

How to ensure legal certainty when accessing genetic resources?

InnCoCells Academy
ABS session
October 4, 2021

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Innovative high-value cosmetic products from plants and plant cells



Pierre Fabre

PIERRE FABRE Laboratories

Created in 1962 by Mr Pierre Fabre (pharmacist)
Ethical drugs, OTC & Dermocosmetics
11,000 employees, Turnover (2020): 2.3 Bn €

Expertise in phytochemistry
38 % of the turnover is generated by plants

Shareholder: Pierre Fabre Foundation 86%



First steps in Plant sourcing...



Legal Access?



- Protected species (CITES, National, Regional, Local laws...)
- Drug control regulations
- Properties issues (authorization of the land owner)
- Plant health control legislations
- Narcotic regulations
- Custom regulations
- **Regulations on Biodiversity Access and Benefit Sharing (A.B.S.)**

Access and Benefit Sharing **Prior Informed Consent**

Rio Convention

Jail penalties

Art. 8 j

Nagoya Protocol

Sanctions

Genetic resources

MAT

PIC

ABS **TK**

CBD

ANC (National Competent authorities)

Sanctions

Biopiracy

Infraction

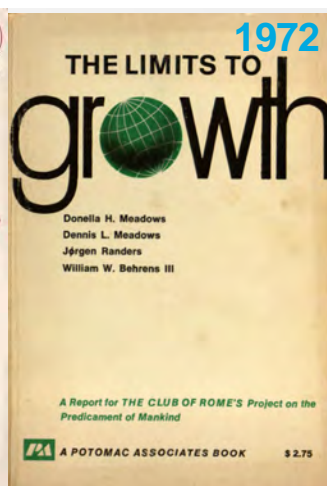
European Regulation 511/2014

Mutually Agreed Terms

Biological resources

NFP (National Focal Points)

Emergence of environmental awareness



United Nations Environment Programme



1972 Stockholm 1st Earth Summit

Birth UNEP: *United Nations Environment Programme*



1982 Nairobi 2nd Earth Summit



1992 Rio de Janeiro 3rd Earth Summit

- Convention on Biological Diversity
- Framework Convention on Climate Change
- UN Convention to Combat Desertification



Rio: conjunction of 3 trends



Convention on
Biological Diversity

From 1970

Awareness of environmental & cultural losses

1971-1980

Hope of economic Eldorado
with patented genetic resources

US Supreme Court case:
Chakrabarty / Diamond (June 1980)



1990- ~

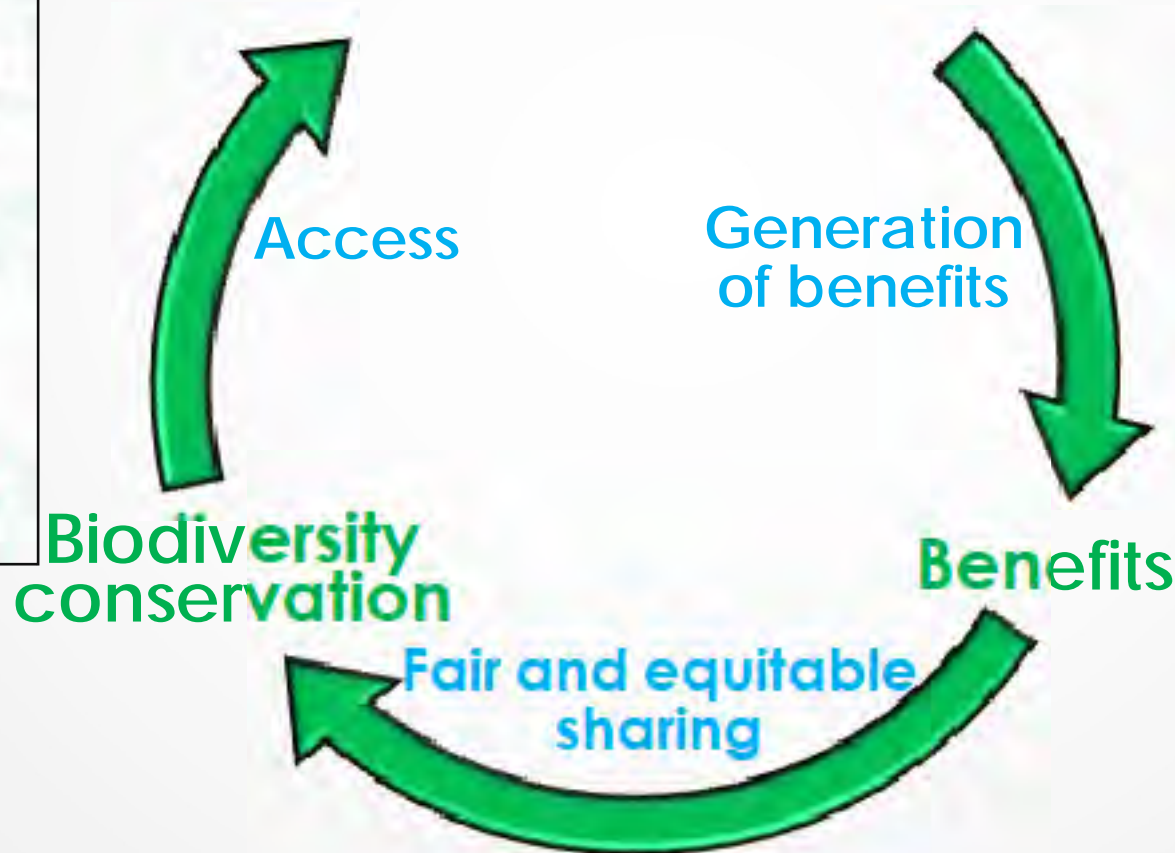
Success of Finance
Solutions = monetisation



Virtuous circle of the Convention on Biological Diversity + Nagoya Protocol



Sustainable use of
Genetic Resources (GR)
& Traditional Knowledge (TK)



