

# Nagoya Protocol, CBD, Digital Sequence Information (DSI): Implications for Genebanks

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# Access to genetic resources and the fair and equitable sharing of benefits arising from their utilisation (ABS)

Convention on Biological Diversity (CBD)

Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization (NP)

Regulation (EU) No 511/2014 (EU ABS Regulation)  
Commission Implementing Regulation (EU) 2015/1866

EU MS national legislation implementing the EU ABS Regulation

(some EU MS also legislate on access to their GR)



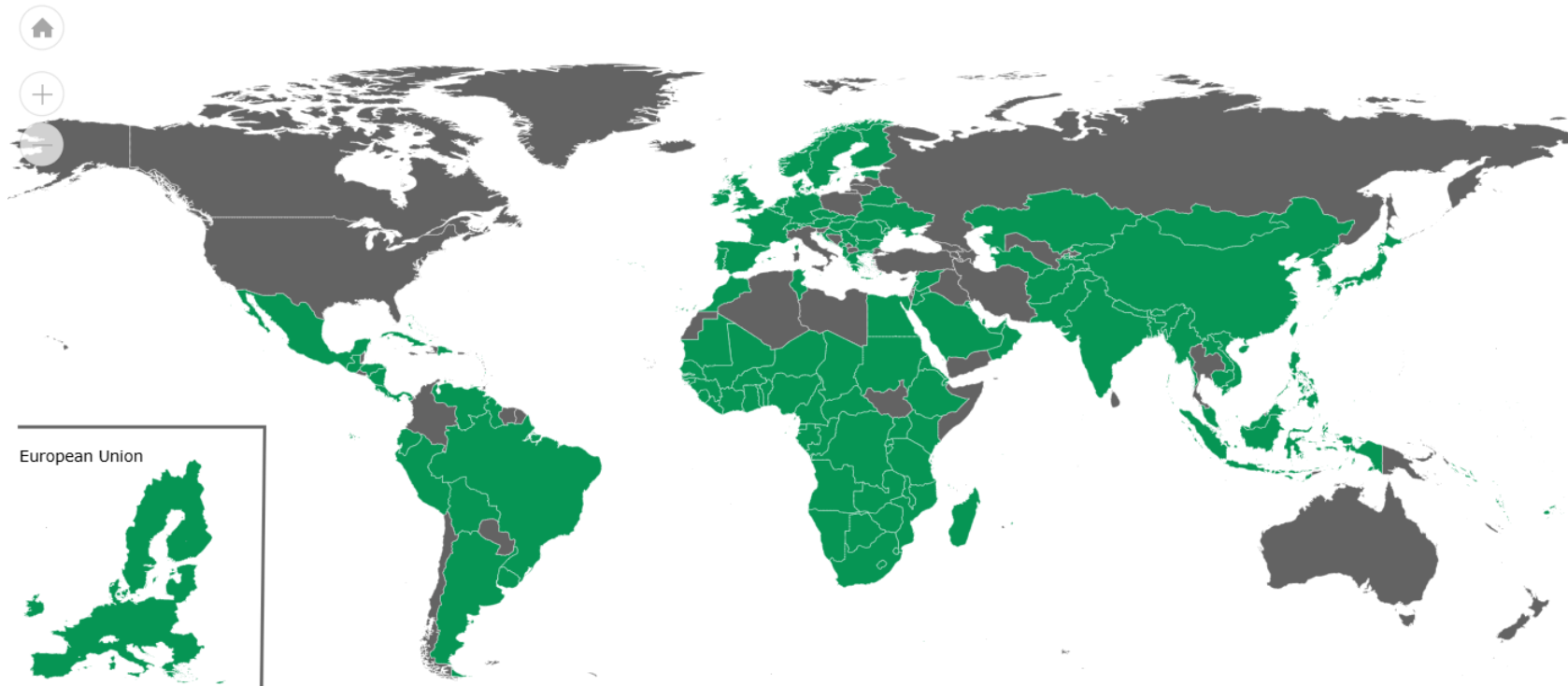
# Nagoya Protocol

- Implements the 3<sup>rd</sup> objective (ABS) and Article 15 of the CBD
- Entry into force **12/10/2014**, 142 Parties
- Provides an international legal framework for:
  - A. Access to genetic resources** (and traditional knowledge associated with genetic resources): countries have the right to regulate access to their genetic resources. → Access might be subject to **prior informed consent (PIC)** by the providing country.
  - B. Benefit sharing:** based on **mutually agreed terms (MAT)** between the provider and the user.
  - C. Compliance by users:** Parties to the NP shall ensure that users of genetic resources within their jurisdiction comply with ABS legislation of the providing country.



