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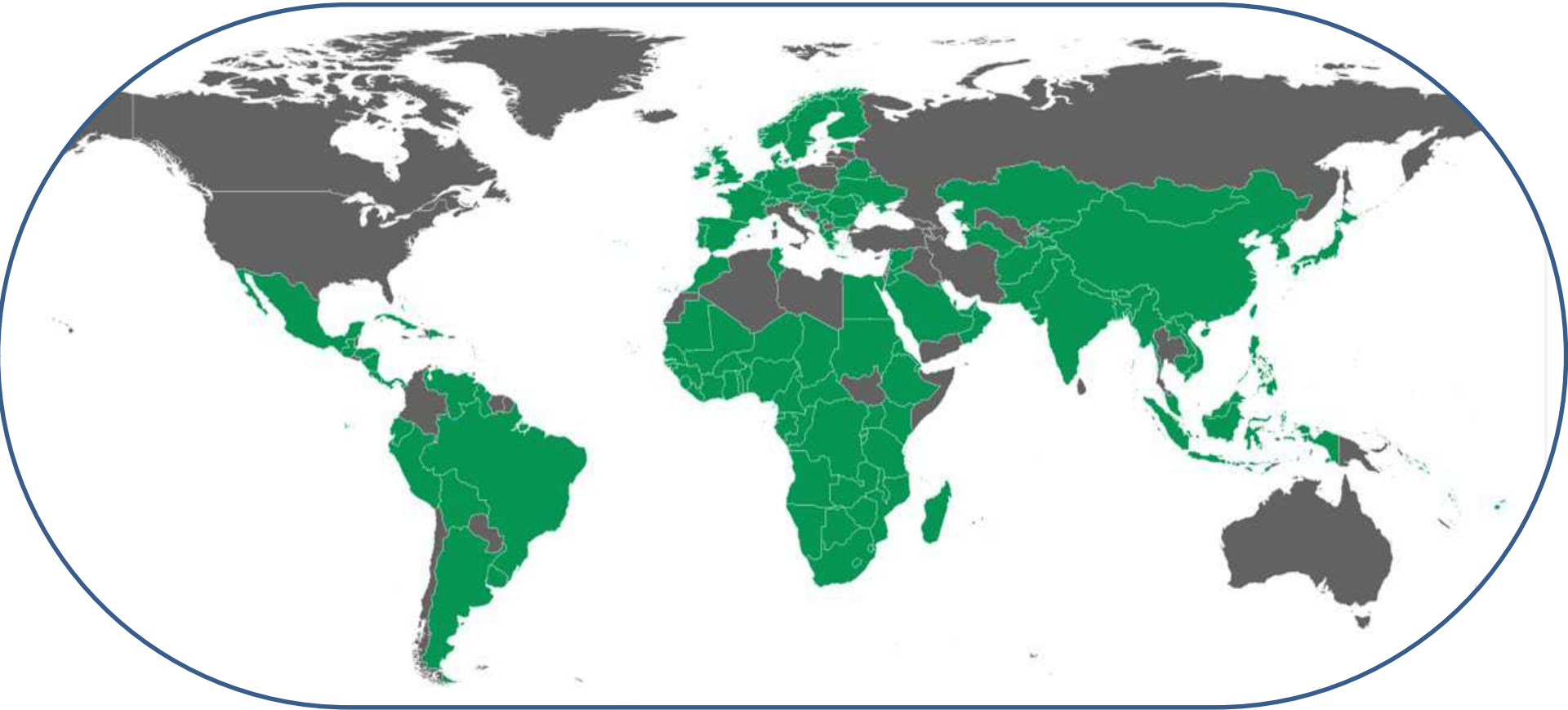
# CETAF Workshop on Access and Benefit Sharing – The Basics

