

ABS: a guide for researchers in the EU



EUROPEAN COMMISSION

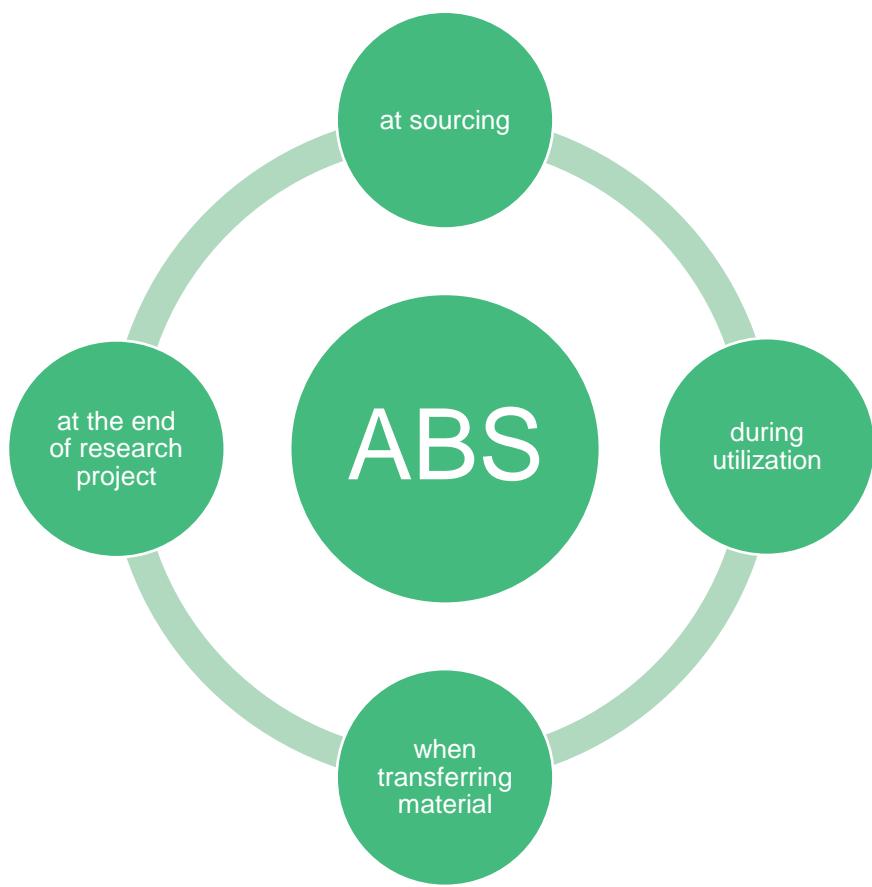
Directorate-General for Environment
Directorate F Green Diplomacy & Multilateralism
Unit F.3 Green Environmental Cooperation & Multilateralism

Contact: ENV ABS Team

E-mail: ENV-F3-NAGOYA-ABS@ec.europa.eu

*European Commission
B-1049 Brussels*

ABS: a practical guide for researchers in the EU



Manuscript completed in December 2025

1st edition

This document has been prepared for the European Commission however it reflects the views only of the authors, and the European Commission is not liable for any consequence stemming from the reuse of this publication.

Luxembourg: Publications Office of the European Union, 2025

© European Union, 2025



The reuse policy of European Commission documents is implemented by Commission Decision 2011/833/EU of 12 December 2011 on the reuse of Commission documents (OJ L 330, 14.12.2011, p. 39). Unless otherwise noted, the reuse of this document is authorised under a Creative Commons Attribution 4.0 International (CC BY 4.0) licence (<https://creativecommons.org/licenses/by/4.0/>). This means that reuse is allowed provided appropriate credit is given and any changes are indicated.

Contents

Foreword	6
1. Introduction	7
1.1. Where does the concept Access and Benefit-Sharing come from?	7
1.2. How does ABS work?	9
1.3. Benefit-sharing	12
1.4. Compliance Measures – The Nagoya Protocol	15
1.5. Monitoring Utilisation	16
1.6. ABS Clearing-House (ABSCH)	19
2. How ABS compliance is ensured in the European Union	22
2.1. What genetic resources and activities are covered by the EU ABS Regulation?	23
2.1.1. Material scope of the EU ABS Regulation	23
2.1.2. Temporal scope: Access on or after 12th October 2014	27
2.1.3. Geographical scope	28
2.1.4. Utilisation	31
2.2. How to comply as a researcher?	37
2.2.1. Seeking of information and obtaining permits	37
2.2.2. Due Diligence Declaration	39
3. Tools established by the EU ABS regulations to aid compliance	44
4. Useful links	46
5. Glossary, abbreviations and acronyms	47
6. Checklist for in situ sourcing of research material	53
7. Checklist for ex situ sourcing of research material	57
8. Checklist for Due Diligence Declaration under the EU ABS Regulation at the receipt of research funding	58

Foreword

Access and Benefit-Sharing (ABS) refers to the international and national regulation of access to and use of genetic resources and associated traditional knowledge, as well as the sharing of benefits arising from this use between providers and users. The Nagoya Protocol, which aims to provide a transparent legal framework for ABS, entered into force on 12 October 2014.

Researchers who use genetic resources and/or traditional knowledge associated with them need to be aware of their legal responsibilities. Since 2014, the European Union (EU) has been a Party to the Nagoya Protocol and has adopted legislation requiring compliance from both European and foreign scientists conducting their research in the EU (EU Regulation 511/2014, also referred to as “the EU ABS Regulation”). Importantly, the EU ABS Regulation and related ABS obligations are not limited to research and development activities with a commercial aim, but also to non-commercial research and development. This makes compliance essential for academic users in universities and public research institutes.

This information guide is designed to support researchers in the EU, particularly in the academic sector, by providing guidance on ABS and on how to meet the requirements of the EU ABS Regulation. It explains key concepts and principles of ABS, outlines the scope of the EU ABS Regulation and details the obligations researchers must fulfil when using genetic resources in the EU. In addition, this guide offers tools and recommendations to assist researchers in complying with ABS requirements.

ABS is not only a matter of legal compliance – it is also a vital mechanism that allows countries to strengthen their ability to conserve biodiversity and promote its sustainable use. Non-commercial research has a major part to play in this, by contributing knowledge, building capacity and sharing of non-monetary benefits.

We hope this guide will support researchers in contributing to these important goals.

1. Introduction

This information guide is intended to help researchers understand what **Access and Benefit-Sharing (ABS)** is and why it was developed. It follows the concept from its origin in the 1992 **Convention on Biological Diversity (CBD)**, through the adoption of the **Nagoya Protocol** in 2010, to its implementation in the EU through the EU ABS Regulation (Regulation (EU) No 511/2014) in 2014.

This guide explains key terms and concepts and sets out the steps to be followed by researchers to comply with the EU ABS Regulation. Various important terms and acronyms are explained in “terminology text boxes”. A glossary is also provided in Chapter 4; terms included in the glossary appear in **bold** the first time they are mentioned in the main text. Additionally, three checklists can be found:

- Chapter 5: Checklist for in-situ sourcing of research material
- Chapter 6: Checklist for ex-situ sourcing of research material
- Chapter 7: Checklist for Due Diligence Declarations under the EU ABS Regulation at the receipt of research funding

This guide draws on the Guidance document on the *scope of application and core obligations of Regulation (EU) No 511/2014*¹, published by the European Commission, which should be consulted for more detailed information.

1.1. Where does the concept Access and Benefit-Sharing come from?

For decades, researchers have collected animals, plants, and microorganisms for study. Over time, this has led to the creation of extensive collections and widespread scientific knowledge. While much of this work is academic, research has also generated commercial products in fields such as pharmaceuticals, agriculture, cosmetics, and biotechnology. However, the benefits of this research - particularly financial ones - have not always been shared

Provider Country

The country supplying genetic resources, either from in-situ sources (wild or domesticated species in their natural environment) or ex-situ sources (e.g. collections), whether or not the material originated there.

Country of Origin

As defined in CBD Article 2, this is the country that possesses the genetic resources in in-situ conditions.

¹ Commission notice “Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance

with the countries from which the biological resources were sourced (**country of origin**).



Genetic Resources (GR)

According to CBD Article 2, genetic resources are genetic material of actual or potential value. Genetic material refers to any material of plant, animal, microbial or other origin containing functional units of heredity. This broad definition means that any biological material containing genes is potentially subject to ABS obligations.



Prior Informed Consent (PIC)

Refers to permission given to a user by the Competent National Authority of a provider country to access a genetic resource. PIC may be included in various documents, not necessarily in a standalone form.



Mutually Agreed Terms (MAT)

A contractual agreement between the provider of genetic resources or traditional knowledge associated with genetic resources and a user. It defines the conditions for access, utilisation, and benefit-sharing. MAT may be part of other legal documents and are not always separate.

This imbalance sparked international discussions on how to ensure the fair and equitable sharing of benefits - both monetary and non-monetary - arising from the use of **genetic resources (GR)**. These discussions, held in various forums including the CBD, led to ABS being adopted as one of the Convention's key objectives.

The 1992 **Convention on Biological Diversity (CBD)**, which entered into force in December 1993, establishes the principle that States have sovereign rights over their genetic resources.

This principle, rooted in UN General Assembly Resolution 1803 (XVII) of 1962, is enshrined in Article 15 of the CBD. The third objective of the CBD is the fair and equitable sharing of benefits arising from the utilisation of genetic resources.

Under the CBD, countries may determine access to their genetic resources through national legislation. In exchange for granting access, they are entitled to receive a share of the benefits - monetary or otherwise - resulting from their use. This principle is the foundation of **Access and Benefit-Sharing (ABS)**. Access must be based on **Prior Informed Consent (PIC)** and benefits must

be shared under **Mutually Agreed Terms (MAT)**. These benefits support the first two objectives of the CBD: the conservation and

sustainable use of biodiversity. ABS also provides an incentive for **provider countries** to facilitate access and protect **associated traditional knowledge (aTK)**.

measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union" (2021/C 13/01) available at <https://circabc.europa.eu/ui/group/3f466d71-92a7-49eb-9c63-6cb0fadf29dc/library/794aecbb-d925-414c-89a3-3db389239271/details?download=true>

In 2010, the **Nagoya Protocol (NP)** was adopted as a supplementary agreement to the CBD. It provides a more detailed framework for ABS, including clearer rules for obtaining access and ensuring benefit-sharing. It also introduces compliance mechanisms to make sure users follow the ABS laws of provider countries.

The **EU ABS Regulation** implements the Nagoya Protocol within the EU.

Genetic Resources and Traditional Knowledge

ABS rules apply to both genetic resources and traditional knowledge associated with them (aTK). To avoid repetition, references in this guide to genetic resources should be understood to include traditional knowledge, unless otherwise specified.

1.2. How does ABS work?

Countries hold sovereign rights over the genetic resources found within their jurisdiction. This means they have the authority to determine whether, and under what conditions, others may access these resources. Many countries have chosen to exercise this right by establishing national Access and Benefit-Sharing (ABS) frameworks, which set legal and administrative requirements for accessing genetic resources and sharing the benefits arising from their utilisation.

Figure 1 provides a simplified overview of how ABS works under the CBD.

The specific procedures for access and use of genetic resources vary from country to country, depending on their domestic ABS laws. In some cases, access is managed by a single governmental body; in others, it may involve multiple regulatory authorities, including regional authorities and **Indigenous Peoples and Local Communities (IPLCs)**.

It is important to note that not all countries have enacted ABS-specific legislation, also because not all countries are a Party to the Nagoya Protocol. However, other restrictions on access may still apply - for example, those related to endangered species, protected areas, or export controls.



Note: National ABS regulations vary widely. For example, some countries distinguish between commercial and non-commercial research, with simplified procedures for the latter. Others apply different rules depending on whether the material comes from domesticated or wild species. See **Figure 1** for a simplified overview of how ABS works under the CBD.

A crucial early step in any project involving genetic resources is to identify and understand the national ABS rules of the relevant provider country. This process can be time-consuming, and researchers should allocate sufficient time in their planning.

In some countries, having a local counterpart or collaborator is a legal requirement and can also be extremely helpful. Local partners are often more familiar with national ABS procedures and may provide access to useful information.

Finding National Legislation and Regulations

To ensure compliance, researchers must:

- Determine the applicable national ABS laws of the provider country
- Obtain any required **permits or agreements**
- Ensure that all activities are carried out **in line with the conditions** set by the provider country

Many countries, particularly those that are Parties to the Nagoya Protocol, have published their ABS legislation and procedural guidelines on the **ABS Clearing-House (ABSCH)**.

