

The Nagoya Protocol on ABS and EU regulation 511/2014

A practical view of things



Outline

- The Convention on Biological Diversity
- Nagoya Protocol on Access and Benefit Sharing
- EU regulation



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)**

(1992)

ABS in the CBD

- ✓ 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
- ✓ Entry into force: **12 October 2014**, 1st COP/MOP Nov. 2014

NP: Scope

- This Protocol shall apply to **genetic resources** **within the scope of Article 15 of the Convention** and to the **benefits arising from the utilization of such resources** ... (and) ... to **traditional knowledge** associated with genetic resources ... (NP)



NP: definitions

- 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 (NP - EU)
- 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)

NP: 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** (CBD Art. 15 § 3)

NP: Operational Principles

- Compels Parties to take **legislative, administrative and policy measures** re. **access**, and **compliance**
- Access to GR 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 (CoC)

NP: 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 PIC

European regulation

Rationale:

- EU is a party to the CBD.
- In 2010 Council emphasized
 - Importance of NP;
 - 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.**
- Ensures respect of relations between the NP and other relevant international processes (eg: health, agriculture).

European regulation

- Aim: ensuring **user compliance to country of origin legislation** for users within the EU.
- Targets **all users conducting R&D using GR and TK** associated with GR in the Union.
- Phased entry into force:
 - Rule: 12 October 2014
 - Exceptions: articles 4, 7 and 9.

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.



Dura lex sed lex...