Practicalities

- A two-hour session in total
- Plenty of time for Q&A
- Feel free to raise your virtual hand during the presentation
- Please keep your mic muted until given the floor
- Do use the chat function for questions or comments throughout the whole session

VLAAMSE INTERUNIVERSITAIRE RAAD

The Nagoya Protocol

Access to Genetic Resources
Fair and Equitable Benefit Sharing

Filip Colson

VLAAMSE
INTERUNIVERSITAIRE
RAAD

The Convention on Biological Diversity (CBD)

- The Earth's biological resources are vital to humanity's economic and social development. As a result, there is a growing recognition that biological diversity is a global asset of tremendous value to present and future generations. At the same time, the threat to species and ecosystems has never been so great as it is today.
- In 1989 UNEP gathered a group of experts to prepare an international legal instrument for the conservation and sustainable use of biological diversity.
- The experts were to take into account "the need to share costs and benefits between developed and developing countries" as well as "ways and means to support innovation by local people".

https://www.cbd.int/history/

CBD objectives

1. The conservation of biological diversity
2. The sustainable use of the components of biological diversity
3. The fair and equitable sharing of the benefits arising out of the utilization of genetic resources

Convention on Biological Diversity

CBD Article 15 - Access to Genetic Resources

1. Recognizing the **sovereign rights** of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.

2. Each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention.

3. For the purpose of this Convention, the genetic resources being provided by a Contracting Party, as referred to in this Article and Articles 16 and 19, are only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention.

4. Access, where granted, shall be on **mutually agreed terms** and subject to the provisions of this Article.

CBD Article 15 - Access to Genetic Resources

5. Access to genetic resources shall be subject to **prior informed consent** of the Contracting Party providing such resources, unless otherwise determined by that Party.

6. Each Contracting Party shall endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties.

7. Each Contracting Party shall take legislative, administrative or policy measures, […] with the aim of **sharing in a fair and equitable way** the results of research and development and **the benefits arising from the** commercial and other **utilization of genetic resources** with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms.

CBD Article 8(j) - Traditional Knowledge [...]

Each contracting Party shall, as far as possible and as appropriate:

Subject to national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and **encourage the equitable sharing of the benefits arising from the utilization of such knowledge**, innovations and practices.

Introduction

Introduction

Click here to view the brochure on Traditional Knowledge

Traditional Knowledge and the Convention on Biological Diversity

What is traditional knowledge?

Traditional knowledge refers to the knowledge, innovations and practices of indigenous and local communities around the world. Developed from experience gained over the centuries and adapted to the local culture and environment, traditional knowledge is transmitted orally from generation to generation. It tends to be collectively owned and takes the form of stories, songs, folklore, proverbs, cultural values, beliefs, rituals, community laws, local language, and agricultural practices, including the development of plant species and animal breeds. Sometimes it is referred to as an oral traditional for it is practiced, sung, danced, painted, carved, chanted and performed down through millennia. Traditional knowledge is mainly of a practical nature, particularly in such fields as agriculture, fisheries, health, horticulture, forestry and environmental management in general.

The Nagoya Protocol (NP)

- *The 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*
- Art. 4.4. This Protocol is the instrument for the implementation of the access and benefit-sharing provisions of the Convention. […]

The Nagoya Protocol objective

The objective of this Protocol is the fair and equitable **sharing of the benefits** arising from the utilization of genetic resources, including by appropriate **access** to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components.

The Nagoya Protocol

- The NP applies to genetic resources (GR) and traditional knowledge (TK) associated with GR that are covered by the CBD, and to the benefits arising from their utilization.
- Entered into force on 12 October 2014
- The CBD has 196 Parties
- The NP has 129 Parties

CBD, NP, EU ABS Regulation's use of terms

- Genetic resources: any material of plant, animal, microbial or other origin containing functional units of heredity and of actual or potential value.
- The genetic resources can be wild, domesticated or cultivated, accessed in-situ as well as ex-situ.
- Derivative: 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.
- Utilization of genetic resources: to conduct research and development on the genetic and/or biochemical composition of genetic resources […]

CBD, NP, EU ABS Regulation's use of terms

- Access: the acquisition of genetic resources or of traditional knowledge associated with genetic resources in a Party to the Nagoya Protocol
- Illegally accessed genetic resources: genetic resources and traditional knowledge associated with genetic resources which were not accessed in accordance with the national access and benefit-sharing legislation or regulatory requirements of the provider country that is a Party to the Nagoya Protocol requiring prior informed consent

CBD, NP, EU ABS Regulation's use of terms

- Provider country: the country of origin of the genetic resources or any (other) Party to the Protocol that has acquired the genetic resources in accordance with the Convention
- Country of origin: the country which possesses the genetic resources in in-situ conditions

GR's out of scope of the Nagoya Protocol

- FAO's International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)
- WHO's Pandemic influenza preparedness (PIP) Framework for the sharing of influenza viruses and access to vaccines and other benefits
- Human genetic resources

NP and EU ABS Regulation: is your research in scope?

- **EU ABS Regulation** EU 511/2014 […] on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union
- **Implementing Regulation** EU 2015/1866 (registered collections, best practices and monitoring of user compliance)
- **Guidance document** 2021/C 13/01 on the scope of application and core obligations of the 2014 Regulation
- Both the EU ABS Regulation and the Implementing Regulation are directly applicable in all Member States of the EU, regardless of the status of the Nagoya Protocol's ratification in different Member States

OVERVIEW OF CONDITIONS FOR APPLICABILITY OF THE EU ABS REGULATION

		Within scope (cumulative conditions (*))	Outside of scope
Geographic scope (provenance of GR (**))	*Access in ...*	Areas within a country's jurisdiction	Areas beyond national jurisdiction or covered by Antarctic Treaty System
	Provider country is ...	Party to the Nagoya Protocol	Not a Party to the Protocol
	Provider country has ...	Applicable access legislation	No applicable access legislation
Temporal scope	*Access ...*	On or after 12 October 2014	Before 12 October 2014
Material scope	*Genetic resources*	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
	Utilisation	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)	*R & D ...*	Within the EU	*Exclusively* outside of the EU

