Access and Benefit Sharing (ABS) in the Convention on Biological Diversity

A brief introduction

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Outline

I. ABS in context

ABS and

the **UN Convention on Biological Diversity (CBD),** its

Nagoya Protocol (NP) on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS); and in the

EU regulation concerning ABS in NP

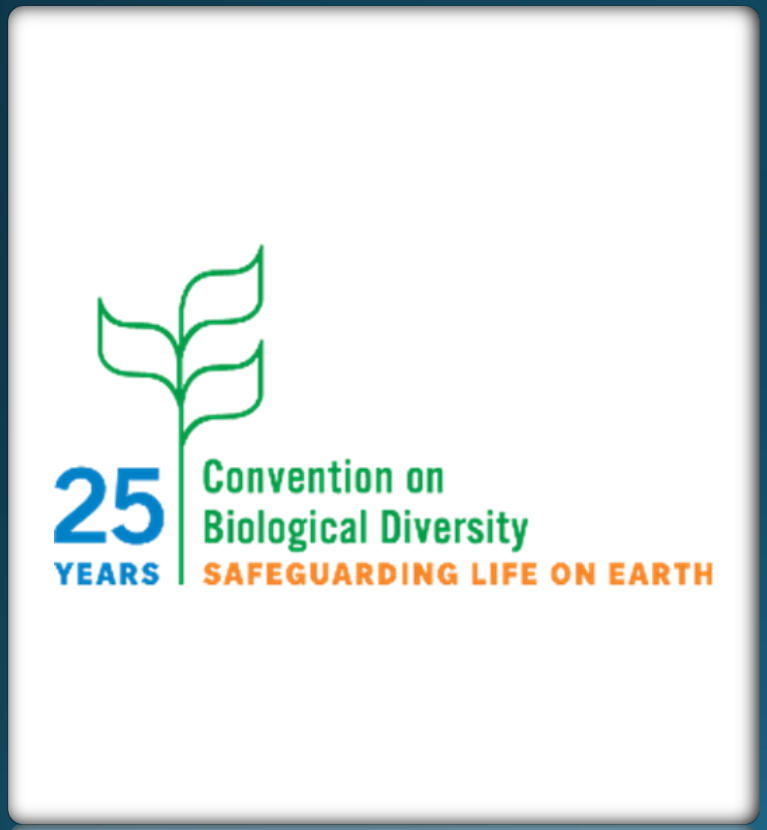
II. Up next

- The Global Multilateral Benefit Sharing Mechanism (NP Art 10)
- "DSI": digital sequence information on genetic resources

Acronyms unlimited…

I. ABS in context

The UN Convention on Biological Diversity



- "aka" CBD
- A multilateral, **legally-binding** convention
- Result of the Earth Summit, Rio de Janeiro, 1992
- One of three "Rio Conventions" (CBD, UNFCCC, UNCCD)
- Present: 196 Parties, incl. EU (most recent: Andorra)

The UN Convention on Biological Diversity

3 MUTUALLY SUPPORTIVE OBJECTIVES

The conservation of biological diversity

The sustainable use of the components of biological diversity

The fair and equitable sharing of the benefits arising out of the utilization of genetic resources (GR)