The ABS Regulation of the European Union

Compliance obligation for all users  
utilizing GR within the EU



# Nagoya Protocol: OBLIGATIONS OF THE PARTIES



# Nagoya Protocol:

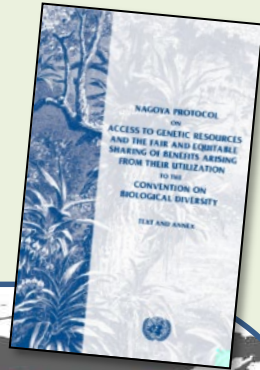
## OBLIGATIONS OF THE PARTIES

### Basic Principles of Access & Benefit Sharing

- (1) States have **sovereign rights** over their genetic resources and may regulate access and utilization (**national laws regulating access**)
- (2) Before accessing a genetic resource a potential user has to obtain a permit (**Prior informed Consent, PIC**) from the providing country's authorities and negotiate Mutually Agreed Terms (MAT), if necessary
- (3) Benefits generated out of the utilization of genetic resource have to **be shared** fairly and equitably with the providing country
- (4) Parties shall take appropriate, **effective** and proportionate **legislative measures to provide that GR** utilized within their jurisdiction **have been accessed in accordance with domestic access laws** of Providing Countries (**national laws regulating compliance of users**)

# Nagoya Protocol: OBLIGATIONS FOR THE PARTIES

## National Access laws



## National laws on users



- EU Regulation 511/2014
- Implementing Regulation 2015/1866



- National Implementation



# Nagoya Protocol:

## OBLIGATIONS FOR THE PARTIES

### Example Research and Nagoya Compliance:

### Checkpoint communiqués of German National Focal Point to CBD Secretariat

#### Research - Genetic resources: F.9 (17) 2015-Bio Grant of permission in compliance to Nagoya Protocol to take 45 tissue samples of hawk moths to Germany for genetics analysis

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[CHECKPOINT COMMUNIQUÉ](#) | GERMANY | ABSCH-CPC-DE-281034-1 | CP: FEDERAL AGENCY FOR NATURE CONSERVATION | SOURCE: PAKISTAN | IRCC NOT AVAILABLE | 13 NOV 2025

#### Research - Genetic resources: Export Clearance Certificate, certificate number 0001, Tanzania, faecal, hair, tissue, blood samples from spotted hyaenas

Research - Genetic resources: Export Clearance Certificate, certificate number 0001, Tanzania, faecal, hair, tissue, blood samples from spotted hyaenas

[CHECKPOINT COMMUNIQUÉ](#) | GERMANY | ABSCH-CPC-DE-279954-1 | CP: FEDERAL AGENCY FOR NATURE CONSERVATION | SOURCE: UNITED REPUBLIC OF TANZANIA | IRCC NOT AVAILABLE | 31 JUL 2025

#### Research - Genetic resources: Export Clearance Certificate, certificate number 0001, Tanzania, faecal, hair, tissue, blood samples from spotted hyaenas

Research - Genetic resources: Export Clearance Certificate, certificate number 0001, Tanzania, faecal, hair, tissue, blood samples from spotted hyaenas

[CHECKPOINT COMMUNIQUÉ](#) | GERMANY | ABSCH-CPC-DE-279953-1 | CP: FEDERAL AGENCY FOR NATURE CONSERVATION | SOURCE: UNITED REPUBLIC OF TANZANIA | IRCC NOT AVAILABLE | 31 JUL 2025

#### Research - Genetic resources: Export Clearance Certificate, certificate number 0001, Tanzania, faecal, hair, tissue, blood samples from spotted hyaenas

Research - Genetic resources: Export Clearance Certificate, certificate number 0001, Tanzania, faecal, hair, tissue, blood samples from spotted hyaenas

[CHECKPOINT COMMUNIQUÉ](#) | GERMANY | ABSCH-CPC-DE-279952-1 | CP: FEDERAL AGENCY FOR NATURE CONSERVATION | SOURCE: UNITED REPUBLIC OF TANZANIA | IRCC NOT AVAILABLE | 31 JUL 2025