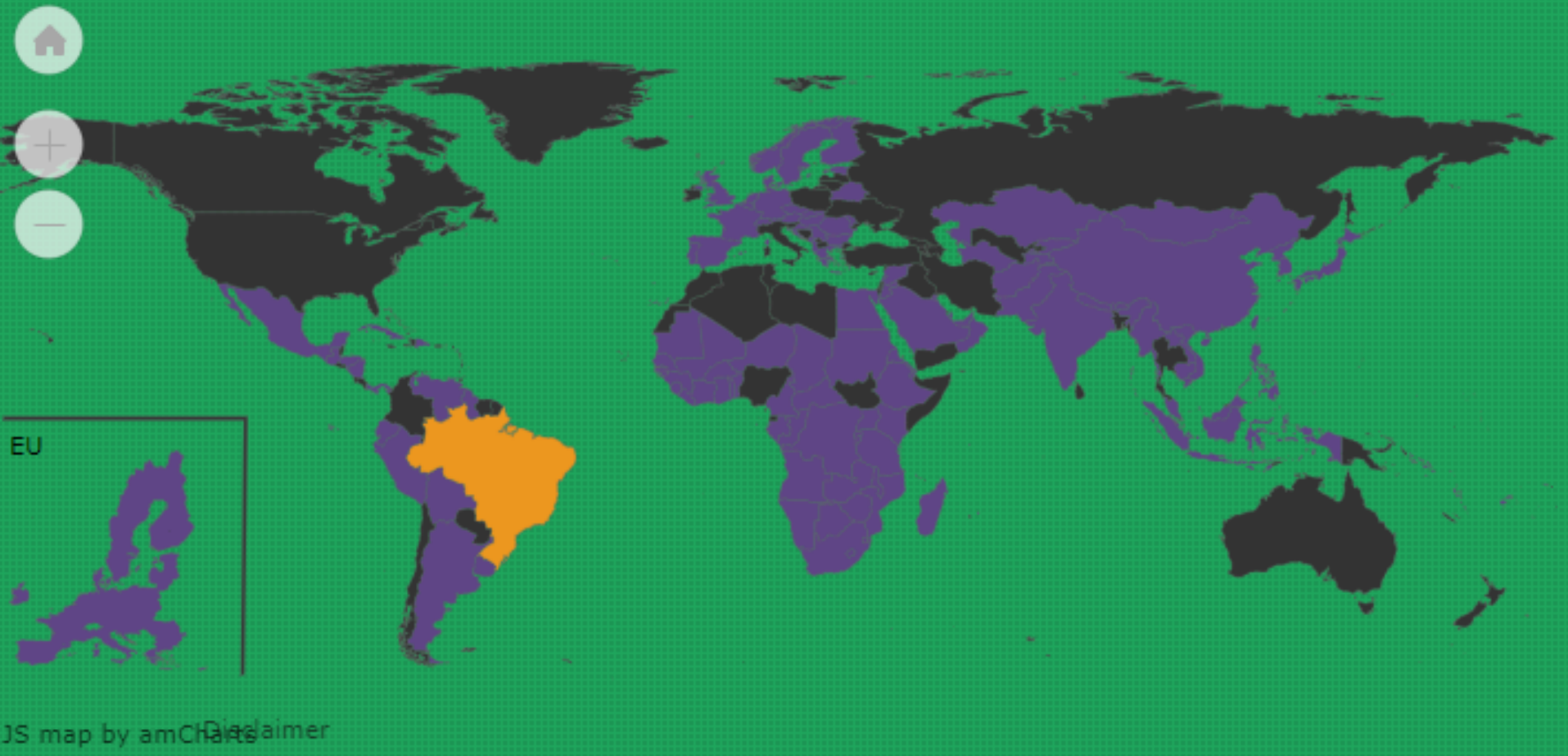
(*) To be within the scope, all conditions must be fulfilled.

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

NP and EU ABS Regulation: is your research in scope?

- For information on possible access measures (adopted by EU Member States and others), please consult their country profile on the international ABS Clearing-House.

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

177	ABS National Focal Point
124	Competent National Authority
264	Legislative, Administrative or Policy Measure
21	ABS Procedure
3	National Model Contractual Clause
2141	Internationally Recognized Certificates of Compliance

129 Parties to the Nagoya Protocol

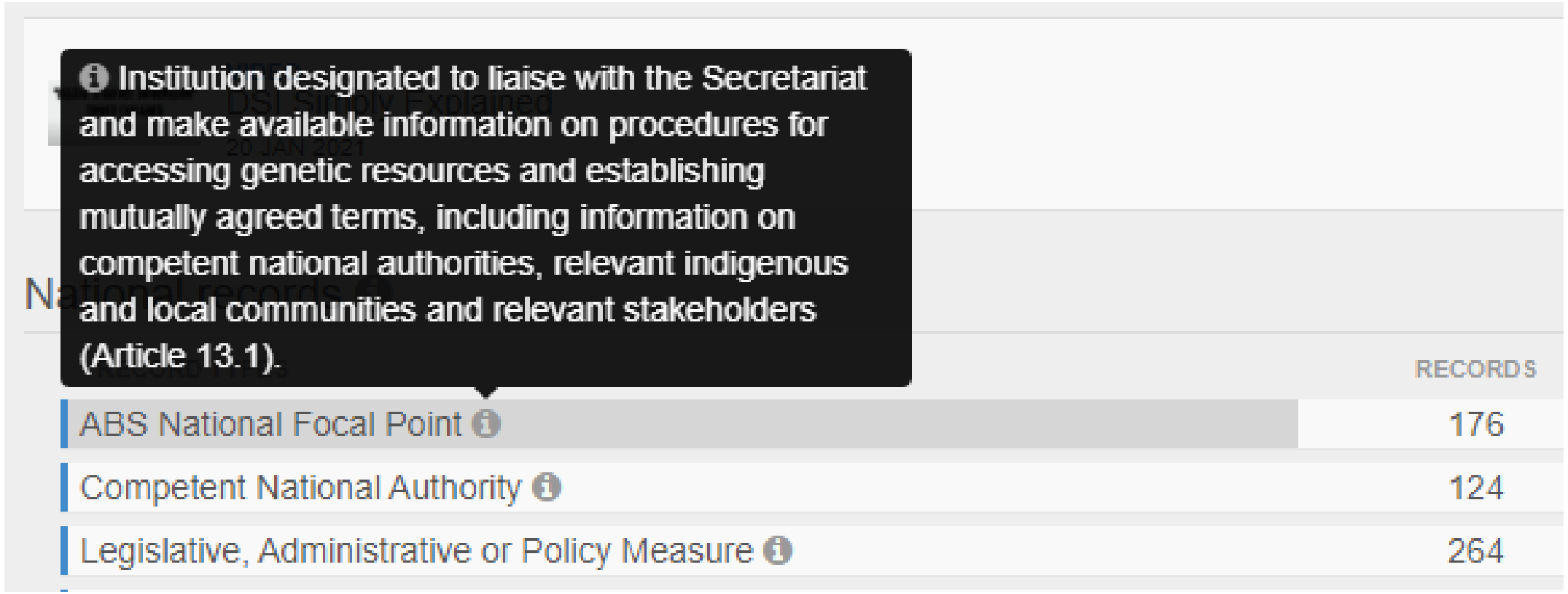
1 Ratified, not yet Party

69 Non-Parties

- ABSCH demo

National records

RECORD TYPES	RECORDS
ABS National Focal Point	176
Competent National Authority	124
Legislative, Administrative or Policy Measure	264
ABS Procedure	21
National Model Contractual Clause	3
Internationally Recognized Certificates of Compliance	2110
National Websites or Databases	52
Checkpoint	69
Checkpoint Communiqué	44
Interim National Reports on the Implementation of the Nagoya Protocol	98


