Practical Guide to the EU ABS Regulation:

Compliance steps and case studies for forest genetic resources

OPTFORESTS

Multilevel BIODIVERSITY for RESILIENT forests in the face of climate change

Funded by the European Union

Cover photos: Adobe stock

Contents

1. Summary

1.1. Objectives

The objective of this milestone is to make the EU Access and Benefit Sharing (ABS) Regulation more accessible for researchers working with forest genetic resources. Specifically, this milestone aims to: (1) provide a clear, step-by-step guide to the key procedures that researchers must fulfil in order to comply with Regulation (EU) No 511/2014; (2) present concrete examples illustrating how the regulation applies or not to common research scenarios in forest genetics; and (3) deliver multimedia material (illustrations and videos) for two selected examples to further facilitate understanding and uptake of the guidance document.

1.2. Rationale

The Nagoya Protocol and its implementing instrument in EU law, the Regulation (EU) No 511/2014, establish binding obligations for all users of genetic resources conducting research and development in the European Union. Even though the regulation has been in force since 2014, compliance remains a significant challenge for many scientists, including in the field of forest genetics, where the line between regulated “utilisation” and non-regulated activities is often unclear.

Researchers working with forest genetic resources routinely collect plant material across national borders, exchange samples between institutions, and conduct genomic, physiological, or breeding research that may or may not constitute “utilisation” under the regulation. The legal complexity and the diversity of research contexts often lead scientists to be uncertain whether their activities fall within scope and, if so, which procedural steps they must follow. Not complying with the Regulation my lead to penalties, while being too cautious can limit legitimate scientific exchange.

Within the OptFORESTS project, Task 8.3 specifically addresses the need to translate the EU ABS Regulation into practical, researcher-friendly guidance. The present milestone responds directly to this need by combining a structured, step-by-step procedural guide with targeted examples drawn from real-world forest genetic research scenarios. The addition of multimedia materials (illustrations and videos) for two of these examples further assists the understanding, making the guidance accessible to a wide audience across partner countries and institutions.

1.3. Teams involved

EFI, LUKE, INRAE, GIS, BFW

2. Introduction

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS) to the Convention on Biological Diversity is a supplementary agreement to the Convention on Biological Diversity. It provides a transparent legal framework for the effective implementation of one of the three objectives of the CBD: the fair and equitable sharing of benefits arising out of the utilization of genetic resources.

The Nagoya Protocol on ABS was adopted on 29 October 2010 in Nagoya, Japan and entered into force on 12 October 2014. Its objective is the fair and equitable sharing of benefits arising from the utilization of genetic resources, thereby contributing to the conservation and sustainable use of biodiversity.

In Nagoya Protocol there are three core obligations for its contracting parties:

- Access obligations
- Benefit-sharing obligations
- Compliance obligations

The EU Access and Benefit Sharing (ABS) Regulation (Regulation (EU) No 511/2014) brings EU law into line with the compliance obligations of the Nagoya Protocol. The rules apply when genetic resources, or the traditional knowledge associated with them, are used in research and development (R&D) for their genetic properties and/or biochemical composition, including through the application of biotechnology. The ultimate objective is to ensure that benefits from using genetic resources in the EU are shared fairly and equitably with the country providing these resources.

To achieve this, the EU ABS Regulation requires users (e.g. researchers, breeders, companies) to ensure that any genetic resources they utilize in R&D were accessed in accordance with the provider country's ABS rules. In order to comply with EU ABS Regulation, the user should obtain necessary permits, keep records, and possibly report to the relevant competent authorities.

The following sections present a step-by-step guide to help researchers navigate the EU ABS compliance, from checking whether the regulation applies to their study, to record-keeping and due diligence declarations. The guide is complemented by eight examples specifically tailored to common scenarios in forest genetic resources research, illustrating situations where the regulation does and does not apply. For two of these examples, multimedia materials, containing an illustration and an accompanying explanatory video, have been developed to further support understanding.

