SEEK, KEEP & TRANSFER

A STEP-BY-STEP GUIDE TO ABS COMPLIANCE WHEN UTILIZING MARINE GENETIC RESOURCES

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This guide is delivered by the EBB (European Blue Biobank) project[11] with support of the European Marine Biological Resource Centre (EMBRC-ERIC) ABS Working-Group.

This guide is a to-do-list to assist public and private sector scientists conducting research using biological resources to ensure compliance with regards to Access & Benefit Sharing (ABS).

DISCLAIMER

The recommendations in this document in no way supersede official texts applied at the national level, in the European Union and/or internationally, such as those displayed on official platforms (national ABS websites, EU ABS web pages, ABS Clearing House site), neither does it substitute for the ABS policies, procedures and standards in place at the scientist's institute or company.

For further guidance, it is recommended that scientists seek dedicated ABS support from their organisation and/or from the ABS Competent National Authority for research in their country.

Research on marine biological resources also fall under complementary regulations, such as access to maritime territories, that will not be examined here.

[11] European Marine Biological Resource Centre Biobank – Financing programme: 2014 - 2020 INTERREG VB Atlantic Area- Grant Number: EAPA_501/2016.

YOU NEED TO KNOW

What is ABS? Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS) is the mechanism adopted by the Nagoya Protocol (NP) to the Convention for Biological Diversity (CBD), in force since 12 October 2014, under which signatory countries ensure that genetic resources used in research and development on their territory are lawfully accessed and that the country of origin can be awarded benefits for their utilization. ABS requires scientists, before conducting a project with genetic resources, to obtain access permits and negotiate an agreement from the country from which the resources originate and to keep track of their utilization.

ABS Simply explained:
https://www.youtube.com/watch?v=09zflWUIKTQ&list=PLFxz19cUN2XISQiFjv5K16u8wmDowHiET&index=7

Who is this guide for? Individual scientists from academia or the private sector conducting research on biochemical and/or genetic activities of genetic resources either in the European Union as they are bound by the EU ABS obligations, or outside the European Union, should they decide to implement ABS best practices. It complements recommendations for ABS best practices for institutions delivered in the EMBRC guide to ABS compliance (link provided at the end of the document).

What is ABS due diligence? Exercising due diligence is an integral part of conducting a project and managing risks. In ABS this means taking reasonable care to ensure that the genetic resources are legally accessed in accordance with applicable ABS legislation in the country of origin of the resource and that its utilization and supply (if applicable) is undertaken within agreed terms. Under Article 4 of the European Regulation 511/2014 (EU ABS Regulation), performing due diligence is an obligation for ABS compliance in the European Union. Due diligence implies seeking ABS information on the genetic resource to be utilized, obtaining permits, keeping ABS information pertaining to the genetic resource during and after utilization, and transferring this information to subsequent users. If the project is undertaken outside the EU, it is not impacted by EU ABS due diligence obligations. However, the project may decide to implement the due diligence obligations in place in the EU as good practice to contribute to facilitating the transfer of genetic resources worldwide and securing international research projects utilizing genetic resources.

Which resources are referred to in this guide? ABS covers access to and utilization of "genetic resources", defined as any material of plant, animal, microbial or other origin containing functional units of heredity of actual or potential value, including its derivatives, i.e. naturally occurring biochemical compounds[12]. ABS applies to genetic resources accessed within national jurisdiction, including maritime exclusive economic zones (EEZs) which can extend 350 nautical miles from the coastline. For the sake of clarity, simplification and legal certainty, the resources referred to in this guide are non-human biological material and natural compounds removed from their habitat and either

[12] From the definitions of the terms "genetic material", "genetic resources" and "biotechnology" in Art. 2 CBD, and "utilization of genetic resources" and "derivatives" in Art 2 NP.

obtained *in situ* (fieldwork), *ex situ* (via collections, resource centres, biobanks), or through a transfer of material (from colleagues or purchased).

A TO-DO-LIST FOR EXERCISING DUE DILIGENCE FOR ABS COMPLIANCE

Before starting a fundamental or applied research project involving resources, it is recommended to follow the following 6-step iterative process to answer the questions:

1. *Where do the resources used for my project come from?*
2. *Is my project impacted by ABS?*
3. *If so, where do I find information about ABS?*
4. *If required, how do I negotiate ABS permits?*
5. *How do I demonstrate ABS compliance?*
6. *How do I manage the ABS documentation?*

STEP 1. Check the resource ID => the ABS Necessary Information

Before obtaining resources to conduct your research activities, whether by fieldwork, via a collection, a biobank, a resource centre, or by transfer of material from a colleague, you must ensure that you are in possession of the following information:

The place and date of access:

Where and when was the GR originally sampled? The country and ideally exact location (including geographical coordinates) of the sample site, as well as sample date (at least month and year).

By whom? Name of the person(s) who collected the resource and the organisation they represent.

Its description:

What is the name of the resource? Ideally the scientific name (latin binomial), genus and species, but otherwise a common name (either specific to the organism or the general category of organism or type of sample).