Institution designated to liaise with the Secretariat and make available information on procedures for accessing genetic resources and establishing mutually agreed terms, including information on competent national authorities, relevant indigenous and local communities and relevant stakeholders (Article 13.1).
RECORDS
ABS National Focal Point 176
Competent National Authority 124
Legislative, Administrative or Policy Measure 264

National records

Certificate constituted from the information on the permit or its equivalent registered in the ABS Clearing-House, serving as evidence that the genetic resource which it covers has been accessed in accordance with prior informed consent and that mutually agreed terms have been established. It contains the minimum necessary information to allow monitoring the utilization of genetic resources by users throughout the value chain (Article 17).

RECORD TYPES	RECORDS
ABS National Focal Point	176
Competent National Authority	124
Legislative, Administrative or Policy Measure	264
ABS Procedure	21
National Model Contractual Clauses	3
Internationally Recognized Certificates of Compliance	2110
National Websites or Databases	52
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Belgium

Party Status:	**Party to the Nagoya Protocol**
Entered into force on:	**07 Nov 2016**
Ratification on:	**09 Aug 2016**
Signatory:	**Signed on 20 Sep 2011**
CBD Country Profile:	www.cbd.int/countries/?country=be

– ABS National Focal Point (NFP) 1

Ms. Salima Kempenaer

Directorate General (DG5) Environment Federal Public Service of Public Health, Food Chain Security and Environment Place Victor Horta 40, box 10 B-1060 Brussels

ABS NATIONAL FOCAL POINT | BELGIUM | ABS-NFP-BE-210317-5 | 21 AUG 2020

– Competent National Authority (CNA) 2

Direction générale opérationnelle de l'Agriculture, des Ressources naturelles et de l'Environnement

The DG is responsible to check compliance in the Walloon Region for the Nagoya Protocol

COMPETENT NATIONAL AUTHORITY | BELGIUM | ABSCH-CNA-BE-241209-3 | SUB-NATIONAL | 19 AUG 2020

Agency Nature & Forests (Agentschap voor Natuur en Bos)

The Agency is responsible for inspecting the compliance to the Nagoya Protocol in the Flemish Region.

COMPETENT NATIONAL AUTHORITY | BELGIUM | ABSCH-CNA-BE-241208-5 | SUB-NATIONAL | 06 FEB 2020

Brazil

Party Status: Not a Party to the Nagoya Protocol

Signatory: Signed on 02 Feb 2011

CBD Country Profile: www.cbd.int/countries/?country=br

+ ABS National Focal Point (NFP) 1

+ Competent National Authority (CNA) 1

– Legislative, Administrative or Policy Measure (MSR) 3

Select the ABS Measures to be displayed in the overview

1. **Brazilian Biodiversity Law**
NATIONAL / FEDERAL | LAW | LEGALLY BINDING | ENTRY INTO FORCE: 20 MAY 2015

2. **Provisional Act nº 2.186-16 dated August 23, 2001**
NATIONAL / FEDERAL | LAW | LEGALLY BINDING | ENTRY INTO FORCE: 24 AUG 2001

3. **MATERIAL TRANSFER AGREEMENT – MTA**
NATIONAL / FEDERAL | REGULATORY OR ADMINISTRATIVE MEASURES | LEGALLY BINDING | ENTRY INTO FORCE: 18 SEP 2018

Chile

Party Status:	**Not a Party to the Nagoya Protocol**
Signatory:	**No**
CBD Country Profile:	www.cbd.int/countries/?country=cl

+ ABS National Focal Point (NFP) 1
+ Competent National Authority (CNA) 0
+ Legislative, Administrative or Policy Measure (MSR) 0
+ ABS Procedure (PRO) 0
+ National Model Contractual Clause (NMCC) 0
+ Internationally Recognized Certificates of Compliance (IRCC) 0
+ National Websites or Databases (NDB) 0
+ Checkpoint (CP) 0
+ Checkpoint Communiqué (CPC) 0
+ Interim National Reports on the Implementation of the Nagoya Protocol (NR) 0

India

Party Status:	**Party to the Nagoya Protocol**
Entered into force on:	**12 Oct 2014**
Ratification on:	**09 Oct 2012**
Signatory:	**Signed on 11 May 2011**
CBD Country Profile:	www.cbd.int/countries/?country=in

+ ABS National Focal Point (NFP) **1**
+ Competent National Authority (CNA) **1**
+ Legislative, Administrative or Policy Measure (MSR) **29**
+ ABS Procedure (PRO) **1**
+ National Model Contractual Clause (NMCC) **0**
+ Internationally Recognized Certificates of Compliance (IRCC) **1360**

Australia

Party Status:	**Not a Party to the Nagoya Protocol**
Signatory:	**Signed on 20 Jan 2012**
CBD Country Profile:	www.cbd.int/countries/?country=au

− ABS National Focal Point (NFP) 1

Ms. Kat Miller

Director Biodiversity Policy Section Department of Agriculture, Water and the Environment GPO Box 787 Canberra ACT 2601

ABS NATIONAL FOCAL POINT | AUSTRALIA | ABS-NFP-AU-209260-10 | 17 JUN 2020

+ Competent National Authority (CNA) 0

+ Legislative, Administrative or Policy Measure (MSR) 0

+ ABS Procedure (PRO) 0

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5. Has your country designated a national focal point as provided in Article 13?

Yes

Use the text entry to provide further information

The Ministry of Environmental Protection is responsible for leading and organizing the implementation of the Convention on Biological Diversity and acts as national focal points for the Convention and its Protocols.