If the relevant information is not available online, researchers should:

- Contact the **ABS National Focal Point (NFP)** listed on the ABSCH
- Reach out to in-country counterparts or national institutions
- Consult national government websites and conduct targeted internet searches

While the ABS Clearing-House is a valuable starting point, not all countries keep it updated. Therefore, it's strongly recommended to seek information from **multiple sources**.

Despite national differences, most countries follow a similar ABS process (see [Figure 1](#)). To access genetic resources and/or traditional knowledge associated with them (aTK) for utilisation, researchers must first obtain Prior Informed Consent (PIC). This is a formal permission - typically granted by the **Competent National Authority (CNA)** - to collect and use the resource. Access is only permitted once PIC has been granted.

The next step is agreeing on Mutually Agreed Terms (MAT). This is a contract between the provider country (or an authorised individual/provider) and the user, outlining the conditions of use, benefit-sharing arrangements (monetary and/or non-monetary), and rights to transfer the resource to third parties. In some cases, PIC and MAT may be combined into a single permit, often using standard clauses. As national systems vary, procedures, authorities, and document titles may differ.

Additional permissions may also be required, for example from landowners or Indigenous Peoples and Local Communities (IPLCs), particularly where traditional knowledge is involved. In such cases, separate PIC and MAT may be needed from IPLCs, including specific benefit-sharing arrangements.

Information on a country's ABS requirements can be found via the **ABS Clearing-House (ABSCH)** or by contacting the country's **ABS National Focal Point (NFP)** (contact details available on the ABSCH or the CBD Parties list).

The time - from a few days to several months or more - needed to obtain permits varies widely depends on the national context. Importantly, provider countries are not obliged to grant PIC, and if PIC or MAT cannot be agreed, access and utilisation may not proceed.

What is Access?

The term access is mentioned several times in the Nagoya Protocol and the EU ABS Regulation. It is not explicitly defined in the CBD or the Nagoya Protocol. However, Article 3.3 of the **EU ABS Regulation** defines access as:

“The acquisition of genetic resources or of traditional knowledge associated with genetic resources in a Party to the Nagoya Protocol.”

This definition should be understood broadly. The EU ABS Regulation does not require EU Member States to regulate access to genetic resources (GRs) but to **establish mechanisms to ensure that users within the EU comply with ABS requirements** set by provider countries under the Nagoya Protocol.

There is no harmonised EU-wide system or mechanism. Most Member States have **not introduced specific legislation** governing access to their genetic resources. Researchers should therefore consult the **ABS Clearing-House** for information on the access rules applicable in individual EU Member States.

Countries, also EU Member States, that are **not Parties to the Nagoya Protocol** may still establish mechanisms to ensure compliance with ABS requirements, and users, also within the EU are expected to adhere to these rules. This is a matter of international law and national jurisdiction, not the EU ABS Regulation.

In practical terms, access may involve:

- Directly collecting genetic resources from their **natural habitats (in situ)**
- Acquiring them from **collections, markets, or other researchers (ex situ)** (e.g. gene banks, botanical gardens, private collections, seed suppliers)
- Obtaining them from **third countries or intermediaries**

A checklist for in situ sourcing of research material is provided in Chapter 5.

A checklist for ex situ sourcing of research material is provided in Chapter 6.

 **Helpful Hint: Sourcing from a third country or an intermediary**

If the intermediary is part of the original provider country's supply chain, it may still require their ABS compliance. If sourced from third countries, it requires compliance with both the original provider's ABS laws and the intermediary country's rules (if applicable).

1.3. Benefit-sharing

Although central to the ABS system, benefit-sharing is a term rarely used outside this context and has no universally agreed definition. In practice, it means that research conducted on genetic resources should provide benefits - monetary or non-monetary - to the provider country.

Examples of benefit-sharing include:

-  A list of species collected
-  Co-authorship or joint research projects
-  Training opportunities
-  Access fees, milestone payments, or royalties

A non-exhaustive list of benefit-sharing options is provided in the Annex to the Nagoya Protocol. Both parties may propose additional benefits when negotiating Mutually Agreed Terms (MAT), and all agreed benefits should be clearly documented.

Some countries use standard clauses in their agreements. For example:

"The Access Party will offer a taxonomic duplicate of each Sample taken to an Australian public institution..."

In other cases - especially where monetary benefits are concerned - terms are negotiated individually with the Competent National Authority (CNA) or another authorised provider. If multiple entities are involved, agreements should be checked for consistency.

Finding the Competent National Authority

The contact details of Competent **National Authorities (CNAs)** can be found on the **ABS Clearing-House**. A country may have:

- One CNA for all biodiversity types, or
- Multiple CNAs with different responsibilities (e.g. by sector or region)

If CNA details are not listed, researchers should contact the country's **ABS National Focal Point (NFP)** for guidance. Contact details are available via the ABS Clearing-House or the list of CBD Parties.

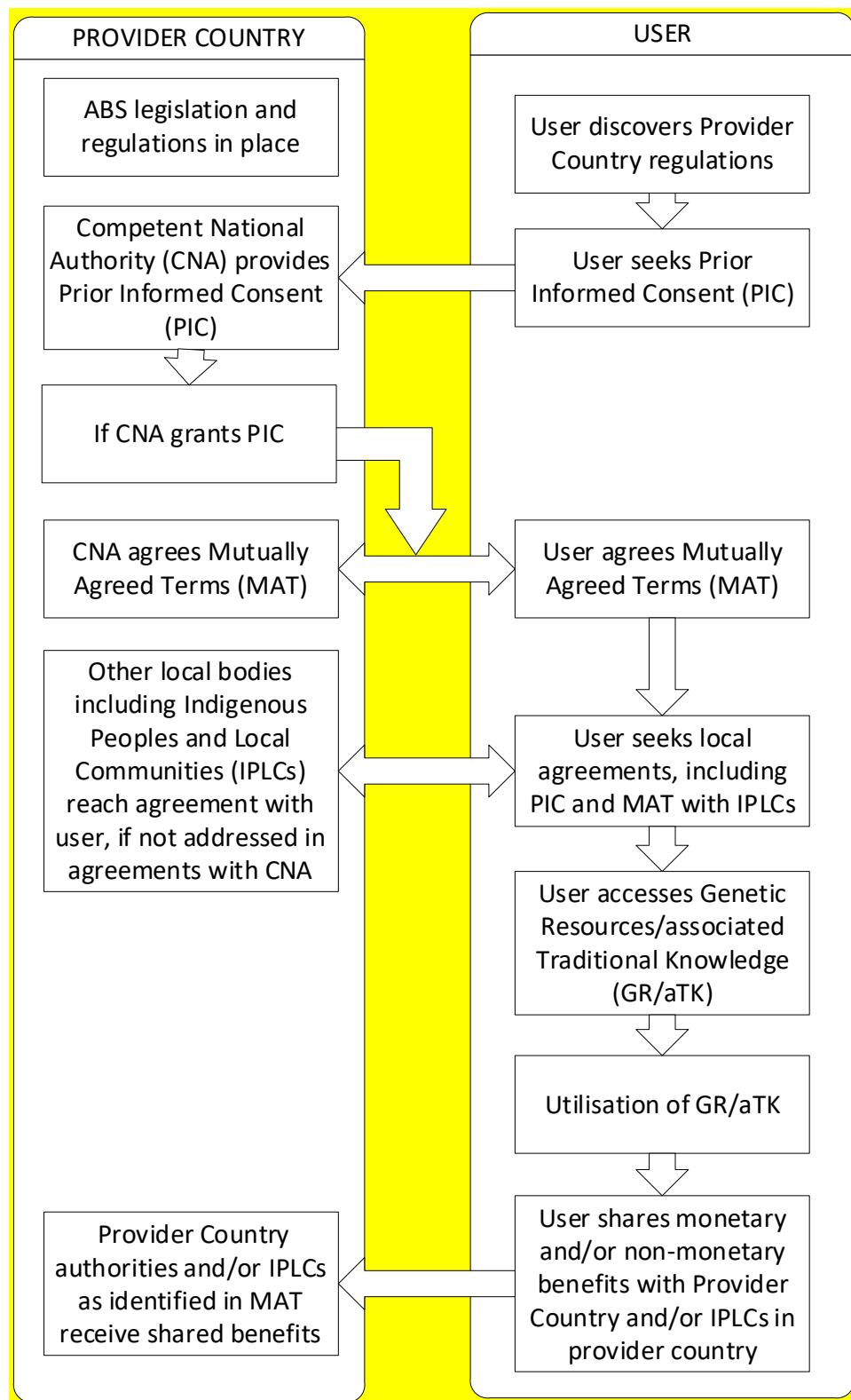


Figure 1. Simplified ABS process to obtain access and establish benefit-sharing agreements.

Note: Competent National Authorities (CNAs) are not obliged to grant Prior Informed Consent (PIC), and if PIC or Mutually Agreed Terms (MAT) cannot be agreed with CNAs, IPLCs, or other relevant bodies, access and utilisation may not proceed.

1.4. Compliance Measures – The Nagoya Protocol

Following the entry into force of the Convention on Biological Diversity (CBD), many countries adopted domestic Access and Benefit-Sharing (ABS) measures. These require users to obtain permission and agree on benefit-sharing terms (MAT) before accessing genetic resources. However, enforcing these obligations once resources were exported and used abroad proved difficult.

To address this, the Nagoya Protocol was adopted. It builds on the CBD by establishing a common framework for access and compliance and introduces specific obligations for monitoring the utilisation of genetic resources across borders.

Figure 2 illustrates the general ABS workflow as outlined in the Nagoya Protocol, yet national implementation varies considerably.

Under the Protocol, all Parties must take measures to:

-  Legal Access: Ensure genetic resources (GR) and associated traditional knowledge (aTK) are accessed legally (with Prior Informed Consent – PIC)
-  Contractual Terms: Confirm Mutually Agreed Terms (MAT) are in place
-  Benefit-Sharing: Share information with the provider when utilising GRs/aTK

The aim is to prevent the illegal use of resources and ensure fair benefit-sharing.

Compliance with ABS Laws of Non-Parties

Some countries that are not Parties to the **Nagoya Protocol** have enacted their own ABS legislation. Users, also within the EU, must comply with these national laws, when accessing or using genetic resources from these countries.

Utilisation

The **Nagoya Protocol** defines *utilisation* as:

“Conducting research and development on the genetic or biochemical composition of genetic resources.”

This definition is used in Article 3.5. of the **EU ABS Regulation**, as elaborated in the European Commission's guidance.

However, some **provider countries** may apply broader definitions, requiring benefit-sharing for a wider range of activities or narrower definitions.

Researchers must comply with the **domestic ABS legislation** of provider countries, regardless of narrower or broader definitions used elsewhere.

What if there is no ABS legislation in place in the provider country?

If ABS legislation does not exist in the provider country, or the country is in the process of adopting access legislations to their genetic resources, you are not required to comply with any access requirements.

However, it is advisable that you retain relevant information as a proof. This could for instance be in the form of a correspondence with the provider country authorities, and/or detailed sampling reports, with records of time and coordinates of collection.

Even when no access measures are in place, you might still need other permits and should seek information about these. Examples include sampling permits, for instance to collect specimens from a protected area, and import/export permits for endangered species under the CITES². None of these permits, however, fall under the ABS framework and these permits and the legislation that sets out the requirements will not be published on the ABS Clearing-House.

1.5. Monitoring Utilisation

Each Party to the Protocol must designate one or more “**checkpoints**” (e.g. research funding bodies, patent offices, academic publishers) to collect or receive relevant information from users. This includes:

- Whether Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT) were obtained,
- The type of utilisation taking place, and
- Any associated documentation.

Helpful Hints:

Signing of Agreements

Note that where a signature is required on a permit, PIC or MAT document that constitutes a contract the user's signature should be of someone with the right to do so. If you are acting on behalf of an organisation such as a museum, herbarium, gene bank or research body you should discover from the organisation who is empowered to have such representation rights. If you sign a contract on behalf of an organisation

² See Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) at www.cites.org

but without legal representation rights, the contract will not be valid, but you as signatory may incur liabilities in the provider country.

Transfer of MAT

When you source a genetic resource ex-situ and a MAT is present and the PIC applies to the R&D you plan to undertake, the benefit-sharing responsibilities as set out in the MAT may also transfer to you. It is therefore important to check if this is the case, whether you will be able to fulfil these benefit-sharing obligations if they do transfer and, if neither is the case, seek new MAT from the provider country.

