How does Nagoya and Access and Benefit Sharing affect the use of your research?

November 15, 2024

Webinar by Ceratium

Szonja Csörgő, ISF Secretariat

What is ABS?

ABS = access and benefit sharing – but what does it mean?

Access:
- To what?
- By whom?
- From where?
- For what purpose?

Benefit:
- What benefit?
- From/for what?
- By whom?

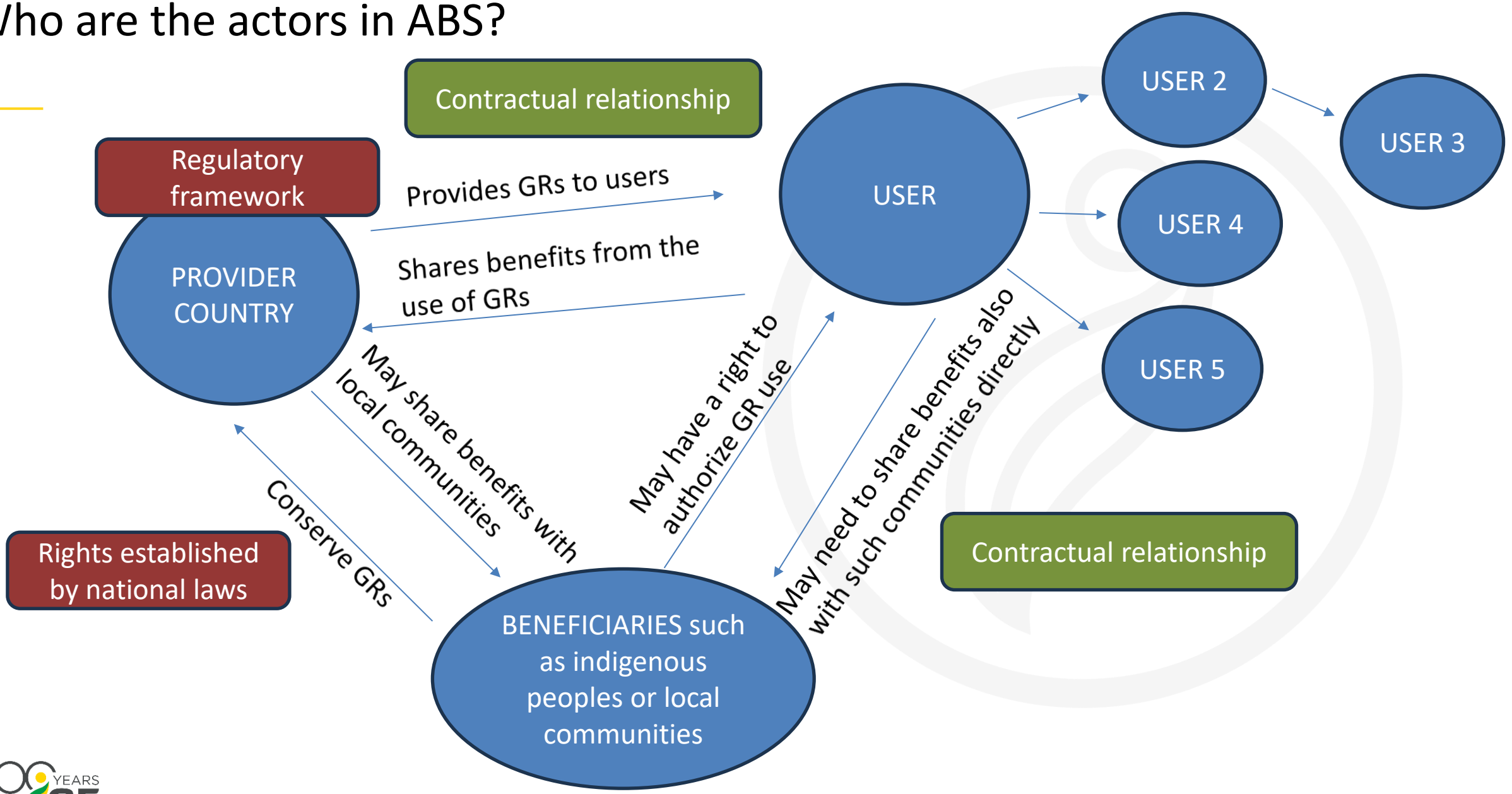
Sharing:
- Of what?
- By whom?
- With whom?