The ABS Clearing-House unique ID containing relevant information

ABSCH-NFP-CN-3767

6. Has your country designated one or more competent national authorities as provided in Article 13?

No

Use the text entry to provide further information

China is developing a regulation on access to genetic resources and benefit-sharing from their utilization, which will further confirm national competent authorities for access to genetic resources and benefit-sharing.

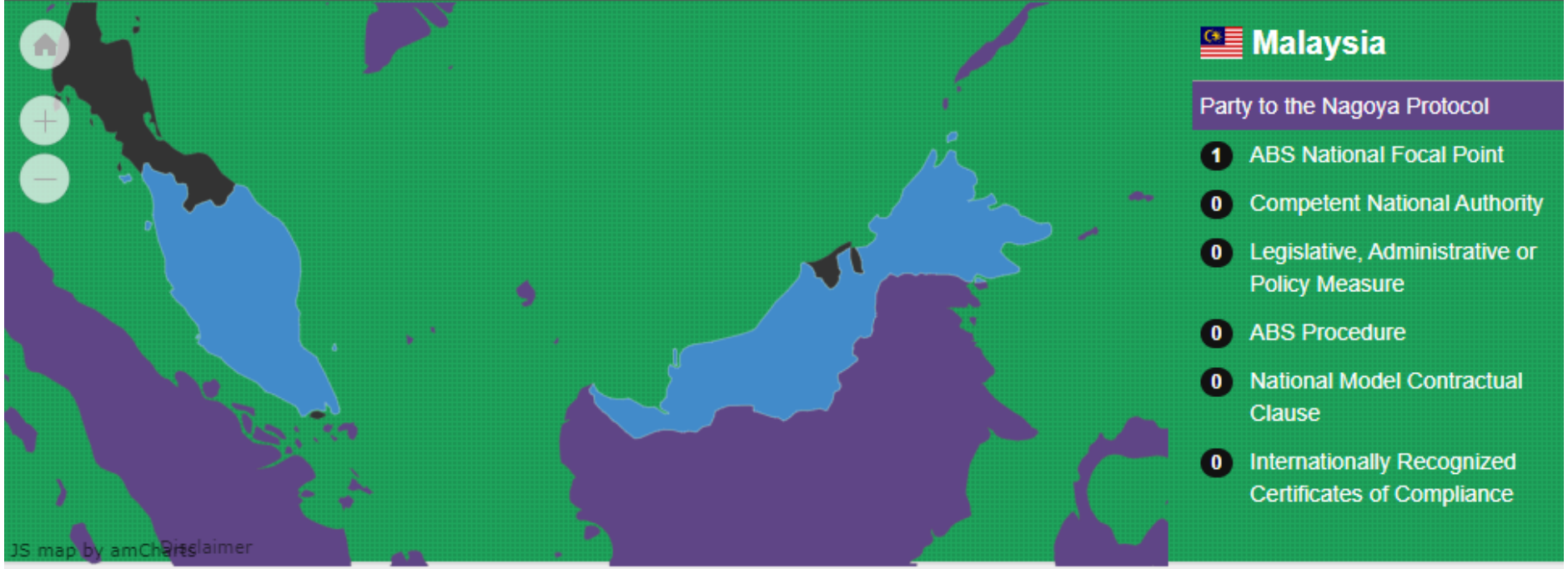
At this stage, China is using a system of management coordinated by the Ministry of Environmental Protection while other relevant departments manage ABS-related matters in their respective areas. These departments mainly include the environment, science and technology, water resources, agriculture, forestry, customs administration, examination and quarantine, intellectual property rights administration and Chinese medicine administration.

7. Has your country made available to the ABS Clearing-House permits or their equivalent issued at the time of access as evidence of the decision to grant prior informed consent (PIC) and of the establishment of mutually agreed terms (MAT)?

No

Please provide a summary of the main difficulties and challenges encountered for making this information available

The operation of ABSCH is still in an initial stage as China has ratified the Nagoya Protocol recently. China will submit relevant information to ABSCH as required by relevant provisions of the Nagoya Protocol and related COP-MOP decisions as China is improving its domestic laws/regulations and management system in this regard.



Malaysia

Party Status:	**Party to the Nagoya Protocol**
Entered into force on:	**03 Feb 2019**
Accession on:	**05 Nov 2018**
Signatory:	**No**
CBD Country Profile:	www.cbd.int/countries/?country=my

+ ABS National Focal Point (NFP) 1

+ Competent National Authority (CNA) 0

+ Legislative, Administrative or Policy Measure (MSR) 0

https://www.tandfonline.com/doi/full/10.1080/00222933.2020.1851935

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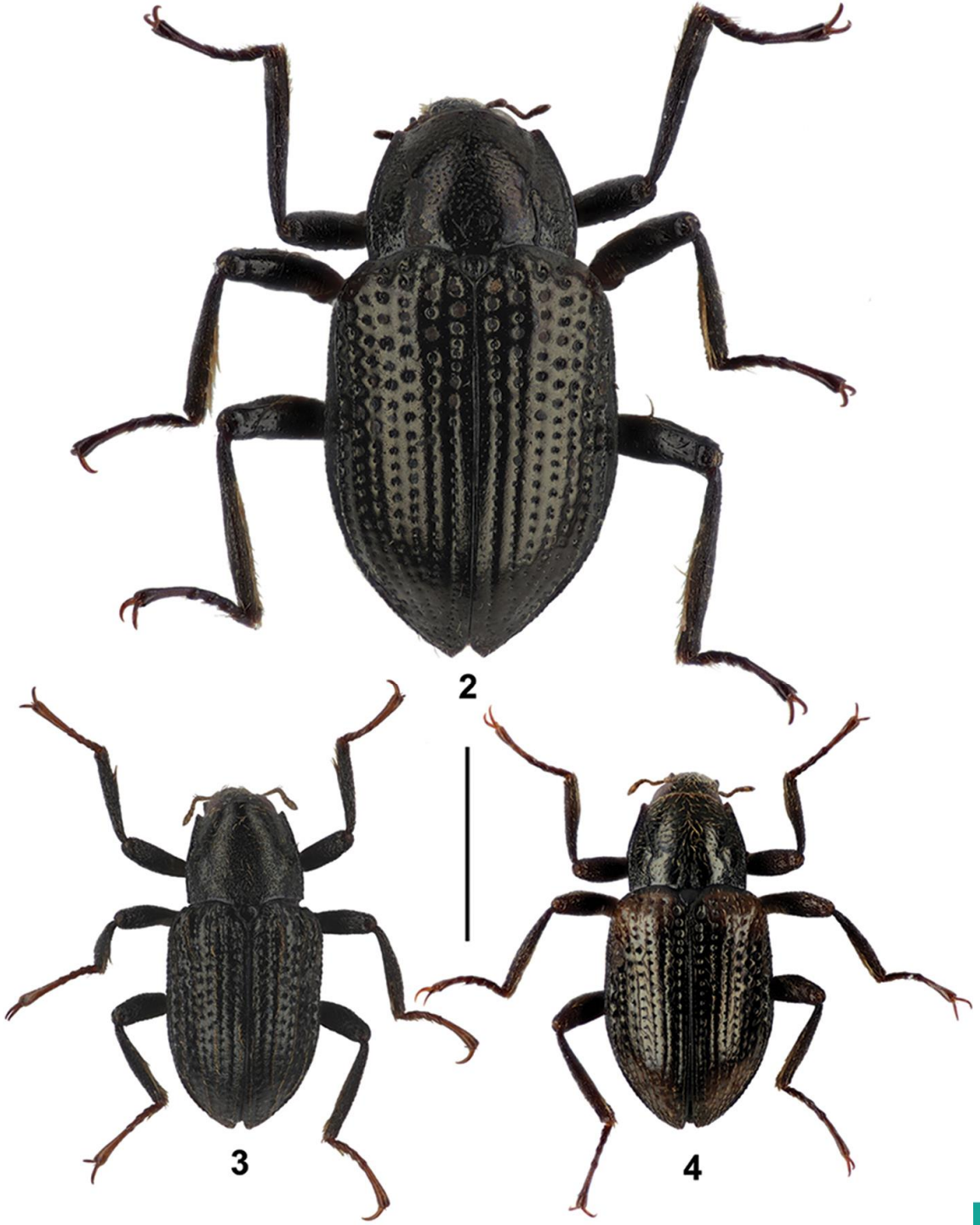


