

7 to hallow or consecrate by religious rite or word



Biopiracy:

The discovery of and misappropriation and commercialization of biological compounds, traditional knowledge and all processes relating to them, known to the indigenous people, by any person being in a dominant position and obtaining intellectual property rights upon such discovery without authorization, fair compensation or any commemoration to the source.

- Literally means “the patenting of life”

<https://witfeeder.wordpress.com/2020/01/09/biopiracy-and-intellectual-property-rights/>

What's the problem with biopiracy?

1) Profit over nature - Loss of ecology

- Loss of biodiversity is altering ecosystems and failing to replenish local habitat
- 40 percent of the drugs behind the pharmacist's counter in the Western world are derived from plants that people have used for centuries, including the top 20 best selling prescription drugs in the United States today

2) Profit over people - Extraction resources and knowledge from indigenous people

- Indigenous have been decimated, colonized, ignored, manipulated and taken advantage of, and stripped of rights and land.
- Irreversible loss of traditional knowledge of the medicinal use of plants is occurring in tandem with species extinction.
- Traditional knowledge must spread for the betterment of humanity, but not at their disadvantage.
- The poorest people in the world live in the world's most biodiverse regions
- They have the right to protect knowledge, be recognized, and radically rewarded and blessed!

3) Violation of UN treaties and international laws - The buck stops here.

- There is an extensive history of biopiracy in pharmaceutical development and psychedelic companies are poised to be front and center, with the apparent violations of existing international treaties.
- Failing to remunerate lineages holders is inherently unethical and potentially illegal under international law.

Relevant Sample Case Examples of Biopiracy

Ayahuasca in Ecuador

USA citizen Loren Miller, from the International Plant Medicine Corporation claimed to have 'discovered' a new Ayahuasca variety in Ecuador and he filed a US patent for using ayahuasca to treat psychiatric diseases in 1986. In 1999, thirteen years later, the Co-ordinating Body of Indigenous Organizations of the Amazon Basin (COICA) legally challenged the patent based on lack of novelty which resulted in the cancellation of the patent and Miller being declared an enemy of Amazonian indigenous peoples.



Tumeric in India

In 1997, India's Council of Scientific and Industrial Research (CSIR) forced the US Patent and Trademark Office (PTO) to revoke a patent filed 2 years earlier by researchers in the USA on the use of powdered turmeric for wound healing, due to lacking the “novelty”. So far, 226 patents have been successfully revoked based on Indian traditional knowledge.



African Indigenous Plants

Thousands of patents on African plants have been filed. Africa plants such as Devil’s Claw and Katafray for arthritis, Hoodia gordonii for appetite suppression, baobab oil for skin care all cultivated for generations in Africa, and now iboga.

“They are stealing the loaf and sharing the crumbs”. Dr. Egziabher, the Institute for Sustainable Development in Ethiopia



Inside EU Life Sciences

Updates on Legal Developments in the EU Life Sciences Industry

FROM COVINGTON & BURLING LLP

German government has started enforcement of the Nagoya Protocol and reviews compliance of pharmaceutical companies

By Dr. Dr. Adem Koyuncu and Bart Van Vooren on May 25, 2018

THE ECONOMIC TIMES

English Edition | E-Paper

India looking to ensure swift enforcement of
Nagoya Protocol

THE NATIONAL LAW REVIEW

**Global Enforcement of the Nagoya Protocol in Life
Sciences Industries**

Thursday, December 8, 2016

“Need to Know” UN Declarations for psychedelic biotech

1. UN Declaration on the Rights of Indigenous Peoples (UNDRIP)

Adopted 2007, the most comprehensive international instrument on the rights of indigenous peoples. In 46 Articles, it establishes a universal framework of minimum standards for survival, dignity and well-being of the indigenous peoples.



