Use of genetic resources: The brave new world of ABS?

Essencia/bio.be seminar

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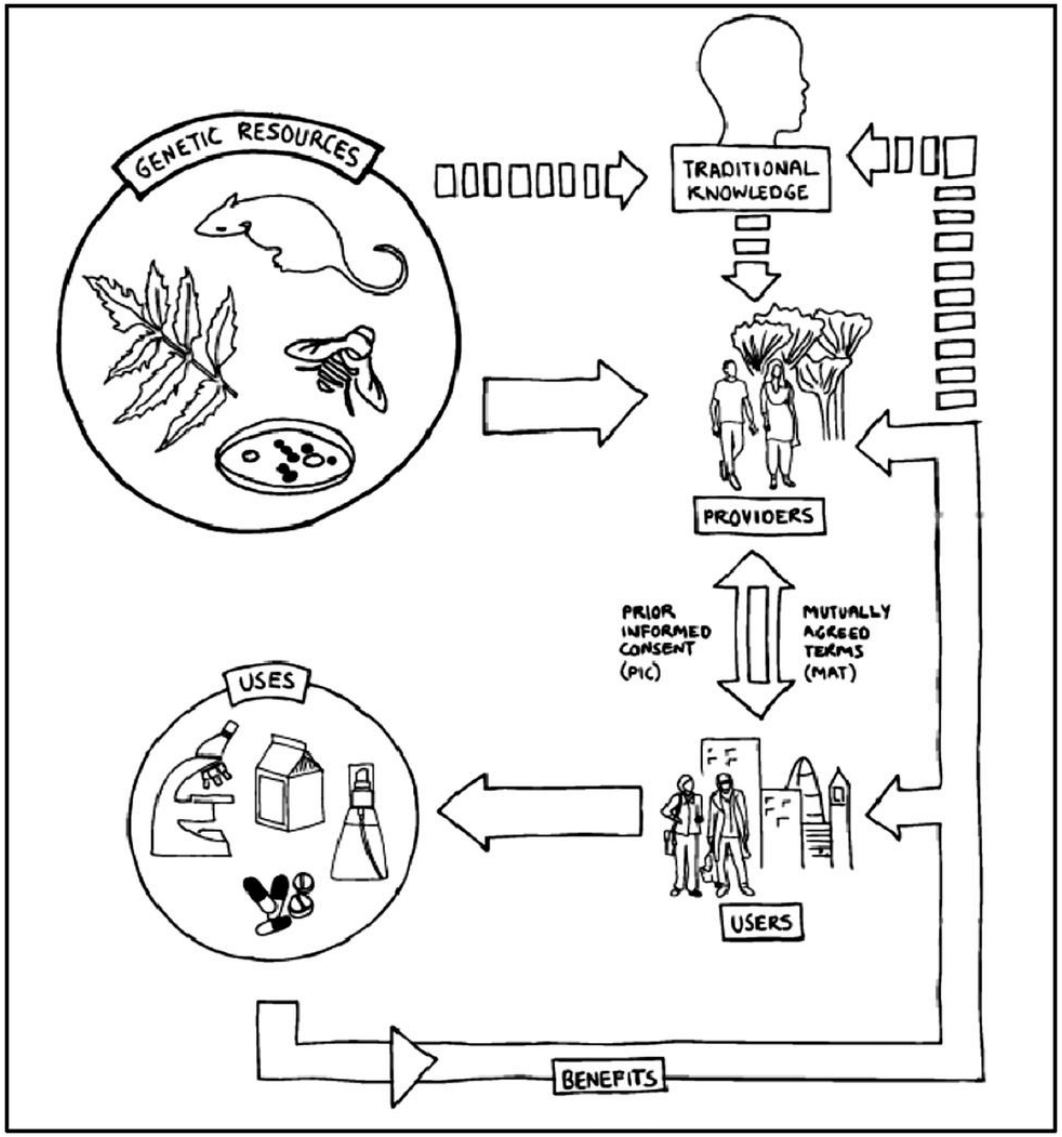
Dominic Muyldermans, Senior legal adviser, ABS-int

ABS: the basics

Provider
In situ
Ex situ

Rights holder
Country
User
Collection

User (=person/ legal entity)



Sharing of benefits

ABC of ABS

1. **Access:**
   - Å Sovereign rights on genetic resources;
   - Å Each state to decide whether access is regulated or not;
   - Å Prior Informed Consent;
   - Å Facilitated access for non-commercial research.
2. **Benefit sharing:**
   - Å Monetary and non-monetary;
   - Å Subject to a contractual agreement (bilateral approach of the Nagoya Protocol);
   - Å Mutually Agreed Terms.
3. **Compliance:**
   - Å Obligation for parties to have an effective system in place to ensure all necessary permits are obtained for genetic resources sourced from other countries;
   - Å Provider country – Country of use;
   - Å Political context of ABS negotiations.