Grouvellinus leonardodicaprioi sp. n., G. quest sp. n., G. andrekuipersi sp. n.
https://doi.org/10.3897/zookeys.754.24276

We, the Editor and Publisher of *Journal of Natural History*, have retracted the following article: Hendrik Freitag, Christian Molls, Aglaia M. Bouma, Jhoana M. Garces, Marzia Rossato, Emanuela Cosentino & Massimo Delledonne (2019) Additional new species of *Grouvellinus* Champion 1923 (Insecta, Coleoptera, Elmidae) discovered by citizen scientists and DNA barcoded in the field applying a novel MinION-based workflow, Journal of Natural History, 53:41-42, 2593-2620, DOI: 10.1080/00222933.2019.1709669

The collection permit from Sabah Biodiversity Centre in Malaysia does not allow for the publication of these data, which formed the basis of the article above.

The authors were made aware of this problem with their permit by the Sabah Biodiversity Centre following publication of their paper, and informed Taylor & Francis promptly. They have been fully cooperative with the publisher and the Sabah Biodiversity Centre and have agreed to the necessary action.

We have been informed in our decision-making by our policy on publishing ethics and integrity and the COPE guidelines on retractions. The retracted article will remain online to maintain the scholarly record, but it will be digitally watermarked on each page as "Retracted".

Retraction guidelines

DOI: https://doi.org/10.24318/cope.2019.1.4

https://publicationethics.org/retraction-guidelines

Summary

Editors should consider retracting a publication if:

- They have clear evidence that the findings are unreliable, either as a result of major error (eg, miscalculation or experimental error), or as a result of fabrication (eg, of data) or falsification (eg, image manipulation)
- It constitutes plagiarism
- The findings have previously been published elsewhere without proper attribution to previous sources or disclosure to the editor, permission to republish, or justification (ie, cases of redundant publication)
- It contains material or data without authorisation for use
- Copyright has been infringed or there is some other serious legal issue (eg, libel, privacy)
- It reports unethical research
- It has been published solely on the basis of a compromised or manipulated peer review process
- The author(s) failed to disclose a major competing interest (a.k.a. conflict of interest) that, in the view of the editor, would have unduly affected interpretations of the work or recommendations by editors and peer reviewers.

Steps involved in ABS

1. Assess the relevance of ABS for your intended research (check scope of the Nagoya Protocol).
2. If your research falls under ABS, go to the ABS Clearing House to:
    1. Obtain the contact details of the ABS National Focal Point of your provider country;
    2. Check whether the provider country is Party to the Nagoya Protocol and has ABS regulation in place (relevant for the application of the EU legislation).
3. Contact the ABS National Focal Point of your provider country and inquire about:
    1. Conditions to apply for Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT);
    2. Other specifics of the national legislation/regulation (e.g. specific conditions for utilization, benefit sharing).
    3. Inquire which additional permits may be necessary (e.g. research permits, export permits).

Steps involved in ABS

4. Apply for PIC and negotiate MAT.
5. During research, comply with MAT and the legislation of your provider country. Comply with EU and Belgian legislation, if applicable.
6. Share benefits as agreed in the MAT.
7. After finalization of the research, proceed with the collected material as agreed in the MAT. When transferring material to ex-situ facilities or third parties, include relevant ABS documentation.
8. Store proof of legitimate access (PIC, MAT) according to the requirements of due diligence; keep records accessible for 20 years after the research has been concluded

The ABC of ABS (Access and Benefit Sharing)