ABS is a legal framework to regulate access to genetic resources and provide for the obligation for users to share benefits with the providers who provide (and conserve) those resources.

For some, **ABS is a political concept** looked at as a way to bring balance between Global South and Global North.

So, ABS is a technical, legal and political discussion often with a lot of emotions.

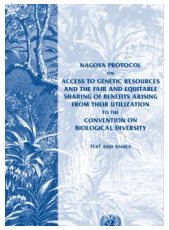
Who are the actors in ABS?



How is ABS organized?

ABS can be regulated at different levels and can be organized in different ways

Modalities of organizing ABS

Level of regulation	Bilateral	Multilateral
International	Convention on Biological Diversity  	The International Treaty ON PLANT GENETIC RESOURCES FOR FOOD AND AGRICULTURE
Regional	REGULATION (EU) No 511/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL 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 Utilization in the Union	
National	National ABS laws	
Local	e.g.: ABS laws in States of Federal States	

The evolution of ABS frameworks

Convention on Biological Diversity

- 1992/93 adoption & entry into force of the CBD
- 2010 adoption of the Nagoya Protocol
- 2014 entry into force of the Nagoya Protocol
- 2017 start of discussions on Digital Sequence Information
- 2022 adoption of DSI decision 15/9
- 2024 adoption CBD COP 16 decision on the modalities of an MLM for DSI

The International Treaty ON PLANT GENETIC RESOURCES FOR FOOD AND AGRICULTURE

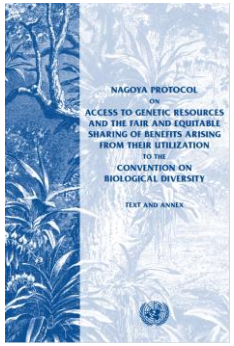
- 1981 International Undertaking on PGRFA
- 2001 adoption of the Treaty – a legally binding instrument
- 2004 Treaty enters into force
- 2006 SMTA enters into force
- 2013 start of the MLS enhancement process
- 2017 start of DSI discussions within the enhancement process
- 2022 re-start of the MLS enhancement process