3. Results

3.1. Determine if EU ABS Regulation applies

Not all use of genetic material fall under ABS rules. The user should evaluate each specific case according to the EU ABS Regulation's criteria:

1. **Material:** The material must involve genetic resources (plant material that contain genetic information), derivative or traditional knowledge associated with genetic resources
2. **Access date**: The genetic material, derivative or traditional knowledge associated with genetic resources must have been accessed after 12 October 2014, when the Nagoya Protocol entered into force.
3. **Location check:** The research must take place, even partially, in an EU member state.
4. **Nagoya protocol compliance:** The provider country must be a party to the Nagoya protocol
5. **Legislation checks:** The provider country must have an ABS legislation at the time of access
6. **Material's utilization:** The genetic material should be utilised, which means that the user should conduct R&D on the material's genetic and/or biochemical properties. For example, planting and growing tress without conducting R&D is not considered "utilization" under ABS.

If all the criteria hold true, the genetic material falls under ABS. In case it does not fall, the user should keep a written document (e.g. printouts or notes citing the ABS Clearing-House or legislation) explaining why the case is out of scope and retain it in their project files for at least 20 years in case of future audits.

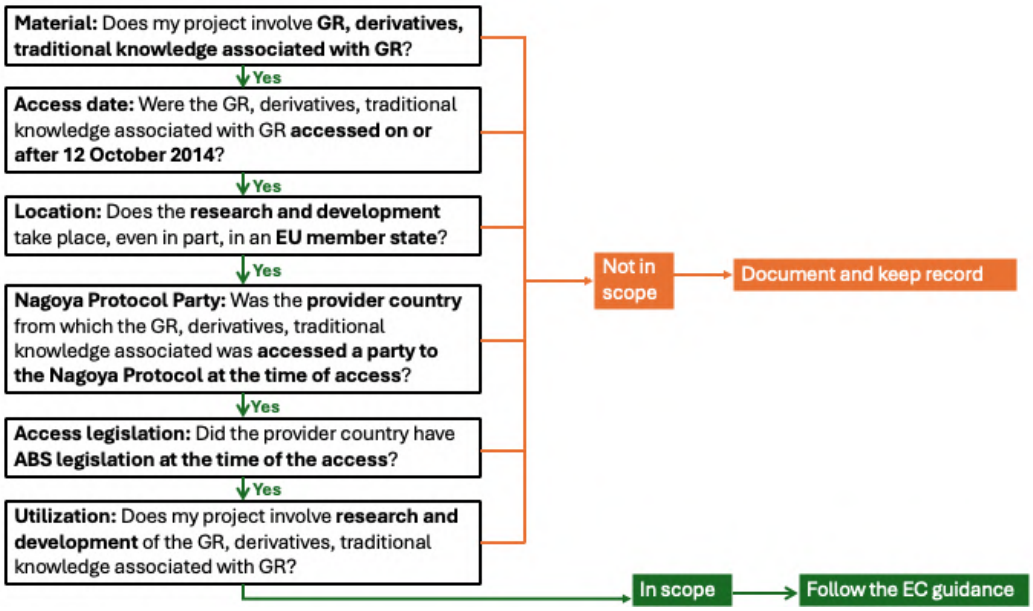


Figure 1. Flowchart showing the steps that a user should follow to determine if the project falls under the EU ABS regulation (adapted by Chris Lyal's, EC consultant, presentation)

3.2. A step-by-step guide towards EU ABS Regulation compliance

STEP 1: Identify the provider country and the relevant ABS requirements

If the genetic material falls under EU ABS compliance, the user should refer to its country of origin (where it was collected or sourced). The obligations depend on each provider country's ABS laws.