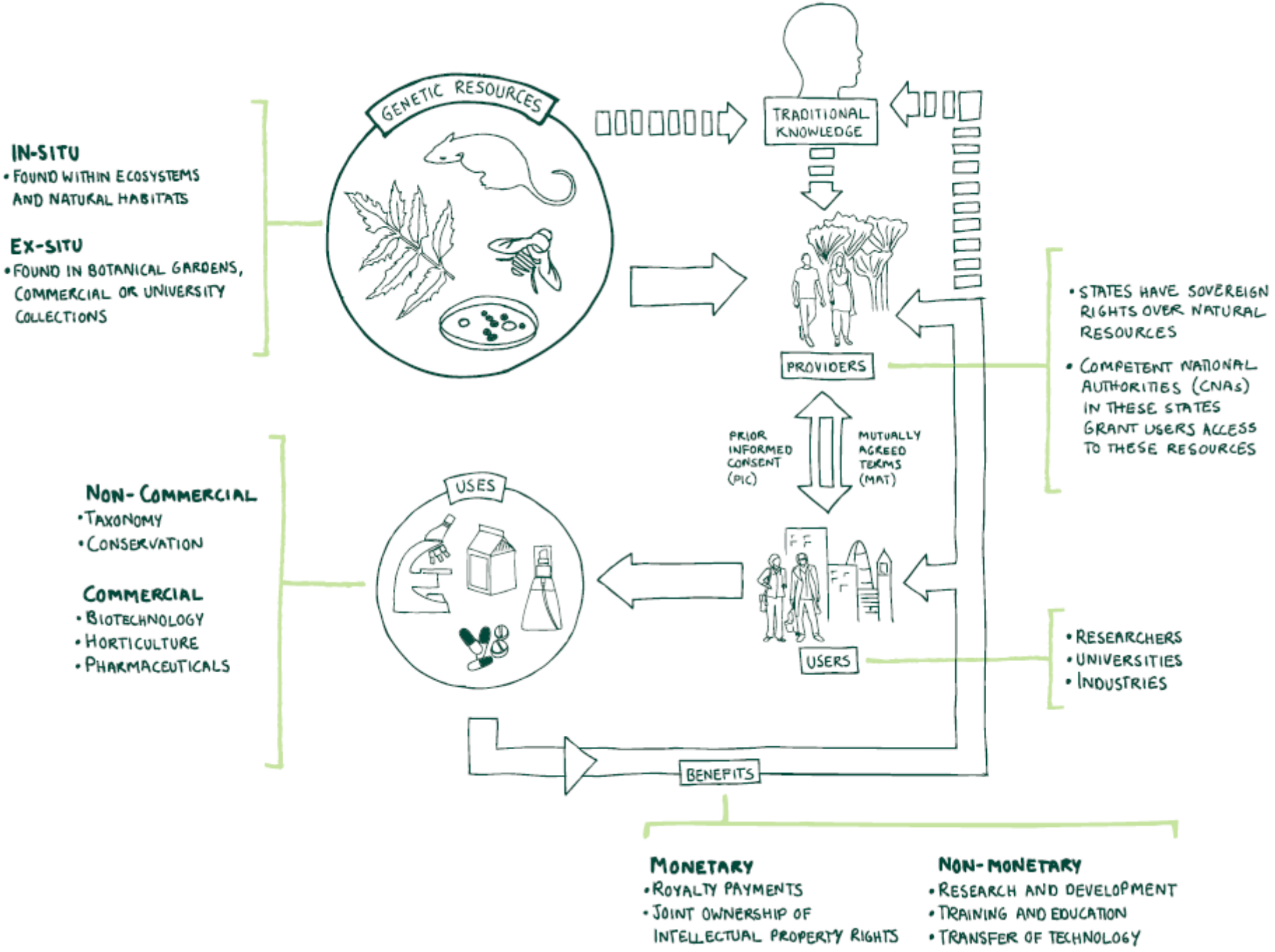
- Access: Prior Informed Consent (PIC), scope of permitted utilization, issued by competent authority
- Benefit Sharing: Mutually Agreed Terms (MAT), monetary or non-monetary, agreement between user and country of origin
- Compliance: measures defined by the country of utilization, in our case specified in EU Regulation 511/2014 and concomitant

PIC & MAT

- Prior Informed Consent: unilateral administrative permit given by the Competent Authority of the provider country and by additional providers, such as an indigenous or local community, to an individual or an institution prior to accessing genetic resources
- Mutually Agreed Terms: bilateral contract between providers and users to establish the conditions of access and utilization of the resources and the benefits to be shared. The contract needs to respect the regulatory requirements of the provider country and of the country where the resources will be utilized.

Due Diligence Declaration templates

- See the annexes of the EU 2015/1866 Implementing Regulation, specifically Annex II: Template for a due diligence declaration to be submitted at the stage of research funding […]
  - Place of access
  - Description of the genetic resources or traditional knowledge […]
  - Identifier of access permit or its equivalent, where available
- Not all information has to be transmitted to the ABSCH and some information can be marked as confidential
  - Date of access
  - PIC and MAT specifics
  - …



Source:
www.cbd.int/abs

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Case studies of scope, utilization and GR's

- Digital Sequence Information (DSI)
- Marine Genetic Resources
- Micro-organisms
- Taxonomy
- Intent

DSI

CBD webinar series on DSI:

1. understanding DSI,
2. DSI under the CBD,
3. policy options for ABS and DSI

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Digital Sequence Information (DSI): scope

Table 1. Clarifying the scope of digital sequence information on genetic resources

	Information related to a genetic resource			
	Genetic and biochemical information			**Associated information**
Group reference	*Group 1*	*Group 2*	*Group 3*	
High-level description of each group	DNA and RNA	Group 1 + proteins + epigenetic modifications	Group 2 + metabolites and other macromolecules	
Examples of granular subject matter	• Nucleic acid sequence reads; • Associated data to nucleic acid reads; • Non-coding nucleic acid sequences; • Genetic mapping (for example, genotyping, microsatellite analysis, SNPs, etc.); • Structural annotation.	• Amino acid sequences; • Information on gene expression; • Functional annotation; • Epigenetic modifications (for example, methylation patterns and acetylation); • Molecular structures of proteins; • Molecular interaction networks.	• Information on the biochemical composition of a genetic resource; • Macromolecules (other than DNA, RNA and proteins); • Cellular metabolites (molecular structures).	• Traditional knowledge associated with genetic resources • Information associated with digital sequence information Groups 1, 2 and 3 (for example, biotic and abiotic factors in the environment or associated with the organism) • Other types of information associated with a genetic resource or its utilization.

DSI

- It could be argued that the [Nagoya] Protocol deals with access to and utilisation of genetic resources as such and therefore does not regulate issues concerning digital information obtained from genetic resources.
- However, the implications of this distinction are still to be considered by the Parties to the Protocol, in the light of recent technological developments.
- Without prejudice to the outcome of that consideration, the use of digital data obtained from gene sequencing, which is frequently stored in publicly available databases, could be considered to be **out of scope** of the ABS Regulation.