This information is then transmitted to:

- The ABS Clearing-House (ABSCH), and
- The Competent National Authority (CNA) of the provider country.

The provider country can then verify whether the reported utilisation aligns with the granted permissions, and whether benefits have been shared as agreed. If the resource was accessed without proper consent, or benefits have not been provided, the provider country may take action.



Note: The exact way monitoring is implemented may vary between countries, depending on their national legislation and regulatory systems. See [Figure 2](#) for a general overview of the process.

While **Figure 2** illustrates the general ABS workflow as outlined in the Nagoya Protocol, national implementation varies considerably. Provider countries may use different terminology, may not refer explicitly to Prior Informed Consent (PIC) or Mutually Agreed Terms (MAT), and may combine or rename the steps - for example, using the term **Material Transfer Agreement (MTA)**. In some cases, access may be granted before MAT is negotiated, and countries may choose not to permit the export of certain genetic resources (GR).

 **Key point:** It is essential that users understand the **specific procedures, terminology, and legal requirements** in the provider country and respond accordingly.

Material Transfer Agreement

The use of a Material Transfer Agreement (MTA) is a well-established practice in the exchange of biological material among researchers and biological collections.

 **Don't get confused!**

MAT = contract between the provider country or provider of the genetic resource and a user seeking access to the genetic resource

MTA = contract between two entities, for instance gene banks or taxonomists, exchanging material stating the rights of each and setting conditions for transfer.

Scope of ABS Measures vs. Definitions of 'Utilisation'

Under the Nagoya Protocol:

The **Nagoya Protocol** applies only when genetic resources are "utilised", as defined in the Protocol - i.e. **research and development on the genetic or biochemical composition** of those resources.

However, under their **sovereign rights**, provider countries may adopt broader or narrower definitions of utilisation in their **domestic ABS legislation**. This means that ABS obligations may apply to additional activities, such as **morphological screening** or other types of analysis that do not involve genetic or biochemical research.

Under the EU ABS Regulation:

While users must **respect the provider country's broader and narrower definitions** and comply with its national ABS laws, for the purposes of compliance with the **EU ABS Regulation**, only the **EU definition of utilisation (Article 3.5)** - as clarified in the **Commission Guidance Document** - is applicable (see Section 2).

Article 3.5: '*utilisation of genetic resources*' means to conduct research and development on the genetic and/or biochemical composition of genetic resources,

including through the application of biotechnology as defined in Article 2 of the Convention.

 **Dual Compliance Risk:**

A user may be in compliance with the EU ABS Regulation (if the activities do not fall within the definition provided by Article 3.5 of the EU ABS Regulation) but may not be in compliance with the provider country's ABS legislation.

1.6. ABS Clearing-House (ABSCH)

To support the exchange of ABS information between countries and users, the CBD Secretariat established the Access and Benefit-Sharing Clearing-House (ABSCH).

In earlier sections, the ABSCH has been introduced as an information portal providing:

-  Lists of Parties to the Nagoya Protocol
-  National ABS legislation
-  Contact details for National Focal Points (NFPs) and Competent National Authorities (CNAs)
-  Official CBD documents and notifications

Another crucial function of the ABSCH is to serve as a repository of compliance-related documentation.

Internationally Recognized Certificate of Compliance (IRCC)

The **IRCC** is a permit (or equivalent) issued by a provider country and published on the ABSCH. Each IRCC includes a unique identifier and may contain:

-  Details of the provider country and its authority
-  The user and intended utilisation
-  Confirmation of PIC and MAT

 **Note:** Under Article 6.3(e) of the Nagoya Protocol, Parties that require PIC are expected to publish such permits on the ABSCH to establish an IRCC. However, this might not always be the case in practice.

The IRCC serves as evidence that genetic resources were accessed in accordance with ABS requirements.

Checkpoint Communiqué (CPC)

The **Checkpoint Communiqué (CPC)** is the corresponding document generated by the user country. It contains information on:

-  The utilisation of the genetic resource
-  The identity of the user
-  The link to the original permit (or IRCC, if available)

In the EU, this information is submitted via the **Due Diligence Declaration (DDD)**. If an IRCC exists, it should be referenced in the DDD.

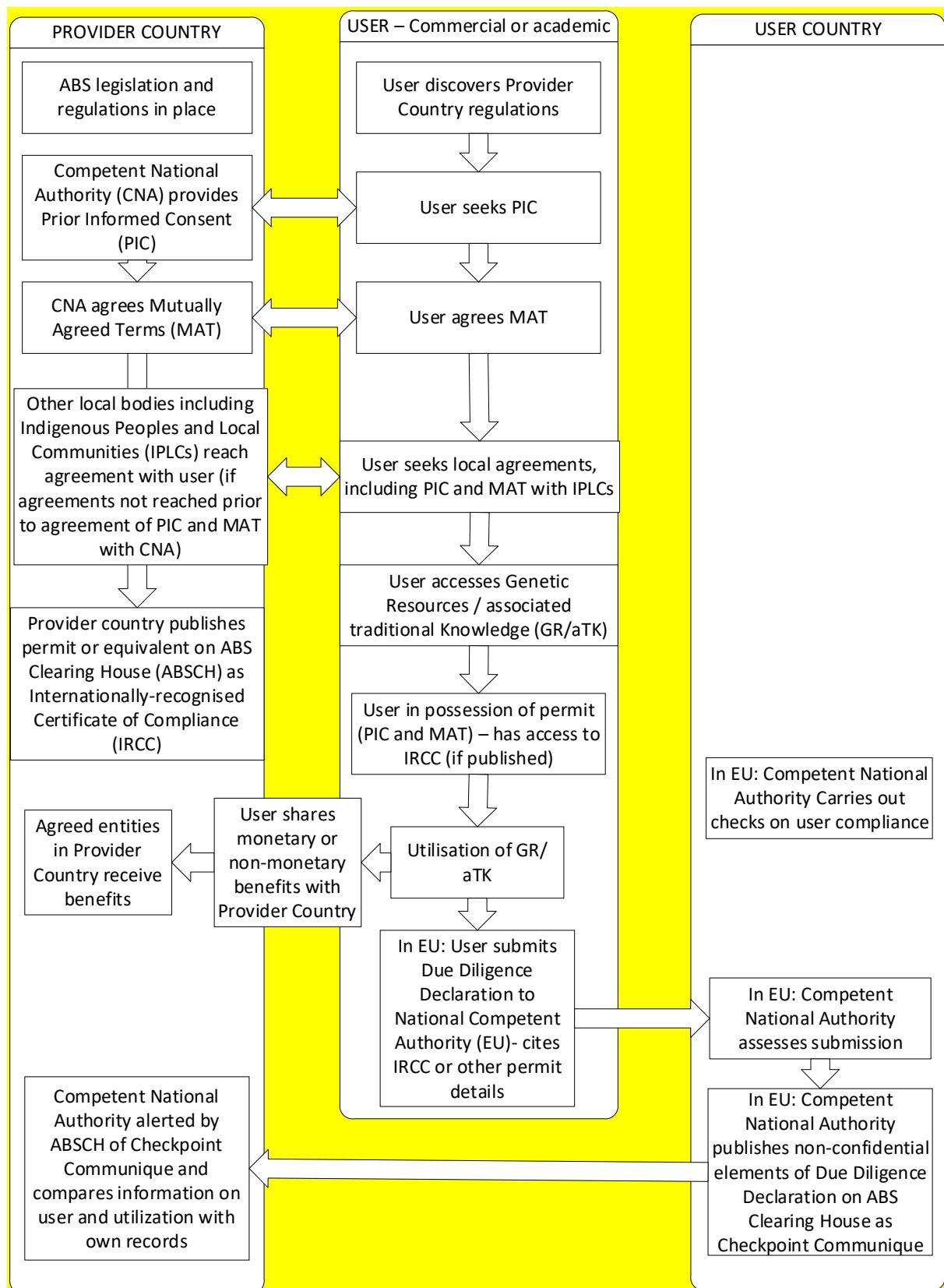


Figure 2. Overview of the ABS process, including compliance measures under the Nagoya Protocol. Terminology reflects usage in the Nagoya Protocol and the EU ABS Regulation.

2. How ABS compliance is ensured in the European Union

Within the European Union, compliance measures under the Nagoya Protocol are harmonised across the Member States through implementation of the EU ABS Regulation³, which entered into force on the same day as the Nagoya Protocol (12 October 2014), and the Commission Implementing Regulation⁴, which came into force on 9 November 2015.

This means that all users in the EU, including academic researchers, have to follow the same rules and legal interpretations of their activities regardless of where in the EU they conduct their R&D activities, and whether or not they are permanent residents or conducting research while visiting from other countries.



Due Diligence Concept

As an EU user accessing or utilizing genetic resources (GRs) or associated traditional knowledge (aTK), you must follow due diligence to ensure compliance with the EU ABS Regulation.

This includes:

- ✓ Seek, record, and share key information about the GR/aTK (e.g., origin, permits).
- ✓ Submit details in Due Diligence Declarations at required checkpoints.
- ✓ Keep records for 20 years after utilization ends.

For full details, see Chapter 2.2.

There may however be some differences in methods of reporting to national authorities and penalties for non-compliance, which vary across Member States.

The EU ABS Regulation is based on the Due Diligence Concept.

The scope of application of the EU ABS Regulation and core obligations of users are provided in the Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014, initially issued in 2016 and later replaced with a revised and extended version published by the European Commission in 2021⁵.

A detailed examination of the term 'utilisation' under the EU ABS Regulation is provided in the Guidance

³ Regulation (EU) No 511/2014 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

⁴ Commission Implementing Regulation as regards the register of collections, monitoring user compliance and best practices EU No 2015/1866 (October 2015)

⁵ Available at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.C_2021.013.01.0001.01.ENG&toc=OJ%3AC%3A2021%3A013%3ATOC

document of the Commission and under Chapter 2.1.4.

 **Note:** Even if an activity does not constitute 'utilisation' under the EU definition, it may still be subject to the provider country's ABS requirements.

2.1. What genetic resources and activities are covered by the EU ABS Regulation?

Does the EU ABS Regulation Apply to You? Yes, in case these 6 cumulative criteria are met:

-  Genetic Resources (GRs) (and associated traditional knowledge)
- Covered by the Nagoya Protocol
-  Accessed after 12th October 2014
-  From a Nagoya Protocol Party
-  With national ABS laws (provider country must have regulations)
-  Utilised within the EU
-  By a natural/legal person

All six conditions must apply simultaneously.

For more information:

- **Figure 3.** provides the illustration of a decision tree to assess whether research is in scope of the EU ABS Regulation.
- Detailed examples are in the EU Commission Guidance.
- Check the ABS Clearing-House or contact your national authority.

2.1.1. Material scope of the EU ABS Regulation

The EU Regulation applies to utilisation of genetic resources, traditional knowledge associated with genetic resources and, in some cases, '**derivatives**' (see below).

Exclusions from EU ABS Regulation

The Nagoya Protocol (and EU ABS Regulation) does not apply to:

-  Human genetic material⁶
-  Genetic resources from Areas Beyond National Jurisdiction⁷
-  Genetic resources under specialised ABS instruments – the EU recognises:
 - Plant genetic resources falling under the International Treaty on Plant Genetic Resources for Food and Agriculture – ITPGRFA⁸
 - Influenza strains falling under the Pandemic Influenza Preparedness (PIP)⁹ Framework of the World Health Organisation (WHO)

The examples below provide more information on the material scope of the EU ABS Regulation.

 *Example 1: Application of specialised ABS instrument and Research and Development on coconuts*

1a) Coconut plants are accessed from a Party to the Nagoya Protocol for research in the EU on possible cosmetic ingredients in their tissues. This is Research and Development and falls therefore within scope of the EU ABS Regulation.

1b) Coconut plants are accessed from a Party to the Nagoya Protocol for breeding experiments in the EU to produce yield. As it is being accessed and utilised for food and agriculture research, which means it is not within the scope of the EU ABS Regulation, but coconut is a crop listed in Annex 1 of the ITPGRFA. If the provider country is a Party to the ITPGRFA and a Standard Material Transfer Agreement (SMTA) has been concluded, the R&D falls outside the scope of the EU ABS Regulation but inside the scope of the ITPGRFA.

1c) Coconut plants are received under an SMTA from third persons or entities who themselves received them under an SMTA from the Multilateral System of the ITPGRFA. The R&D on these plant genetic resources for food and agriculture (PGRFA) falls outside of the scope of the EU ABS Regulation as well (section 5.2.1. of the EU Guidance document).