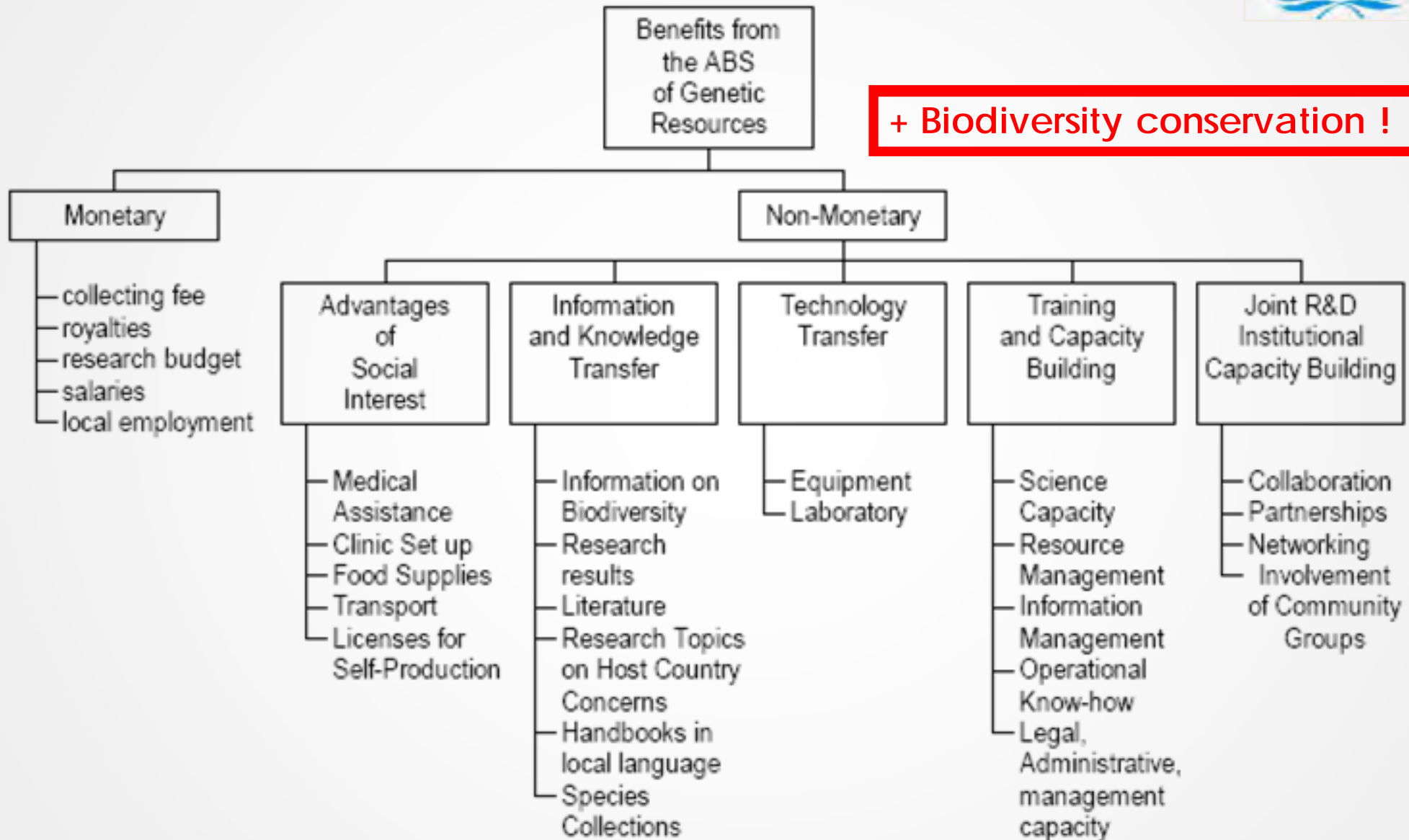
CDB Consensus

- Each state is **sovereign** over its resources and establishes the modalities of access (art. 3 & 15.1)
- Access subject to **prior informed consent** (art.15.1)
- **Fair and equitable sharing of benefits arising from their use** (art.15.7 CDB)
- **Respect for traditional knowledge associated with GR** (art.8j CDB)
- **Patent recognition** (art.1 & 16)

Examples of Benefit Sharing



+ Biodiversity conservation !



History of ABS legislations



Convention on Biological Diversity
Rio de Janeiro, Brazil
3-14 June 1992



18-29 October 2010 Nagoya, Japan

Nagoya Protocol
Nagoya, Japan

19-29 October 2010

Some nations started regulating access to their genetic + biological + traditional knowledge:
Andean nations (1996), Costa Rica (1998), Brazil (2000), India (2002), South Africa (2004)....

Many national ABS regulations enforced

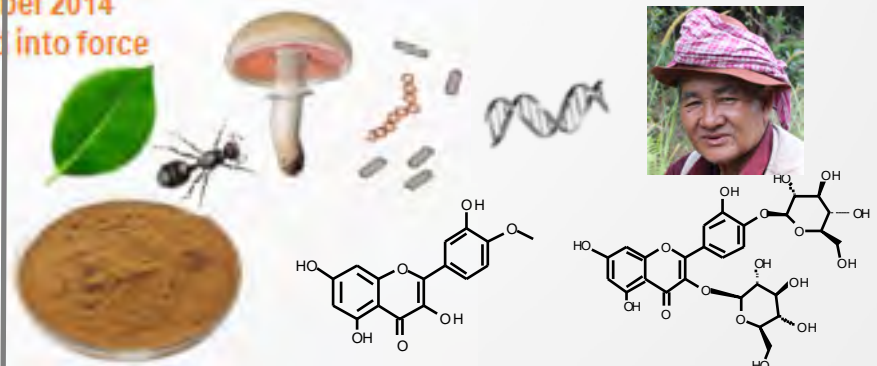
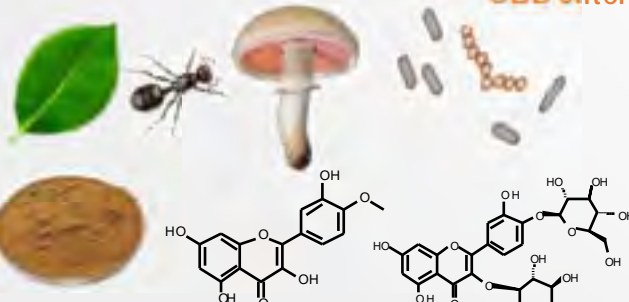
Genetic + biological resources + traditional knowledge

Genetic resources + traditional knowledge

Genetic + biological resources + traditional knowledge

29 December 1993
CBD entered into force

12 October 2014
PN entered into force



Free access, no regulation
Considered as common heritage

Access for R&D to be regulated by national laws

Access to genetic resources for R&D in the broadest sense to be regulated by national laws