DSI

- In any case, the use or publication of such data might be covered by conditions set in the mutually agreed terms, which should be respected. In particular, those who accessed the genetic resources and obtain sequence data from them should respect the conditions of the agreement entered into, and inform subsequent actors about any rights and obligations attached to the data obtained and related to any further uses of it.
- CBD/NP jurisdictions with **domestic measures** on DSI and benefit sharing: Australia (Queensland), Bahrain, Bhutan, Bolivia, Brazil, China, Colombia, Costa Rica, India, Kenya, Malawi, Malaysia, Mozambique, Namibia, Panama, Peru, South Africa

Marine Genetic Resources

- The European Marine Biological Resource Centre network: see EMBRC's ABS page for clear guidance on the impact of ABS on your research

ABS & biological resources

The Nagoya Protocol (NP) is a supplementary agreement to the Convention on Biological Diversity (CBD). Since its entry into force on 12 October 2014, it provides a transparent legal framework for the effective implementation of one of the three objectives of the CBD: the fair and equitable sharing of benefits arising from the use of biological resources (1) (referred to as 'genetic resources' in the

Marine Genetic Resources

- VLIZ, Flanders Marine Institute, has developed PharmaSea, a User Toolkit to support the lawful and sustainable use of marine genetic resources within European marine biotechnology

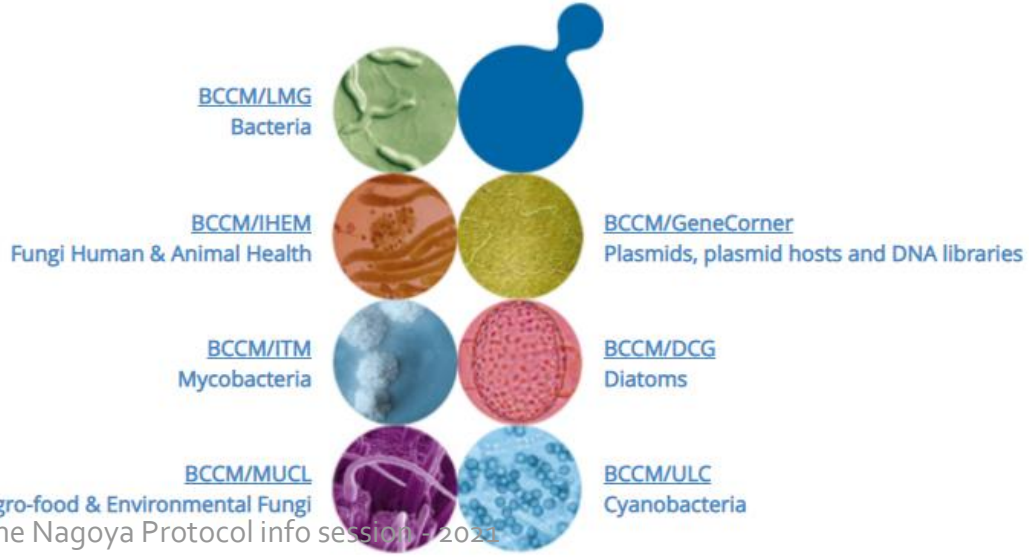
Welcome

The PharmaSea MGR User Toolkit will support the lawful and sustainable use of marine genetic resources (MGR) within European marine biotechnology.

Marine biotechnology R&D often depends upon access to marine organisms, collectively termed marine genetic resources (MGR). Scientists, familiar with the potential challenges of collecting MGR samples in the marine environment, are often less aware of the legal and policy frameworks governing access to MGR. The applicable regimes governing MGR sampling and utilization vary depending on where in the marine environment samples are taken or for what purpose they will be used. Certain obligations also extend to accessing samples from *ex-situ* collections depending on the applicable laws in the State from whose jurisdiction the samples were originally sourced.

Micro-organisms

- There are currently two registered collections in the EU: the Leibniz Institute DSMZ German Collection of Microorganisms and Cell Cultures and the CIRM-CFBP French Collection for Plant-associated Bacteria.
- BCCM, the Belgian Co-ordinated Collections of Micro-organisms provides facilitated access to technically as well as legally fit-for-use microbiological resources.



Taxonomy

- Taxonomic identification of biological or genetic resources, by morphological or molecular analysis, including through use of DNA sequencing, is **not** as such considered to constitute **utilisation** in the meaning of the EU ABS Regulation, as it does not involve the discovery of specific genetic and/or biochemical properties.
- It does not 'create new insight into characteristics of the genetic resource which is of (potential) benefit to the further process of product development', as formulated in the **litmus test**. Instead, the DNA or RNA sequence is being used as a tool to identify the organism.

Taxonomy

- Discovery, description and publication of new species would also **not** qualify as **utilisation** in the meaning of the EU ABS Regulation, as long as this is done without additional research on the genetic and/or biochemical composition of the genetic resources to discover or making use of the properties (functions) of the genes.

Taxonomy

- Provider countries may set conditions in PIC and/or MAT on the generation, storage, publication and/or distribution of digital sequence data obtained from that genetic resource. These conditions remain applicable, even if the activities do not fall within the scope of the EU ABS Regulation.
- However, if the identification or taxonomic description of an organism is combined with research on its specific genetic and/or biochemical composition, specifically the **function of the genes**, this would qualify as utilisation in terms of the EU ABS Regulation

‘function of genes’

(Public research) Research into the function of genes found in forest species without further development

Genetic and biochemical function within accessed genetic resources are investigated in the context of a research project, specific traits are identified, and their genetic background determined. Researchers involved do not consider future product development or commercial application of the results of their research. Their outputs are limited to the publication of the research results in scientific fora.

Research activities that involve analysis of the genetic and/or biochemical composition of the genetic resources are considered utilisation. Hence, these activities fall in the scope of the EU ABS Regulation and researchers have to fulfil due diligence obligations, regardless of whether product development is intended or not.

(Collection holders) Phylogenetic analyses including consideration of function of genes

A taxonomist specialising on a group of venomous snakes collaborates with a protein research laboratory to evaluate the link between species relatedness and venom protein similarities, with potential use for snake-bite treatment with antivenom. A phylogeny is reconstructed on the group of snakes and the function of the venom protein of each species is analysed and compared over the phylogeny. The venoms were extracted from snakes as part of the project.

The construction of the phylogeny itself would be out of scope if the properties of the venom or gene function were not used. However, if the venom protein functions or function of the genes were used for the phylogenetic analysis, it would be in scope.

The comparison of the venoms, even if not directly related to the development of a new antivenom product, constitutes utilisation in the meaning of the EU ABS Regulation as it investigates the biochemical composition of a derivative extracted from a genetic resource (see Section 2.3.4 of the Guidance document).

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‘litmus test’

- As a type of ‘litmus test’, users should ask themselves whether what they are doing with the genetic resources creates new insight into characteristics of the genetic resource which is of (potential) benefit to the further process of product development.
- If this is the case, the activity goes beyond mere description, should be considered research and development and therefore falls under the term ‘utilisation’.