⁶ Note that genetic resources living inside the human body, such as the human microbiota and pathogens, are within the scope of the ABS framework. The only exception is if the microbiome is studied in entirety and *in situ* on or in the human body.

⁷ Genetic resources from Areas Beyond National Jurisdiction are within the scope of the new Agreement under the United Nations Convention on the Law of the Sea on the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction (BBNJ).

⁸ See FAO: <http://www.fao.org/plant-treaty/en/>

⁹ See WHO: <https://www.who.int/influenza/pip/en/>

Example 2: Human genetic resources

2a) Human blood samples acquired from a person residing in a country that is Party to the Nagoya Protocol are studied in the EU for protein structure and function. Since this concerns human genetic resources, the R&D falls outside the scope of the EU ABS Regulation.

2b) Human blood samples taken from diabetic patients in a country that is Party to the Nagoya Protocol are studied in the EU. The research is focussed on the effect of individual taxa from the microbiome within the blood in blocking insulin metabolism. Assuming the provider country exerts sovereign rights, this would be in scope of the EU ABS Regulation, since the research is on individual taxa of the microbiome, isolated from the microbiome of the patients; these are not considered human genetic resources (see Guidance document section 2.3.1.7).

2c) Pathogens from a person entering the EU from a country that is a Party to the Nagoya Protocol are being analysed. R&D on these pathogens in the EU is out of scope of the EU ABS Regulation, independently of the type of R&D that is done on these pathogens, because they were unintentionally introduced (see Guidance document section 2.3.1.5.). However, should a pathogen or pest become established in situ in an EU country, they fall under sovereign rights of the country where they are established and may fall under the scope of the EU ABS Regulation.

Derivatives Under EU ABS Regulation

According to Article 2 e) of the Nagoya Protocol, a derivative "means a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity."¹⁰

Examples of derivatives are proteins, enzymes and oils. However, the Nagoya Protocol does not go into any detail about how derivatives should be addressed in compliance measures.

The EU ABS Regulation applies to derivatives if:

- ✓ They are unmodified (naturally occurring).

¹⁰ Nagoya Protocol Article 2: "Derivative" means a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity.

- ✓ There ascertainable level of continuity between a derivative and the genetic resource from which it was obtained, e.g.:
 - Combined access (derivative + genetic resource) or
 - Mutually agreed terms (MAT) covering derivative R&D.

(See EU Guidance, Section 2.3.4 for case-by-case details.)

Traditional knowledge associated with genetic resources

The Nagoya Protocol also recognizes the rights of holders of Traditional knowledge associated with genetic resources (aTK).

Such aTK could for instance be the use of a plant for specific medicinal purposes by an indigenous community. An example is the use of the *Cinchona calisaya* tree by the Quechua tribes in the Amazon basin, which was later developed into the anti-malaria drug Quinine.

Consequently, in addition to an ethical duty to obtain prior informed consent from and share benefits with the relevant indigenous peoples and local communities this may be a legal obligation within the national ABS legislation.

However, individual provider countries may have different concepts, and these must be followed when seeking access permissions.

Traditional knowledge associated with genetic resources (aTK)

The EU ABS Regulation defines it as '*traditional knowledge held by an indigenous or local community that is relevant for utilisation of the genetic resources and that is as such described in the mutually agreed terms applying to the utilisation of genetic resources*' (Article 3(7) of the Regulation).

For aTK to fall under the EU ABS Regulation, it must:

- Relate to the utilization of genetic resources.
- Be covered by contractual agreements (e.g., MAT).



Helpful Hint: Always verify national definitions to avoid compliance gaps!

Commodities associated with genetic resources

A genetic resource may be sourced as a commodity, for example in a grocery or pet shop. Commodities are not covered by the Nagoya Protocol for their 'designated' use. However, if the use changes to R&D, then this comes within scope of the EU ABS Regulation, and the researcher should approach the provider country and seek to

negotiate appropriate permission and terms. If PIC and MAT cannot be obtained, utilisation should not take place.

 *Example 3: Genetic resources acquired as a commodity*

A researcher purchases a frozen tilapia in a supermarket, eats some, but uses the uncooked parts to investigate the genetic basis of peptides in the collagen. Eating is not in scope of the EU ABS Regulation, but the investigation would be in scope of the EU ABS Regulation if the fish was sourced from a Party to the Nagoya Protocol. Consequently, the researcher should seek the origin of the tilapia and determine whether the provider country is Party to the Nagoya Protocol. If it does, the researcher should seek PIC and MAT and, if these cannot be obtained, he should not utilise the tissues (Art. 4 of the EU ABS Regulation).

2.1.2. Temporal scope: Access on or after 12th October 2014

The EU ABS Regulation only applies to genetic resources and traditional knowledge associated with genetic resources which were accessed on or after 12th October 2014.

Note that if utilisation took place on or after 12th October 2014 but the actual access to the genetic resources took place prior to this date, e.g. by an *ex-situ* collection in the EU (see Example 3), no compliance obligations will apply under the Regulation.

There may, of course, be contractual obligations and obligations under the provider country legislation which should be met.

The requirements of provider country legislation may differ from the scope of the EU ABS Regulation. For example, the provider country may apply utilisation as the 'trigger point' for temporal scope of the Protocol (e.g. as Brazil does by defining 'access' as utilisation) and require benefit-sharing obligations on genetic resources initially accessed prior to 12th October 2014.

In this case, no compliance obligations under the EU ABS Regulation will apply. However, the researcher should comply with the ABS national laws of the country providing access to the resource.

 *Example 4: Date of access.*

4a) A researcher obtains a genetic resource from a collection in the EU in 2017. The genetic resource was accessed in a provider country (now a Party to the Nagoya Protocol) outside the EU prior to 12th October 2014. Utilisation of this genetic resource does not fall within scope of the EU ABS Regulation. However, there may be

contractual obligations (e.g. in the MAT) and obligations under the provider country legislation associated with the genetic resource when it was first accessed.

4b) In 2017, a researcher obtains a genetic resource from a collection in a country which is a Party to the Nagoya Protocol and brings it back to the EU for utilisation. Utilisation of this genetic resource does fall within scope of the EU ABS Regulation. The genetic resource was originally accessed and acquired by the collection in that provider country prior to 12th October 2014. The provider country's ABS regulations apply to all genetic resources collected in the country and held in collections within its borders, irrespective of when these were collected.

4c) A researcher obtains a genetic resource from a collection in a country which is a Party to the Nagoya Protocol in 2017 and brings it back to the EU for utilisation. The genetic resource was accessed and acquired by the collection prior to 12th October 2014 from a 3rd country which did not have ABS laws in place at that time. Since the genetic resource was legally accessed by the collection without ABS obligations, utilisation of this genetic resource does not fall within scope of the EU ABS Regulation.



Example 5: Mismatch between provider country and EU ABS regulations

A researcher obtains and utilises a genetic resource originally accessed in Brazil in 2012 but stored in a collection in the EU from that year. Brazil's ABS legislation uses the term 'access' as equivalent to 'utilisation' and requires notification and registration by the user at set points in the utilisation process. Even though Brazil is a Party to the Nagoya Protocol, the utilisation carried out in the EU is not in scope of the EU ABS Regulation as it was prior of the Nagoya Protocol. However, it is likely to be in scope of the Brazilian legislation. The researcher should comply with the Brazilian legislation.

2.1.3. Geographical scope

Genetic resources accessed from a Party to the Nagoya Protocol

The EU ABS Regulation only applies to genetic resources that were accessed from a provider country which was a Party to the Nagoya Protocol at the time of access. For the most up-to-date list of Nagoya Protocol Parties, consult the ABS Clearing-House.



Example 6: Genetic resources accessed from a country that is not a Party to the Nagoya Protocol.

Colombia (at the time of publication of this document) is not a Party to the Nagoya Protocol but has a national ABS law. Although Colombia has national ABS legislation, utilisation of genetic resources from Colombia is outside the scope of the EU ABS Regulation. Thus if, for instance, a leaf-cutter ant was accessed in Colombia to study its anti-microbial defence systems, the researcher has no compliance obligations under the EU ABS Regulation. However, the Colombian ABS legislation will apply, and the researcher will have to follow the procedures under this law prior to accessing the ants and will also have to abide by any benefit-sharing agreements with Colombia.

 *Example 7: Genetic resources accessed from a Party to the Nagoya Protocol*

Bhutan has been a Party to the Nagoya Protocol since 12 October 2014 and has adopted national ABS legislation. A researcher utilising orchids from Bhutan to study medicinal properties within the EU would be within the scope of the EU ABS Regulation, provided that the access happened after the entry into force of the Nagoya Protocol.

From a country which regulates ABS (and that is Party to the Protocol)

The EU ABS Regulation only applies to genetic resources that are subject to sovereign rights of a provider country that has national legislation or regulatory requirements on access and utilisation of these genetic resources at the time of access.

The Regulation will apply therefore to utilisation of genetic resources which are accessed directly from a provider country or acquired from a collection outside that country if the country was a Party to the Protocol and regulated access to genetic resources at the time of the original access to these samples.

 *Example 8: Genetic resources acquired from a collection*

A researcher acquires a genetic resource from a collection in an EU Member State. The resource was originally accessed in a provider country that was a Party to the Nagoya Protocol at the time and had applicable ABS regulations. Utilisation of the genetic resource is in scope of the EU ABS Regulation, and the researcher should check whether the genetic resource was collected legally, and whether the PIC and MAT associated with it allow its transfer and utilisation as planned. If not, the researcher should approach the provider country and seek to negotiate appropriate permission and terms. If PIC and MAT cannot be obtained, utilisation should not take place.

Some countries have decided not to regulate access to their genetic resources and thus have no access legislation. Others regulate only a selection of its genetic resources, for example wild genetic resources or genetic resources found in protected areas. Others may explicitly provide for an exemption for non-commercial use.

From a country which does not regulate ABS (and that is Party to the Protocol)

While the EU as a whole is a Party to the Nagoya Protocol, not all EU Member States regulate access to their genetic resources. Utilisation of unregulated genetic resources does not fall in scope of the EU ABS Regulation. Users may find it helpful to keep records of the checks they made to demonstrate the lack of applicable legislation at the time of access.

Example 9:

France has national ABS legislation in place, whereas Germany currently does not regulate access. Researchers accessing genetic resources in France must comply with French ABS laws, but any genetic resources accessed in Germany are not subject to access-related ABS obligations under EU law.

From a country that is not Party to the Protocol

Compliance with non-Party Member State laws is not enforced by the **EU ABS Regulation**. The EU's legal obligations only extend to Nagoya Protocol Parties. However, EU users might still need to comply with national ABS legislation in place. This means:

- The EU does not monitor or penalize non-compliance with ABS laws of non-Parties.
- Users must independently verify and follow the rules of the provider country (e.g., obtaining permits, benefit-sharing agreements).

2.1.4. Utilisation

Utilisation in the sense of the EU ABS Regulation, in line with the **definition** in the Nagoya Protocol.

Key Exclusions are:

- Acquisition, storage, or collection management.
- Taxonomic work without gene function analysis.
- Characterisation and use of GRs as tools (e.g., DNA barcoding).
- Pre-commercial/commercial activities (e.g., marketing, sales)

A case-by-case assessment is required. The Commission Guidance (Section 2.3.3 and Annex II) provides examples and detailed scenarios.

The EU ABS Regulation only applies to genetic resources which are utilised within the EU, i.e. within the territory of an EU Member State.

If R&D on a genetic resource takes place partly outside the EU and partly in a Member State, this still comes within scope of the EU ABS Regulation.

Some examples are provided below.

Utilisation

Under the EU ABS Regulation, Article 3.5 'utilisation of genetic resources' means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention.

Example 10: place of utilisation

A Hungarian research group collected spiders from Kenya in 2019. Kenya is a Party to the Nagoya Protocol with national ABS legislation, and the utilisation occurs within an EU Member State. If the researchers study whether the spider's poison can be used as a pain killer, this is considered utilisation of the genetic resource and is thus in scope of the EU ABS Regulation.

Example 11: joint research

A PhD student carries out research involving utilisation of genetic resources in India. The project is supported by a grant. The unpublished results are shared with the supervisor in the EU, who participates in the analysis and publication. If the student and supervisor are part of the same funded project, then the analysis in the EU - even if no GR are present - is in scope of the EU ABS Regulation. If the supervisor is merely advising and not carrying out any analysis, then this is not R&D and therefore not in scope of the EU ABS Regulation. Other researchers may participate informally by giving advice or as co-authors of scientific papers. However, if they are not part of the funded project, their activities are not in scope of the EU ABS Regulation.