**Research - Genetic resources: BMBF-PEKRIS, FKZ 03F0746A, 2016–2019, PEKRIS II, FKZ 03F0828A, 2019–2023, Bettina Meyer, ICBM, Uni Oldenburg. Physiology and life cycle of salps, adaptability to a warming ocean. The species *Salpa fusiformis* was sampled in March 2017 and 2021 at the Institut de la Mer de Villefranche, France. Due to unforeseen changes in the experimental design, unpredictable occurrence of the salp blooms and COVID-19 restrictions, the use of the samples for transcriptomic analyses was only determined in the final project phase, with publication of the data in 2025: "Müller, Svenja J., et al. Time Matters : Transcriptomic Insights..." Although the PEKRIS II funding has ended, samples of *Thalia democratica* for which the transcriptome was generated still remain. The physical sample material was processed at AWI only, with sample preparation performed by PhD student Svenja Müller, who had a guest contract/temporary employment with AWI.**

Research - Genetic resources: BMBF-PEKRIS, FKZ 03F0746A, 2016–2019, PEKRIS II, FKZ 03F0828A, 2019–2023, Bettina Meyer, ICBM, Uni Oldenburg. Physiology and life cycle of salps, adaptability to a warming ocean. The species *Salpa fusiformis* was sampled in March 2017 and 2021 at the Institut de la Mer de Villefranche, France. Due to unforeseen changes in the experimental design, unpredictable occurrence of the salp blooms and COVID-19 restrictions, the use of the samples for transcriptomic analyses ...

[CHECKPOINT COMMUNIQUÉ](#) | GERMANY | ABSCH-CPC-DE-279898-1 | CP: FEDERAL AGENCY FOR NATURE CONSERVATION | SOURCE: FRANCE | ABSCH-IRCC-FR-276266-1 | 22 JUL 2025

#### Research - Genetic resources: CocoaChain - Quality improved raw cocoa and cocoa-based products with flavour profiles on demand - From farm to chocolate bar

Research - Genetic resources: CocoaChain - Quality improved raw cocoa and cocoa-based products with flavour profiles on demand - From farm to chocolate bar

<https://absch.cbd.int/en/countries/DE/CPC?status=All;>  
accessed 15 Mar 2026

# The European ABS Regulation on utilisation

## SUBJECT MATTER

- Is **applicable to all users** utilising GR within the EU, including **guest researchers from outside the EU** bringing own samples
- Establishes **due diligence obligations and compliance checks** for all users utilising GR within the EU
- **Requires documentation and eventually reporting** of accessed and utilised GR for fulfilling due diligence obligations
- **Introduces compliance checks** to ensure that due diligence obligations are observed

# The Regulation EU (No) 511/2014 in detail:

## SUBJECT MATTER

The EU Regulation establishes rules governing **compliance** of users of genetic resources **with the Nagoya Protocol**



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The EU Regulation establishes rules governing **compliance** of users of genetic resources **with the Nagoya Protocol**

- It **does not regulate access** to genetic resources in EU Member States
  - ▷ some EU MS have national access legislation (e.g. ES, FR)
  - ▷ most EU MS grant free access

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## SUBJECT MATTER

The EU Regulation establishes rules governing **compliance** of users of genetic resources **with the Nagoya Protocol**

- It **does not regulate access** to genetic resources in EU Member States
  - ▷ some EU MS have national access legislation (e.g. ES, FR)
  - ▷ most EU MS grant free access
- It **does not regulate benefit-sharing**
  - ▷ this has to be negotiated individually
  - ▷ agreed between provider and user in mutually agreed terms (MAT)

# The European ABS Regulation on utilisation: EU (No) 511/2014

- published in the Official Journal of the European Union: 20 May 2014;  
available in various languages  
[http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L\\_.2014.150.01.0059.01.ENG](http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2014.150.01.0059.01.ENG)
- **entered into force on 9 Jun 2014;**  
applicable since 12 Oct2014 (entry-into-force of the NP)
- **directly applicable and legally binding** in all EU Member States  
(no matter whether they are parties to the Nagoya Protocol or not)
- Further details on register of collections, best practice, compliance  
(Articles 5, 7 and 8) are laid down in **Implementing Regulation (EU)  
2015/1866**

# The European ABS Regulation on utilisation: Relevant Legal Acts

- **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

[http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L\\_.2014.150.01.0059.01.ENG](http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2014.150.01.0059.01.ENG)

- **Commission Implementing Regulation (EU) 2015/1866** of 13 October 2015, laying down details on Articles 5, 7 and 8 of Regulation 511/2014