2. *Convention on Biological Diversity (CBD)

- Entered 1993



3. *Nagoya Protocol

- After 6 years of negotiation, Adopted 2010

4. *Access and Benefit Sharing Agreement & Clearing House

- Application of Nagoya protocol



5. * Free, Prior, Informed Consent (FPIC)

- Separate agreement



6. UNESCO Recommendation on Open Science

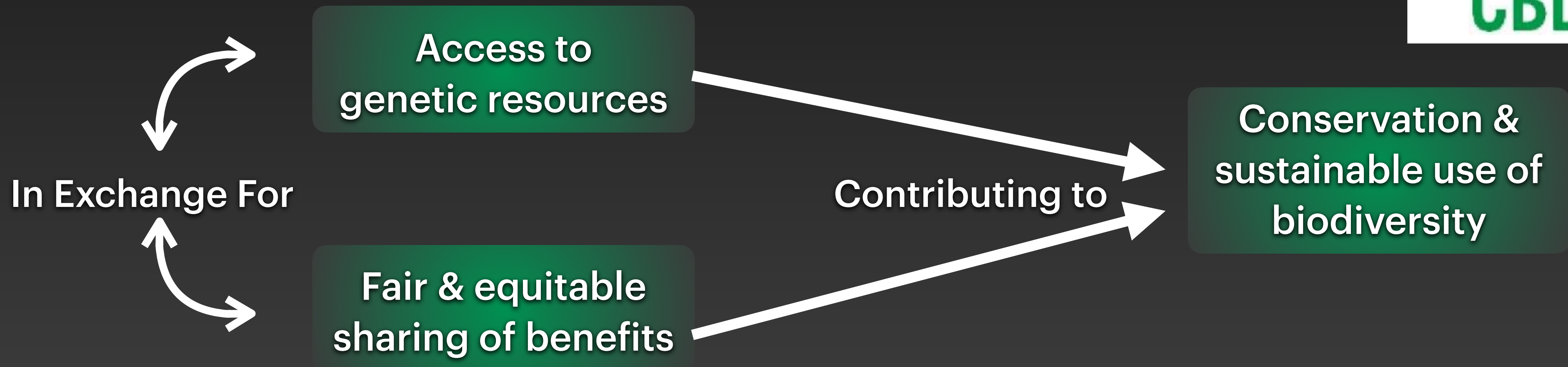


United Nations ~ Convention on Biological Diversity

- Initiated 1992 at United Nations Conference on Environment and Development
- The only international instrument pertaining to this issue
- Ratified globally by virtually every country (196 parties), except US and the Vatican

The Convention's three objectives are:

- 1) The conservation of biological diversity
- 2) The sustainable use
- 3) ****The fair and equitable sharing of benefits**



What is the Nagoya Protocol?

The Nagoya Protocol is an international agreement that covers biodiversity and the application of benefits arising from use.

Adopted in 2010 in Nagoya, Japan and entered into force in 2014.

A transparent legal framework for the implementation of the third objective of the CBD, which is:

*****the fair and equitable sharing of benefits arising out of the utilization of genetic resources.**

The Nagoya Protocol covers traditional knowledge associated with genetic resources.

Created in response to numerous historical cases of biopiracy against indigenous people

Not yet ratified in the US, but companies are still internationally bound to it

36 Articles in Total ~25 Page document. Available for download:

<https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf>

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



3 Basic Pillars of Nagoya Protocol

- 1) Countries may require that a company seeking access to any biological material receives government authorization before acquiring it.
- 2) Countries may impose conditions for “equitable benefit-sharing.” For example, requiring that a percentage of profits from products are paid to a public fund in that country (e.g. Gabon).
- 3) All 100+ parties to the Nagoya Protocol must enforce compliance with the ABS-requirements of the provider countries.

**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



Emphasis on traditional knowledge

Our understanding of genetic resources comes from the inseparable link with traditional knowledge of indigenous and local communities which has been handed down over generations.

Access to traditional knowledge as linked with genetic resources will strengthen the ability of these communities to benefit from the use of their innovations and practices.

Traditional knowledge... which may be oral, documented or in other forms, reflects a rich cultural heritage relevant for conservation and sustainability.

"Western medicine is protected. Wildlife is protected.