Within EU: If the material comes from another EU member state, the user should check if the country has national access measures under the Nagoya Protocol. EU member states can set their own access rules (Prior Inform Consent [PIC] and permit requirements) for genetic resources, derivative or traditional knowledge associated with genetic resources**. In case the provider country has no ABS laws,** formal PIC is not required, but the user should document this (e.g. an official statement or email from that country's ABS National Focal Point confirming no permit needed, or a printout of the country's ABS Clearing-House profile indicating "no ABS requirements") and keep a record**.**

Non-EU: If the material comes from outside the EU, the user should determine if that country is a Party to the Nagoya Protocol and whether it has ABS legislation in place. The user should check the ABS Clearing-House (ABSCH) website to find the country's profile and if the country has any declared legal requirements for access to genetic resources. Many countries require PIC from a designated national authority before the user can obtain samples, as well as a Mutually Agreed Terms (MAT) contract with the material provider. The ABSCH will usually provide the contact details of the National Focal Point (NFP) or Competent National Authority (CNA) who can clarify the procedure. If the country is not a Nagoya Protocol Party or has no ABS law, the procedure is the same as in an EU country with no requirements: the user should document this (e.g. an official statement or email from that country's ABS National Focal Point confirming no permit needed, or a printout of the country's ABS Clearing-House profile indicating "no ABS requirements") and keep a record.

STEP 2: Obtain necessary permits and agreements (PIC and MAT)

If the provider country's laws apply and require ABS measures, the user **must get permission** *before* acquiring or using the genetic material:

- **Contact the Competent Authority:** The provider country's ABS Competent Authority or National Focal Point should be contacted to apply for access, and they inform on the process and any application forms or any other permits needed. The user should provide information about the material (species, quantity, location), the intended use (research, breeding, etc.), and the institutions/people involved.
- **Prior Informed Consent (PIC)**: This is the formal permission from the provider country to access the genetic resources, derivative or traditional knowledge associated with genetic resources. The user should complete any application and obtain an **access permit** or PIC certificate from the authority, as required by that country's law. The permit will detail conditions for access and use.
- **Mutually Agreed Terms (MAT)**: This is a contract (or set of conditions) between the user and the provider (could be the government or an authorized provider) that sets out the **benefit-sharing** obligations and usage terms
- **Documentation:** When the provider country grants access, the user should receive official documentation: an access permit, or a PIC certificate, and/or a MAT

(contract or permit conditions). Many countries will also register the permit on the ABS Clearing-House, which generates an Internationally Recognized Certificate of Compliance (IRCC), which is a digital certificate of the permit. The user should retain copies of all permits, contracts, and correspondence of this documentation.

STEP 3: Comply with permit and begin utilization

After securing PIC and MAT (when required), the user can utilize the genetic material for research or breeding, but strictly adhere to the terms:

- **Allowed use:** The genetic material can only be used for the purposes and scope described in the permit request or MAT.
- **Sharing with third parties:** Transferring material to any third party is now allowed unless it was indicated in the MAT or if the user obtains additional consent or approval of the provider country to send the material to another collaborator. In the latter case the recipient must agree to the same MAT conditions under a new agreement.
- **Benefit-Sharing**: If the MAT requires benefit-sharing during the project (e.g. submitting annual reports, sharing data, or paying a fee), the user must fulfil those obligations and keep evidence of compliance with these terms (receipts, confirmation of report submissions, etc.).

STEP 4: Transfer or exchange genetic material to third parties (within EU)

If the user needs to send material to another institution or receive material from another collaborator, the ABS compliance should be maintained:

- **Providing material to others:** The user should pass on all relevant ABS information upon material sending. The recipient also becomes a “user” under the EU ABS Regulation and has the same obligations. Also, a new MTA should be established.
- **Receiving material from others:** The user should ask for the documentation of the material and perform due diligence on the material’s origin.

STEP 5: Maintain records and submit required declarations

The user has an ongoing obligation to demonstrate due diligence according to the EU ABS Regulation

- **Record keeping:** The user must keep all ABS-related documentation for 20 years after the end of the utilization of the genetic material (e.g. when the project or breeding programme is completed, or the final product is commercialised).
- **Due diligence declarations:** The user must formally declare their due diligence at certain checkpoints. (a) if the genetic material utilised in research receives external funding (e.g. EU Horizon project or national funding), the user must submit a declaration to their national ABS authority after the first funding instalment but before the final project report, (b) when a product based on genetic material reaches the final stages of development. These declarations are submitted through the European Commission’s online DECLARE portal (or via the user’s national authority)
- **National Compliance Checks:** Each EU Member State has designated Competent Authorities to enforce and guide compliance with the ABS Regulation. They may conduct inspections or ask the user to provide records.