International framework on ABS

1. **Convention on Biological Diversity**: art 15: “access to genetic resources”
    1. Entered into force on 29 December 1993.
2. **The Nagoya Protocol** on access to genetic resources and the fair and equitable sharing of benefits arising from their utilisation:
    1. Adopted on 29 October 2010;
    2. entered into force on 12 October 2014;
3. Many countries have enacted or are currently developing **national ABS laws**;
4. ABS rules are relevant for a wide variety of sectors and activities;
5. **Specialised international instruments**:
    - International Treaty on Plant Genetic Resources for Food and Agriculture in the context of FAO;
    - Pandemic Influenza Preparedness framework in the context of WHO.

National legal framework

1. **Access:**
   - ABS regimes in provider country:
     - National laws on PIC and MAT;
     - National contract law;
     - International private law.
2. **Compliance:**
   - Compliance rules established in country of use *re* necessary permits of provider country.
3. **Specialised international instruments**

Legal framework in the EU

1. **Access:**
   - Access rules in national laws of member states;
   - France, Spain and Germany are finalising national laws.
2. **Compliance:**
   - EU Regulation No 511/2014:
     - Entered into force on 12 October 2014;
     - Articles 5, 7 and 9 enter into force on 12 October 2015, subject to an additional implementing act;
   - Commission Implementing Regulation (likely entry into force early November);
   - Guidance documents (incl sector specific);
   - Some elements dealt with under national law, i.a. sanctions.
3. **Specialised international instruments**

Access: national laws

1. Prior Informed Consent (PIC)?

- Sovereign rights are the basis for requiring PIC;
- PIC required or not:
  - Simplified access for non- commercial research?
  - Intended use – how to define “commercial” use?
- Competent national authority to issue a permit;
- Role of indigenous people re traditional knowledge?

2. Mutually Agreed Terms (MAT)

- MAT, even if PIC is not required;
- Monetary and non-monetary benefit sharing (open list in Nagoya Protocol);
- Written agreement with competent national authority;
- Terms on change of intent;
- Complex element of ABS practice.

3. Where?

- ABS Clearing House;
- National focal points;
- Research partners.