But our knowledge isn't, like it's worth nothing,"

- T.J. Matiba, president of South Africa's Council of Traditional Healers

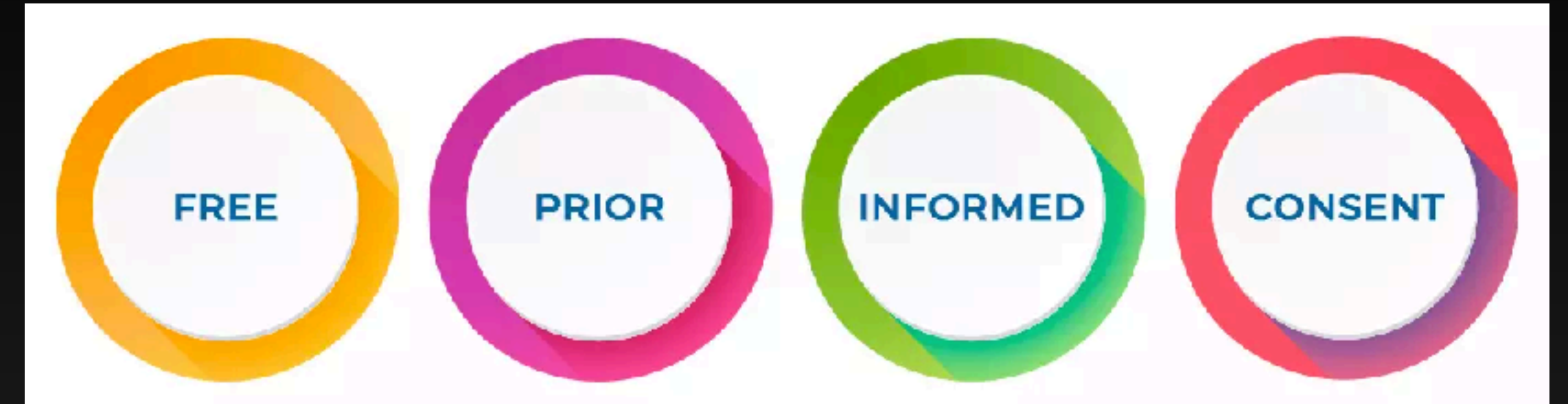
NAGOYA PROTOCOL ON ACCESS TO GENETIC RESOURCES AND THE FAIR AND EQUITABLE SHARING OF BENEFITS ARISING FROM THEIR UTILIZATION TO THE CONVENTION ON BIOLOGICAL DIVERSITY

TEXT AND ANNEX



Free, Prior and Informed Consent (FPIC)