Funded by the European Union

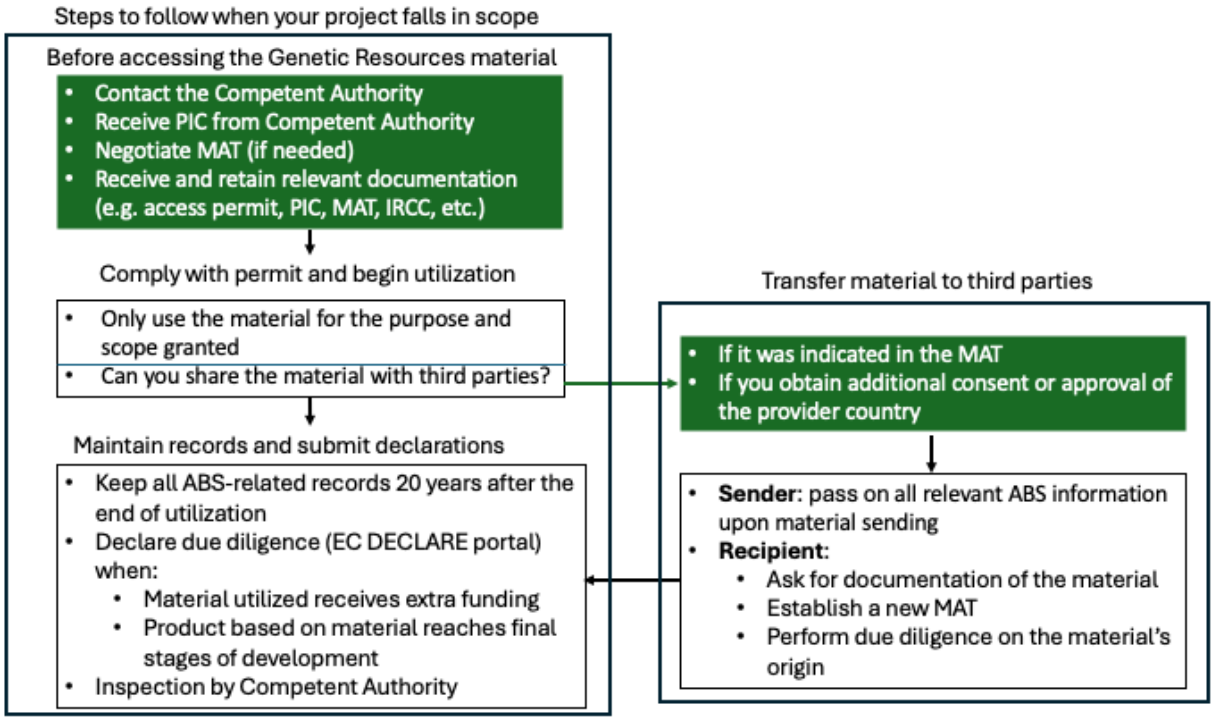


Figure 2. Flowchart with steps to be followed when a project falls in scope with the EU ABS Regulation