100 YEARS 1924-2024 ISF

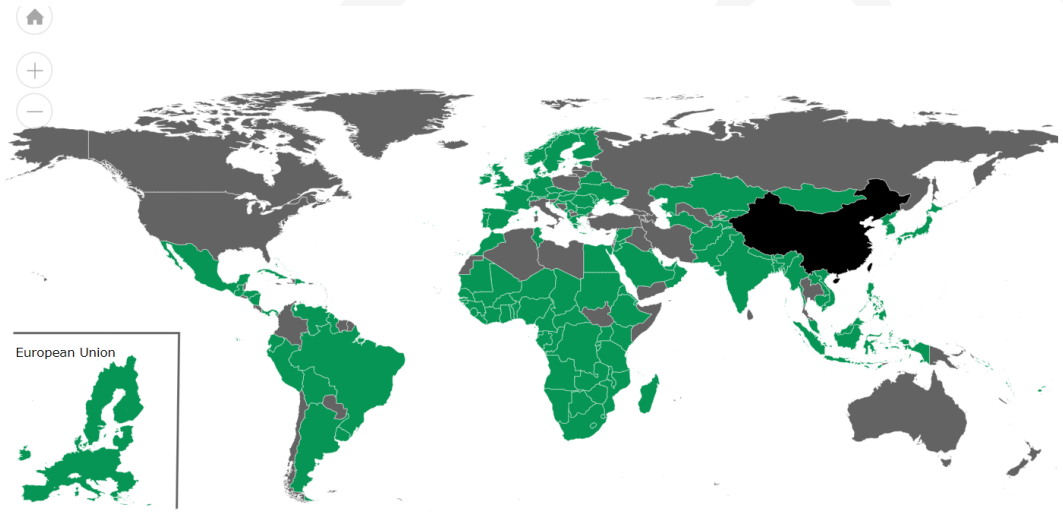
The CBD & its Nagoya Protocol

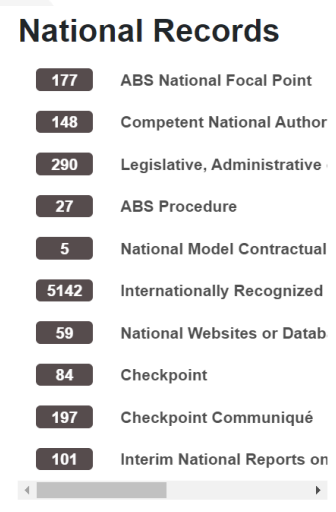
CBD: 196 Contracting Parties
Nagoya Protocol: 141 Contracting Parties

Convention on Biological Diversity



Implemented in national ABS laws in Contracting Parties





Key features:

- **Scope:** all GRs (not human), under the jurisdiction of Parties (*in situ*/*ex situ*), accessed after entry into force
- **How to access**: negotiate bilateral agreement with provider country (+local communities, if appl) – PIC & MAT
- **How to share benefits:** negotiate with provider country (+ local communities) in the contractual arrangements
- **Compliance**: check points foreseed in NP – users may be checked when commercial product put on market
- **Cumulative obligations**: benefit-sharing obligations may be cumulated in one product
- **No cut off point**: benefit-sharing obligations may need to be passed on to subsequent users

The International Treaty & its Multilateral System

The International Treaty
ON PLANT GENETIC RESOURCES FOR FOOD AND AGRICULTURE

↓

Multilateral System (MLS) of access and benefit-sharing

↓

Standard Material Transfer Agreement (SMTA)

IT PGRFA: 152 Contracting Parties

Key features:

- **Scope:** of the Treaty: all PGRFA; scope of the MLS: crops on Annex I (64 crop species); PGRFA under management & control of Parties & in the public domain (only *ex situ* material); for use in research, breeding & training for food & feed purposes
- **How to access**: Under the conditions of SMTA – standard contract: predictable terms, no negotiation
- **How to share benefits:** According to SMTA - % of sales of product including MLS material (Article 6.7); voluntary payment (Article 6.8); % of the sales of all products of a crops (Article 6.11); in-kind benefit sharing
- **Compliance**: No compliance checks foreseen; no specific compliance mechanism
- **Cumulative obligations**: benefit-sharing obligations do not cumulate in one product
- **Cut off point**: at commercialization benefit-sharing obligations stop - NOT passed on to subsequent users

What does this complexity mean for a user of genetic resources?

- Needs to understand the frameworks
- Needs to be able to find out what the applicable legislation is to each different case of access
- Needs to negotiate ABS contracts
- Needs to have databases in place to document accessions for compliance reasons
- Needs to follow up on [benefit sharing and other] obligations
- Needs to deal with authorities / compliance checks

In practice:

- Not all user entity may have the capacity to deal with ABS
- Goals of the ABS concept might not be fulfilled

Where to find information?

Official sources for users:

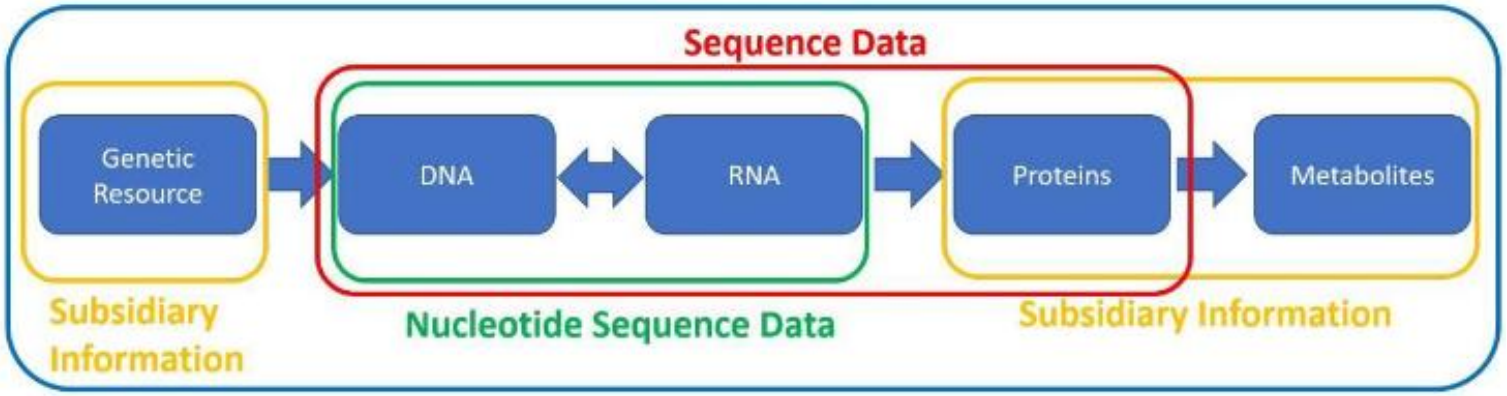
- CBD ABS Clearing House
- National clearing house pages
- National Focal Points for CBD / National Focal Points for the Treaty (note that in most countries those are in different ministries!)

Industry sources:

- EU ABS Navigator/ ABS website (resources from Euroseeds)

What about DSI?

What is DSI? – we still don't know…



Why do we talk about it?

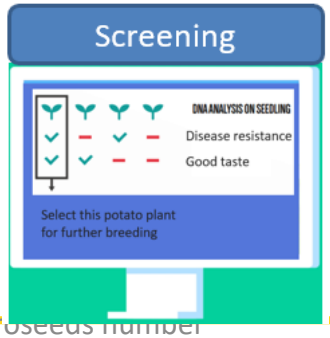
Political idea to expand ABS also to the use of information derived from GRs in the hope of more monetary income

Use of DSI in plant breeding
Some examples…

Marker-assisted selection

Genome editing

Screening



Characterization

Where are we now?

CBD COP16 decision on DSI:

- Access to DSI remains open
- MLM on the use of public DSI
- All users in given sectors making benefits in commercial use, have to pay – plant breeding is one of the sectors
- 1% of revenue or 0.1% of profit into a global fund
- Users not having a commercial benefit - no obligation to pay – e.g.: public research
- Effect on partnerships??

EU ABS Regulation

Regulation at EU level

Article
15

COMPLIANCE WITH DOMESTIC LEGISLATION OR REGULATORY REQUIREMENTS ON ACCESS AND BENEFIT-SHARING

1. Each Party shall take appropriate, effective and proportionate legislative, administrative or policy measures to provide that genetic resources utilized within its jurisdiction have been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the other Party.

2. Parties shall take appropriate, effective and proportionate measures to address situations of non-compliance with measures adopted in accordance with paragraph 1 above.

3. Parties shall, as far as possible and as appropriate, cooperate in cases of alleged violation of domestic access and benefit-sharing legislation or regulatory requirements referred to in paragraph 1 above.

REGULATION (EU) No 511/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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 Utilization in the Union

(Text with EEA relevance)

Main elements:

- applies to genetic resources under sovereign rights and to aTK, accessed after the entry into force of the Nagoya Protocol for the Union
- establishes a system of self-assessment (due diligence obligation)
- establishes a self-declaration (obligation to make a due diligence declaration)
- foresees deterring sanctions by Member States
- provides for monitoring & compliance checks

Regulation at EU level

Why is ABS a tricky issue?