The source from which the resource was directly obtained:

When and from whom was the resource obtained for the current research project? This applies if the resource is accessed via a third party (colleague, resource centre, etc.).

The presence or absence of rights and obligations relating to ABS:

Is there ABS documentation attached to the resource? Prior Informed Consent (PIC), Mutually Agreed Terms (MAT) and/or Internationally Recognized Certificate of Compliance (IRCC), or proof that reasonable efforts were made to obtain these (see Step 3).

If so, what are the conditions for subsequent utilization of the resource? The IRCC or the MAT (see STEP 6) provides the conditions of use agreed upon by the country of origin with the previous user

Other permits, contracts or conditions of use:

Are there other administrative permits attached to the resource? For example, national/regional/Marine Protected Area sampling permits, TRACES documentation, CITES permit.

Are there contracts attached to the utilization of the resource? For example, Material Transfer Agreement, Consortium Agreement, project contracts.

What are the contractual conditions of utilization?

This information is the minimum data requirement for conducting ABS due diligence and is essential to initiate the subsequent steps in this step-by-step guide. An IRCC contains all of this information.

ACTION

Collect and securely store data for any and all resources entering into your research project. If you coordinate the project, put in place an ABS management system (database and procedures) to monitor the exchange of resources within the project, ensuring that ABS necessary information is attached to each resource.

TIPS

Ensure acquisition of this ABS information in the very early stages of preparation of your research project since ABS negotiations, if required, may take time and hinder the course of your research activities.

If you obtain the genetic resources used in your project via a collection from the EU ABS register or from a collection with best practices of ABS management, the resource should be transferred to you with the ABS "necessary information".

STEP 2. Determine whether your project is subject to ABS

Considering the complexity of the ABS framework, the multiple layers of legal texts, and varying interpretation of terms such as *"genetic resources"* and "*utilization",* which depends on national laws, diagnosis of whether your project is subject to ABS may prove to be a challenge. In a nutshell, your project is impacted by ABS when resources are utilized "*to conduct research and development on the genetic and/or biochemical composition of genetic resources including through the application of biotechnology".* ABS may thus apply to both fundamental and applied research, particularly since countries, Parties and non-Parties to the Nagoya Protocol, may adopt national laws that complement and specify the scope of ABS on their own genetic resources (e.g., Digital Sequence Information), but if there is any doubt it is recommended to consider by default that your project is subject to ABS and hence proceed to the subsequent steps.

ACTION

Evaluate the activities conducted in your project and if the situation is unclear, contact the ABS support team in your institution, your legal contact person, or the ABS Competent National Authority for research in your own country for guidance.

STEP 3. Gather ABS information => the ABSCH and the ABS National Focal Point

If your project falls within the scope of ABS, a permit may be required before initiating the research activities. You can find out whether the country of origin of the resources you will use applies national ABS legislation via the Access and Benefit Sharing Clearing-House web site (ABSCH: www.absch.cbd.int) (Figure 1). ABSCH provides information on the NP status, national ABS legislation and the person to contact for information (ABS National Focal Point or Competent authority) for every country in the world. It also functions as a permanent repository of IRCCs (see Step 4).

If the country of origin of the resource used in your project is party to the NP, you must verify whether it has adopted national legislation concerning access to and use of its resources. This information should be available on the ABSCH site, but in all cases, it is recommended to contact the ABS National Focal Point of the country of origin of the resource before starting your research project to verify this information in case it is out of date on the ABSCH site.

If the country of origin has implemented national legislation, you will need to obtain the permit to access the resource (Prior Informed Consent - PIC) and negotiate the conditions of utilization and benefit sharing (Mutually Agreed Terms - MAT) (see Step 4).