Utilisation by a natural or legal person

The EU ABS Regulation applies to all users, including all natural and legal persons who utilise genetic resources within the EU, irrespective of whether the utilisation is commercial or non-commercial.

The EU ABS Regulation hence applies to individual researchers, as well as research organisations, such as universities and other academic institutions, and to both private and public bodies. In all cases the researcher needs to ensure compliance, so institutions need to clearly define responsibilities regarding due diligence obligations within the organisation (see Section 3.5.1. of Guidance document).

If you are part of a project that takes place in several institutions or countries, the project coordinator may make a due diligence declaration on behalf of all the project partners. If this is agreed, this agreement should be documented at an early stage of the project to give clarity on responsibilities and ensure information is managed appropriately. It will also provide evidence to the competent authority if required.

R&D with Subcontractors/Service Providers

Research and development activities are frequently carried out by subcontractors or service providers. Some universities provide such services as well as making use of them. The activities carried out by service providers potentially fall in scope of the EU

ABS Regulation, and it is important that there is clarity on who has responsibility for compliance, the service provider or service requestor.

If the following four conditions are met and are explicitly set out in the service agreement, the service requestor has the obligation to comply with all obligations under the EU ABS Regulation related to the material provided to the service provider (see Section 3.5.2. of the Guidance document):

1. Limited Scope of Work: the service provider can only perform tasks specifically described in the agreement. No independent R&D or exploitation rights on GRs or results are allowed.
2. Material & Data Management: the service provider must return or destroy all GRs and data post-service. If they are archiving copies, the service requestor must be notified.
3. No Rights Granted: the service provider has no rights to GRs or intellectual property from the work.
4. Confidentiality & No Transfer: the service provider is neither allowed to transfer the GRs/data with third parties or other countries nor to publish results without approval. They have an obligation to keep all information received and generated under the service agreement confidential

A clear contract is a way to clarify who has due diligence responsibilities, including the responsibility to submit a due diligence declaration; the Commission Guidance Document provides the necessary provisions in such a contract in its section 3.5.2. This contract should be retained by both parties to recall responsibilities and provide evidence to the competent authority if required.

Transfer of genetic resources

Transfer of genetic resources between users is covered by the EU ABS Regulation (Article 4).

Whenever a genetic resource is transferred, for instance to a subsequent user, a research collaborator or a collection, this should be done in accordance with the content of the PIC and MAT. Note that transfer of a genetic resource is sometimes explicitly forbidden in the PIC or MAT. Permission to transfer needs to be sought from the Competent National Authority of the provider country.

In addition, the first user (or their organisation, depending on how responsibilities are arranged) is obliged to provide the subsequent user with all relevant ABS permits, contracts and information. Users should transfer the relevant ABS documentation even if the subsequent user does not explicitly ask for them.

A helpful tool to facilitate transfer of information is a Material Transfer Agreement (MTA). The MTA:

- Provides legal certainty by clearly defining the rights and obligations of both the sender and the receiver.
- Particularly important in the case of complex (scientific) consortia with multiple research entities involved from different countries.
- Should specify which party has to fulfil the benefit-sharing obligations.

You will also need to manage the provisions of the PIC and MAT, to ensure that all obligations are met and that the provisions are not infringed.

 **Helpful Hint:** Although not mandatory, it is advisable to include in or annex to the MTA the PIC and MAT of the genetic resource that is being exchanged (where applicable). This will help researchers providing genetic resources to other users to fulfil the transfer obligations under the EU ABS Regulation.

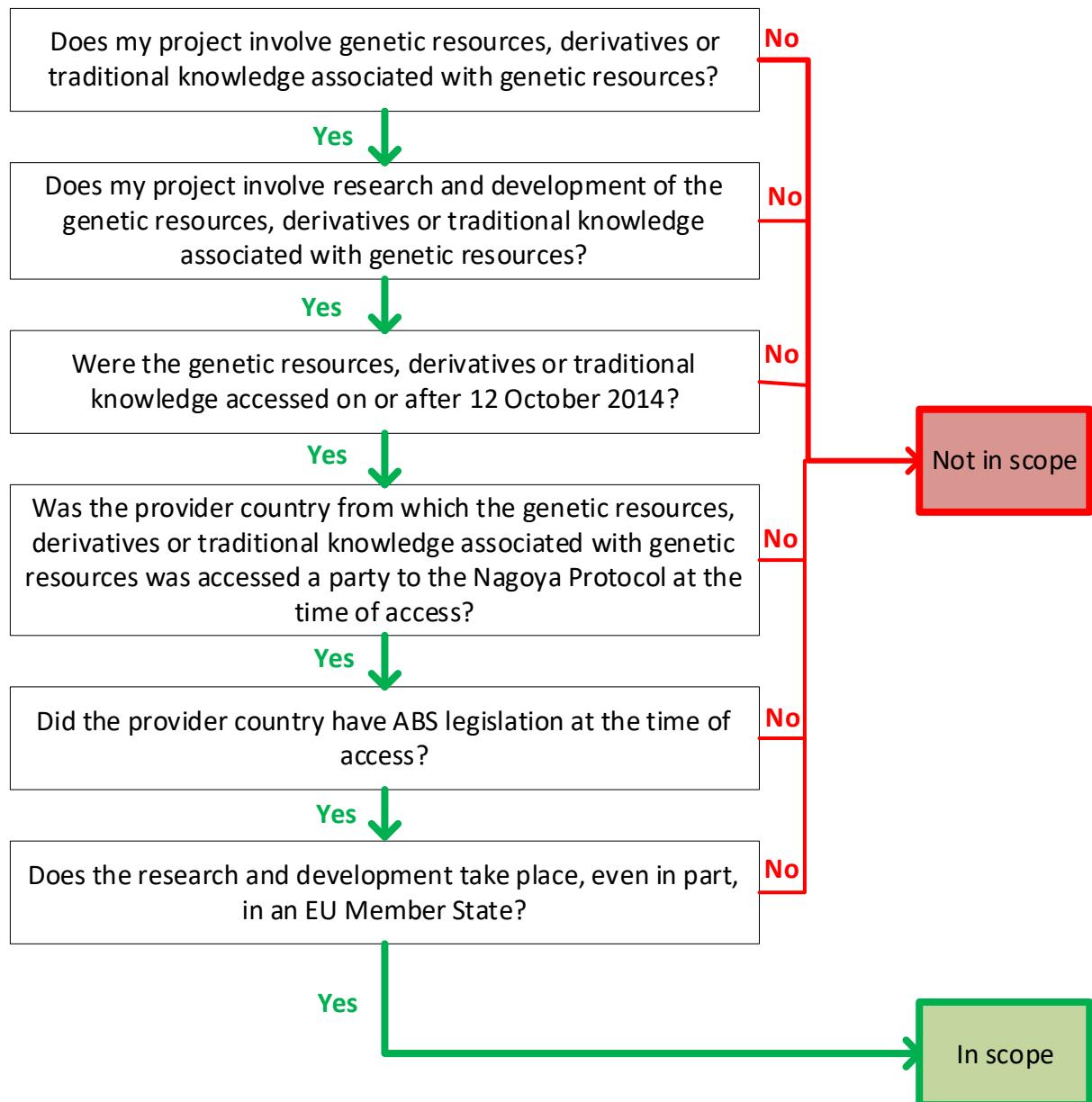
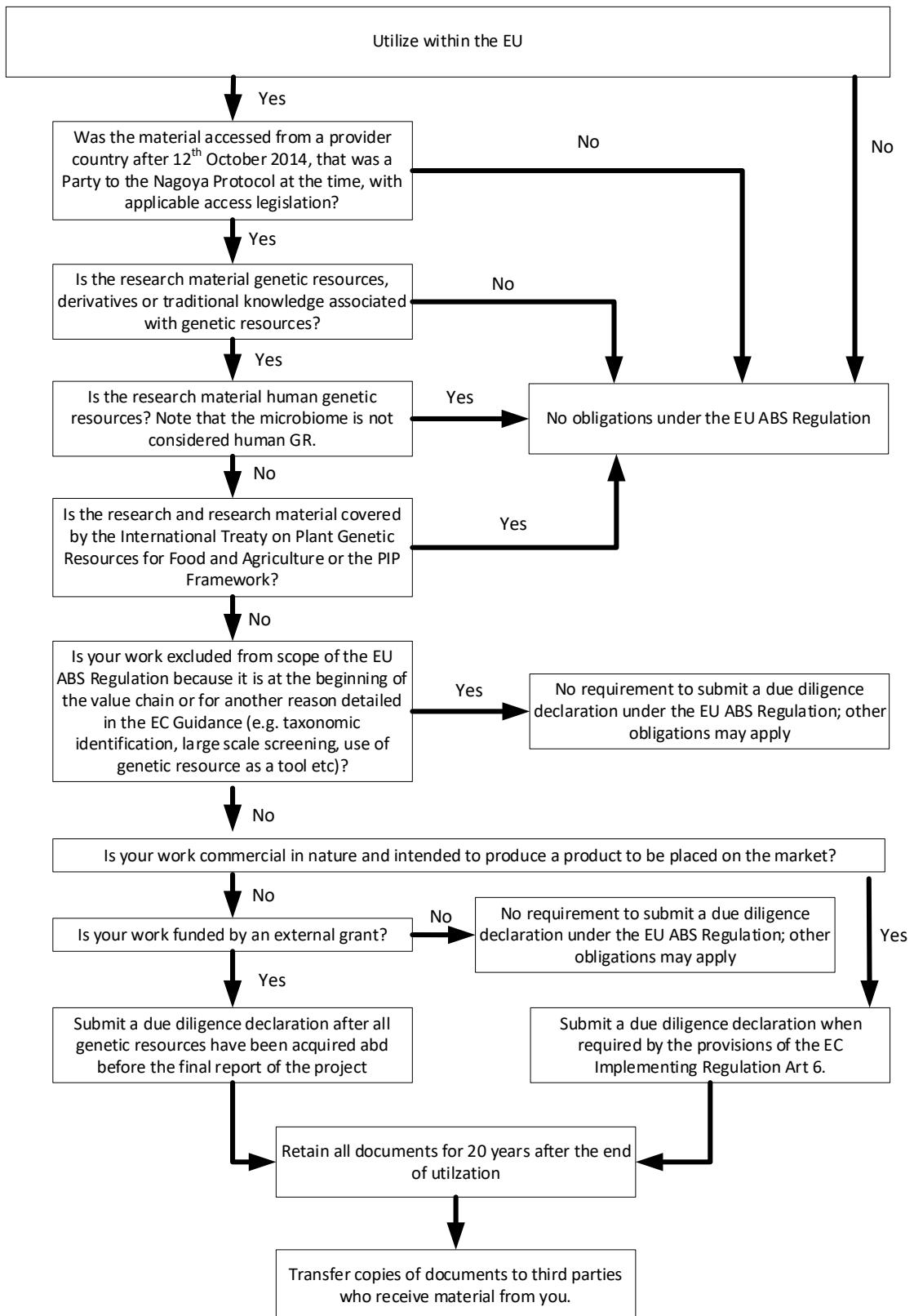


Figure 3. Decision tree to assess whether research is in scope of the EU ABS Regulation. See Guidance document section 2.3.3.1 for a discussion of the concept of Research and Development under the EU ABS Regulation.

Note: This assumes that appropriate steps to ensure legal access or acquisition and seeking information have been followed. If there is any doubt in this, stop utilization and seek the appropriate information and, if necessary, permissions.



2.2. How to comply as a researcher?

In order to facilitate the fulfilment of due diligence obligations under the EU ABS Regulation all information related to the sampling, utilization and transfer between users of the genetic resource should be collected and retained. Users (either individual researchers or institutions, see section 3.5.1. of the Guidance document) must exercise due diligence when obtaining, using and transferring genetic resources.

To document and support these obligations users are required to 1) seek, 2) keep and 3) transfer all relevant information and permits covering their utilisation of genetic resources.

Figure 4 provides a flow chart showing how to exercise due diligence as regards seeking information and **Chapter 7** provides a checklist of the information that needs to be collected for the declaration. Keeping this information and transferring it to subsequent users provides a means of obtaining a complete picture of the genetic resource's whereabouts and uses throughout the value chain. This will ultimately help you or others to complete your due diligence declaration(s) (see next sections).