The UN Convention on Biological Diversity

Art 15 of CBD

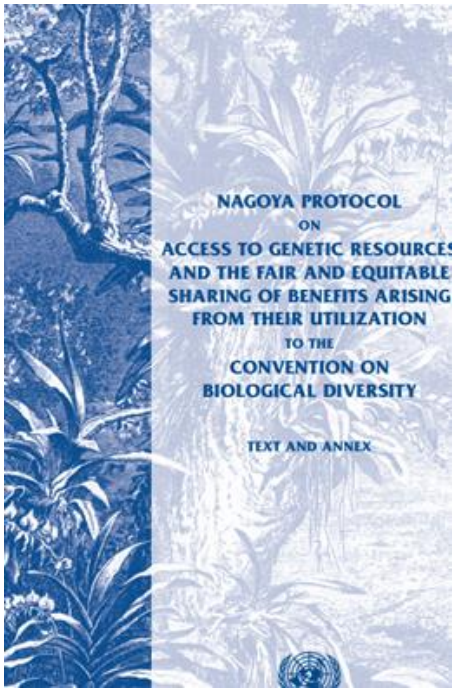
- Recognizes **sovereign right of states** …
- … over **their natural resources**
- Requests Parties to **facilitate access** to **genetic resources** (GR) and associated **traditional knowledge** (TK) based on **mutually agreed terms** (MAT) and subject to **prior informed consent** (PIC)

(1992)

The Convention on Biological Diversity

- ✓**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: *CBD COP X, Nagoya, Japan, 2010*
- ✓Objective: "the Fair and Equitable Sharing of the Benefits Arising from the Utilization of Genetic Resources"
- ✓50 ratifications: July 2014; presently 113 Parties (incl. EU)
- ✓Entry into force: **12 October 2014**

The Nagoya Protocol on ABS



- Compels Parties to take **legislative, administrative and policy measures** re. **access**, and **compliance**, and make this information available through the ABS Clearing-House (ABS CH)
- Access to GR and associated TK based on **Mutually Agreed Terms** (MAT), subject to **Prior Informed Consent** (PIC) as evidenced by Permit
- Provider country should notify ABS CH of permit which may become **Internationally Recognized Certificate of Compliance** (IRCC)

Ultimate goal : legal certainty & transparency

The Nagoya Protocol on ABS: Exclusions

- Non-NP territory: non-Parties to NP,
- Non-CBD territory: marine areas beyond national jurisdiction, Antarctica
- Human genetic resources
- Specialized/specific international ABS instruments available *(e.g., in framework International Treaty on Plant Genetic Resources - ITPGRFA, WHO's Pandemic Influenza Preparedness Framework)*
- (Provider country legislation does not require MAT / PIC)

Transposition into relevant international and national law

- ✓EU regulation
- ✓BE federal and regional law

…. depending on **competences**

European regulation

Rationale:

- EU is a party to the CBD and NP.
- In 2010 Council emphasized
  - Importance of NP
  - Need for a coherent compliance framework
  - Political sensitivity of timing to ensure EU and MS presence in further NP international negotiations in 2014 (COP-MOP1).

European regulation

Regulation *511/2014* of 16 April 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 Utilisation in the Union.

Commission Implementing Regulation (EU) *2015/1866* of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices

(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

Not legally binding

European regulation

- Aim: ensuring **user compliance to provider country legislation, in accordance with the NP,** for users within the EU.

  (Access: MS competence)

- Phased entry into force:
  - 511/2014: Rule: **12 October 2014**;
  - exceptions: articles 4, 7 and 9: 12 October 2015

  (user compliance [4], monitoring of user compliance [7], checks on user compliance [9])
  - 2015/1866: adopted 13 October 2015, into force 9 November 2015

European regulation

Key features:

1) **Users** have to exercise ***due diligence*** to ensure that

- GR and TK associated with GR were accessed (= acquired) and used in accordance with applicable legal requirements and;
- benefits are fairly and equitable shared upon mutually agreed terms, based on applicable legal requirements.
- To attest to this, users are to seek, keep and transfer to subsequent users certain information relevant to access and benefit-sharing until 20 years after end of utilisation.

European regulation

Key features:

2) **EU Member States and EU** should **monitor user compliance.**

European regulation

Key features:

3) Scope:

- **Activity**: research and development, incl. biotechnology
- **Material**: following strict interpretation of definitions in CBD/NP
- **Geographic**: NP "provider country" Parties: (*countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention*)
- **Temporal**: post 12 October 2014, NP ratification date; "access & utilization"

European regulation

Key features beyond NP obligations *(voluntary)*:

- Concept of EU-recognised ABS codes of conduct and best practices.
- Creates a register of collections.
- Provides for **sanctions** against breaching the regulation.

