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The Nagoya Protocol on ABS and EU regulation 511/2014

A practical view of things

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Outline

- The Convention on Biological Diversity
- Nagoya Protocol on Access and Benefit Sharing
- EU regulation
- Some uncertainties, difficulties…

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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)

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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

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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

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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)

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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)

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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)

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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)

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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

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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).

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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.**
- Ensures respect of relations between the NP and other relevant international processes (eg: health, agriculture).

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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.

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European regulation

Key features:

- Users have to exercise **due diligence** to ensure that
  - GR and TK associated with GR used were accessed in accordance with applicable legal requirements and;
  - benefits are fairly and equitable shared upon mutually agreed terms, based on applicable legal requirements.

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European regulation

Key features:

- To attest to this, users are to **seek, keep and transfer** to subsequent users certain information relevant to access and benefit-sharing.

- Introduces **monitoring of user compliance** by MS.

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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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Structures

- NP
  - Parties:
    - **National Focal Point**: Liaison with SCBD
    - **Competent National Authorities**: procedures, access, permits for access
    - **Compliance checkpoints**: collect and tranfer info on PIC, MAR, source and utilization of GR and associated Traditional Knowledge (TK) to CNA, Party granting PIC, ABS CH **but** while protecting confidential information
  - CBD:
    - **ABS Clearing-house**: receives info on national measures, NFP and CNA, and permits

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Structures

- EU MS:
  - **Competent Authorities** (CA)*: responsible for application of Regulation, compliance checks

COM:

- **Register of collections**
- Recognition and register of **best practices**
- **ABS FP** => liaison with SCBD

*compliance checkpoints of NP

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Uncertainties…

- Start?
  - Coming into force of NP and EU reg:
    - Accessing non-BE GR by BE researchers: NP since 12/10/2014, EU reg. applies since 09/06/2014; art. 4, 7, 9: 12/10/2015
    - Accessing BE GR by foreigners: xxx

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Uncertainties…

- Ownership of GM and associated TK
  - pre-CBD* or pre- NP: everything registered in BE collection = Belgian?
  - CBD or NP: domestic law of country of origin
  - “citizen science” and deposition of type specimens?

*Entry into force 29 December 1993, ratification by Belgium 22 November 1996

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Uncertainties..;

- Structures?
  - NFP, CNA, Compliance Checkpoint / CA missing in BE and many provider Countries
  - EU and CBD ABS CH
  - Register of Collections, best practices
- informational “Genetic resources” (genbank)

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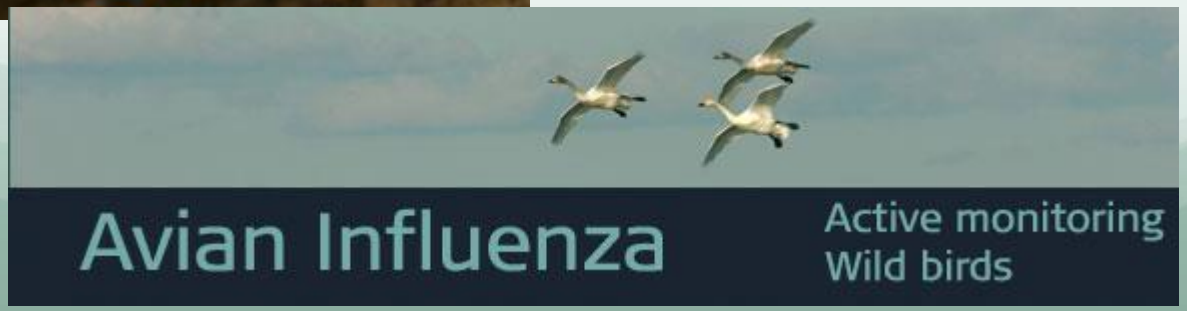
… and difficulties

Multinational collaboration and secondary access to GR

- 2003-2014
- Australia, France, Papua New Guinea, Panama, Vanuatu
- 100+ experts in tropical biodiversity.
- 40+ academic institutions in 18 countries

Migratory species



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Present RBINS practices

Approach to access/utilization of non-BE GR:

- ✓ Adhere to domestic law of provider and user country on *ad hoc* basis
- ✓ Strong in collaboration (capacity building, technology transfer)

Management of access/utilization of BE GR:

- ✓ Exchange of/ access to specimens: rules for exchange/access/destructive sampling to be signed by user (equivalent to PIC & MAT, no “permit by CNA”)
- ✓ Collections service with central database (DARWIN)
- ✓ Development of best practices for collections management (in collaboration with EU partners)
- ✓ Work towards registration of collection(s)

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Dura lex sed lex…