# Access and Benefit-Sharing Clearing House

## Parties to the Nagoya Protocol



European Union

JS map by amCharts

**142** Parties to the Nagoya Protocol

**0** Ratified, not yet Party ⓘ

**56** Non-Parties

### National Records

- 177** ABS National Focal Point
- 169** Competent National Authority
- 307** Legislative, Administrative or Policy I
- 40** ABS Procedure
- 13** National Model Contractual Clause
- 6329** Internationally Recognized Certificate
- 68** National Websites or Databases
- 108** Checkpoint
- 377** Checkpoint Communiqué
- 101** 1st National Reports on the Implemer
- 101** Interim National Reports on the Imple

Disclaimer



# Germany

Party to the Nagoya Protocol

(since 20 Jul 2016)

Signatory: Signed on 23 Jun 2011

CBD Country Profile: [www.cbd.int/count](http://www.cbd.int/count)

## Provisions on temporal scope

- EU ABS Regulation - REGULATION (EU) No 511/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 2014 on access to genetic resources and the fair and equitable sharing of benefits arising from their utilization in the Union ( **Article 2** )
- Commission notice — Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 on access to genetic resources and the fair and equitable sharing of benefits arising from their utilisation in the Union ( **Section 2.2** )

## Reference to any other relevant articles and sections

- EU ABS Regulation - REGULATION (EU) No 511/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 2014 on access to genetic resources and the fair and equitable sharing of benefits arising from their utilization in the Union : **Non-Annex1 plant genetic resources for food and agriculture exchanged us**

## ACCESS

No provisions for this element

## BENEFIT-SHARING

No provisions for this element

## COMPLIANCE

### Compliance with domestic legislation or regulatory requirements of the other Party (Article 15 and 16)

- Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 on access to genetic resources and the fair and equitable sharing of benefits arising from their utilization in the Union ( **Article 5, 6 and Annex II, III** )
- EU ABS Regulation - REGULATION (EU) No 511/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 2014 on access to genetic resources and the fair and equitable sharing of benefits arising from their utilization in the Union ( **Articles 4, 7, 9, 11;** )
- Commission notice — Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 on access to genetic resources and the fair and equitable sharing of benefits arising from their utilisation in the Union ( **Entire document** )

EXPORT

Last updated on: 31 Jan 2023 **1**

Last updated on: 28 Mar 2023 **1**

Last updated on: 12 Jan 2021 **6**

**0**

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Last updated on: 07 Jun 2018 **1**

Last updated on: 04 Jul 2016 **1**

Last updated on: 19 Dec 2023 **75**

Last updated on: 16 Feb 2018 **1**

# Implementation in the EU

- **Regulation (EU) No 511/2014** of the European Parliament and of the Council 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 = **EU ABS Regulation** (applicable since **12/10/2014**; **due diligence obligation for users**, monitoring and checks on compliance)
- **Commission Implementing Regulation (EU) 2015/1866** of 13 October 2015 laying down **detailed rules for the implementation** of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices
- **Guidance document on the scope of application and core obligations** of EU ABS Regulation (published 08/2016, updated 01/2021; not legally binding; aims to further explain certain aspects of EU legislation & assist users and national authorities in identifying and meeting due diligence obligations)
- National legislation in EU MS implementing the EU ABS Regulation