Taxonomy

(Public research) Taxonomic identification of human pathogens or associated organisms

In analytic work performed in national laboratories, DNA sequence analysis may be required e.g. to assess the presence of previously derived virulence factors and/or resistances to antimicrobial agents. Genetic resources (specimens for identification) will need to be accessed, and often moved internationally to be submitted to expert taxonomists. Identified voucher material [preserved sample of the original specimens (genetic resource)] is often deposited in both the provider country and the country where the DNA sequence was analysed, where suitable repositories exist.

Taxonomic identification of specimens is not considered to constitute utilisation in the meaning of the EU ABS Regulation, where it does not include research and development on the genetic and/or biochemical composition of the genetic resource, in particular in the form of discovery of specific genetic and/or biochemical functions. It only establishes the identity of the genetic resource (specimen) and generates passport data. However, in cases where research and development is performed on the genetic and/or biochemical composition of such pathogens, including for example on virulence factors and resistance traits, due diligence requirements apply.

(Public research) Environmental DNA metabarcode analysis of water samples to discover the numbers of fish species present

Water samples are taken from a river to discover the number of different fish species present. It makes use of DNA released into the water by organisms. To obtain a biodiversity inventory the DNA is purified from the water samples, DNA markers are targeted and sequenced, and the sequences discovered are taxonomically assigned by comparison with reference sequences in a database. The function of the genes is not investigated. Because only the sequence is used, and the functions are not studied or considered, such inventory studies do not constitute utilisation under the EU ABS Regulation.

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Taxonomy

- CETAF, the Consortium of European Taxonomic Facilities, offers a wonderful code of conduct and best practices on ABS (officially recognized by the European Commission).

Natural Science Collections and Access and Benefit Sharing

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Intent, pathogens

- Pathogens may appear together with travelling individuals, where it is also not the intention to distribute the pathogenic organisms (and where furthermore it may be impossible to identify the country of origin of such organisms).
- This may concern aphids or other pests present on plants or timber imported as commodities, bacteria such as *Campylobacter* present on imported meat, or Ebola viruses carried by travellers or by other individuals (e.g. sick health care workers) that are transferred to an EU Member State for medical treatment.

Intent, pathogens

- The Regulation does not apply to pathogenic organisms or pests present on a human, an animal, a plant, a micro-organism, food, feed or any other material, which as such are introduced unintentionally to a place in the EU territory, be it from a third country or from a Member State with access legislation in place.

— A new viral disease of tomatoes, called tomato brown rugose fruit virus, was first observed in the Near East in 2014, and has since been detected in the EU. Virus isolates taken from imported fruits are used for analysis; since the particular organisms isolated originated in another country and are unintentionally introduced any utilisation is out of scope of the EU Regulation.

— Research on the virus also made use of virus isolates from plants growing in EU countries after the virus had established itself in the EU; these isolates from populations established in the EU were compared with those of other countries as well as with related plant viruses. In particular, genetic properties related to spreading and survival of the virus were studied. Since this study involved research into pathogens that had become established in EU countries and were collected in situ there, the relevant ABS regulations of the country where they were accessed apply, and the use of the genetic resource involved (tomato virus) is in scope of the EU ABS Regulation.

Intent, pathogens

— A person who recently visited various countries in East Asia reported to a doctor after her return to the EU with severe pneumonia-like symptoms. In hospital the person was diagnosed as suffering from Severe Acute Respiratory Syndrome (SARS). Samples were taken from the patient for further diagnosis and confirmation of the infectious agent. A coronavirus was isolated from these samples. The DNA sequence of the isolate was compared with other SARS-associated coronavirus isolates, and symptoms of the patient were compared with those of other SARS patients showing slightly different symptoms (nature and severity of the symptoms, period over which symptoms remained in relation to differences of the genome sequences of the virussec isolates). All isolates were from patients who contracted the virus outside the EU. Since this study involved research into a pathogen brought into the EU unintentionally, the use of the genetic resource involved (SARS causing coronavirus) is out of scope of the EU ABS Regulation.

Intent, pathogens

- Should a pathogen or pest become established *in situ* in an EU country following introduction, they fall under sovereign rights of the country where they are established.
- If the country has enacted access legislation applicable to such species and other conditions for applicability of the EU ABS Regulation are met, utilisation of such genetic resources is in scope of the EU ABS Regulation.

Impossible to identify the provider country

- The EU ABS Regulation does not forbid utilisation of genetic resources of unknown origin.
- However, if new information arises that allows the provider country to be identified then the Regulation could apply.
- Likewise, the competent authorities might ask for reasons and justifications why certain material is considered to fall outside of the scope of the Regulation during checks. It is therefore advisable to keep evidence and proofs of such reasons and justifications.

Benefit sharing in the context of academic, non-commercial research

Sharing of Academic benefits

- Provide access to scientific data resulting from the research, including the necessary infrastructure
- Provide access to ex-situ facilities
- Integrate partners into the reviewing process
- Co-publish research findings with research partners
- Support the academic careers of research partners
- Maintain institutional and professional relationships

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Benefit sharing in the context of academic, non-commercial research

Capacity building, scientific cooperation, participation, technology transfer

- Train local researchers in the field and in the laboratory
- Share samples
- Secure finance for maintenance of collections
- Provide research infrastructure (e.g. laboratory equipment)
- Provide communication infrastructure
- Integrate local researchers into scientific and practical work, integrate local assistants into practical work
- Implement research on a cooperative basis: cooperative project design and implementation

Benefit sharing in the context of academic, non-commercial research

Increased availability of information and knowledge

- Provide ongoing information about research, progress and expected results
- Inform all involved stakeholders about results in a form that is adapted to the target audience
- Maintain contact with (local) representatives of administration, government agencies and research institutes

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The Digital Paper Trail

- User compliance monitoring happens through a web-based application, DECLARE. It allows users to submit their due diligence declarations to the relevant competent authorities responsible for their implementation.
- The Nagoya Protocol obliges states to ensure that users operating under their jurisdiction comply with the requirements of states that provide genetic resources and traditional knowledge.
- Belgium has 2 Competent Authorities, the Nature and Forest Agency (ANB) in Flanders and the SPW Agriculture, Ressources naturelles et Environnement in Wallonia. One more competent authority remains to be installed, in Brussels, and federal law is still under preparation.

The Extras

- Check out the VLIR website on the Nagoya Protocol and ABS and download the Checklist for Researchers
- You are invited to join the VLIR Nagoya Protocol Learning Network. It acts as a venue for collecting information on current developments, sharing views, highlighting potential areas of concern. It aims to explore emerging questions and discussions around the policy and practice of academic users of (traditional knowledge related to) genetic resources in the context of the CBD and the Nagoya Protocol

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Nagoya Protocol and ABS at your institution's research department

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Thanks!

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