the Nagoya Protocol on Access and Benefit Sharing

and its consequences for life sciences research and valorisation of research data

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Outline

I. A bit of 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(s) concerning ABS in NP

II. Implications for research

Due diligence…

III. Up next

- National access and compliance measures
- Utilisation of digital sequence information
- Global benefit sharing mechanism

Sources

- CBD text: https://www.cbd.int/convention/text
- Nagoya Protocol text: https://www.cbd.int/abs/text/default.shtml

- 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 the scope of the EU ABS Regulation (EU) No 511/2014: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2016.313.01.0001.01.ENG

I. A bit of 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), one of seven biodiversity-related conventions (CBD, CITES, CMS, ITPGRFA, RAMSAR, WHC, IPPC)
- Present: 196 Parties, incl. EU (and Belgium – most recent: Andorra)

The UN Convention on Biological Diversity

3 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**

  = "Access and Benefit Sharing, ABS"

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 Nagoya Protocol on ABS

- ✓Bonn Guidelines: CBD COP VI, The Hague, NL, 2002
- ✓**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
- ✓50 ratifications: July 2014; presently 96 Parties (incl. EU and Belgium)
- ✓Entry into force: **12 October 2014,** 1st COP/MOP Nov. 2014; 2nd Dec 2016

The Nagoya Protocol on ABS

- Compels Parties to take legislative, administrative and policy measures re. **access**, **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

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).

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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

- More guidance documents in preparation: on animal breeding, biocontrol and biostimulants, biotechnology, cosmetics, food and feed, plant breeding, and pharmaceutical sectors; for collections holders and Research institutions)

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European regulation

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

- 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

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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.

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European regulation

Key features:

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

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European regulation

Key features beyond NP obligations:

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

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II. Implications for research in the EU

Scope: which utilization?

- Utilization of genetic resources: … to conduct **research and development** on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention

=> Potentially **ALL research and development in the EU…**

(NP - EU)

Scope: what material?

- Genetic resource: genetic material of actual or potential value

(CBD – EU)

- Genetic material: any **material** of plant, animal, microbial or other origin containing functional units of heredity

(CBD – EU)

⇒**… on any material that contains FUH (genes) …**

Geographic scope

For the purpose of this Convention:

- the genetic resources being provided by a Contracting Party … are only **those that are provided by … countries of origin** of such resources or by the Parties **that have acquired the genetic resources in accordance with this Convention**
- the genetic resources being provided **by a Contracting Party**, …

=> … from any country, that has ratified the Nagoya Protocol

Exclusions

- Specialized/specific international ABS instrument (e.g., in framework International Treaty on Plant Genetic Resources ITPGRFA, WHO's Pandemic Influenza Preparedness Framework)
- Human genetic resources
- (Provider country legislation does not require MAT / PIC)

- Marine areas beyond national jurisdiction, Antarctica
- When bilateral approach is not applicable

Temporal scope

The genetic resource must be **accessed** and **utilised** as of 12 October 2014 (EU!)

From and by a Contracting Party: ratification date!

Due diligence must be demonstrated as of 12 October 2015

Due diligence: what?

To ascertain that the GR & TK have been accessed in accordance with applicable ABS legislation:

- Take "reasonable measures" re. seeking, keeping, transfering and analysing information on GR & TK;
- May vary depending on circumstances, including when intended use of GR & TK changes;
- Before ("obligation of conduct") and during ("obligation of result") utilization of GR & TK

or discontinue utilisation.

Due diligence: how?

User should:

- **Check ABS Clearing-House** for information on provider Party's legislative, administrative or policy measures on ABS;
- If no information on ABS Clearing-House, user **contacts National Focal Point**
- If no answer despite "reasonable attempts", **user decides** whether or not to utilize GR & TK

Or:

- User obtains GR from a registered collection (and keeps information)

Due diligence check

By reference to an **Internationally Recognised Certificate of Compliance** (IRCC)

If no IRCC: user presents information on

- Date and place of access
- Description of GR & TK
- Source of the GR & TK
- Presence of rights and obligations related to ABS
- Access permits
- MAT

Due diligence declarations

Two "checkpoints":

- At the stage of public and private research funding (template see annex II of 2015/1866)
- At the stage of final development of a product (template see annex III of 2015/1866)

If non- compliance: discontinue utilisation or sanctions
(*Dura lex sed lex*)

III. Up next

Up Next

1. National access and compliance measures

Check your national ABS Focal Point or ABS CA

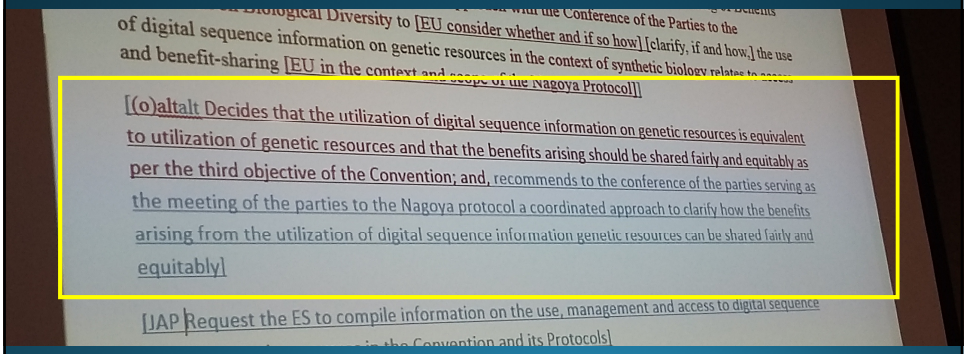
Belgium:

- No official information available as yet
- Competences complicate compliance

Up Next

2) Utilisation of digital sequence information

CBD COP 13 Mexico 4-17 Dec 2016: developing countries want "equivalence"


Biological Diversity to [EU consider whether and if so how] [clarify, if and how,] the use of digital sequence information on genetic resources in the context of synthetic biology relates to and benefit-sharing [EU in the context and scope of the Nagoya Protocol]]

[(o)altalt Decides that the utilization of digital sequence information on genetic resources is equivalent to utilization of genetic resources and that the benefits arising should be shared fairly and equitably as per the third objective of the Convention; and, recommends to the conference of the parties serving as the meeting of the parties to the Nagoya protocol a coordinated approach to clarify how the benefits arising from the utilization of digital sequence information genetic resources can be shared fairly and equitably]

[JAP Request the ES to compile information on the use, management and access to digital sequence

Up Next

2) Utilisation of digital sequence information

UNEP/CBD/COP/13/L.29, 16 December 2016

4. *Decides* to establish an Ad Hoc Technical Expert Group ….

5. *Requests* the SBSTTA to consider the outcomes of the AHTEG to make a recommendation on the potential implications of the use of digital sequence information on genetic resources for the three objectives of the Convention for the consideration of the COP XIV;

Up Next

3) Global multilateral benefit-sharing mechanism:

when bilateral approach not applicable; no PIC / MAT,…

UNEP/CBD/NP/COP-MOP/2/L.15/Rev.1, 17 December 2016

Sources

- CBD text: https://www.cbd.int/convention/text
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- Regulation (EU) No 511/2014 : http://data.europa.eu/eli/reg/2014/511/oj
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Questions?

I may not have answers…