# Scope of applicability of the EU ABS Regulation

## ANNEX I

### OVERVIEW OF CONDITIONS FOR APPLICABILITY OF THE EU ABS REGULATION

		Within scope (cumulative conditions (*)	Outside of scope
Geographic scope (provenance of GR (**))	Access in ...	Areas within a country's jurisdiction	Areas beyond national jurisdiction or covered by Antarctic Treaty System
	Provider country is ...	Party to the Nagoya Protocol	Not a Party to the Protocol
	Provider country has ...	Applicable access legislation	No applicable access legislation
Temporal scope	Access ...	On or after 12 October 2014	Before 12 October 2014
Material scope	Genetic resources	Not covered by a specialised international ABS instrument	Covered by a specialised international ABS instrument
		Non-human	Human
		Obtained as commodities but subsequently subject to R & D	Used as commodities
	Utilisation	R & D on genetic and/or biochemical composition	No such R & D
Personal scope		Natural or legal persons utilising GR	Persons <i>only</i> transferring GR or commercialising products based on it
Geographic scope (utilisation)	R & D ...	Within the EU	<i>Exclusively</i> outside of the EU

(\*) To be within the scope, all conditions must be fulfilled.

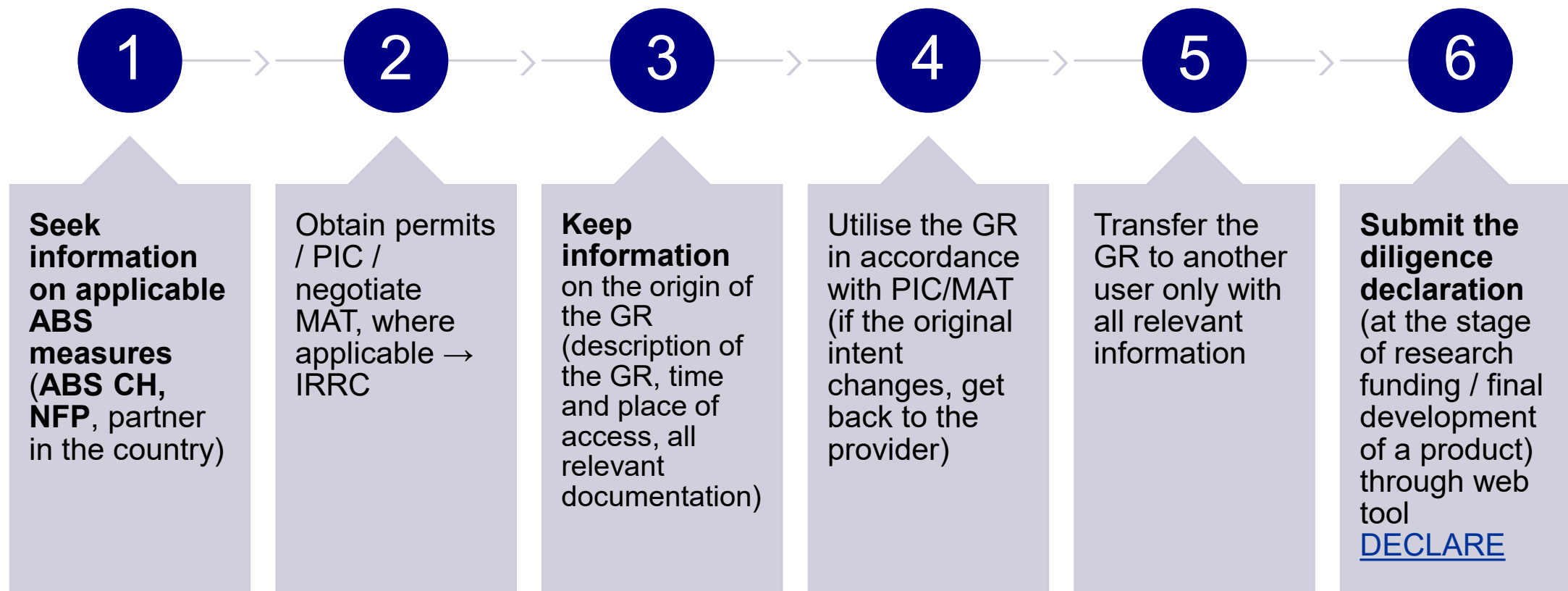
(\*\*) GR = genetic resource; to be read as also including 'traditional knowledge associated with genetic resources', where appropriate.

ABS legislation and regulatory requirements in provider countries might go beyond the scope of the EU ABS Regulation.

All users are expected to respect such national legislation and requirements.



