Introduction: Nagoya in the international and European context

Outline

- Origin: the Convention on Biological Diversity
- Nagoya Protocol on Access and Benefit Sharing
- EU regulation

The Convention on Biological Diversity

The 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” (UNFCCC, CBD, UNCCD)
- Now: 194 Parties, incl. EU (and Belgium)

The 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**
- **= ABS**

ABS in the CBD

- Art 15 of CBD:
  - Recognizes **sovereign right of states** over their natural resources
  - Requests Parties to **facilitate access** to genetic resources based on **mutually agreed terms** (MAT) and subject to **prior informed consent** (PIC)

The Nagoya Protocol

Nagoya Protocol

- Adopted in 2010
- Entry into force: 12 October 2014
- 104 Parties
- 3rd Meeting of the Parties November 2018, Sharm El-Sheikh, Egypt

Nagoya Protocol

Objective:

- "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, …, thereby contributing to the conservation of biological diversity and the sustainable use of its components."

- Based on:
  - Prior informed consent -> access
  - Mutually agreed terms –> benefit-sharing
  - Compliance -> monitoring

Nagoya Protocol

- Article 6. Access to Genetic Resources

- In the exercise of sovereign rights over natural resources, … **access to genetic resources for their utilization shall be subject to the prior informed consent … unless otherwise determined by that Party.**

Nagoya Protocol

- Article 5. Fair and Equitable Benefit-sharing

- In accordance with Article 15, paragraphs 3 and 7 of the Convention, **benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization shall be shared in a fair and equitable way with the Party providing such resources** that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention. Such sharing shall be upon mutually agreed terms.

Nagoya Protocol

- Article 17. Monitoring the Utilization of Genetic Resources

- 1. **To support compliance**, each Party shall take **measures**, as appropriate, **to monitor and to enhance transparency about the utilization of genetic resources**. Such measures shall include:

(a) The designation of one or more **checkpoints**, as follows:

…

The EU regulation

Pillars of the Nagoya Protocol
"the ABC of ABS"

Implemented at Member States level Not EU level

Subject to contractual agreement

EU Regulation 511/2014 & concomitant

EU Regulation - key features

- 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.

EU Regulation - key features

Monitoring

Two checkpoints → due-diligence declarations

- **Funding (public and private) of research**
- **Final stage of product development**

  => elaborated in Implementing Regulation

Exchange of information through ABS Clearing House

EU Regulation - key features

Compliance checks

Checks on user compliance

- **Risk-based approach**
- **Carried out by MS authorities**

Penalties for infringements

- **MS rules will apply**

EU Regulation - key features

Facilitating compliance

Voluntary instruments to facilitate compliance

- **Register of collections**
- **Recognition of best practices**

=> elaborated in Implementing Regulation

EU Regulation - Scope

Does the activity fall under the scope of the ABS regulation?

- Geographically?
- Temporally?
- On substance, incl. specialised instruments?

EU Regulation - Scope

Geographic scope

- ✓ GR/TKaGR from Parties to the Protocol

- ✓ access legislation in place – info from:
  - **ABS Clearing-House** https://absch.cbd.int/
  - **Provider country‘s National Focal Point**
  - **Users‘ partners in third countries**

- ✓ Areas beyond national jurisdiction out of scope

EU Regulation - Scope

Temporal scope

✓ GR/TK accessed after NP entry into force

No retro-active effect of EU legislation
Time of access (not utilisation) determines applicability
Provider-country legislation may diverge
(but does not affect temporal scope of EU Regulation)

EU Regulation - Scope

Material scope

- ✓ Utilisation = research and development (≠ commodities/trade)
- ✓ Genetic resources

  Excluding GR governed by specialised inter-national instruments on ABS (ITPGRFA, WHO PIP)
- ✓ Traditional knowledge associated with GR

EU Regulation - Scope

Guidance documents

Horizontal guidance on scope of the EU Regulation

Sector-specific (incl. cosmetics) guidance on utilisation

- **External consultants under EC guidance and with stakeholder input & MS expert support**
- **Still on-going**

- Thank you