Belgian national and regional law

Focus on :

- **Access**: competence based on territoriality

⇒ terrestrial: FL, WAL, BXL

⇒ marine within territorial sea, federal collections: Fed

- **Monitoring of compliance and sanctions:**

⇒ Regional competence: BXL, FL, WAL

Work ongoing…

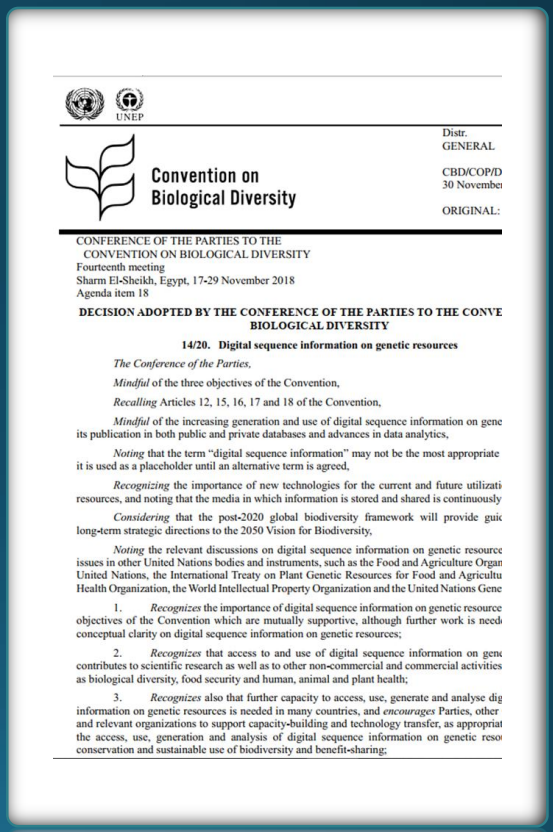
More to come...

II. Up next

1: digital sequence information on genetic resources

https://www.cbd.int/doc/decisions/cop-14/cop-14-dec-20-en.pdf

- CBD COP 14 decision 14/20
- NP MOP 3 decision 3/12



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ORIGINAL:

CONFERENCE OF THE PARTIES TO THE
CONVENTION ON BIOLOGICAL DIVERSITY
Fourteenth meeting
Sharm El-Sheikh, Egypt, 17-29 November 2018
Agenda item 18

DECISION ADOPTED BY THE CONFERENCE OF THE PARTIES TO THE CONVE BIOLOGICAL DIVERSITY

14/20. Digital sequence information on genetic resources

The Conference of the Parties,

Mindful of the three objectives of the Convention,

Recalling Articles 12, 15, 16, 17 and 18 of the Convention,

Mindful of the increasing generation and use of digital sequence information on gene its publication in both public and private databases and advances in data analytics,

Noting that the term "digital sequence information" may not be the most appropriate it is used as a placeholder until an alternative term is agreed,

Recognizing the importance of new technologies for the current and future utilizati resources, and noting that the media in which information is stored and shared is continuously

Considering that the post-2020 global biodiversity framework will provide guic long-term strategic directions to the 2050 Vision for Biodiversity,

Noting the relevant discussions on digital sequence information on genetic resource issues in other United Nations bodies and instruments, such as the Food and Agriculture Organ United Nations, the International Treaty on Plant Genetic Resources for Food and Agricultu Health Organization, the World Intellectual Property Organization and the United Nations Gene

1. *Recognizes* the importance of digital sequence information on genetic resource objectives of the Convention which are mutually supportive, although further work is need conceptual clarity on digital sequence information on genetic resources;

2. *Recognizes* that access to and use of digital sequence information on gen contributes to scientific research as well as to other non-commercial and commercial activities as biological diversity, food security and human, animal and plant health;