2.2.1. Seeking of information and obtaining permits

If the genetic resource is to be accessed within a provider country for utilisation in the EU, the user should identify the relevant ABS laws and regulations and determine whether the country is a Party to the Nagoya Protocol. This information may be found on the ABS Clearing- House, or via contacting the national ABS National Focal Point/Competent National Authority of the country (contact details on the ABS Clearing-House). If required under national regulations, PIC should be sought from the relevant authority, and MAT agreed.

If the genetic resources are obtained from a collection or another third party outside the country of origin, the user should determine the provider country and request all permits and information from the entity or person providing the genetic resource, including a reference to the IRCC, if one has been created. These need to be evaluated to determine:

- 1) whether the information and documentation are complete and
- 2) whether the existing PIC and MAT allow transfer to a new user and
- 3) cover the intended R&D activities for which the genetic resource is being sourced.

If this is not the case, a new PIC will need to be obtained from the provider country and new MAT will need to be negotiated. The relevant Competent National Authority of that

country should be contacted (the contact details should be on the ABS Clearing-House).

 **Note** that the documents obtained will need to be kept for a period of 20 years after utilisation has finished; this is not only mandatory under the EU ABS Regulation.

Insufficient information

The EU ABS Regulation [Article 4(5)] states that: “When the information in their possession is insufficient or uncertainties about the legality of access and utilisation persist, users shall obtain an access permit or its equivalent and establish mutually agreed terms or discontinue utilisation”.

However, the Guidance document (section 3.2) specifies that: “If despite reasonable attempts to obtain an answer from the NFP there is none, the (potential) users need to decide for themselves whether or not to access or utilise the genetic resources in question. The necessary steps in order to establish the applicability of the EU ABS Regulation are then considered to have been undertaken”. Nevertheless, the user should be aware of their liability for any infringement of the provider country regulations and, should new information about the procedures to be taken become available, the user should seek to follow them. The user may find it helpful to document the attempts at communication with the NFP for use in any subsequent discussion with their national regulator.

The Guidance document (in section 3.3) also stipulates that “if the provider country cannot be identified despite best efforts to do so, utilisation may proceed, subject to the caveat that if new information is discovered that allows the country to be identified, the provisions of Article 4(5) need to be observed (section 3.3).”

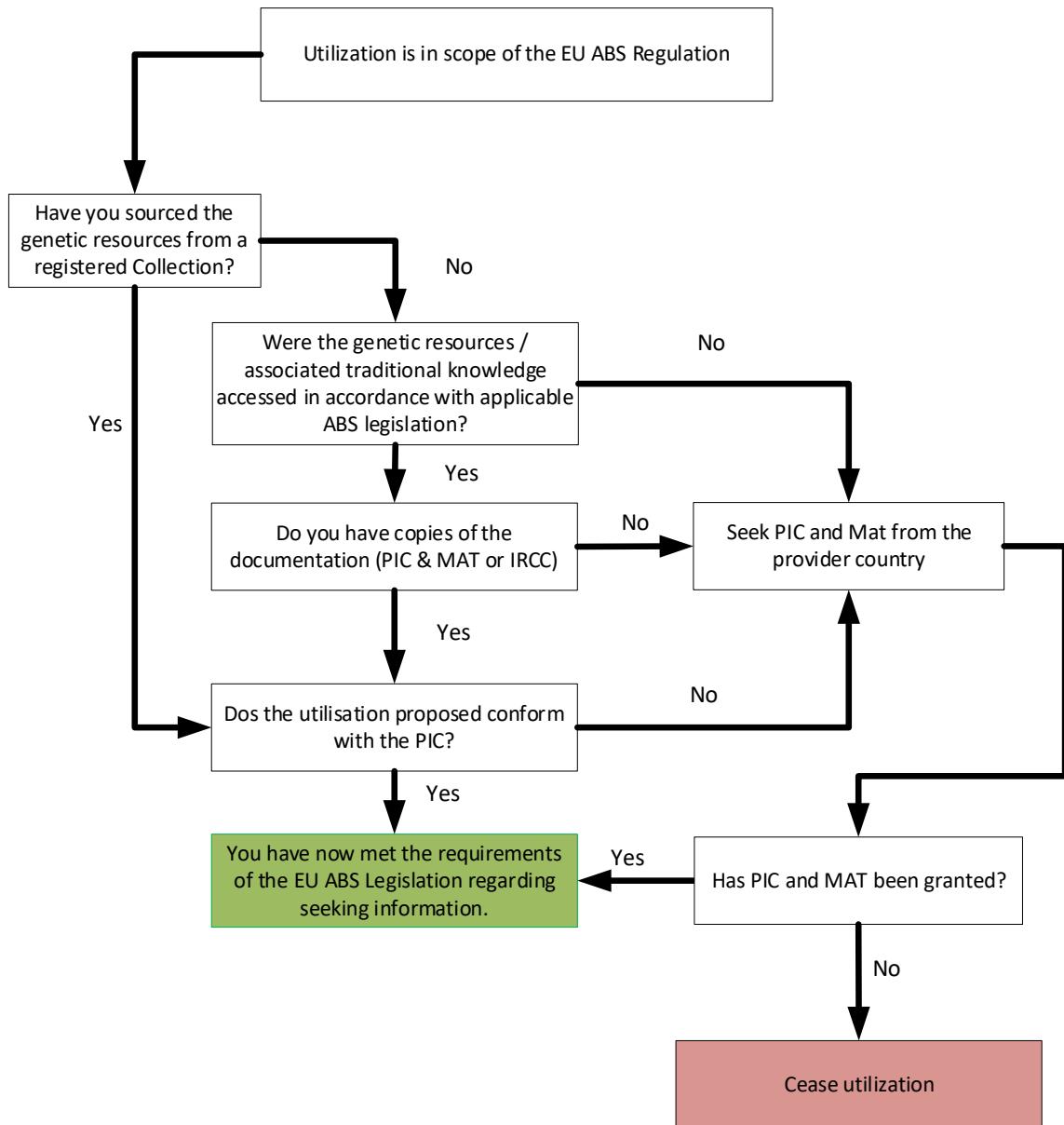


Figure 3. This assumes that appropriate steps to ensure legal access or acquisition and seeking information have been followed. If there is any doubt in this, stop utilization and seek the appropriate information and, if necessary, permissions.

2.2.2. Due Diligence Declaration

A further requirement for users of genetic resources in the EU is to submit a '**Due Diligence Declaration**', assuming conditions described below are met. These declarations are required at two stages of the research and development chain:

- at the stage of research funding, and

- b) at the stage of final development of a product.

For academic users, a declaration at the first stage will be the most common one. The second declaration is less common for academic researchers and will usually be done in a more commercial environment.

Declaration at the stage of Research Funding

A Due Diligence Declaration ...

- is required when utilisation is funded by a public or private grant (It is not required if the research and development is funded from internal organisational sources.)
- made after the first funding instalment has been received and after all the genetic resources for the project have been acquired (but at the latest at the end of the project, when the final report is submitted.)

This is the first checkpoint under the EU ABS Regulation and is set out in Art. 7(1) of that Regulation.



Note Some academic researchers find that the research can lead to a commercial product. At this point the researcher may transfer the result of utilization to another entity for further R&D to produce that product.

- If this is a simple transfer to the other entity that entity will be responsible for making a due diligence declaration at the end of product development.
- If, however, the first researcher offers the outcome of the research on the open market, this itself will trigger the need for such a declaration.
- If, the first research is involved in the further R&D (e.g., in a spin-off company), that researcher is likely to be responsible for the declaration.

This declaration will be made in the same way as the declaration at the stage of research funding.

At the stage of final development

A Due Diligence Declaration made only once, prior to the first of the five following events:

- i. market approval or authorisation is sought for a product developed via the utilization of genetic resources and traditional knowledge associated with genetic resources;

- ii. a notification required prior to placing for the first time on the Union market is made for a product developed via the utilization of genetic resources and traditional knowledge associated with genetic resources;
- iii. placing on the Union market for the first time a product developed via the utilization of genetic resources and traditional knowledge associated with genetic resources for which no market approval, authorisation or notification is required;
- iv. the result of the utilization is sold or transferred in any other way to a natural or legal person within the Union in order for that person to carry out one of the activities referred to in points (i), (ii) and (iii);
- v. the utilization in the Union has ended and its outcome is sold or transferred in any other way to a natural or legal person outside the Union.

The Commission Implementing Regulation¹¹ details how this point should be assessed in its Article 6, but it is broadly considered to be when a product is placed on the Union market, or when the product of utilization leaves the EU.

Submitting a Due Diligence Declaration

Due Diligence Declarations should be made available to the **Competent Authority (CA)**¹² of the EU Member State where the utilisation happens. If the utilisation happens in more than one Member State, only one due diligence declaration has to be submitted, to the CA of choice.

The up-to-date list of CAs in the EU Member States can be found on the EU ABS website¹³. Submission in Member States is made using the **DECLARE** tool described below.

 **Note:** In a research consortium in which different partners are involved, the project leader/coordinator can make the Due Diligence Declaration on behalf of the research consortium, even if the researchers are in different Member States

The declaration includes both information that will be published on the ABS Clearing-House in a Checkpoint Communiqué, and information that is for the use of the CA only

¹¹ Commission Implementing Regulation as regards the register of collections, monitoring user compliance and best practices EU No 2015/1866 (October 2015)

¹² 'Competent Authority' is the EU term for the 'Competent National Authority'.

¹³ EU ABS Website:

https://ec.europa.eu/environment/nature/biodiversity/international/abs/index_en.htm

List of CAs:

<https://ec.europa.eu/environment/nature/biodiversity/international/abs/pdf/For%20EUROPA%20%20Competent%20Authorities%20under%20the%20EU%20ABS%20Regulation.pdf>

and not published on the ABS Clearing-House. Subject to agreement, some of the submitted information can be kept confidential.

Chapter 7 provides a Checklist for the due diligence declaration under the EU ABS Regulation at the receipt of research funding.

The submitter is also required to make the following declarations:

"I declare that I will keep and transfer to subsequent user(s) a copy of the internationally recognised certificate of compliance as well as information on the content of the mutually agreed terms relevant for subsequent users", or "I declare that I am in possession of the following information, which I will keep and transfer to subsequent user(s): (a) date of access; (b) person or entity having granted prior informed consent, where applicable; (c) person or entity to whom prior informed consent was granted (where applicable), if not granted directly to me or my entity; (d) mutually agreed terms, where applicable; (e) the source from which I or my entity obtained the genetic resource and traditional knowledge associated with genetic resources; (f) presence or absence of rights and obligations relating to access and benefit-sharing, including rights and obligations regarding subsequent applications and commercialisation".

Using the DECLARE tool for Due Diligence Declarations

In most EU Member States, the Due Diligence Declaration can be electronically filed via the DECLARE tool, a guide to this system is available online¹⁴.

Prior to submitting a first declaration, the organisation of the user needs to register with DECLARE, using the same login as used for the EU Funding Portal. The DECLARE tool can be accessed here: <https://webgate.ec.europa.eu/declare/>.

The DECLARE tool guides the user through the submission process, following the structure set out in Annex II to the Commission Implementing Regulation. The system uses simple tick boxes, multiple choice questions and open question entry fields. The start screen is shown in Figure . A detailed instruction video can be found on the EU ABS website¹⁵.

While users are strongly advised to use DECLARE, a paper declaration can still be submitted to the CA of the country where the user operates.¹⁶.

¹⁴ User guide / Questions and answers – DECLARE NAGOYA IT system - <https://circabc.europa.eu/ui/group/3f466d71-92a7-49eb-9c63-6cb0fadf29dc/library/03ade20f-c623-4c96-a4fe-6d71408cb76e/details?download=true>

¹⁵ <https://audiovisual.ec.europa.eu/en/video/I-193088>

¹⁶ This is the case for Spain, for instance. In Spain, researchers are obliged to use the national system.



DECLARE
Data submission portal

Home Declarations ▾ My Organisation Register new organisation Genetic Resource User Administrator

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.

I declare that I have fulfilled the obligations under Article 4 of Regulation (EU) No 511/2014. * ⓘ

I am making this declaration for the utilisation of: *

Genetic resources
 Traditional knowledge associated with genetic resources

This declaration concerns *

Product
 Result of the utilisation ⓘ
 Outcome of the utilisation ⓘ

Figure 4. Start screen of DECLARE, as seen when a user is starting to make a Due Diligence Declaration

2.2.3. Keeping of information

The researcher must keep all records of ABS permits and information for 20 years after the end of utilisation of the genetic resource. This obligation to keep information, together with the obligation to transfer information, aims to ensure that the necessary information related to the genetic resource is available throughout the value chain in the EU.