- ABS obligations stem from international treaties but are translated into regulatory and contractual obligations for users
- Awareness is key but not always obvious – you must know what you can use and what your obligations are but finding it out is a challenge
- Compliance is a must but often complicated – solution is sometimes avoidance, with negative effect on the use of GRs

Under the EU ABS Regulation

- Need to know what comes in & whether it was accessed in compliance with applicable ABS laws
- Need to track the use of GRs
- Need to know what goes out and where & if there is an obligation to make a declaration or transfer obligations
- Be prepared for and collaborate in compliance checks

Why is it important for academia/public research?

ABS obligations in general

- All users need to comply although in some cases for academic (non-commercial) research no or different conditions apply
- Transfer of research results to commercial users might be complex (need to renegotiate terms)
- BUT in any case, compliance by public research is key – collaborations, public-private partnerships

Under the EU Regulation

Article 7

Monitoring user compliance

1. The Member States and the Commission shall request all recipients of research funding involving the utilisation of genetic resources and traditional knowledge associated with genetic resources to declare that they exercise due diligence in accordance with Article 4.

Why is it important for academia/public research?

2020 Commission Guidance Document

2.4. Personal scope: the regulation applies to all users

The due diligence obligations stemming from the EU ABS Regulation apply to all users of genetic resources falling within the scope of the Regulation. A user is defined in the Regulation as 'any natural or legal person that utilises genetic resources or traditional knowledge associated with genetic resources' (Article 3(4) of the Regulation). This is independent of the users' size or of the intent of the use (commercial or non-commercial). Thus the due diligence obligation applies to individuals, including researchers, and to organisations such as universities or other research organisations, as well as to small and medium sized enterprises and multinational companies, which utilise genetic resources or traditional knowledge associated with genetic resources. In other words, the entities carrying out utilisation activities (researchers or other organisations) have to comply with the due diligence obligations of the EU ABS Regulation as long as all other conditions are fulfilled regardless of their size or whether they are profit or non-profit entities.

Why is it important for academia/public research?

Commission Implementing Regulation 2015/1866:

Article 5

Due diligence declaration at the stage of research funding

1. A recipient of funding for research involving the utilisation of genetic resources and traditional knowledge associated with genetic resources shall make the due diligence declaration requested pursuant to Article 7(1) of Regulation (EU) No 511/2014 to the competent authority of the Member State in which the recipient is established. If the recipient is not established in the Union and the research is carried out in the Union, the due diligence declaration shall be made to the competent authority of the Member State in which the research is carried out.

2. The due diligence declaration shall be made by submitting the completed template set out in Annex II. It shall be made after the first instalment of funding has been received and all the genetic resources and traditional knowledge associated with genetic resources that are utilised in the funded research have been obtained, but no later than at the time of the final report, or in absence of such report, at the project end. The time of submission of such declaration may be further specified by the national authorities.

3. Where the same research project is funded from more than one source or involves more than one recipient, the recipient(s) may decide to make only one declaration. That declaration shall be submitted by the project co-ordinator to the competent authority of the Member State in which the project co-ordinator is established. If the project co-coordinator is not established in the Union and the research is carried out in the Union, the due diligence declaration shall be made to the competent authority of one of the Member States in which the research is carried out.

4. Where the competent authority that receives the declaration referred to in paragraphs 2 and 3 is not responsible for its transmission pursuant to Article 7(3) of Regulation (EU) No 511/2014, it shall forward that declaration to the competent authority responsible for such transmission without undue delay.

5. For the purposes of this Article and Annex II, 'funding for research' means any financial contribution by means of a grant to carry out research, whether from commercial or non-commercial sources. It does not cover internal budgetary resources of private or public entities

Why is it important for academia/public research?

2020 Commission Guidance Document

4.1. Due diligence declaration at the stage of research funding

The first checkpoint (defined in Article 7(1) of the Regulation) concerns the research stage, when a research project involving utilisation of genetic resources and traditional knowledge associated with genetic resources is subject to external funding in the form of a grant ([35]). The EU ABS Regulation does not make a distinction between public and private funding. Both types of funding for research are covered by the obligation to declare due diligence as provided for in Article 7(1).