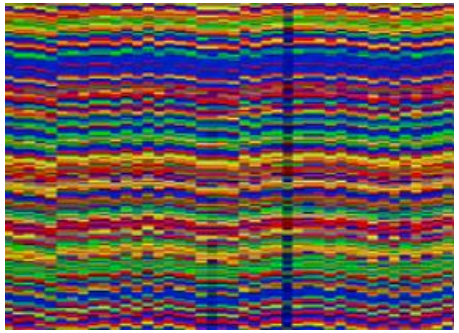
3. *Recognizes* also that further capacity to access, use, generate and analyse dig information on genetic resources is needed in many countries, and *encourages* Parties, other and relevant organizations to support capacity-building and technology transfer, as appropriat the access, use, generation and analysis of digital sequence information on genetic reso conservation and sustainable use of biodiversity and benefit-sharing;

DSI: digital sequence information on genetic resources

Why and what:

§1. *Recognizes* the importance of digital sequence information on genetic resources for the three objectives of the Convention which are mutually supportive, although

further work is needed to provide conceptual clarity on digital sequence information on genetic resources;



DSI: digital sequence information on genetic resources

Why and what:

§5. *Also notes* that **some Parties have adopted domestic measures that regulate the access to and use of digital sequence information on genetic resources** as part of their access and benefit-sharing frameworks;

and

§7. *Notes* that, when genetic resources are accessed for their utilization, **mutually agreed terms can cover benefits arising from the commercial and/or non-commercial use of digital sequence information** on these genetic resources, in accordance with applicable domestic measures;

DSI: digital sequence information on genetic resources

So:

§6: Further notes that, as there is a **divergence of views among Parties** regarding benefit-sharing from the use of digital sequence information on genetic resources, Parties **commit to working towards resolving this divergence** through the process established in the present decision, with the aim of strengthening the fulfilment of the third objective of the Convention and Article 15, paragraph 7, without prejudice to the circumstances to which this article applies;

DSI: digital sequence information on genetic resources

Process:

§9 and 10. Collect information from Parties and Stakeholders;

§11. Establish and Ad-Hoc Technical Expert Group (AHTEG);

§11. b-e Four peer-reviewed studies on various aspects;

§12. Requests the open-ended working group … to consider the outcomes of the AHTEG and to make recommendations to the COP 15 on how to address digital sequence information on genetic resources in the context of the post-2020 global biodiversity framework;

§13. … cooperate with other intergovernmental organizations to inform them of the process defined above and to take into account the work, approaches and outcomes that these organizations generate in the area in question.

DSI: digital sequence information on genetic resources

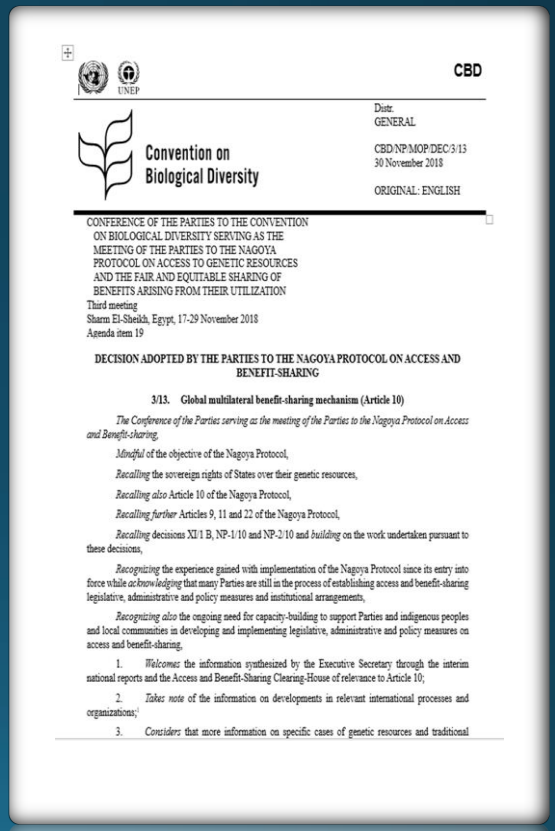
Strikingly absent:

- "Open access" vs "public access"
- Countries of origin vs provider countries
- Modalities
- Bilateral versus multilateral approach

2: Global Multilateral Benefit Sharing Mechanism

https://www.cbd.int/doc/decisions/np-mop-03/np-mop-03-dec-13-en.pdf:

- NP MOP 3 decision 3/12



CBD

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30 November 2018

ORIGINAL: ENGLISH

CONFERENCE OF THE PARTIES TO THE CONVENTION ON BIOLOGICAL DIVERSITY SERVING AS THE MEETING OF THE PARTIES TO THE NAGOYA PROTOCOL ON ACCESS TO GENETIC RESOURCES AND THE FAIR AND EQUITABLE SHARING OF BENEFITS ARISING FROM THEIR UTILIZATION
Third meeting
Sharm El-Sheikh, Egypt, 17-29 November 2018
Agenda item 19

DECISION ADOPTED BY THE PARTIES TO THE NAGOYA PROTOCOL ON ACCESS AND BENEFIT-SHARING

3/13. Global multilateral benefit-sharing mechanism (Article 10)

The Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol on Access and Benefit-sharing,

Mindful of the objective of the Nagoya Protocol,

Recalling the sovereign rights of States over their genetic resources,

Recalling also Article 10 of the Nagoya Protocol,

Recalling further Articles 9, 11 and 22 of the Nagoya Protocol,

Recalling decisions XI/1 B, NP-1/10 and NP-2/10 and *building* on the work undertaken pursuant to these decisions,

Recognizing the experience gained with implementation of the Nagoya Protocol since its entry into force while *acknowledging* that many Parties are still in the process of establishing access and benefit-sharing legislative, administrative and policy measures and institutional arrangements,

Recognizing also the ongoing need for capacity-building to support Parties and indigenous peoples and local communities in developing and implementing legislative, administrative and policy measures on access and benefit-sharing,

1. *Welcomes* the information synthesized by the Executive Secretary through the interim national reports and the Access and Benefit-Sharing Clearing-House of relevance to Article 10;

2. *Takes note* of the information on developments in relevant international processes and organizations;

3. *Considers* that more information on specific cases of genetic resources and traditional

Global Multilateral Benefit Sharing Mechanism

- What?

"Article 10. Global Multilateral Benefit-sharing Mechanism

Parties shall consider **the need for and modalities of a global multilateral benefit-sharing mechanism** to address the fair and equitable sharing of benefits derived from the utilization of genetic resources and traditional knowledge associated with genetic resources that occur **in transboundary situations or for which it is not possible to grant or obtain prior informed consent**. The benefits shared by users of genetic resources and traditional knowledge associated with genetic resources through this mechanism shall be used to support the conservation of biological diversity and the sustainable use of its components globally."

Global Multilateral Benefit Sharing Mechanism

NP MOP 3/12:

§3. *Considers* that **more information** on specific cases of genetic resources and traditional knowledge associated with genetic resources that occur in transboundary situations or for which it is not possible to grant or obtain prior informed consent, accompanied by an explanation as to why such cases cannot be covered under the bilateral approach of the Nagoya Protocol as well as options for addressing those cases, including through a global multilateral benefit-sharing mechanism **would assist in the consideration of Article 10**;

Global Multilateral Benefit Sharing Mechanism

Process:

§4. Collect information from Parties and Stakeholders;

§5. A peer-reviewed study of cases that would fall within scope of art 10;