# Users: how to proceed?



# Collection holders (not registered)

No direct obligations from EU legislation

X

- When utilisation takes place in the same institution: collection = user
- User obtaining GR from a collection might be in scope of the EU ABS Regulation and proceed with due diligence (needs relevant documentation)
  - Due diligence is recommended:
    - To access, keep and transfer GR only with relevant information and documents
    - Inform users if information/documents are not available



# Institutional/project arrangements



**Recommended:** internal regulations / guidelines at the level of project/institution



**Why?** Clear procedures at the level of the institution help understanding the responsibilities of different actors (hierarchy, visiting researchers, etc.) and facilitate due diligence



**What?** How to proceed when accessing and utilising genetic material, rights and responsibilities when communicating with the provider, signing PIC/MAT, keeping the documentation, submitting due diligence declarations to DECLARE, etc.



**Useful infographic:** <https://www.nagoyaprotocol-hub.de/wp-content/uploads/2022/03/Infographic-institutional-compliance-measures-1.pdf>

# Further information & guidance

- [ABS Clearing House \(ABS CH\)](#)  
(NFP contact details, information on access legislation and other ABS measures, virtual library)
- [EC website](#)
- National Focal Points / Competent (National) Authorities in your country
- [German Nagoya Protocol HuB](#)



# Ongoing evaluation & assessment



28 February 2026: deadline for **national reports** on the implementation of the Nagoya Protocol as well as Regulation (EU) No 511/2014 (EU ABS Regulation):

<https://absch.cbd.int/en/reports>



19–30 October 2026, Armenia: Nagoya Protocol COP-MOP 6 – second **assessment and review of the effectiveness of the Nagoya Protocol**



2026/2027: **evaluation of the EU ABS Regulation and the review of its functioning** and effectiveness in achieving the objectives of the Nagoya; will cover effectiveness, efficiency, coherence, relevance and EU added value

# Digital sequence information (DSI) on genetic resources

- **CBD COP 15/9:** Recognises the need for fair and equitable benefit-sharing from DSI and decides to develop a multilateral mechanism, including a global fund
- **CBD COP 16/2:** Establishes the multilateral mechanism and the [Cali Fund](#) and sets out core modalities:
  - **Who should contribute:** large companies ( $\geq 2$  of: assets USD 20m / turnover USD 50m / profit USD 5m) in sectors directly or indirectly benefiting from the use of DSI (e.g. pharma, biotech, agriculture, food, cosmetics); indicative rate: 0.1% turnover or 1% profit
  - **Who is not targeted:** public research and academic institutions, and public databases (expected to continue sharing non-monetary benefits + provide clear information on the origin of the DSI (when available), to inform researchers about benefit-sharing obligations and to implement the principles TRUST, FAIR and CARE)
  - **Use of funds:** biodiversity conservation and sustainable use, particularly in developing countries; at least 50% to Indigenous Peoples and local communities
  - **Non-monetary benefit-sharing:** encouraged for all DSI users (e.g. capacity-building, technology development)
  - **Governance:** Steering Committee oversees operation, allocation and transparency
- **CBD COP 17:** expected to review progress and provide further guidance to operationalise the multilateral mechanism and the Cali Fund, including key outstanding elements



# Related international developments (genetic resources & DSI)

- June 2023 – **BBNJ Agreement** (UNCLOS): Agreement on the conservation and sustainable use of marine biodiversity in areas beyond national jurisdiction
  - Includes ABS-related provisions for marine genetic resources (MGR): notification/registration of collection and use, information on origin, and deposition of MGR and DSI in public repositories/databases
  - Entry into force: 17 January 2026
- May 2024 – **WIPO GRATK Treaty**: Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge
  - Requires disclosure of origin/source of genetic resources and traditional knowledge in patent applications
- May 2025 – **WHO Pandemic Agreement**: framework for pandemic prevention, preparedness and response
  - To be opened for signature once the **PABS annex** is adopted (access to pathogens and benefit-sharing), including a system for sharing pathogen samples for use in developing diagnostics, medicines and vaccines
- **ITPGRFA (Plant Treaty)**: ongoing reform of the Multilateral System (MLS) and SMTA
  - Key issues: subscription system, expansion of Annex I, and inclusion of DSI



# Thank you for your attention.



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