EU Implementation of the Nagoya Protocol Guidance on Scope and Utilization

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EU Implementing Legislation

- **Nagoya Protocol** on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization to the CBD (in force since 12.10.2014)
- **EU Regulation No. 511/2014** on compliance measures for users from the Nagoya Protocol (in force since 12.10.2014, except Arts. 4,7 and 9 one year later)
- **Commission Implementing Regulation (EU) 2015/1866** (in force since 2.11.2015) on Registered Collections; Due Diligence Declarations at the stage of research funding and final development of a product; Best Practice
- **National Law** in EU Member States in force on compliance (sanctions) in: United Kingdom; Germany; Denmark; Slovakia, Hungaria and Croatia and in addition on access in Spain

Guidance on the Scope of Application and Core Obligations of EU No. 511/2014

- **Commission Notice (2016/C 313/01)**, published on 27.8.2016 – **legally non-binding**
- Scope
  - **Geographic** : provider countrys (country of origin's) access law
  - **Temporal** : accessed after 12.10.2014 in provider country
  - **Material** :
    - Genetic Resources
      - functional units of heredity = genes
      - genetic material – digital sequence data out of scope
    - Commodities: only if utilized in scope
    - Pathogens: only if intentionally accessed (acquired) in scope
    - Derivatives: only in scope if access is combined with access to genetic resource

Commission Notice (2016/C 313/01)

- Obligations of Users
  - Users shall exercise **due diligence** to ascertain that genetic resources and *associated traditional knowledge* which they **utilize** have been accessed in acordance with relevant ABS legislation… (Art. 4 EU 511/2014)
  - «Utilization»:
    - «R&D on the genetic and/or biochemical composition of genetic resources» (Art. 2 EU 511/2014)
    - no definition of R&D in the Protocol nor EU Regulation:
      - ordinary meaning (Oxford Dictionary)
      - OECD's Frascati Manual (five criteria: novel, creative, uncertain, systematic, transferable / reproducible)
      - some general examples are provided, e.g. testing/reference tools
      - sector specific examples in the Sector Specific Guidance
    - Territorial application: EU

Sector Specific Guidance

- **Seven sectors**: animal breeding, bio control/stimulants, biotech, cosmetics, food & feed, pharmaceutical and plant breeding
- **Case studies** (in; out; border-line) along the research and development chains of the different sectors should illustrate the understanding and applicability of the term **utilization** of genetic resources
  - Proposed by sectorial **experts** designated by the Commission
- **Process**: meeting of the sectorial experts to develop 1st. draft; followed by broader stakeholder meetings; revised drafts, incl. feedback from Commission & EU Member States; review by experts; finalization of Guidelines in Q1,2/2017 by the Commission
- **Legal status: non - binding**

Challenges for Users – Recommendations

- **Legal certainty** on access legislation in provider countries: supposed to be on the ABS – Clearing House Internet site (Art. 14 Nagoya Protocol)

  Global Catalogue: provide key elements or links to such legislation to facilitate user's compliance with the Nagoya Protocol

- **Temporal trigger** of access legislation

  Global Catalogue: indicate if access or utilization triggers ABS obligations

- **Public information** of genetic resources

  Global Catalogue: indicate if public information (sequence or other structural information) triggers ABS obligations

- **Pathogens** with emergency potential for health and food/feed safety

  TRUST as model: provide for «Fast-track» procedures for access and «Regularizing procedures» for PIC/MAT

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