Consequences of Nagoya Protocol



- **If R&D conducted on genetic resources (art. 2c) laws of the source country apply. Access has to be negotiated before R&D beginning studies**
- Biodiversity (plants, animals, microorganisms and fungi) is under the **sovereignty** of host nations. Therefore nations are free to put in place more or less restrictive regulations (even for **commercial utilization !**)
- In European Union Member states:
 - Compliance
 - Controls and sanctions by Member states on their territory. If infringement severe penalties (+ risks to reputation)
 - Due Diligence obligations
 - When external funding received
 - Or before commercialization
- Some legal uncertainties are generated by ABS national laws

International & national levels

International agreements applicable only to the signatory countries



Convention on Biological Diversity

Nagoya Protocol

Regulations applicable directly to users of GR or TK

Infranational
regulations



Documents not legally binding, indicative for users of GR or TK

Eur. Commission guidance 2016/C 313

Best practices guides...

Nagoya Protocol vs ABS national laws

132 ratifications (to date) :

Gabon, Jordan, Rwanda, Seychelles, Mexico, Laos, India, Fiji, Ethiopia, Panama, Mauritius, South Africa, Albania, Micronesia, Botswana, Syria, Mongolia, Comoros, Honduras, Tajikistan, Ivory Coast, Bissau Guinea, Indonesia, Bhutan, Norway, Egypt, Myanmar, Burkina Faso, Benin, Kenya, Guyana, Vietnam, Hungary, Denmark, Namibia, European Union (16 May 2014), Samoa, Spain, Guatemala, Uganda, Belarus, Vanuatu, Niger, Burundi, Gambia, Madagascar, Mozambique, Sudan, Peru, Switzerland, **Uruguay (14 July 2014)**, Malawi, United Arab Emirates, Guinea, Marshall Islands, Lesotho, Dominican Republic, Cambodia, DR Congo, Congo, Kyrgyzstan, Kazakhstan, Liberia, Mauritania, Croatia, Cuba, Philippines, Djibouti, Pakistan, Slovakia, Togo, UK, Senegal, Germany, Czech Republic, Zambia, Finland, China, Belgium, Bulgaria, Netherlands, Moldova, France, Mali, Sweden, Swaziland, Bolivia, Luxembourg, Sierra Leone, Cameroon, Malta, Argentina, Antigua and Barbuda, Sao Tome and Principe, Qatar, Angola, Zimbabwe, Ecuador, Chad, Lebanon, Tanzania, Afghanistan, Palau, Austria, Central African Republic, Tuvalu, Saint Kitts and Nevis, Venezuela, Serbia, Malaysia, Estonia, Nepal, Eritrea, Romania, Maldives, Ghana, Democratic People's Republic of Korea, Tonga, Solomon Islands, Greece, Nicaragua, Oman, Saudi Arabia, Montenegro, Turkmenistan, Brazil, Kiribati, Tunisia,.....

International enforcement of Nagoya Protocol since 12 October 2014





The 3 key questions



① Is there an ABS regulation enforced in the Source Country to Date ?

NO

YES

② Restricted access for the planned Utilisation ?

NO

YES

FREE ACCESS

ACCESS TO BE NEGOTIATED

③ Is the European Regulation **511-2014** applicable ?

For EU users + 10 cumulative conditions → Due Diligence Declaration(s)

- External funding received for your research
- Before commercialisation of GR/TK derived products



YES

DUE DILIGENCE DECLARATION(S) TO BE DONE



What falls in the scope of ABS regulations ?

Apply to

- ❖ Genetic resources (GR) subject to R&D = Plants, fungi, animals, microorganisms
- ❖ Wild or cultivated/farmed GR
- ❖ Traditional knowledge associated with GR
- ❖ Collections of GR
- ❖ GR/TK accessed where states exercise sovereign rights after national laws enforcement

Does not apply to

- ❖ GR or TK accessed before national laws enforcement
- ❖ GR from areas beyond national jurisdictions: International waters, space, Antarctic (to date)
- ❖ Commodities in the absence of R&D. Nevertheless benefit sharing is required by some national ABS laws even in absence of R&D on commodities (e.g. Brazil, India...) !
- ❖ *Ex-situ* collections. But some countries have claims on *ex-situ* collections (e.g. Brazil) !
- ❖ Human genetic resources
- ❖ GR used as tool or reference
- ❖ Unintentional access (microorganisms)
- ❖ Digital Sequence Information (to date)



What is generally requested by Biodiversity Authorities?

- Description of the project / duration
- Names, roles and relationships between researchers
- Local institutions, researchers involved
- Parts confidential when applicable
- Benefit sharing monetary & non-monetary programme

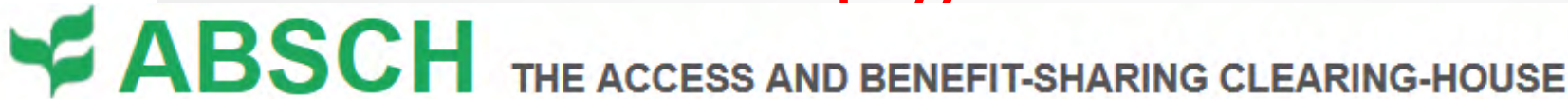
Duties

- Access Permit for the detailed project and researchers (No change of intent, participants...)
- Duration/ date of issuance, date of expiry
- Reporting on the results
- Milestones & Benefit Sharing