<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32015R1866>

# The Regulation EU (No) 511/2014 in detail:

Art. 1: Subject matter

Art. 2: Scope of the Regulation

Art. 3: Definition of Terms

**Art. 4: Due diligence obligation: user must ensure to use only legally acquired GR**

Art. 5: Register of Collections: EU system to obtain GR from ex-situ sources

Art. 6: Competent authorities and focal point

**Art. 7: Monitoring user compliance: two check points, 1) reception of research funding, 2) final stage of product development**

**Art. 8: Best Practise:** procedures, tools and mechanisms acknowledged as Best Practice to minimise checks by national authorities

**Art. 9: Checks on User Compliance**

Art. 10: Records of Checks

Art. 11: Penalties

Art. 12-14: Final Provisions

# The Regulation EU (No) 511/2014 in detail:

## SCOPE: What is in? - 4 key questions

1. **Material Scope:** any **biological material** containing DNA, RNA or derivatives (proteins, metabolites, pathogens etc.)
2. **Utilisation Scope:** aims the intended research to **investigate the genetic or biological composition**
3. **Temporal Scope:** was the date of access to **obtain the biological material on or after 12 October 2014** (the actual collecting dates are irrelevant)
4. **Geographic Scope:** was the original country providing the genetic resources **at the time of access party** to the NP **AND** had **ABS access laws in place**

# The Regulation EU (No) 511/2014 in detail:

## SCOPE: What is not?

- human genetic material (excluding human microbiota, viruses, etc.)
- GR/TKaGR falling under specialised international instruments, such as the “International Treaty on Plant Genetic Resources for Food and Agriculture” (ITPGRFA) or the “Pandemic Influenza Preparedness (PIP) Framework”

**Associated GR are** covered if utilised for research & development outside such these frameworks

# The Regulation EU (No) 511/2014 in detail:

## SCOPE: summary

The Regulation is only applicable if all of the following conditions are met:

1. GR / TKaGR is accessed (i) from a country that is Party to the Nagoya Protocol (NP) that has (ii) national access legislation in force

Not covered:

- GR from areas beyond national jurisdiction  
[Marine Genetic Resources will be covered from 2026 under BBNJ]
- GR/TKaGR from countries that are not party to the NP
- GR/TKaGR from countries that do not regulate access

2. GR / TKaGR were accessed from a country after the entry-into-force of the NP
  - GR/TKaGR that were accessed before 12 October 2014 are not covered
3. GR / TKaGR are utilised according to Art. 3(5) of the EU Regulation
  - collecting, storing, trading, commercializing (without utilization)
4. Utilisation of GR / TKaGR takes place within the EU
  - Utilisation outside of the UE

# The Regulation EU (No) 511/2014 in detail:

## SCOPE: summary

### What is the meaning of “out of scope”?

- ▶ If you utilise biological material within the EU, you need to observe the ***obligations of users*** under Art.4 and exercise due diligence (Documenting, compliance)
- ▶ **Out of scope means**, you are out of scope of Art. 7 (**no reporting obligations under DECLARE**), because your use does not constitute utilisation in the meaning of the Nagoya Protocol
- ▶ For genomic sequencing (partly), proteomics and metabolomics, there is no clear cut distinction; as a rule of thumb, **research investigating expression/functions of genes may require reporting** under Art.7

# The Regulation EU (No) 511/2014 in detail:

## OBLIGATIONS OF USERS (Article 4)

1. **Users** shall exercise **due diligence** to ascertain that GR and TKaGR which they utilise have been accessed in accordance with applicable ABS legislation or regulatory requirements, and that benefits are fairly and equitably shared [...]