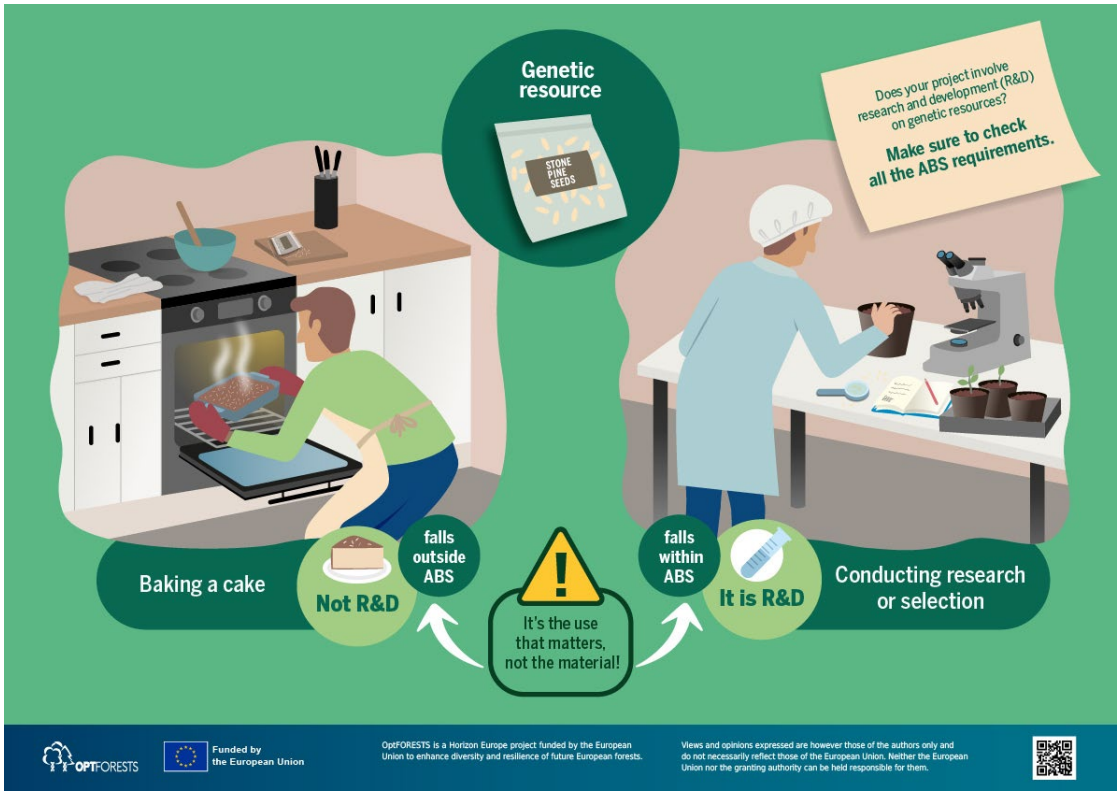
3.3. Examples

Example 1: It's about the use not about the material itself

Stone pine

Stone pine seed is a genetic resource. A researcher buys a package of seed and bakes a cake for their colleagues. Baking a cake and eating is not R&D and does not fall under EU ABS Regulation. However, next week the researcher buys the same product from a supermarket and starts growing plants for testing and further selection (for whatever trait). In this case the activity is R&D and the researcher needs to check the other conditions for being in the scope of the NP (starting from which country the seed was exported, if the provider country is a party to NP, does it regulate its GR etc).

> *Trade and exchange of genetic resources as commodities (such as agricultural, fisheries or forestry products – whether for direct consumption or as ingredients, e.g. in food and drink products) fall outside the scope of the Regulation.*
>
> *However, if and when research and development is carried out on genetic resources which originally entered the EU as commodities, the intended use has changed and such new use falls within the scope of the EU ABS Regulation (provided the other conditions for application of the Regulation are also met)*
>
> *(Source: EC Guidance Document on the EU ABS Regulation* 2021/C 13/01[1]*)*



The illustrated video is available in the OptFORESTS YouTube Channel: https://youtu.be/iV9wMEKszVs?si=r_vXVZ0UFlzTipsa