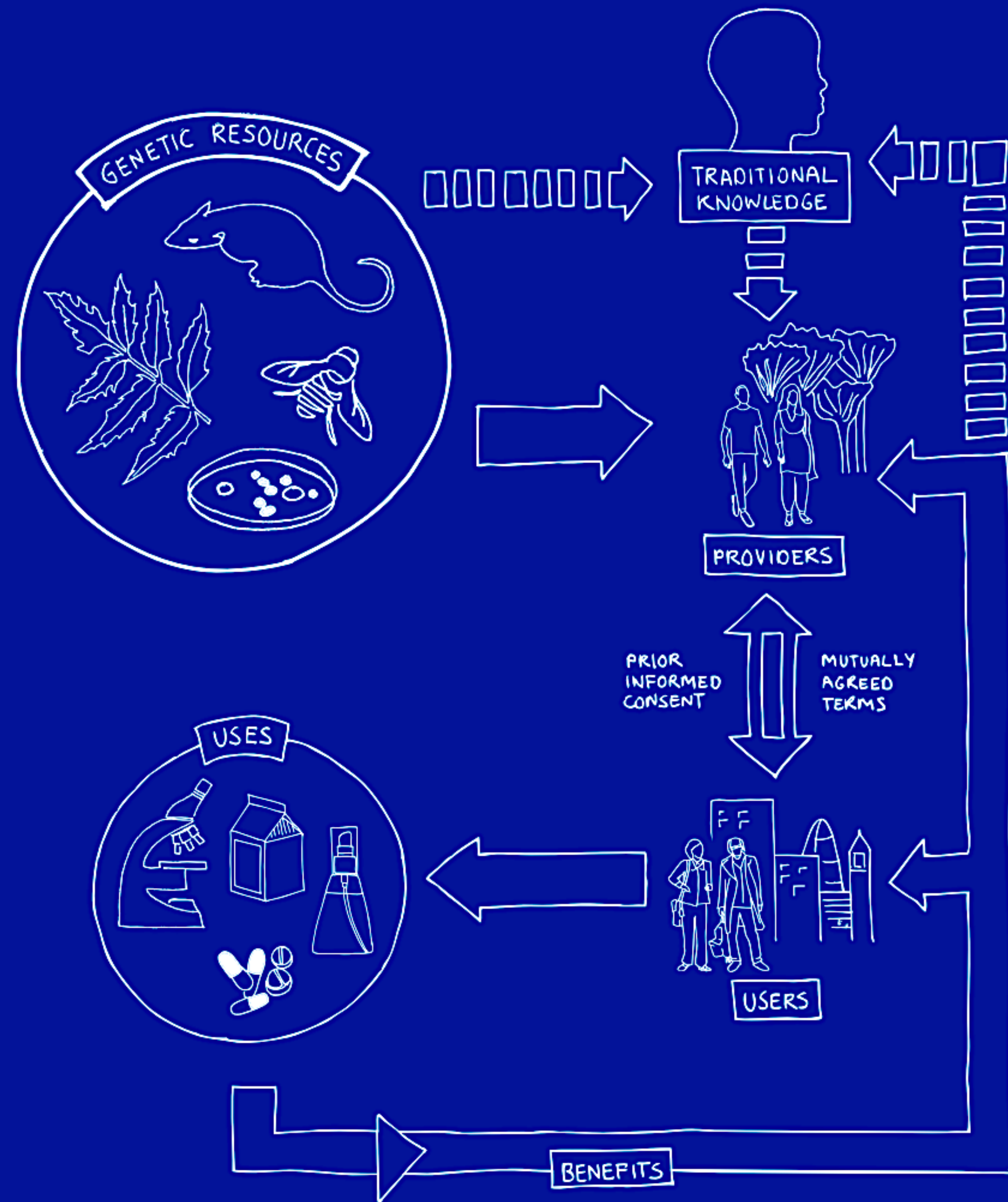
(FPIC) is a specific right that pertains to indigenous peoples and is recognized in the United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP).



- Free:** No coercion, manipulation, or intimidation has been used in the process of engaging with the community
- Prior:** Community is consulted well in advance of the project
- Informed:** Community received all relevant information to the project and is fully comprehended
- Consent:** Community agrees to the project in question

Convention on Biological Diversity: ABS

The Nagoya Protocol on Access and Benefit-sharing



Access Benefit Sharing - Clearing House



The Clearing-House serves to implement the Nagoya Protocol.

Addresses how 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)

Links the association between compounds and indigenous knowledge

Includes internationally recognized certificate of compliance.

Benefit-sharing can occur through:

Sharing technology, research results, training, profits, contributing to poverty reduction or indigenous health, preservation of indigenous habitats or knowledge, and sustainable development

The "**ABC's**" of ABS:

- **Access** – Enhancing legal certainty, clarity on how to access genetic resources and associated traditional knowledge.
- **Benefit-sharing** – Increase opportunities for sharing benefits from the use of genetic resources and associated traditional knowledge.
- **Compliance** – Ensure compliance with ABS measures and transparency in monitoring the utilization of genetic resources through the value chain.