Compliance: EU Regulation

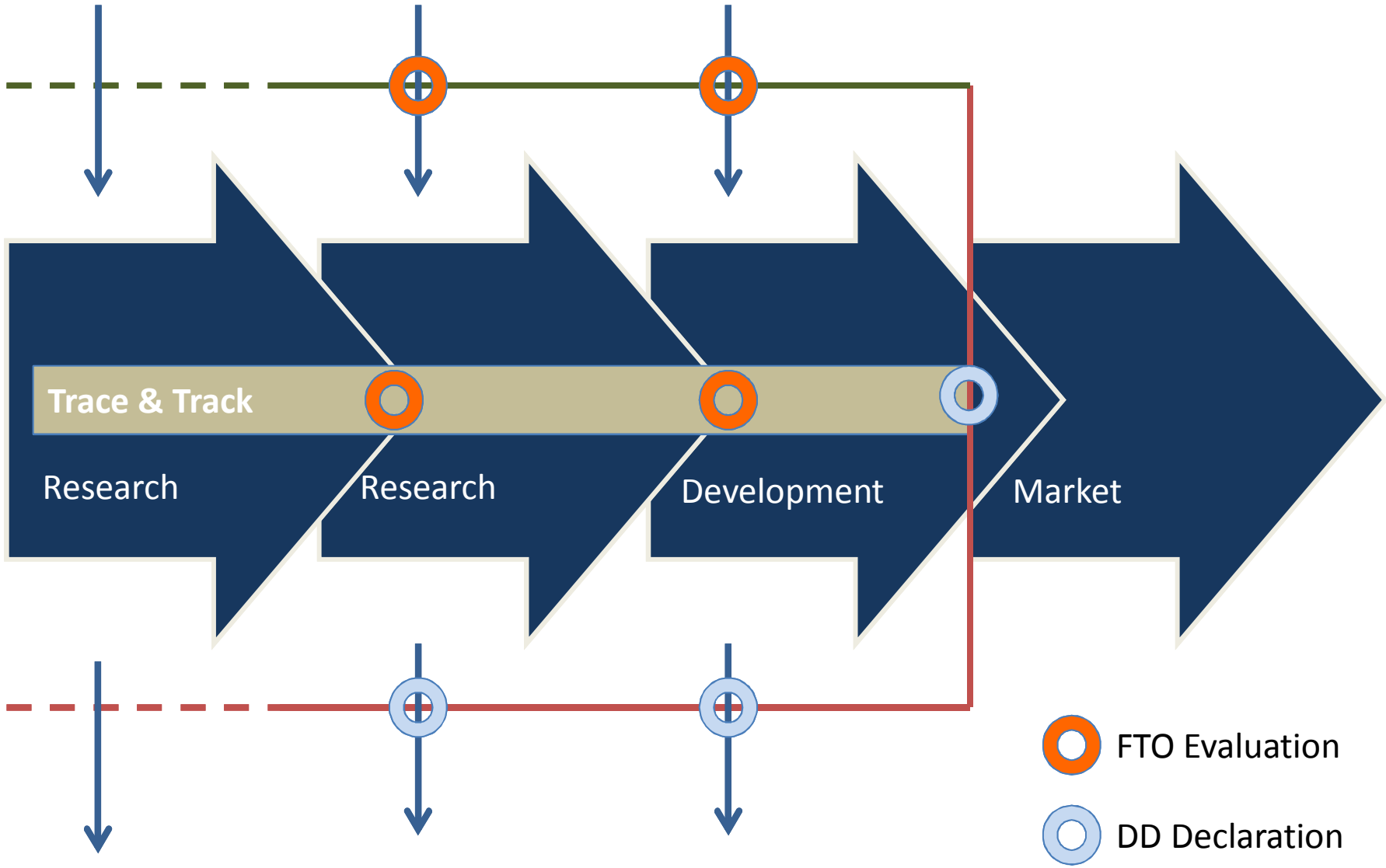
Scope

1. **Genetic resources over which states exercise sovereign rights and traditional knowledge associated with genetic resources** that are accessed after the entry into force of the Nagoya Protocol for the Union;

Å Genetic resources (…) to which **national access and benefit sharing legislation** or regulatory requirements of **a Party to the Nagoya Protocol** are applicable;

Å Compliance under national law might go further than EU Regulation;

1. *Genetic material (cfr GR)*: any material of plant, animal, microbial or other origin containing functional units of heredity:
   - ï Not biological resources/commodities;
   - ï Information?
2. *Utilisation:* conduct R&D on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology:
   - ï Research and/or development;
   - ï Not use as a control or merely as a tool;
   - ï Biotechnology: any technological application that uses biological systems, living organisms, or derivatives thereof to make or modify products or processes for specific use.
3. *Traditional knowledge associated with GR:* (…) that is relevant for the utilisation of the GR and is as such described in the MAT.


Trace & Track
Research
Research
Development
Market
FTO Evaluation
DD Declaration

Summary of obligations

1. **Ongoing** process of trace and track;
2. **Formalities and obligations** in each phase;
3. **Freedom To Operate:**
   - ï FTO evaluation when acquiring material;
   - ï FTO evaluation while using material.
4. **Access & benefit sharing:**

Å National law:

- ï PIC?
- ï MAT re benefit sharing

5. **Compliance:**

Å EU ABS Regulation

Å + National law:

- ï Material scope;
- ï Temporal scope.

EU ABS Regulation: due diligence obligations

1. **Compliance:**

Å EU ABS Regulation: due diligence system:

- ï **Information management**: **Seek-keep-declare-transfer-retain**
  - Å Obtain information;
  - Å Manage information;
  - Å Declare/submit information:
    - ï Research funding;
    - ï Final stage of development.
  - Å Transfer information if and as needed;
  - Å Retain information.
- ï **Material management:**
  - Å Use material in accordance with obligations.
  - Å Discontinue use in case of persisting uncertainty or insufficient information.

Your organisation is recommended to:

Essential for Access:

1. Acquire material in accordance with all applicable laws;
2. Enter into relevant agreements;
3. Comply with terms of permits and agreements;
4. Renegotiate conditions in case of change of use, if needed.

Essential for due diligence:

1. Establish trace and track system;
2. Setup an information management system;
3. Transfer information further down the value chain;
4. Submit due diligence declarations as required.

Advisable:

1. Use unique identifiers;
2. Establish an internal ABS toolkit;
3. Train your researchers and staff;
4. Best practices?

Questions?

dominic.muyldermans@abs-int.eu

ABS-int is a multi-disciplinary team that consists of professionals with different backgrounds, including science, law and regulatory. It is dedicated to offer support for complying with access and benefit sharing obligations as determined by the 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, and implementations like the European Regulation (EU) No 511/2014. ABS-int's activities include awareness raising, training, audits & inspections, track & trace systems, contract drafting and negotiation, documentation, and legal and scientific advice.

ABS-int, Technologiepark 3, B-9053 Zwijnaarde, Belgium – www.ABS-int.eu