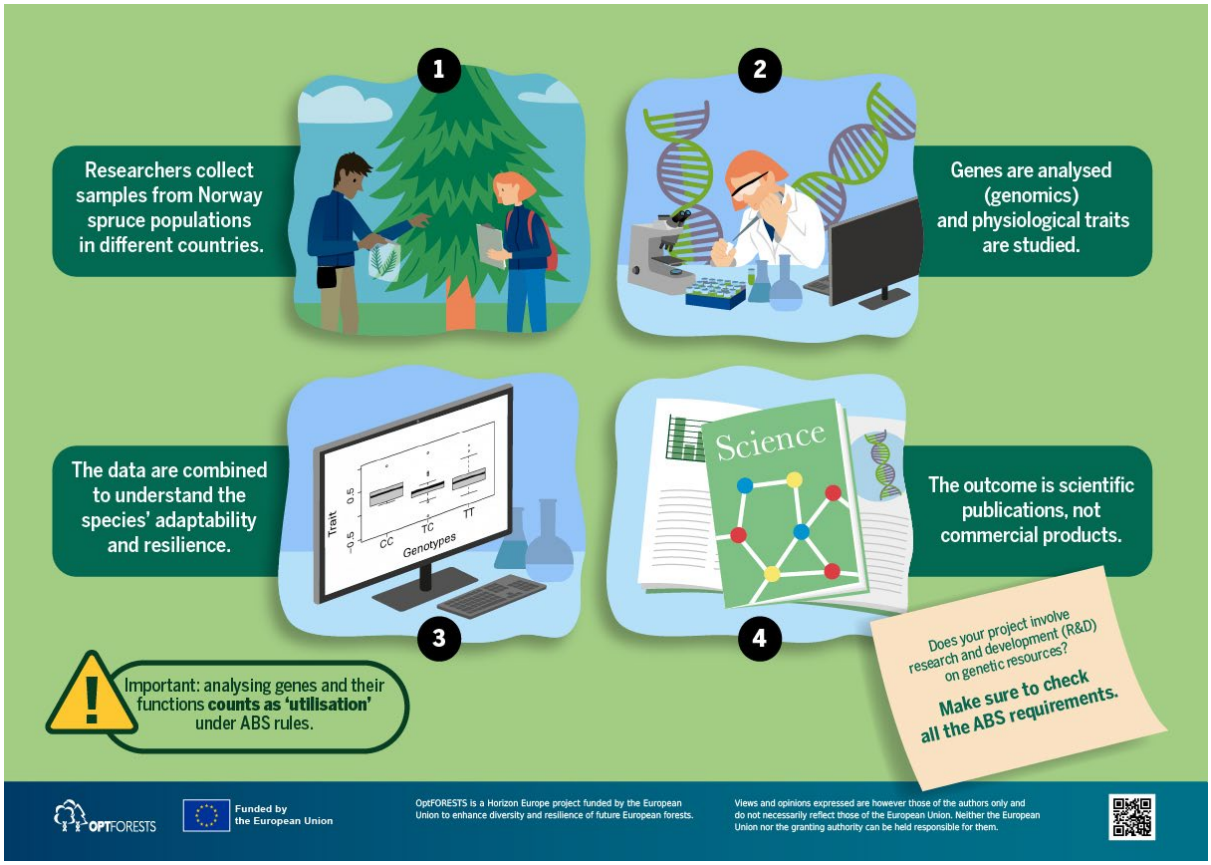
[1] European Commission (2021). Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union. 2021/C 13/01, pp. 1–68. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=oj:JOC_2021_013_R_0001

Example 2: Functions and genetic traits fall under EU ABS Regulation

Norway spruce

A research group is collecting samples from a range of spruce populations and making a genomic analysis. Another group in the same project is measuring hydraulic traits in the same populations. A third group is combining the datasets to create information on adaptability and resilience. Results are published in scientific journals. This type of research is not purely taxonomic and is considered utilization and therefore the researchers need to check if the countries where the sampling is done are parties to the Nagoya Protocol and if they regulate their genetic resources. This needs to be done before sampling and if the country so demands, a Prior Informed Consent needs to be acquired, and Mutually Agreed Terms need to be negotiated.