Access and Benefit Sharing Clearing-House



THE ACCESS AND BENEFIT-SHARING CLEARING-HOUSE



About the ABSCH

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The Access and Benefit-Sharing Clearing-House (ABSCH) is a platform for exchanging information on ABSCH and a key tool for facilitating the implementation of the Nagoya Protocol. ⓘ

National Records

- 176 ABS National Focal Point
- 124 Competent National Authority
- 264 Legislative, Administrative or Policy Measure
- 21 ABS Procedure
- 3 National Model Contractual Clause
- 2262 Internationally Recognized Certificates of Compliance
- 52 National Websites or Databases

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



About the ABSCH

Search

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National Reports

Forums

CBD > ABSCH > Country Profiles > Gabon



JS map by amCharts Disclaimer

Gabon

Party to the Nagoya Protocol

- 1** ABS National Focal Point
- 0** Competent National Authority
- 0** Legislative, Administrative or Policy Measures
- 0** ABS Procedure
- 0** National Model Contractual Clause
- 0** Internationally Recognized Certificates of Compliance
- 0** National Websites or Databases
- 0** Checkpoint



Gabon

Party Status:	Party to the Nagoya Protocol
Entered into force on:	12 Oct 2014
Acceptance on:	11 Nov 2011
Signatory:	Signed on 13 May 2011
CBD Country Profile:	www.cbd.int/countries/?country=ga

– ABS National Focal Point (NFP)

1

M. Emmanuel Bayani Ngoyi

Chargé d'études du Directeur général de l'environnement et de la protection de la nature Ministère des Eaux, des Forêts, de la Mer, de l'Environnement, chargé du Plan Climat, des Objectifs de développement durable et du Plan d'affectation des terre

Gabon Background

Europeans arrived in Gabon in the 15th century which started the abandonment of ancestral initiatory traditions, due to the forced evangelization and the Slave Trade.

Gabon later occupied France in 1839 and Gabon did not gain independence until 1960.

When Gabon gained its independence from France in 1960, Libreville was declared the capital (named “free town” after the liberation of slaves)

Gabon contains one of the most rich areas of endemic plants species in all of tropical Africa and timber is the largest export.

Due to use of raw materials and farming, two thirds of the forest could be lost by 2040 if nothing is done.



Gabon - Nagoya and Iboga

In 2011, Gabon became the first country in the world to sign the Nagoya Protocol

President of the Gabonese declared Iboga a “national cultural heritage” and “national treasure” in 2000

In 2019, Gabon signed a decree prohibiting the export of iboga pending approval of the Nagoya Protocol

But now several psychedelic companies are capitalizing on Iboga (mainly of Gabonese origin) and its chemical constituents, have filed for patents for its clinical use, and disregarded the Nagoya Protocol.



Iboga + Bwiti History

Used for millennia, connected to Abydos Temple in Egypt used for divination practices and given to ancient Egyptians by the Pygmies