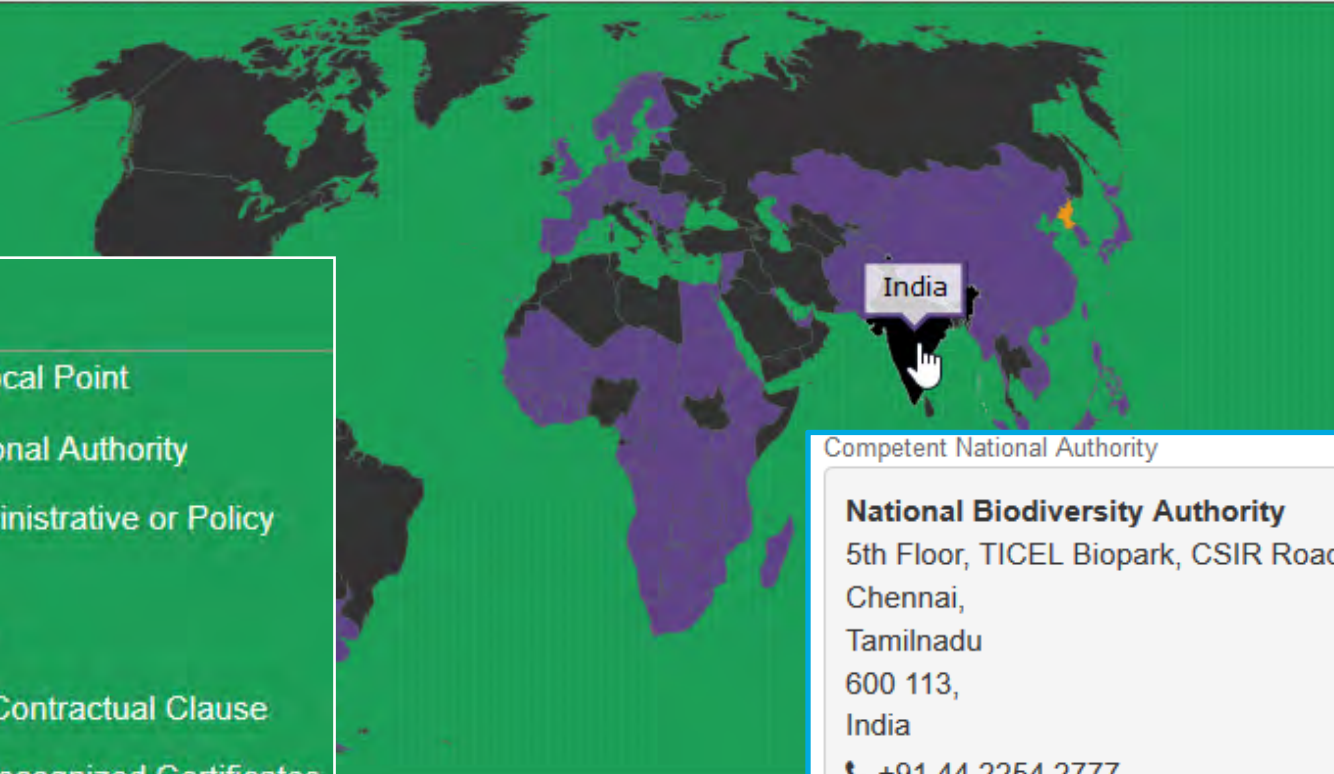
How to get information contacts + regulations ?

<https://absch.cbd.int>



Home | About the ABSCH | Search | Submit | Country Profiles ▾ | National Reports

CBD > ABSCH > Country Profiles



 **India**

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

Competent National Authority

National Biodiversity Authority
 5th Floor, TICEL Biopark, CSIR Road, Taramani
 Chennai,
 Tamilnadu
 600 113,
 India

☎ +91 44 2254 2777
 📠 +91 44 2254 1200

✉ secretary@nbaindia.org
 ✉ chairman@nba.nic.in
 ✉ secretary@nba.nic.in

🌐 [National Biodiversity Authority \(http://www.nbaindia.org\)](http://www.nbaindia.org)



In practice:

① Identification and contact with the biodiversity National Competent Administration (NCA)

② Negotiation with NCA

Biodiversity National Competent Authorities (NCA) of the source country

Prior Informed Consent (PIC)

Mutually Agreed Terms (MAT)

User of GR or TK Academics or Industries

Benefit Sharing

Provider of GR or TK: University, enterprise, local community...

③ Access

③ Delivery of Permit by National Competent Authority

④ Registration of Access permit

ABS Clearing House
CBD Secretary
(Montreal, Canada)

⑤ Delivery of Internationally Recognized Certificate of Compliance (IRCC)

⑥ Controls

⑦ Due Diligence Declaration

National Competent Authorities of countries Party to Nagoya Protocol

European Commission



IRCC Internationally Recognized Certificates of Compliance



The Access and Benefit-Sharing Clearing-House (ABSCH)

ABSCH-IRCC-FR-245933-1 Internationally recognized certificate of compliance constituted from information on the permit or its equivalent made available to the Access and Benefit-sharing Clearing-House

In accordance with Article 17, paragraph 2, of the Nagoya Protocol on Access and Benefit-sharing, a permit or its equivalent issued in accordance with Article 6, paragraph 3 (e) and made available to the Access and Benefit-sharing Clearing-House, shall constitute an internationally recognized certificate of compliance.

General Information

Issuing country

FRANCE

Verification link (view latest version)

<https://absch.cbd.int/database/ABSCH-IRCC-FR-245933>

ABS-CH Unique Identifier (UID)

ABSCH-IRCC-FR-245933-1

Issuing Authority

- Competent National Authority: ABSCH-CNA-FR-240495-3

COMPETENT NATIONAL AUTHORITY

Ministère de la transition écologique et solidaire/ Direction générale de l'aménagement, du logement et

de la nature / Direction de l'eau et de la biodiversité / Bureau de l'encadrement des impacts sur la biodiversité
Tour Sequoia / 92055 La Défense Cedex / FRANCE Paris, Ile de France
92055 La Défense Cedex,
France
Phone: +33 1 40 81 30 29, + 33 01 40 81 91 28
Email: catherine.cumunel@developpement-durable.gouv.fr, Guillaume.Faure@developpement-durable.gouv.fr, apa@developpement-durable.gouv.fr
ABSCH-CNA-FR-240495-3

Details of the permit or its equivalent

Reference number of the permit or its equivalent

TREL1734890A/47

Date of issuance of the permit or its equivalent

25 Jun 2018

Prior Informed Consent (PIC) Information

Confirmation that prior informed consent (PIC) obtained or granted

YES

Provider The person/entity that holds the right to grant access to the genetic resource in accordance with domestic legislation.