Retaining information

In an academic setting, with often many short-term projects in which genetic resources are sourced and used, the obligation to keep records on the ABS status for 20 years after the end of utilisation, might prove to be a challenge.

Organisations such as universities and research institutions should therefore consider carefully how best to maintain a searchable archive, preferably digital.

3. Tools established by the EU ABS regulations to aid compliance

To support the due diligence system, the EU ABS Regulation provides the possibility of developing and using tools which facilitate compliance, namely *Best practices* and the *Register of collections within the Union*.

Best practices

Best practices can play an important role in identifying due diligence measures that are particularly suitable for achieving compliance with the Nagoya Protocol at an affordable cost and with a high level of legal certainty.

A best practice under Art 5 of the EU ABS Regulation can consist of procedures, tools or mechanisms which, when effectively implemented, help users of genetic resources to comply with the user obligations under the EU ABS Regulation.

Associations of users or interested parties can prepare a description of best practices they have developed and implemented and submit it to the European Commission to have it recognised as a best practice in accordance with the requirements of the EU ABS Regulation.

Recognised best practices can be found in an online register¹⁷.

Competent authorities of the Member States should consider that the implementation of a recognized best practice by a user reduces the risk of non-compliance and justifies a reduction in compliance checks.

Registered Collections

Collections can apply to the Competent Authority of the Member State where they are established to be recognized as a “registered collection”.

To obtain this status, a collection has to demonstrate:

- it applies standardized procedures for accepting, storing and supplying genetic resources and related information;
- its capacity to supply genetic resources to third parties with documentation providing evidence that the genetic resources have been accessed in accordance with applicable ABS legislation.

¹⁷ Register of accepted best practices: <https://circabc.europa.eu/ui/group/3f466d71-92a7-49eb-9c63-6cb0fadf29dc/library/734959ea-bd14-4843-88fd-773270c525bb/details?download=true>

The list of registered collections can be found online¹⁸.

Users obtaining a genetic resource from a registered collection shall be considered to have exercised due diligence regarding the seeking of information obligation under the EU ABS Regulation. This means that the user will not be expected to ('seek') the information listed in Article 4(3) of the Regulation, although they should check that the rights and obligations are applicable to their proposed utilisation.

The obligation to supply the genetic resources together with all the relevant information rests with the holder of the registered collection. However, the duty to keep and transfer this information rests with the user. The obligation also remains to make a Due Diligence Declaration when external funding is received and/or at the final stage of development of a product.

¹⁸ Register of accepted best practices: <https://circabc.europa.eu/ui/group/3f466d71-92a7-49eb-9c63-6cb0fadf29dc/library/734959ea-bd14-4843-88fd-773270c525bb/details?download=true>

4. Useful links

CBD ABS Clearing-House: <https://absch.cbd.int/>

CBD Nagoya Protocol website: <https://www.cbd.int/abs/>

Text of the Nagoya Protocol: <https://www.cbd.int/abs/text/> (in the six official UN languages)

European Commission website on ABS:

https://environment.ec.europa.eu/topics/nature-and-biodiversity/sharing-natures-genetic-resources_en

Text of EU ABS Regulation (in all 24 EU languages)

- Regulation (EU) 511/2014: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32014R0511>
- Commission Implementing regulation: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32015R1866>
- Commission Guidance document: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.C_2021.01.0001.01.ENG&oc=OJ%3AC%3A2021%3A013%3ATOC

DECLARE: <https://webgate.ec.europa.eu/declare/web/domain> (Log In required).

User Guide: <https://circabc.europa.eu/ui/group/3f466d71-92a7-49eb-9c63-6cb0fadf29dc/library/03ade20f-c623-4c96-a4fe-6d71408cb76e/details?download=true>

Competent Authorities of EU Member States:

<https://circabc.europa.eu/ui/group/3f466d71-92a7-49eb-9c63-6cb0fadf29dc/library/0694d830-f952-4e5b-8f75-afe888d12d3a/details?download=true>

Register of accepted best practices: <https://circabc.europa.eu/ui/group/3f466d71-92a7-49eb-9c63-6cb0fadf29dc/library/734959ea-bd14-4843-88fd-773270c525bb/details?download=true>

Register of registered collections: <https://circabc.europa.eu/ui/group/3f466d71-92a7-49eb-9c63-6cb0fadf29dc/library/929bd3de-3a8a-4a70-9835-9ce7b74b4fba/details?download=true>

5. Glossary, abbreviations and acronyms

ABS	See 'Access and Benefit-Sharing'.
ABSCH	See 'Access and Benefit-Sharing Clearing-House' (also known as 'ABS Clearing-House').
Access and Benefit-Sharing (ABS)	Term used to refer to the way in which genetic resources or traditional knowledge associated with such resources are accessed and how the benefits that result from the utilisation of such resources and are shared with the countries and/or indigenous peoples and local communities providing them.
Access and Benefit Sharing Clearing-House (ABSCH)	Global information portal on ABS under the Nagoya Protocol, maintained by the CBD Secretariat. It makes available National information submitted by Parties (ABS National Focal Point, Competent National Authorities, Checkpoints, ABS legislation, ABS procedures, National model contractual clauses, IRCCs, checkpoint communiques, national websites or databases). It also includes information published by the CBD Secretariat, and resources published by many stakeholders globally.
aTK	See 'Traditional knowledge associated with genetic resources'.
CA	See 'Competent Authority'.
CBD	See 'Convention on Biological Diversity'
Change of intent	Alteration of the intended use of a genetic resource from what was declared in application for access and agreed in MAT. If the proposed utilisation is not covered by the initial PIC, new PIC has to be obtained from the provider country prior to utilisation.
Checkpoints	General: Parties are to designate checkpoints along the value chain, that are to collect or receive information provided by users related to the utilisation of genetic resources. The information collected or received by the checkpoints is meant to inform and alert relevant authorities as to how their genetic resources are being used. The information collected or received at checkpoints is made available as a record on the ABS

Clearing-House called a Checkpoint Communiqué (CPC).

In EU: points along the value chain (from research to commercialisation) where Due Diligence Declarations should be submitted to a Competent Authority. These are at the stage of research funding (when research is funded by a grant, and after the first funding instalment has been received and after all the genetic resources for the project have been acquired, or at the latest at the end of the project, when the final report is submitted) and at the final stage of development of a product of utilisation.

Checkpoint Communiqué	Information collected by a Checkpoint (EU: by a Competent Authority at a checkpoint under the EU ABS Regulation in the form of a Due Diligence Declaration) and uploaded to the ABS Clearing-House. It appears in a standard format as a Checkpoint Communiqué. When it appears in the ABS Clearing-house, notification is automatically sent to the CNA that issued the permit or equivalent to the Competent Authority in the country of use and to the person or entity that was granted PIC.
CNA	See 'Competent National Authority'
Competent Authority (in EU)	Authority designated by EU Member States for the purpose of implementing the EU ABS Regulation.
Convention on Biological Diversity (CBD)	International legally binding agreement, adopted in 1992 and entering into force in December 1993. Its objectives are the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of the benefits arising from the utilisation of genetic resources.
Competent National Authority (CNA) (in Parties to the Nagoya Protocol)	Agency established by a country responsible for granting access to their genetic resources. They represent providers on a local or national level and can issue PIC and negotiate MAT. Within a country, other actors (e.g. IPLCs) may also have the rights to agree PIC and MAT in addition to the CNA. Within the EU the CNA is also responsible for monitoring utilisation within the Member State. Countries outside the EU may have other responsibilities assigned to the role.
Country of origin of genetic resources	The country which possesses those genetic resources in <i>in situ</i> conditions. (CBD Art 2). See also 'Country providing genetic resources' and 'Provider Country'

Country providing genetic resources	See 'Provider country'.
DDD	See 'Due Diligence Declaration'
DECLARE	Online tool developed by the European Commission to facilitate the filing of Due Diligence Declarations.
Derivative	The Nagoya Protocol defines this as "a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity".
Due Diligence Declaration (DDD)	Declaration made by the user of a genetic resource in the EU to its CA as part of the due diligence obligations.
Ex-situ genetic resources	Genetic resources found outside of their natural habitat, such as in collections, botanical gardens, zoos, gene banks and seed banks.
Genetic material	Term used in the CBD. It means any material of plant, animal, microbial or other origin containing functional units of heredity.
Genetic resources (GR)	Term used in the CBD. It means all genetic material of actual or potential value. Essentially, the term encompasses all living organisms (plants, animals and microbes) that carry genetic material potentially useful to humans. Genetic resources can be taken from the wild, domesticated or cultivated. They can be sourced from: natural environments (<i>in situ</i>) or human-made collections (<i>ex situ</i> ; e.g. botanical gardens, gene banks, seed banks and microbial culture collections).
GR	See 'Genetic resources'.
Indigenous peoples and local communities (IPLCs)	The CBD and the Nagoya Protocol do not define this term. It is left to the Parties of the Protocol to define this term in their implementing measures. In the context of the Nagoya Protocol, IPLCs are generally understood to encompass communities living in close relationship with nature and holding genetic resources and Traditional knowledge associated with genetic resources.

<i>In-situ</i> resources	genetic	Genetic resources found in ecosystems and in their natural habitat and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties.
Internationally Recognized Certificate of Compliance (IRCC)	of	Document on the ABS Clearing-House generated by the CNA of the providing country uploading the PIC or the access permit. The IRCC has a unique identifier and serves as evidence that PIC has been granted, and MAT has been signed.
IPLCs		See 'Indigenous peoples and local communities'.
IRCC		See 'Internationally Recognized Certificate of Compliance'.
MAT		See 'Mutually Agreed Terms'.
Material Transfer Agreement (MTA)		Contract between a sending and receiving entity when material is exchanged or deposited. The MTA typically contains the rights and obligations of both sender and receiver with respect to the research material. It may serve to inform the recipient of PIC and MAT associated with the material.
MTA		See 'Material Transfer Agreement'.
Mutually Agreed Terms (MAT)		Contractual agreement between the provider of genetic resources or traditional knowledge associated with genetic resources (in many cases public authorities of the provider country and/or indigenous communities in case of aTK) and a natural or legal person accessing the genetic resource and/or traditional knowledge associated with genetic resources for the utilisation thereof (a 'user'), on the conditions for access, utilisation and benefit-sharing. Note that MAT may be included in a variety of documents, not necessarily a separate 'Mutually Agreed Terms' document.
Nagoya Protocol (NP)		The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation to the Convention on Biological Diversity is an international legally binding agreement under the CBD which aims at sharing the benefits arising from the utilisation of genetic resources in a fair and equitable way. It entered into force on 12 October 2014.

National Focal Point (NFP) on ABS	Agency established by a country that can provide information on the national ABS legal framework, and all other relevant information related to the implementation of the ABS administrative, legislative and policy measures in the country.
NFP	See 'National ABS Focal Point'.
NP	See 'Nagoya Protocol'.
PIC	See 'Prior Informed Consent'.
Prior Informed Consent (PIC)	Permission given to a user by the Competent National Authority of a provider country to access a genetic resource. The term is also used in relation to the right of IPLCs to take a free and informed choice on whether they wish to give access to genetic resources or traditional knowledge associated with genetic resources. Parties to the Nagoya Protocol are obliged to include their IPLCs in the process of granting access to genetic resources and traditional knowledge associated with genetic resources. Note that PIC may be included in a variety of documents, not necessarily a separate 'Prior Informed Consent' document.
Provider (of genetic resource or aTK)	Entity that provides access to genetic resources or traditional knowledge associated with genetic resources, and who should be involved in negotiation of MAT with the user. It can be different from the Competent National Authority, e.g. an institute that has been delegated the competence to grant access, or in addition to the Competent National Authority, e.g. holders of aTK.
Provider country	The 'provider country' or 'country providing genetic resources' means the country supplying genetic resources collected from in-situ sources, including populations of both wild and domesticated species, or taken from ex-situ sources, which may or may not have originated in that country" (CBD Article 2). The provider country can either be "the country of origin of the genetic resources or ... any (other) country that has acquired the genetic resources in accordance with the Convention" (see section 1.2 of the Commission Guidance document and Articles 2 and 15 of the CBD).