The language of Article 7(1) of the Regulation makes it clear that such a declaration needs to be requested by the Member States and the Commission. Given that those requests also need to be applicable to private funding not controlled by public authorities, many Member States envisage implementation of this obligation through legislative or administrative measures at national level, and not necessarily through requests targeted to individual recipients of funding.

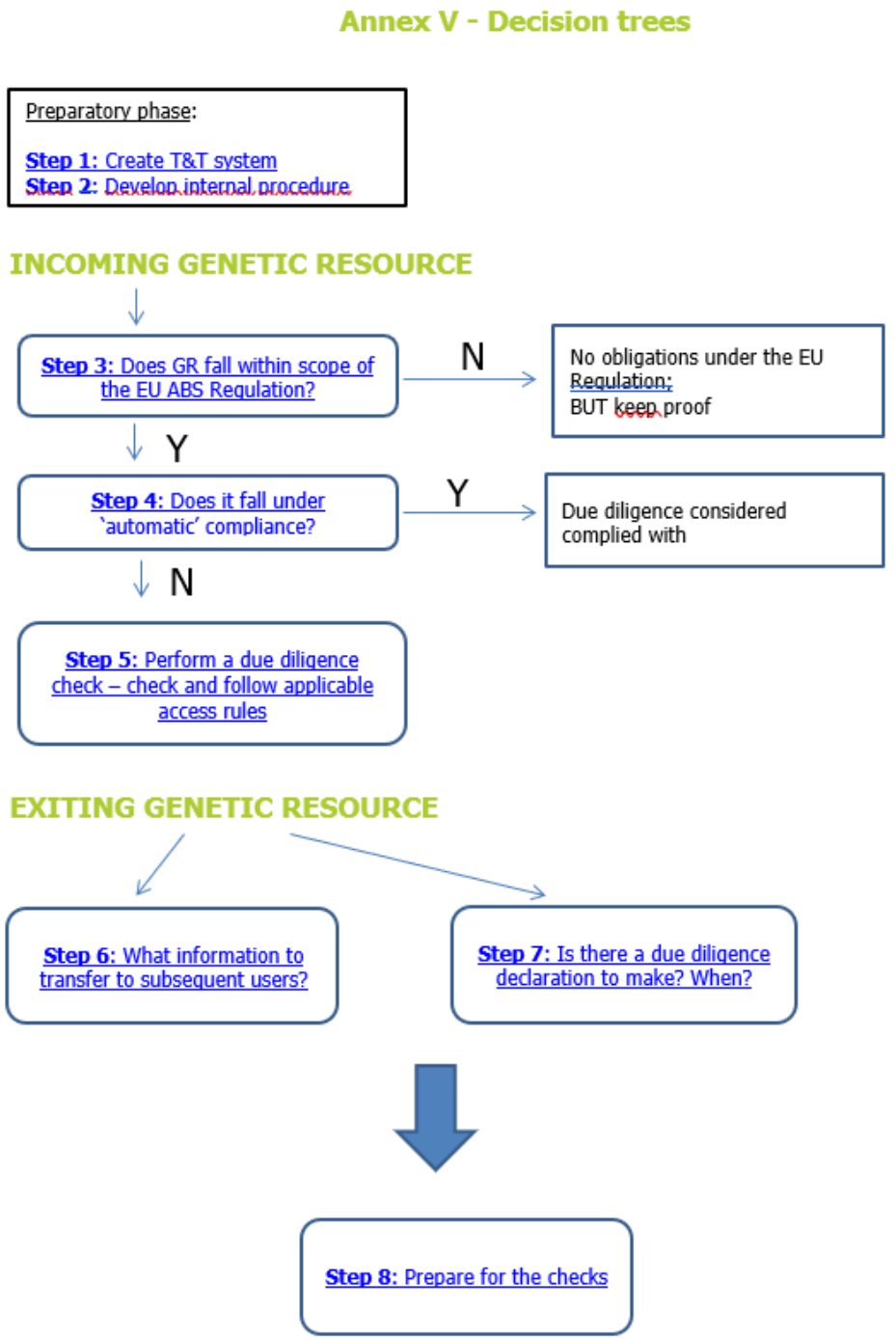
The Implementing Regulation clarifies in Article 5(2) the timing for filing such a declaration. The declaration needs to be made after the first instalment of funding has been received and all the genetic resources and traditional knowledge associated with genetic resources that are utilised in the funded project have been obtained, but in any case no later than at the time of the final report (or in absence of such report, at the project's end). Within the period defined in the Implementing Regulation, the Member States' national authorities may further specify the timing. Again, this can be done either in the context of individually targeted requests or by general legal/administrative provisions.