- Competent National Authority: ABSCH-CNA-FR-240495-3

COMPETENT NATIONAL AUTHORITY

Ministère de la transition écologique et solidaire/ Direction générale de l'aménagement, du logement et de la nature / Direction de l'eau et de la biodiversité / Bureau de l'encadrement des impacts sur la biodiversité
Tour Sequoia / 92055 La Défense Cedex / FRANCE Paris, Ile de France
92055 La Défense Cedex,
France
Phone: +33 1 40 81 30 29, + 33 01 40 81 91 28
Email: catherine.cumunel@developpement-durable.gouv.fr, Guillaume.Faure@developpement-durable.gouv.fr

IRCC Internationally Recognized Certificates of Compliance

durable.gouv.fr, apa@developpement-durable.gouv.fr
ABSCH-CNA-FR-240495-3

Entity to whom PIC was granted

- Organization: MNHN

ORGANIZATION

MNHN

Academic or research Institute

Email: no_email@email.com

Mutually Agreed Terms (MAT) Information

Confirmation that mutually agreed terms (MAT) have been established

YES

Additional information about the mutually agreed terms:

Subject-matter

Subject-matter or genetic resources covered:

Parasites sanguins d'oiseaux

Origine des ressources : Hérault, Seine-Maritime

Information on the utilization of the genetic resource(s)

Type of use allowed by the permit or its equivalent:

Non-Commercial

Specific uses covered by the permit or its equivalent or use restrictions:

Etude de la biodiversité morphologique, moléculaire et génomique des hémoparasites des oiseaux en France

Amendment History

Date	Action	Comment	Unique identifier
03 MAY 2019 14:00	CURRENT VERSION	Permit information published to the ABS clearing-house and certificate constituted.	ABSCH-IRCC-FR-245933-1

Further Information

Questions about the permit or its equivalent constituting an internationally recognized certificate of compliance should be addressed to the competent national authority issuing the permit or its equivalent. Additional information about the permit or its equivalent may be available in the Access and Benefit-Sharing Clearing House | <https://absch.cbd.int/>.

Secretariat of the Convention on Biological Diversity

413 rue Saint-Jacques, suite 800

Montreal, Québec, H2Y 1N9

Canada

Fax: +1 514 288-6588

Email:

Questions about the Nagoya Protocol on Access and Benefit-sharing or the operation of the Access and Benefit-sharing Clearing-House may be directed to the Secretariat of the Convention on Biological Diversity.

<https://absch.cbd.int/countries/FR/IRCC>

Access of GR in EU countries

EU countries with no regulation on access

Access non regulated

**Compliant
access
(Traceability)**

Sharing

France, Spain, Croatia, Malta, Bulgaria...

Access regulated

**Compliance
(Traceability)**

Sharing



**State Gazette
N° 77/9.08.2002**



Law 42/2007



Law 80.2013



Law 2016-1087



**Legal Notice
N° 379-2016**

Mosaic of situations depending on the source country

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

Wild native resources	Cultivated/breeding resources	Introduced resources	<i>Ex situ</i> resources	Wild resources related species	
Natural products	Natural products derivatives	Genetic sequences	Traditional knowledge	Nature of R&D or of industrial sectors	
National actors	Non-national actors	Industry actors	Academic actors	Public lands	Private lands
Commodity formulation	Extracts valorization	Research & Development	Intellectual Protection	Possible retroactivity Evolution of regulation	
Implications of traditional communities by source country		Who should share benefits in value chain? Intermediates, final user...		Mandatory local collaboration ...	

All these different factors impact on:

Freedom of access	Duration of negotiation	Administrative cost	% of benefit sharing	Economical feasibility / Interest for the user
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EU Countries regulating access



COUNTRY	ABS LAWS	ABS IN PRACTISE
SPAIN	Law 42/2007 Art. 71 ABS Royal Decree 124/2017	Authorization procedures For non commercial research (< 2 months) For commercial utilization (< 6 months)
CROATIA	Official Gazette 80/2013 art 88-98	Access Permit & Benefit sharing negotiated with the Ministry of Environment and Nature Protection
FRANCE	Law 2016-1087 (August 8, 2016) Application Decree 2017-848 (May 9, 2017)	Declarative or authorization procedures July 1 st , 2017 - 1 year imprisonment and 150 000 € fine. - Fine increased to € 1 million for unauthorized commercial use



'Free access' EU countries but compliance

COUNTRY	ABS LAWS	ABS IN PRACTISE
GERMANY	Law DS 18/5219 December 1, 2015	Bundesamt für Naturschutz Sanctions: up to € 50 000 in case of intentional breach or negligence
UK	Official Gazette 80/2013 art 88-98	Secretary of State - Department for Business, Innovation & Skills - Regulatory Delivery Sanctions: £ 5000 + 3 months/2 years imprisonment sentence
DANMARK		Danish Nature Agency Sanctions : Fines and up to 2 years imprisonment sentence
FINLAND	Implementation act of NP & CBD	Finnish Environment Institute and Natural Resources Institute Finland Special regime for TK from Sami people Sanctions: Fine & other punishments
HUNGARY	Regulation 3/2016 (I. 20.)	National Environmental and Nature Protection Inspectorat Sanctions: 100 000/10 millions Forints
SLOVAQUIA	Act. 263/2015 December 1, 2015	Environment Ministry Sanctions: planned for non compliance

Examples of biodiversity-rich countries

COUNTRY	ABS LAWS	ABS IN PRACTISE
USA	No ABS regulation	Non CBD, non Nagoya Protocol Party No benefit sharing requested
BRAZIL	Law 13.123 (2015) Application Decree 8.772 (2016)	Benefit sharing by the company which sells the final product max 1% art 20, 0.75% if non-monetary art.22 Access at CGEN, Police = IBAMA
INDIA	Biological Diversity Act (2002) Biodiversity Rules (2004)	Application at National Biodiversity Authority Benefit Sharing 2-5% of net revenue 4 application forms
SOUTH-AFRICA	NEMBA (2004) BABS (2008 & 2015)	National Environmental Management: Biodiversity Act (NEMBA) enforced 2006 BABS (Bioprospecting, Access and Benefit Sharing Regulations) --> "Bioprospecting permit"
PERU	Decree 003-2009 Law 27811 2001	Negotiation Environment Ministry (MINAM) Check points : INDECOPI = IP Institute + National Anti-Biopiracy Commission Benefit Sharing > 5% net revenue
CHINA	ABS Law project	Access and Benefit Sharing regulations to be published soon

Paradoxical effects of ABS laws

OPINION

Death sentence on taxonomy in India

POLICYFORUM

GLOBAL BIOLOGICAL RESOURCES

Could Access Requirements Stifle Your Research?