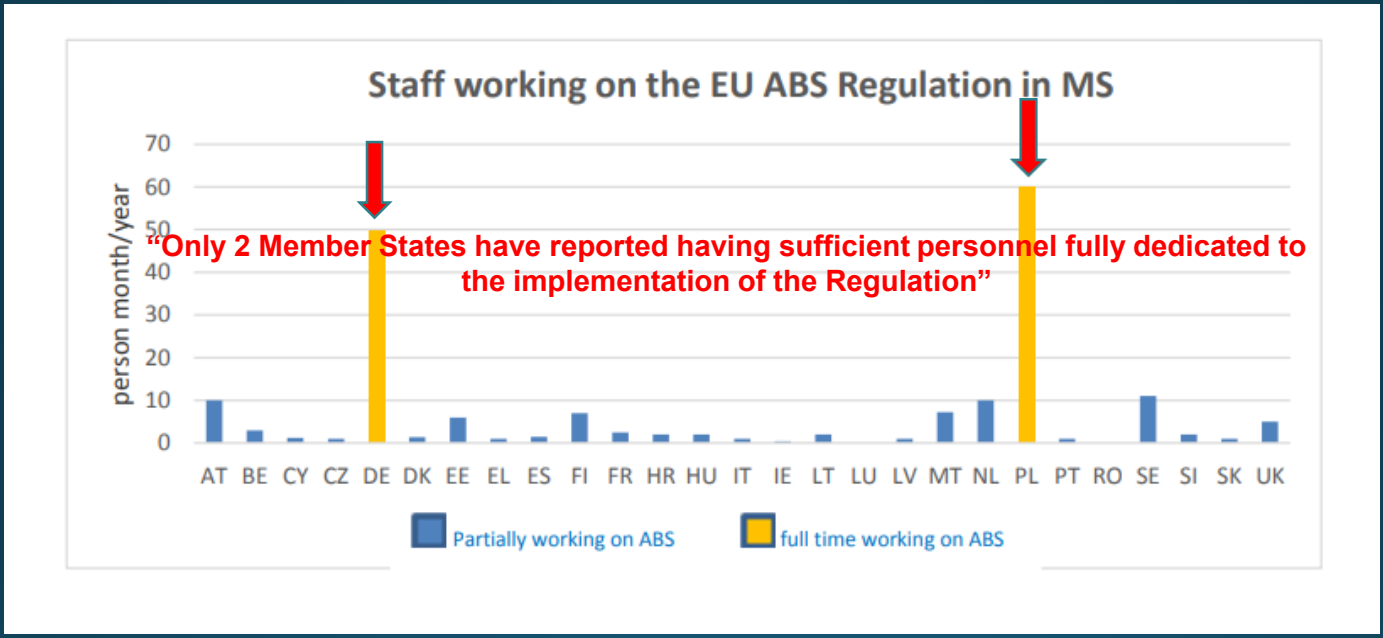
§5. *Requests* the Subsidiary Body on Implementation to … identifying: (a) specific cases, if any, that cannot be addressed through the bilateral approach; and (b) if identified, options for addressing these cases, including a possible global multilateral benefit-sharing mechanism, and make a recommendation to the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol at its fourth meeting.

Sources

- CBD text: https://www.cbd.int/convention/text
- Nagoya Protocol text: https://www.cbd.int/abs/text/default.shtml
- CBD COP 14 and NP COP-MOP 3 decisions: https://www.cbd.int/conferences/2018

- Regulation (EU) No 511/2014 : http://data.europa.eu/eli/reg/2014/511/oj
- EU implementing regulation 2015 / 1866: http://eur-lex.europa.eu/eli/reg_impl/2015/1866/oj
- Guidance on Regulation (EU) No 511/2014: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2016.313.01.0001.01.ENG

Some interesting statistics



Reported EU MS budget: from €1 500 to 60 000, very few € 100 000 or more

Source: REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL on the Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 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, 24 Jan 2019. Based on EU MS reporting, period Oct 2014 – August 2017 (*distributed 01 Feb 2019)*

Questions?