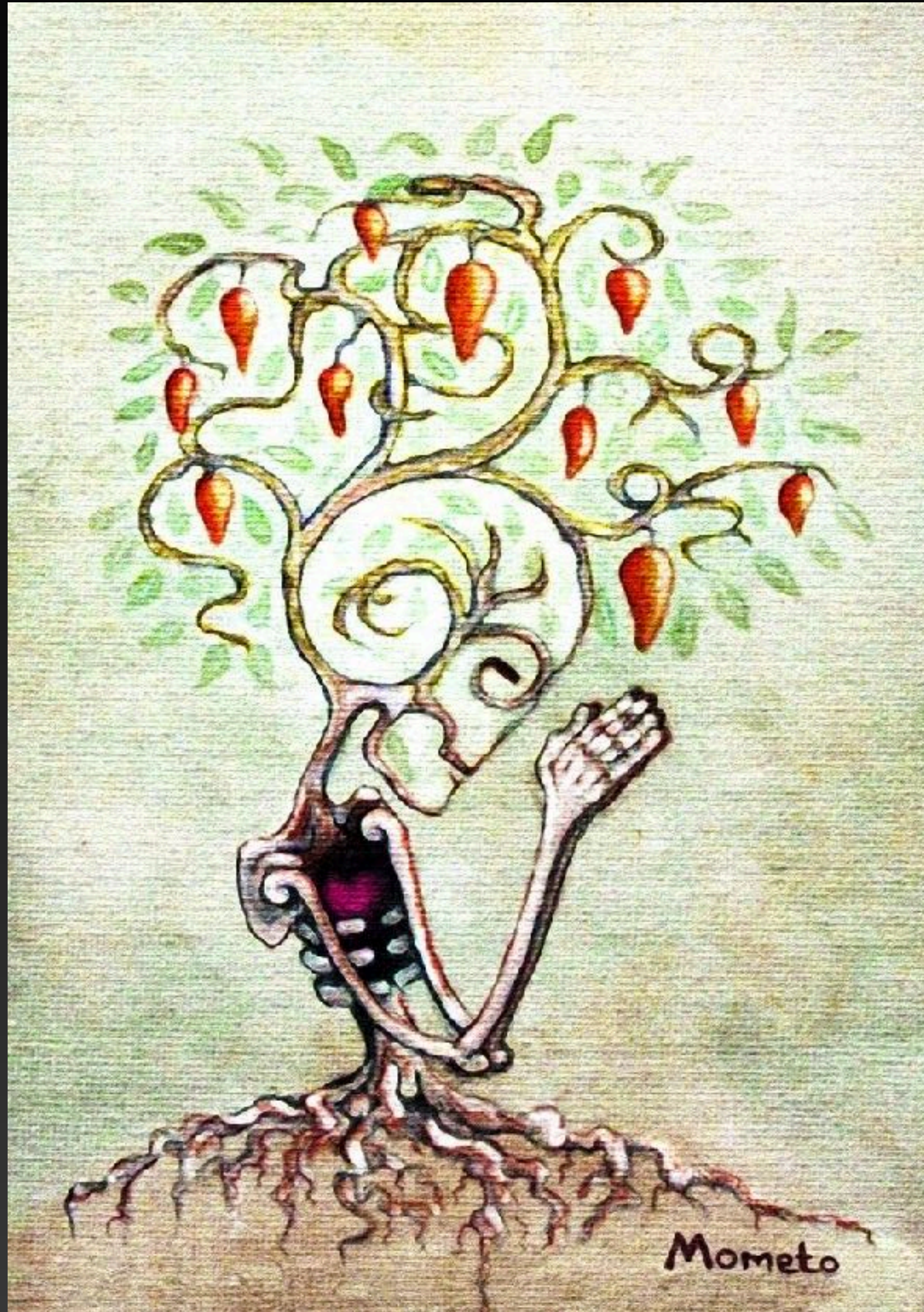
Bwiti is an African Religion that was inspired by the teachings and philosophy of the Babongo Pygmies.

The practice of Bwiti was previously driven underground due to colonization

Bwiti is clearly the source of knowledge for iboga who have utilized it for centuries for cultural teaching, initiatory ritual, healing, and spiritual/ancestral ceremonies



Bwiti traditional knowledge linked to iboga



The highest function of Iboga (means “to care for”) is a spiritual technology that gives access to the invisible world and complete healing.

Bwiti knowledge includes (some examples):

- Natural laws for harmony with self, other, and all existence
- Preparation techniques for mind/body/spirit
- Teachings about the origins of humankind and the cosmos
- Ritual practices and protection for journeying
- How to enhance visions, navigate iboga, and guide journeys
- How to navigate spirit realm and interact with ancestors
- How to work with the spirits of nature for healing and wisdom
- Iboga growing and cultivation
- Mastery of the forest and the natural elements

Bwiti Initiation Includes:

- Rebirth rituals to know the inner self/soul and identify life purpose
- Preparation to forge strength, humility, and patience in the initiate.
- Developing relationship to the sacred for personal and spiritual maturity

Points to ponder

- To date, no biotech companies working with ibogaine or related compounds have demonstrated reciprocity with Gabon, or consulted or included Bwiti traditional knowledge in using the medicine.
- Under the Nagoya Protocol, how could benefit sharing be established between Gabon and companies working with ibogaine or its derivatives?
- How to empower Bwiti/forest dwellers to make full economic use of their heritage and be stakeholders in the development of ibogaine?