Sikina

As the rules for foreign access to biological resources are being negotiated, academic researchers and organizations should make their opinions known.

correspondence

Biodiversity law has had some unintended effects

Moves to prevent unfair exploitation of resources could restrict conservation research.

POLICY FORUM BIODIVERSITY CONSERVATION

When the cure kills—CBD limits biodiversity research

K. Dir

+ See

Scien
Vol. 3
DOI:

Biodiversity law could stymie research

Tighter rules on accessing and developing genetic resources may be counterproductive for conservation.

comment

The Nagoya Protocol could backfire on the Global South

Regulations designed to prevent global inequalities in the use of genetic resources apply to both commercial and non-commercial research. Conflating the two may have unintended consequences for collaboration between the Global North and biodiverse countries in the Global South, which may promote global injustice rather than mitigate it.

Contradictory interests

Providers	Users
"Poor" countries of the South	"Rich" countries in the North
Biodiversity & TK (traditional knowledge) rich	Technologies, Industries rich
Technology & Industry poor	Biodiversity poor
Governments, local communities, NGOs	Academic or Industry researchers.
Control over their GR & TK	Fair & Transparent access
Certainty of benefits sharing after access negotiation	Realistic timelines, clear and fair negotiation
Great expectation of funding	Limited funding opportunities
Interested in economic development, preservation	Interested in innovation
(Biodiversity) legislation often poorly developed	Need of legal security, clarity and transparency

Take-home message: ABCD of ABS



A ACCESS Negotiate access with source country

Nations are sovereign → free access, authorisation, permits...

B BENEFIT SHARING Sharing according to agreed terms

C COMPLIANCE

Controls, sanctions by EU member state where research is conducted
Art 4, 7 & 9 European Regulation



D DUE DILIGENCE

Conformity / European Regulation (conditions of application see next slides)

Annex II when external funding of research on GR e-portal « *declare* »

Annex III before commercialization of GR derived product e-portal « *declare* »

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

(2016/C 313/01)

27.8.2016

EN

Official Journal of the European Union

C 313/19

ANNEX I

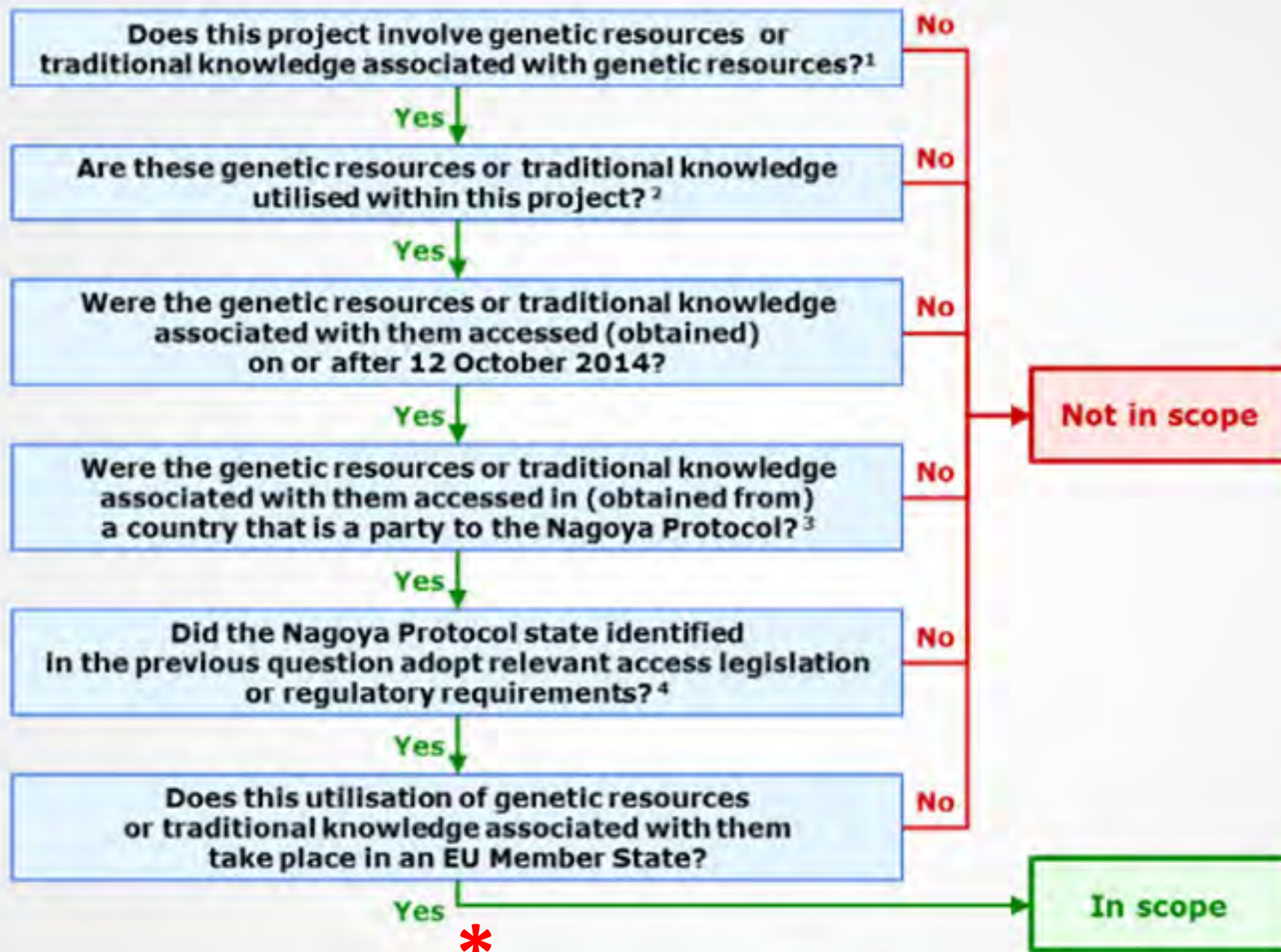
Overview of conditions for applicability of the EU ABS Regulation

		Within scope (cumulative conditions (*)	Outside of scope
Geographic scope (provenance of GR (**))	<i>Access in ...</i>	Areas within a country's jurisdiction	Areas beyond national jurisdiction or covered by Antarctic Treaty System
	<i>Provider country is ...</i>	Party to the Nagoya Protocol	Not a Party to the Protocol
	<i>Provider country has ...</i>	Applicable access legislation	No applicable access legislation
Temporal scope	<i>Access ...</i>	On or after 12 October 2014	Before 12 October 2014
Material scope	<i>Genetic resources</i>	Not covered by a specialised international ABS instrument	Covered by a specialised international ABS instrument
		Non-human	Human
		Obtained as commodities but subsequently subject to R & D	Used as commodities
	<i>Utilisation</i>	R & D on genetic and/or biochemical composition	No such R & D
Personal scope		Natural or legal persons utilising GR	Persons only transferring GR or commercialising products based on it
Geographic scope (utilisation)	<i>R & D ...</i>	Within the EU	Exclusively outside of the EU



(*) To be within the scope, all conditions must be fulfilled.