> ***(Public research) Research into the function of genes found in forest species without further development*** *Genetic and biochemical function within accessed genetic resources are investigated in the context of a research project, specific traits are identified, and their genetic background determined. Researchers involved do not consider future product development or commercial application of the results of their research. Their outputs are limited to the publication of the research results in scientific fora. Research activities that involve analysis of the genetic and/or biochemical composition of the genetic resources are considered utilisation. Hence, these activities fall in the scope of the EU ABS Regulation and researchers have to fulfil due diligence obligations, regardless of whether product development is intended or not.*
> *(Source: EC Guidance Document on the EU ABS Regulation* 2021/C 13/01*)*



The illustrated video is available in the OptFORESTS YouTube Channel: https://youtu.be/wnYLELMaOIo?si=vKt4b1KDgiyGfldL

Example 3: Taxonomy *per se* does not fall under the EU ABS Regulation

***Sorbus* spp.**

A group of scientists collect plant tissue of *Sorbus* spp. throughout Europe to propose a new taxonomic classification of the genus. They do morphological comparisons and DNA analysis, proposing a new classification. Since this type of research does not look into genetic properties (functionality), the study is not considered to be R&D and does not fall under the EU ABS-regulation. In case any other research will be conducted, the Nagoya Protocol status must be revised and if necessary, PIC obtained from the original providing country.

Example 4: Establishing a seed orchard/arboretum with material from a natural stand

Abies alba

A European research centre collects seeds from an outstanding *Abies alba* natural population from another European country to create a seed orchard. The research centre wants to commercialize the seed orchard's material. Because the material collected is either from a natural, non-registered stand or belongs to a category selected, and if the new seed orchard will belong to category qualified, it can be assumed that some improvement on natural material has happened during the process and the activity falls under the EU ABS Regulation.

Abies nebrodensis

A Research Centre established an arboretum from clonal seed of *Abies nebrodensis* created with grafted copies of all the genotypes from an original population. The aim was to promote panmixia, reducing the originally high levels of homozygosity, to produce for reintroduction into the native population, to conserve the original gene pool ex situ, and, with the resulting offspring, to create a dynamic population in a specially chosen site. There was no improvement on the natural material during the process and the activity does not fall under the EU ABS Regulation.

Example 5: Markers assisted selection falls under the EU ABS Regulation

A research group performs an analysis to associate a set of genes with specific traits in *Eucalyptus* sp. plantations. The results will be published in a scientific article. These activities are considered to be research and development on the genetic and/or biochemical composition of the genetic resource and hence to fall within the scope of the EU ABS Regulation.

> ***(Animal breeding) Characterisation of a genetic resource providing knowledge used in breeding*** *Private breeding companies and public research institutions are involved in genotypic and phenotypic characterisation for the purpose of understanding genetic variation within and between breeds and breeding lines. Molecular approaches include the analysis of genetic markers or (whole) genome sequence data. Phenotypic analysis may involve any performance recording as well as the use of biochemical and other measurement tools. Such activities may also be undertaken for the purpose and in the context of whole genome selection, which allows the prediction of breeding values on the basis of DNA information only. The generation of information obtained from genotyping, DNA sequence analysis, as well as phenotypic characterisation and subsequent analysis of these types of data, leads to increased knowledge on individual genetic resources through knowledge of traits and their associated genes and creates added value and potential benefits for the breeder. These activities are also central to whole genome selection strategies, as they allow an estimate of breeding value of every animal (genetic resource) and provide a sound basis for selection. These activities are considered to be research and development on the genetic and/or*

Funded by the European Union

biochemical composition of the genetic resource and hence to fall within the scope of the EU ABS Regulation. The fact that such activity is a standard activity does not preclude its qualification as one of the first steps in research and development. (Source: EC Guidance Document on the EU ABS Regulation 2021/C 13/01*)*

Example 6: Population genetic analysis without any information on traits falls out of EU ABS Regulation

A research group analyses natural populations of Aleppo pine and estimates the genetic distances between and within them using neutral markers. This provides information on the structure of the populations without any information on the traits. This case falls out of the EU ABS Regulation scope.