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- 2. GR** and TKaGR shall only be **transferred and utilised in accordance with MAT** (mutually agreed terms) [...]
- 3. Users** shall **seek, keep and transfer** to subsequent users the following information:
  - date and place of access
  - description of the GR or TKaGR
  - source of the GR/TKaGR and subsequent users
  - presence or absence of ABS rights and obligations
  - access permits and MAT, where applicable




*Countries that grant free access do not necessarily issue a positive proof for it*

# The Regulation EU (No) 511/2014 in detail:

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  - access permits and MAT, where applicable



Or the **Internationally Recognized Certificate of Compliance (IRCC)** which contains the underlined information

# The Regulation EU (No) 511/2014 in detail:

## OBLIGATIONS OF USERS (Article 4, continued)

5. **Discontinue utilisation**, or obtain PIC and establish MAT, if information is **insufficient or uncertainties** about legality persist.
6. Keep relevant information **for 20 years after end** of period of utilisation.

→ Certain exemptions for plant genetic resources (PGR) covered by the *International Treaty on PGR for Food and Agriculture* and for human pathogens.

# The Regulation EU (No) 511/2014 in detail:

## Key requirements of Article 4:

- ✓ Date and place where material was collected
- ✓ Description and identification of the used material
- ✓ Source where material was directly obtained
- ✓ Relevant Permits (e.g. collecting, access, export, import permits)
- ✓ Who is the responsible scientist for the samples
- ✓ Where I can find samples and documents in 20 years



# The Regulation EU (No) 511/2014 in detail:

## MONITORING OF USERS (Article 7)

“At identified points in the chain of activities that constitute utilisation, **users should declare and provide evidence**, when requested, that they have exercised due diligence.”

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“At identified points in the chain of activities that constitute utilisation, **users should declare and provide evidence**, when requested, that they have exercised due diligence.”

→ Article 7(1): **upon receipt of research funding** for projects involving the utilisation of GR or TKaGR

→ Article 7(2): at the **stage of final development** of a **product**

**Provided, your use is in scope of the EU ABS Regulation**

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→ Article 7(2): at the **stage of final development** of a **product**

**Provided, your use is in scope of the EU ABS Regulation**

Details on 7(1) are provided in Implementing Regulation 2015/1866:

- 1 declaration per grant-funded research project (no matter whether grants come from private or public sources)
- declarations are to be made to the competent authority of the grant recipient's country

# The Regulation EU (No) 511/2014 in detail:

## MONITORING OF USERS (Article 7, continued)

### Declarations upon receipt of research funding have to include information on

- the user making the declaration
- the GR or TKaGR
- place of access to the GR or TKaGR
- identifiers of PIC or equivalents
- source of research grant (public or private)

L 275/14 EN Official Journal of the European Union 20.10.2015

ANNEX II

Template for a due diligence declaration to be submitted at the stage of research funding pursuant to Article 5(2)

PART A

Information to be transmitted to the ABS Clearing House pursuant to Article 7(3) of Regulation (EU) No 511/2014

If the information provided is confidential within the meaning of Article 7(5) of Regulation (EU) No 511/2014, please provide it nonetheless, tick the respective box and provide the justification for confidentiality at the end of this Annex.

If you marked as confidential essential information (such as about the genetic resources or traditional knowledge associated with genetic resources, access place, form of utilization), without which the record would not be published on the website of the ABS Clearing House, this information will not be shared with the ABS Clearing House, but it may be passed on directly to the competent authorities of the provider country.

At least one declaration is required per grant received, i.e. different recipients under one grant may choose to submit either individual declarations or a joint declaration, through the project coordinator.

I am making this declaration for the utilization of:

Please tick the appropriate box or boxes:

Genetic resources

Traditional knowledge associated with genetic resources

1. Subject matter of the research or identification code of the grant:

Confidential

2. Recipient or recipients of funding, including contact details:

Name: \_\_\_\_\_

Address: \_\_\_\_\_

E-mail: \_\_\_\_\_

Telephone: \_\_\_\_\_

Website, where available: \_\_\_\_\_

3. Information on exercise of due diligence:

(a)  An internationally recognised certificate of compliance (i) was issued for my (entity's) access or (ii) covers the terms of this access to the genetic resource(s) and traditional knowledge associated with genetic resources.

Where this box is ticked, please indicate the unique identifier of the internationally recognised certificate of compliance:

Please go to point 1 of Part B.