The time of application for the grant or the time of obtaining it has no relevance for whether a due diligence declaration needs to be requested and filed. The only determining factor here is the time of access to the genetic resources (or traditional knowledge associated with genetic resources).

Practical approaches

Setting up an internal scheme for compliance mechanism is key!

Euroseeds ABS website is a great source: https://abs.euroseeds.eu/#



Resources

International Treaty website

CBD website

ABS Clearing House

ISF Genetic Resources guide

ISF positions

ABS site of Euroseeds

Glossary

ABS = Access and Benefit Sharing
CBD = Convention on Biological Diversity
GSD = Genetic Sequence Data
DSI = Digital Sequence Information
PIC = Prior Informed Consent
MAT = Mutually Agreed Terms
GR = Genetic Resources
PGR(FA) = Plant Genetic Resources (for Food and Agriculture)
IT PGRFA = International Treaty on Plant Genetic Resources for Food and Agricultrue
MLS = Multilateral System
SMTA = Standard Material Transfer Agreement
OEWG EFMLS = Open-ended Working Group on the Enhancement of the Functioning of the Multilateral System
ICC = International Chamber of Commerce
GBF = Global Biodiversity Framework
BBNJ = Biodiversity of Areas Beyond National Jurisdiction Treaty
WHO PIP = World Health Organization Pandemic Influenza Preparedness Framework

Seed is Life

Key elements of the Treaty important for plant breeding

The International Treaty ON PLANT GENETIC RESOURCES FOR FOOD AND AGRICULTURE → MLS → Annex I → SMTA

STANDARD MATERIAL TRANSFER AGREEMENT

PREAMBLE

WHEREAS

The International Treaty on Plant Genetic Resources for Food and Agriculture (hereinafter referred to as "the **Treaty**")[1] was adopted by the Thirty-first session of the FAO Conference on 3 November 2001 and entered into force on 29 June 2004;

The objectives of the **Treaty** are the conservation and sustainable use of **Plant Genetic Resources for Food and Agriculture** and the fair and equitable sharing of the benefits arising out of their use, in harmony with the Convention on Biological Diversity, for sustainable agriculture and food security;

The Contracting Parties to the **Treaty**, in the exercise of their sovereign rights over their **Plant Genetic Resources for Food and Agriculture**, have established a **Multilateral System** both to facilitate access to **Plant Genetic Resources for Food and Agriculture** and to share, in a fair and equitable way, the benefits arising from the utilization of these resources, on a complementary and mutually reinforcing basis;

Articles 4, 11, 12.4 and 12.5 of the **Treaty** are borne in mind;

The diversity of the legal systems of the Contracting Parties with respect to their national procedural rules governing access to courts and to arbitration, and the obligations arising from international and regional conventions applicable to these procedural rules, are recognized;

Article 12.4 of the **Treaty** provides that facilitated access under the **Multilateral System** shall be provided pursuant to a Standard Material Transfer Agreement, and the **Governing Body** of the **Treaty**, in its Resolution 1/2006 of 16 June 2006, adopted the Standard Material Transfer Agreement.

- Designed specifically for plant breeding – takes the specificities of the sector well into account
- Multilateralism, standard contractual terms – key for breeders to be able to access GRs quickly
- Predictable conditions & obligations – legal certainty
- Cut off point at commercialization reflects the realities of how plant breeding works
- No cumulative obligations – recognize how plant breeding works (many GRs used in one variety)

100 YEARS 1924-2024 ISF