> ***Collection holders; Animal breeding) Diversity assessment between and within populations*** *A study is undertaken to estimate the genetic distance between breeds and the homogeneity within breeds. It can lead to recommendations for population management, but it does not characterize the genetic and or biochemical functions of genes within each breed. Analysis and description may not be of the whole organism. For example, in animal breeding DNA may be extracted from individual blood samples and genotyped with a public SNP chip to calculate genetic distances. This does not provide information on the phenotype or the performance (e.g. growth, reproduction, and productivity), because the SNP markers have been chosen on the basis of polymorphisms across breeds within the species. The genetic resources are used for classification and identification, but not for searching for a particular trait (genetic functional expression) of a breed correlated to one or more genes or selecting on that basis. Therefore, this is not utilisation in the meaning of the EU ABS Regulation.*
> *(Source: EC Guidance Document on the EU ABS Regulation* 2021/C 13/01*)*

Example 7: Thinking of transferring material? Clear MTAs (Material Transfer Agreements) are needed!

Populus nigra

Cloned material from national collections of 15 European countries is transferred and planted as collections in two European countries. The open-pollinated material produced is then moved to a country outside Europe and a new collection is established. Some individuals of the offspring of the new collection are selected to be included in a breeding programme. In such cases, an MTA (Material Transfer Agreement) should be issued in advance.

Example 8: Using seed orchard seed for further breeding does not fall under the EU ABS Regulation

* A breeder purchases seed orchard seed (from a country that is Party to NP and regulates its GR). The seed comes from a basic material that is listed in FOREMATIS under the category qualified. When the breeder uses this material in their breeding programme the activity is considered to be already bread material and equivalent to using a commercial variety. Therefore, no due diligence obligation applies and no due diligence declaration is needed even if the breeding activity itself is R&D

> *Whereas similarities exist between forest reproductive material and plant commercial varieties as both are defined under EU seed acquis (e.g. the exclusion of marketing restrictions), differences also occur. Given the fact that for the forest reproductive material category 'source-identified' no breeding and/or selection is involved, and for the category 'selected' only a limited degree of selection is employed, forest reproductive material falling under these two categories does not automatically represent a new genetic resource, substantially different from the original population. However, the*

other two categories of forest reproductive material, i.e. 'qualified' and 'tested' can be regarded as new genetic resources different from the ones from which they have been derived.

The cultivation, propagation and marketing of forest reproductive material is not covered by the EU ABS Regulation. However, if a breeder uses forest reproductive material of the categories 'source identified' or 'selected', and in case the material falls within the scope of the EU ABS Regulation, due diligence requirements apply if such material is used for further breeding. (Source: EC Guidance Document on the EU ABS Regulation 2021/C 13/01*)*

4. Conclusions

This milestone has produced a set of practical resources to support researchers working with forest genetic resources and beyond in understanding and complying with the EU ABS Regulation (Regulation (EU) No 511/2014), comprising a structured step-by-step guide and eight examples tailored to common forest genetics research scenarios. The examples demonstrate that the applicability of the regulation is highly context-dependent, based on factors such as the intended use of the material, the provider country's membership of the Nagoya Protocol, and the nature of the research conducted. For two of the examples, multimedia materials, an illustration and an accompanying video, have been developed to convey the key regulatory concepts in an accessible format. Taken together, these outputs contribute to ABS awareness and compliance capacity within the research community across the OptFORESTS consortium and beyond.

5. Annexes

GLOSSARY/DEFINITIONS

Genetic resource means genetic material of actual or potential value.

Genetic material means any material of plant, animal, microbial or other origin containing functional units of heredity. Any plant tissue type (seeds, cuttings, saplings, needles, leaves, etc.) is considered as genetic material.

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.

Traditional knowledge associated with genetic resources means 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.

Funded by the European Union

OPTFORESTS

Multilevel BIODIVERSITY for RESILIENT forests in the face of climate change

Funded by the European Union

This report is based on Milestone MS 13 ("Multimedia material for efficient implementation of ABS") of the OptFORESTS project (No. 101081774). It is intended for guidance purposes only and does not constitute legal advice.

The views expressed are those of the authors and do not necessarily reflect those of the European Union or the European Commission.

2026

Cover photos: Adobe stock