In applying Nagoya to the world and tradition of synthetic psychedelics...

- The corporate psychedelic movement has been built on the backs of clandestine chemists, underground practitioners, academics, drug policy advocates, and non-profit groups
- What would it look like to apply Nagoya protocol to companies working on synthetic psychedelics in demonstrating benefit sharing with relevant groups?



Art - Ben Taylor @ www.mometo.net/

The Spectrum of Historical Use

**Clear indigenous use,
knowledge and
“intellectual property”
For centuries to millenia**



**Lack of
indigenous use,
synthesis decades old**

Iboga / Ibogaine
Ayahuasca / DMT
5-MeO-DMT
Bufotenine
Psilocybin
Mescaline
Salvia Divinorum
Morning Glory/LSA

MDMA
2-CB
Shulgin compounds
Designer synthetic
psychedelics

Conclusions:

Recommendations for psychedelic biotech companies:

1. Investigate and identify all cultural lineages, regions, and people associated with history of compounds
2. Following the **Free, Prior, Informed Consent (FPIC)** protocols, ask permission to respective UN representative (e.g., Gabon, Mexico, Brazil, Peru, etc.),
3. Identify **Nagoya Access Benefit-Sharing Clearing House** procedures and ideal arrangement with relevant parties
4. Structure corporation to allocate support, reciprocity, and profit sharing with indigenous or community groups.
 - Not as an after thought, rather front and center ethic.
 - Failure to abide by UN protocols may result in patent invalidation and legal cases of biopiracy
5. In the case of synthetic psychedelics or New Chemical Entities (NCE), Nagoya principles can apply to the psychedelic community as lineage holders regarding obtaining permission from and inclusion and reciprocity with psychedelic elders, clinicians, practitioners, scientists, researchers, longstanding psychedelic societies or advocacy groups, and individuals disenfranchised by drug laws as collective stakeholders/shareholders
6. Given the task of scaling psychedelics through an extractive (pharma) industry, the sacred and healing nature of such experiences, and broad societal need, new psychedelic biotech companies should be innovative and exemplary as ethical trend setters, going above and beyond adherence to UN protocols and demonstrate radical and generous inclusion and reciprocity —> going from extractive to blessing.

Examples of Gabonese/ Bwiti NGO's for Reciprocity



Blessings of the Forest:

Dedicated to preserving, researching and sharing the natural and cultural heritage of Gabon. We are dedicated to ensuring fair and sustainable use, protecting the resources of the forest and promoting the traditional way of life of the Gabonese forest people.

*Raising awareness about adherence to Nagoya

<https://www.blessingsoftheforest.org/>



Ebando:

The organisation seeks to encourage the transmission of traditional Knowledge and practices including philosophy and oral traditions, art and crafts; and the healing skills of the Bantu and Pygmy peoples from the Ogooué basin region of Gabon.

<https://www.ebando.org/>

Chacruna - Indigenous Reciprocity Initiative of the Americas

<https://chacruna.net/indigenous-reciprocity-initiative/>



The IRI Program's purpose is to encourage investment into Indigenous communities by large donors. The money donated will be distributed evenly among the 30 organizations showcased in the IRI webpage.

Criteria for selection:

1. Each organization is small-scale, targeting specific group of local communities.
2. Each featured initiative is operated by members of the Indigenous communities being supported.
3. Each initiative is locally-designed and implemented to address self-determined needs and priorities.
4. 19 of the 30 organizations deal directly with one specific Indigenous group.
5. 21 out of the 30 featured organizations are wholly Indigenous-run.
6. 9 of the featured projects are led by Indigenous women and focused primarily on women's issues.
7. The non-profits that are externally-based or helmed by non-Indigenous organizers are run by Indigenous leaders and directed by community consensus on a local level.
8. Each organization is multidimensional, aimed at strengthening community resilience and autonomy.
9. Each project is framed around long-term, sustainable strategies, rather than short-term relief efforts.





blessingsoftheforest
Ebando