(b) Where the box in point (a) has not been ticked, please fill in the following information:

(i) Place of access:

Confidential

# The Regulation EU (No) 511/2014 in detail:

## Recognition of BEST PRACTICE (Article 8)

**Voluntary** Codes of Conduct on ABS including user specific tools and measures (= Best Practice) shall **help to exercise due diligence** (and, thereby, to build trust in providing countries)

→ *called for by the Nagoya Protocol*

# The Regulation EU (No) 511/2014 in detail:

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→ *called for by the Nagoya Protocol*

### Provision in EU Reg. 511/2014 :

- Associations of users and other stakeholders may apply to the European Commission for the recognition of their Best Practices
- Users that apply such recognized Best Practice might experience less intensive checks by their competent national authorities

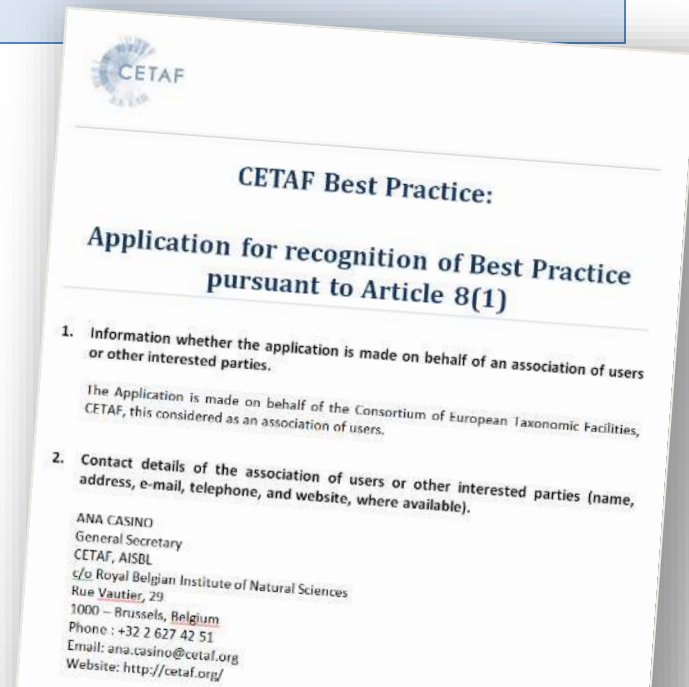
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→ *called for by the Nagoya Protocol*

### CETAF's Code of Conduct and Best Practices on ABS:

- submitted to the Commission in Feb 2016



# The EU ABS Guidance document 2021/C 13/01)

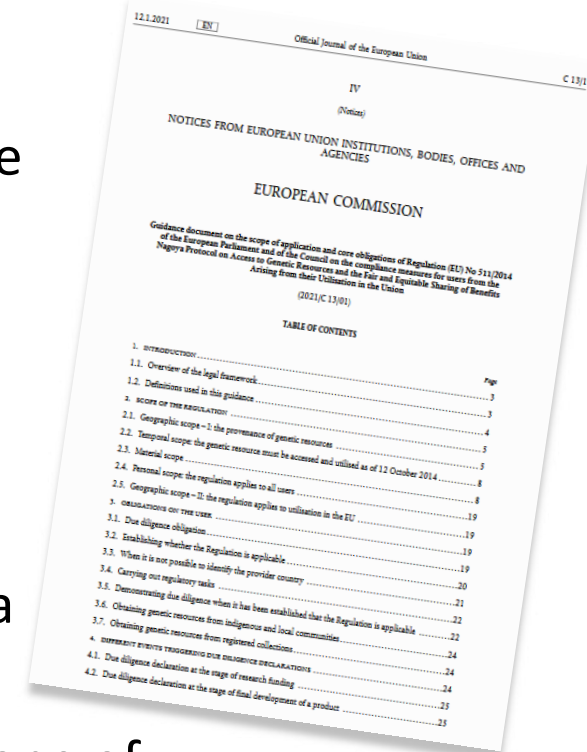
## Easy and clear overview on

- geographic, temporal, material, personal and geographic scope
- Obligations of users utilising in the EU including guidance on what to observe for access, or if the Provider Country is unclear
- Trigger points for Due Diligence Declarations