Traditional knowledge associated with genetic resources (aTK)	Know-how, practices, skills and innovations related to genetic resources that is held by indigenous peoples and local communities. It can be found in a variety of contexts, such as scientific knowledge, agricultural knowledge, technical knowledge, ecological knowledge, medicinal knowledge, etc. The EU ABS Regulation defines the term as “traditional knowledge held by an indigenous or local community that is relevant for the utilisation of genetic resources and that is as such described in the mutually agreed terms applying to the utilisation of genetic resources (Article 3(7) of the Regulation)”.
Users of genetic resources	All actors, institutional and private entities, including individual researchers, both from public and private sectors, who utilise genetic resources.
Utilisation of genetic resources	The Nagoya Protocol defines this as conducting research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology.

6. Checklist for in situ sourcing of research material

Checklist	Actions
Necessary steps when accessing genetic resources and/or traditional knowledge associated with genetic resources	
<p>Check if the provider country is a party to the Nagoya Protocol.</p> <p><i>Note that this is important for compliance with the EU ABS Regulation, but even if the country is not a party to the Protocol, if it might have ABS legislation and you are still obliged to obey it.</i></p>	<ul style="list-style-type: none">Check the countries page on the ABS Clearing-House.
<p>Check if the provider country has legislation in place governing access to genetic resources and/or associated traditional knowledge and relevant for your intended research.</p>	<ul style="list-style-type: none">Check the countries page on the ABS Clearing HouseIf no information available: contact the ABS National Focal Point (NFP) of the provider country.Contact the ABS NFP and/or Competent National Authority (CNA) of the provider country to check if the information posted on ABSCH is up to date.Check if the genetic resources you want to access and the utilization you intend to perform are within scope of the ABS legislation of the provider country.If in doubt, describe your research plans to the CNA of the provider country and ask if PIC and MAT are required.

Checklist	Actions
<p>If the provider country has domestic ABS legislation in place, you should follow the necessary steps to respect the obligations deriving from such laws before accessing the genetic resources.</p> <p>These are usually to obtain a permit (PIC) and if required, negotiate and sign mutually agreed terms (MAT).</p> <p>These may be a single permit, or two different documents (PIC+MAT or equivalents).</p> <p>The content of MAT may vary from case to case, however some countries may have adopted or developed standard contractual clauses (especially in the case of research).</p>	<p>If required:</p> <ul style="list-style-type: none"> Initiate the formal request for access (e.g., seek a permit) from the CNA of the provider country. Negotiate benefit-sharing terms and conditions with the CNA and agree on other relevant aspects such as third-party transfer, or what happens with the samples after the utilization has been completed. Ensure all foreseen uses are included. Sign the Mutually Agreed Terms with the CNA of the provider country or/and provider of genetic resources with authority to establish MAT. <p>Or:</p> <ul style="list-style-type: none"> Register your access and utilization with the provider country if required by their legislation, or follow other procedures set out by provider country. Check if the country will be publishing an IRCC and, if so, record the unique number when it is published; download the form for your records. If the CNA plans to publish an IRCC, you should agree what information is to be published, as you may wish to keep some of it confidential. In addition, there may be other applicable (non-ABS) legislation, or bodies including indigenous peoples and local communities (IPLCs) who have rights to grant access. Appropriate permissions should be sought.

Checklist	Actions
<p>Keep all necessary records.</p> <p>The documents will serve as proof that the genetic resources have been legally accessed, and that you have agreed the conditions to share the benefits.</p> <p><i>If the country has required PIC and MAT, and is also a Party to the Nagoya Protocol, the information and documents will be necessary for you to demonstrate your compliance with the due diligence obligations under the EU ABS Regulation.</i></p>	<p>(a) the Internationally Recognised Certificate of Compliance, including its unique reference number,</p> <p>(b) where no Internationally Recognised Certificate of Compliance is available, information and relevant documents on:</p> <ul style="list-style-type: none"> i. access permits, where applicable; ii. the date and place of access of genetic resources or of traditional knowledge associated with genetic resources; iii. the description of the genetic resources or of traditional knowledge associated with genetic resources utilized; iv. the source from which the genetic resources or traditional knowledge associated with genetic resources were directly obtained, as well as subsequent users of genetic resources or traditional knowledge associated with genetic resources; v. the presence or absence of rights and obligations relating to access and benefit-sharing including rights and obligations regarding subsequent applications and commercialisation. <p>(c) mutually agreed terms, including benefit-sharing arrangements, where applicable.</p>
<p>Are you using Traditional Knowledge associated with the genetic resource (aTK)?</p>	<p>The same rules and procedures explained above (obtain a permit/PIC, negotiate a contract/MAT) will most likely apply. However, it is also possible that there will need to be separate negotiations with the communities where that knowledge is held (IPLCs) to obtain PIC and MAT. If so,:</p> <p>Identify the IPLC that holds the rights over the aTK. Request PIC from a representative of the IPLC. Negotiate benefit-sharing terms and conditions with the IPLC and formalize this in Mutually Agreed Terms.</p>
<p>Further recommendations</p>	
<p>Local partner(s).</p>	<p>Local partners could be asked to help obtain local information e.g., information regarding national or regional ABS laws. Local partners can also be helpful to overcome language and/or cultural barriers.</p> <p>In quite a few national ABS laws, it is an obligation to cooperate with a local partner when accessing and utilizing genetic resources. The local partner may be responsible for obtaining the necessary permits.</p>

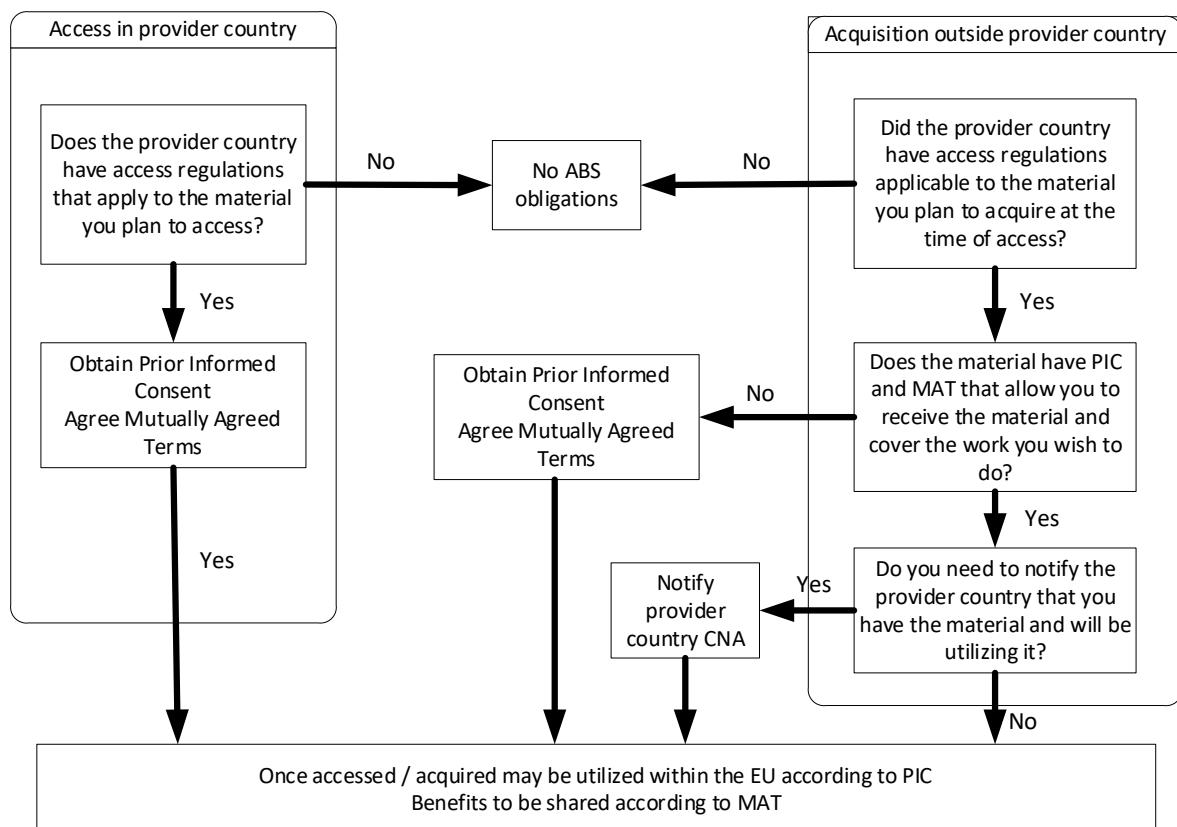
Checklist	Actions
Agreeing on benefit-sharing	<p>In order to formalise MAT, an agreement will have to be reached on benefit-sharing between the provider country representative, usually CNA, and the user. Depending on the provider country, benefit-sharing conditions may be fixed, or the result of a negotiation. In the latter case, the user should prepare for this negotiation, for instance by identifying possible forms of benefit-sharing that seem fair and equitable given the intended use.</p> <p>The annex of the Nagoya Protocol can serve as inspiration for different types of non-monetary and monetary benefit-sharing¹⁹.</p> <p>When negotiating MAT, make sure to not only set the type of benefit-sharing, but also other modalities, such as the timing of the benefit-sharing, and who the recipients will be.</p> <p>Be certain that the benefits agreed can realistically be delivered, and you have authority to agree on them!</p>

¹⁹ <https://www.cbd.int/abs/text/articles/?sec=abs-37>

7. Checklist for ex situ sourcing of research material

When a genetic resource is sourced from a third party (e.g., biological collection, intermediary) outside the provider country where it was originally accessed, for instance from a collection or a biorepository, you should check the ABS status of the genetic resource (see figure below).

If there is no PIC and MAT and this was required, or third-party transfer is not permitted, you should contact the provider country to obtain a new PIC and MAT.



Note: Genetic resources may be obtained as a commodity through wholesale or retail (e.g., in a market or shop). If you intend to carry out research and development on such genetic resources this is a change of use, and you will need to identify the provider country and seek PIC and MAT prior to utilizing, if applicable.

8. Checklist for Due Diligence Declaration under the EU ABS Regulation at the receipt of research funding

If your R&D is in scope of the EU ABS Regulation and is subject to external funding in the form of a grant you will need to **file a due diligence declaration with your Competent Authority** at the appropriate time. The declaration needs to be made after the first instalment of funding has been received and all the 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 a report, at the project's end). This is the first checkpoint under the EU ABS Regulation and is set out in Art. 7(1) of that Regulation. The table below gives the information you will need to submit.

Checklist of information needed for a due diligence declaration	
In all cases	contact details of all the recipients of the research funding if the source of research grant is public or private the Member State or Member States in which the utilization takes place or has taken place subject matter of research or identification of grant if the research is on genetic resources or on traditional knowledge associated with genetic resources
Where an IRCC is available	The unique identifier of the IRCC
Where no IRCC is available	place of access description of the genetic resources or traditional knowledge associated with the genetic resources identifier of the PIC or equivalent permit date of access * person or entity having granted prior informed consent (PIC), where applicable * person or entity to whom prior informed consent (PIC) was granted (where applicable) * mutually agreed terms (MAT), where applicable * the source from which you or your entity obtained the genetic resource * presence or absence of rights and obligations relating to access and benefit-sharing, including rights and obligations regarding subsequent applications and commercialisation *
When the genetic resource was obtained from a registered collection	The registration code of the collection

* These items do not need to be provided for the due diligence declaration. However, you must declare that you are in possession of these items and that you will keep them, or transfer them to subsequent user(s)

Getting in touch with the EU

In person

All over the European Union there are hundreds of Europe Direct centres. You can find the address of the centre nearest you online (european-union.europa.eu/contact-eu/meet-us_en).

On the phone or in writing

Europe Direct is a service that answers your questions about the European Union. You can contact this service:

- by freephone: 00 800 6 7 8 9 10 11 (certain operators may charge for these calls),
- at the following standard number: +32 22999696,
- via the following form: european-union.europa.eu/contact-eu/write-us_en.

Finding information about the EU

Online

Information about the European Union in all the official languages of the EU is available on the Europa website (european-union.europa.eu).

EU publications

You can view or order EU publications at op.europa.eu/en/publications. Multiple copies of free publications can be obtained by contacting Europe Direct or your local documentation centre (european-union.europa.eu/contact-eu/meet-us_en).

EU law and related documents

For access to legal information from the EU, including all EU law since 1951 in all the official language versions, go to EUR-Lex (eur-lex.europa.eu).

EU open data

The portal data.europa.eu provides access to open datasets from the EU institutions, bodies and agencies. These can be downloaded and reused for free, for both commercial and non-commercial purposes. The portal also provides access to a wealth of datasets from European countries.



Publications Office
of the European Union