(**) GR = genetic resource; to be read as also including 'traditional knowledge associated with genetic resources', where appropriate.



http://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/ethics_en.htm

European digital portal « DECLARE »

ANNOUNCEMENTS



Submit declaration -
Research phase



Submit declaration - Final
development phase



Declarations

Current version: 5.50.202109011218 (59607d1) Version date: 2021-09-01 12:22:36

[Top](#) | [Contact](#) | [European Commission](#) | [Environment & Climate Action](#) | [Declare](#) | [Privacy statement](#)

- **Operational since September 2017**
- **Confidentiality insured**

<https://webgate.ec.europa.eu/declare/web/domain>

User manual : http://ec.europa.eu/environment/nature/biodiversity/international/abs/material_en.htm



DECLARE

Data submission portal

- Home
- Declarations ▾
- My Organisation
- Register new organisation

Institut de Recherche Pierre Fabre
Genetic Resource User Administrator

DUE DILIGENCE DECLARATION AT THE STAGE OF RESEARCH FUNDING

pursuant to Article 5 of Regulation 2015/1866

Institut de Recherche Pierre Fabre - France

General Contact Email: -

Genetic resource user is confidential



DECLARE

Data submission portal

- Home
- Declarations ▾
- My Organisation
- Register new organisation

Institut de Recherche Pierre Fabre
Genetic Resource User Administrator

DUE DILIGENCE DECLARATION AT THE STAGE OF FINAL DEVELOPMENT OF A PRODUCT

pursuant to Article 6 of Regulation 2015/1866

Institut de Recherche Pierre Fabre - France

General Contact Email: -

Genetic resource user is confidential

Part A - Information to be transmitted to the ABS Clearing House pursuant to Article 7(3) of Regulation (EU) No 511/2014

If the information provided is confidential within the meaning of Article 7(5) of Regulation (EU) No 511/2014, please provide it nonetheless, tick the respective box and provide the justification for confidentiality.

I declare that I have fulfilled the obligations under Article 4 of Regulation (EU) No 511/2014.

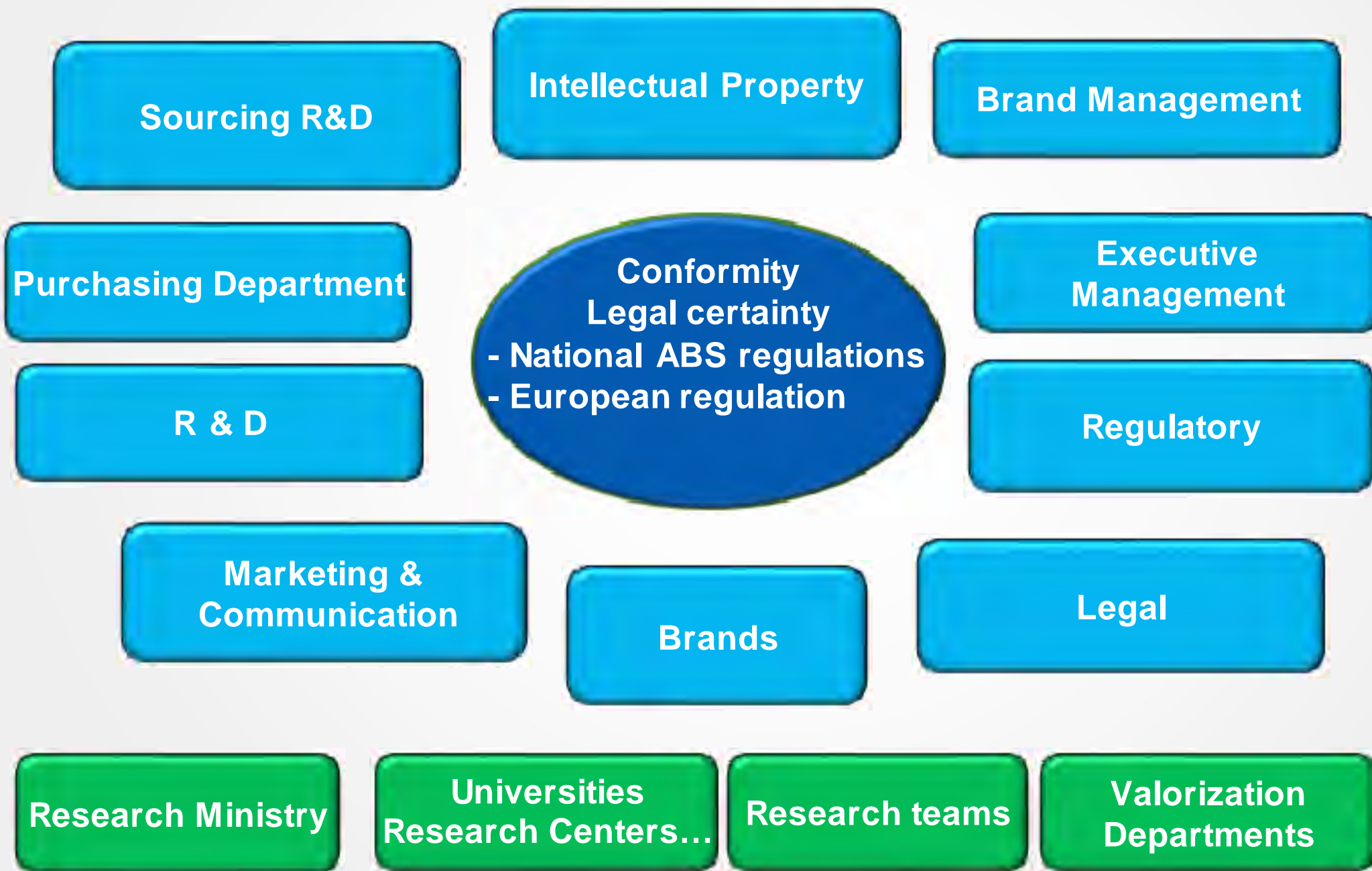
I am making this declaration for the utilisation of:

- Genetic resources
- Traditional knowledge associated with genetic resources

Unclear zones

- Real practical scope of ABS in one specific country?
- Definition of a free commodity
- What technical operations are considered to be R&D?
Ex. Phytochemistry: Purification, mixing, isolation, analyses...
- Changes of intents...
- New uses of a resource acquired prior to implementation of the National Access laws
- Issue of iterative R&D Ex.: improvement of a ingredient sold by an ingredient supplier
- Obligation of certificate of origin (IRCC) for patenting

Services involved in ABS ?



Take-home messages

Access / Benefit Sharing / Compliance Due Diligence Obligation

- Legal access to GR is time consuming process
- Access laws are not fully stabilized and understood
- Be very careful when **patenting**
- Implementation of Nagoya Protocol should **facilitate access, conservation** and should bring **legal certainty** to users
- Development of a sense of pride among companies and employees (teambuilding) to contribute to environmental actions, ethical sourcing...

WORKSHOP:

Access and Benefit Sharing / Practical Advice

Questions & Answers

Question 1

How to operate with domesticated plants i.e. dedicated cultivars and how breeder's rights overlap with the Rio convention ?

✓ It's depend if the GR comes from the wild from an ABS Country or is protected by a plant variety right according to the UPOV Convention

[https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021XC0112\(02\)&from=EN](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021XC0112(02)&from=EN)

12.1.2021

EN

Official Journal of the European Union

C 13/1

A user (plant breeder) developing a new variety using material in the scope of the EU ABS Regulation (i.e. material from a Nagoya Protocol country with enacted ABS legislation, accessed after its entry into force etc. ⁽¹⁷⁾) is subject to due diligence obligations in line with Article 4 of the EU ABS Regulation. Likewise, the user needs to submit a due diligence declaration under Article 7(2) of the Regulation prior to the registration of such a variety or its placing on the market ⁽¹⁸⁾.

Further use of a commercial variety that has been legally placed on the EU market for subsequent breeding programmes does not fall within the scope of the EU ABS Regulation, as the subsequent breeder relies on a new and different genetic resource, different from the initial genetic resource (accessed under the Nagoya Protocol and in scope of the EU ABS Regulation). When a variety is entered in one of the European Catalogues or in a national catalogue or a register of Member States, or when it is indicated on a list of varieties with an official or officially recognised denomination and description, it is considered to be a new variety different from existing varieties of common knowledge.

(2021/C 13/01)

Question 2

Are there any examples of profit sharing that have already been implemented in the cosmetics industry? What form has this sharing taken?

- ✓ Yes many examples. Non-monetary + monetary Benefit Sharing
- ✓ cf. IRCC @ <https://absch.cbd.int> 3045 IRRC

National records 3045 Reference records 0 SCBD records 0

« Prev 1 2 Next » EXPORT

Argentina PARTY TO THE NAGOYA PROTOCOL SIGNATORY ENTRY INTO FORCE: 09 MAR 2017 1

INTERNATIONALLY RECOGNIZED CERTIFICATES OF COMPLIANCE (IRCC) 1

108453535
INTERNATIONALLY RECOGNIZED CERTIFICATES OF COMPLIANCE | ARGENTINA | ABSCH-IRCC-AR-249004-1 | COMMERCIAL | 13 FEB 2020

Belarus PARTY TO THE NAGOYA PROTOCOL ENTRY INTO FORCE: 12 OCT 2014 9

INTERNATIONALLY RECOGNIZED CERTIFICATES OF COMPLIANCE (IRCC) 9

The permit № 10-2-33/4227 19.09.2019 (root samples)
A document confirming the compliance with the Nagoya Protocol issued by the Ministry of Natural Resources and Environmental Protection as a letter of 19.09.2019 № 10-2-33/4227
INTERNATIONALLY RECOGNIZED CERTIFICATES OF COMPLIANCE | BELARUS | ABSCH-IRCC-BY-255414-1 | NON-COMMERCIAL | 05 MAY 2021

The permit 10-2-33/2327 20.05.2020 (Frozen fruits Wild-growing common bilberry)
INTERNATIONALLY RECOGNIZED CERTIFICATES OF COMPLIANCE | BELARUS | ABSCH-IRCC-BY-252270-1 | COMMERCIAL | 05 OCT 2020

The permit 10-2-33/2457 03.06.2019 (50 individuals of the Aquatic Warbler)
INTERNATIONALLY RECOGNIZED CERTIFICATES OF COMPLIANCE | BELARUS | ABSCH-IRCC-BY-246516-2 | NON-COMMERCIAL | UPDATE | 30 MAR 2020

The permit 10-2-33/2348 27.05.2019 (1000 samples of Antarctic organisms (fragments of tissues, bodies or thalli))
A document confirming the compliance with the Nagoya Protocol issued by the Ministry of Natural Resources and Environmental Protection as a letter of 27.05.2019 № 10-2-33/2348
INTERNATIONALLY RECOGNIZED CERTIFICATES OF COMPLIANCE | BELARUS | ABSCH-IRCC-BY-246531-1 | NON-COMMERCIAL | 11 JUN 2019

Question 3

How do states judge the actions implemented through ABS? Have the expected objectives been achieved?

- ✓ ABS contracts have to be honored
- ✓ Expected objectives (Environmental, social development...) are too huge to be achieved

Question 4

Can we foresee changes in relation to the current regulations? In which groups of countries?

- ✓ Biodiversity rich countries are expecting a lot of money from ABS
- ✓ Possible extensions of ABS obligations to “Digital Sequence Information” (“DSI”), GR from International Waters, Antarctic.
- ✓ Crucial importance of open exchange and access to “DSI” in the public domain for research and innovation, including for biodiversity conservation !
- ✓ Urgent need to harmonize and simplify ABS procedures to make the system more workable and effective and to create the required level of legal certainty for both providers and users of biodiversity