## Useful practical guidance (with nerdy taxonomic language) on

- What is utilisation in the meaning of the Nagoya Protocol under the EU ABS Regulation
- What is considered inside and outside of the scope of the EU ABS Regulation

[https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021XC0112\(02\)](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021XC0112(02))



# The EU ABS Guidance document 2021/C 13/01)

## Useful and simple case examples in Annex II

- Valuable guidance for due diligence decisions
- Specific sections address taxonomy
  - ▶ Section 6.1, Taxonomic identification of organisms and taxonomic research (p. 39)
  - ▶ Section 6.2, Characterisation (p. 41)
  - ▶ Section 6.3, Phylogenetic analysis (p. 44)
  - ▶ Section 6.5, Large-scale screening (p. 45)
- Specific advice for collection holders and on acceptance of donations and bequests
- Available in all EU languages (FR, ES, DE, EN, etc.)

# The EU ABS Guidance document 2021/C 13/01)

## Useful and simple case examples in Annex II

- Acquisition
  - ▷ Direct (own field work), indirect (traded pets or plants), confiscated material
  - ▷ Rearing and propagation, including domesticated animals and plants
- Identification and characterisation of organisms
  - ▷ Taxonomic Research and identification of organisms, identification of derivatives or associated GR (pathogens, viruses, invasive or pest species)
  - ▷ Phylogenetic analysis, large-scale screening
- Genetic Resources as tools
  - ▷ Laboratory strains, living cell lines
  - ▷ Using of GR as testing or reference tools
- Breeding
  - ▷ Crossing, selection, reproduction, genome editing, plant and animal breeding

[https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021XC0112\(02\)](https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021XC0112(02))

# Side Note – A short history of the EU ABS legislation

*...and CETAF's engagement*

## **Oct 2012**

European Commission (DG Environment) publishes legislative proposal, accompanied by impact assessment and background study;

First stakeholder consultation meeting

*Since 2012: Active participation in meetings of the Commission, Council and Parliament*

## **Nov 2012 – Sept 2013:**

Debates in EU Council, Parliamentary Committees and Parliament

*May 2013: Position paper incl. amendments to draft Regulation*

## **March – April 2014**

Regulation 511/2014 adopted by Parliament and Council

*2013-2015: Development of CETAF Code of Conduct on ABS and presentation at different occasions, e.g. at COP12 in Korea*

## **20 May 2014**

Regulation 511/2014 published in Official Journal

# Side Note – A short history of the EU ABS legislation

*...and CETAF's engagement*

**2014:** Commission launches discussion paper and draft articles for an Implementing Regulation  
Stakeholder meeting on 9 Dec 2014

**Jan 2015 – Oct 2015:**

Commission and Member States discuss and draft the implementing regulation including it's annexes

**9 November 2015:**

Entry into force of the Commission's  
Implementing Regulation

**Dec 2015 / Jan 2016:**

Draft Guidance on Scope of the Regulation  
Consultation Forum meeting on 21 Jan 2016

**Dec 2020:** Guidance Doc published

*Jan 2015:*

*Position paper on the  
draft implementing  
regulation*

*During 2015: Lobbying  
by CETAF members via  
national contacts*

*Dec '15/ Jan '16:*

*Participation in Stake-  
holder Meeting, written  
comments on Guidance  
Doc.*

# Side Note – A short history of the EU ABS legislation

*...and CETAF's engagement*

**Oct 2015:**

*CETAF Code of Conduct &  
Best Practices published*

**10 May 2019:**

*CETAF Code of Conduct &  
Best Practices 1<sup>st</sup> (and to date  
only) acknowledged Best Practice  
of the EU and globally*

<https://cetaf.org/resources/best-practices/>

<https://environment.ec.europa.eu/topics/>

<https://absch.cbd.int/api/v2013/documents/>



# THANK YOU FOR YOUR ATTENTION!

## The European ABS Legislation

CETAF WORKSHOP ON ABS - Bonn, 22 April 2026



of the world's  
described  
biodiversity



CETAF Legislation and  
Regulations Working Group

[www.cetaf.org](http://www.cetaf.org)

## EXPLORING AND DOCUMENTING DIVERSITY IN NATURE

Through a network of 50+ natural history collections