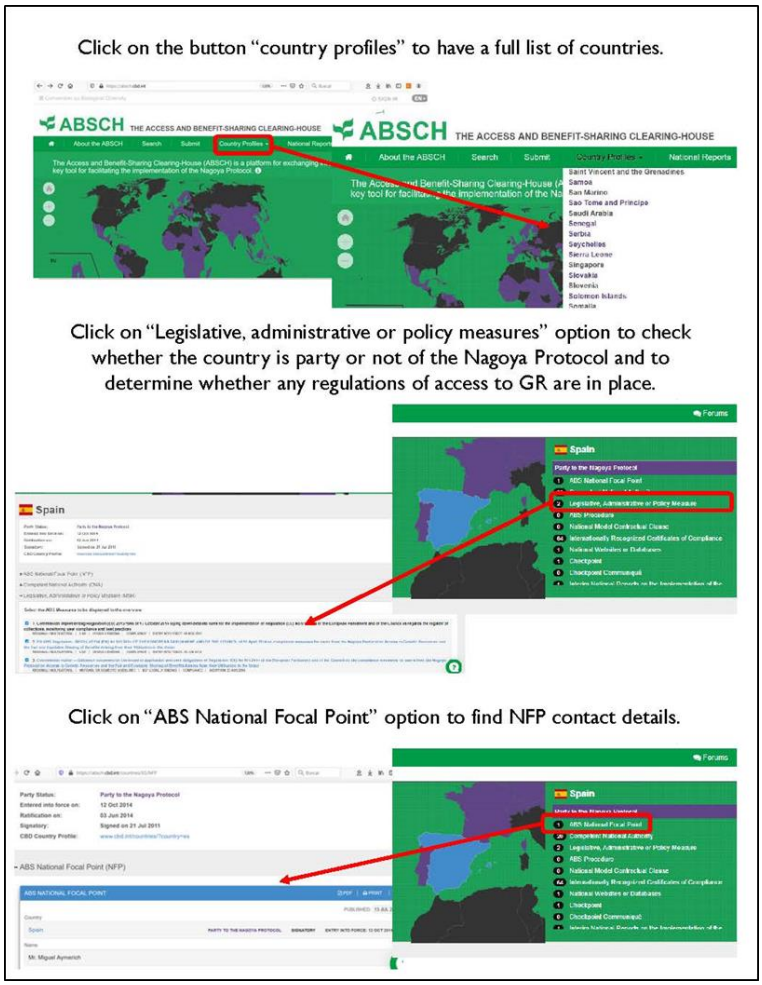


Figure 1. Where to find information: the ABS Clearing House.

ACTION

Write an e-mail to the ABS National Focal Point or Competent authority of the country of origin of the genetic resource you plan to use in order to present your project and ask whether it is necessary to obtain ABS permit (PIC) and negotiate benefit sharing (MAT) and if so, to obtain information about the procedure to do this.

TIPS

If the country is party to the NP and has ABS access legislation but your e-mails are left unanswered, it is recommended to resume this action three times and to cc. the ABS Competent National Authority (CNA) for research in your country at the third attempt.

Regardless of the NP status, it is wise to get in touch with the ABS National Focal Point of the country of origin of the genetic resource at the earliest possible stage of preparation of your project once Step 1 is completed in order to get confirmation of the actions to be undertaken, for the country may hinder your research activities and you may (also) abide by other national rules.

Ensure that you keep copies of all of the e-mails or other correspondence sent.

You may also rely on local partners or your ABS support team or ABS CNA to obtain information.

STEP 4. Negotiate ABS => the ABS PIC / MAT and the IRCC

If the country of origin of the resource confirms that your project falls within the scope of its ABS law, you need to enter into negotiation with its ABS NFP and/or CNA depending on the country.

Procedures vary from country to country, but you will usually be required to fill in a form, sometimes using an on-line platform, usually in English. For projects involving non-commercial use of resources, the ABS NFP and/or CNA generally examines the project and provides a permit (PIC) that may be accompanied by terms for non-monetary benefit sharing (MAT). Once you have received these documents (not before), you can start your project, meaning that you can go sampling or obtain your genetic resource. The procedure may differ for projects involving commercial use: the authorization to use the resource depends upon the negotiation of benefit-sharing mechanisms that are likely to be monetary, which may take a significantly longer time.

The ABS CNA of the country of origin of the resource should send permits to the ABSCH, which issues an IRCC. The IRCC number must subsequently be kept with the resource (see Steps 1, 5 and 6).

ACTION

Prepare a clear and concise description of your project, of the resource(s) using the list in Step 1 and including a summary of the expected outcomes and impacts of your project.

TIPS

You are likely to be able to obtain permits to access resources more easily if your project is conducted as part of collaboration with partners from the providing country. Such partnerships can be included in the MAT as a direct non-monetary benefit.

If you intend to deposit the resource in an open-access collection or biobank (which may also be considered as non-monetary benefit sharing), ensure that this is clearly stipulated in the MAT, which should be transferred to the collection/biobank along with the PIC upon deposit.

STEP 5. Declare ABS compliance => the Due Diligence checkpoints

A NP signatory country is expected to control that its national users comply with ABS. If your country is party to the NP, you will be required to demonstrate compliance at different instances identified as checkpoints, usually when requesting public funding, when filing a patent, or when putting a product on market.

In the EU, control of compliance takes the form of a declaration of due diligence which provides evidence that you have undertaken all of the necessary steps to ascertain the compliance of the resource used and that you hold the necessary documentation to conduct your research (IRCC or Step 1 list with Step 4 permits).

The 2 compulsory checkpoints in the EU are:

Checkpoint 1. Declaration at the stage of research funding: the DECLARE platform (https://webgate.ec.europa.eu/declare/) in funded projects or national platforms if required by your national funding agencies. Note that some countries may use other platforms.

Checkpoint 2. Declaration at the stage of final development of a product: DECLARE or national platforms.

Note that when some countries apply additional checkpoints, the declaration of due diligence is validated by the ABS CNA and transferred to relevant checkpoints.

For non-EU countries, ABS compliance control mechanisms (ABS checkpoints) are different.

ACTION

Contact your ABS support team, ABS CNA and/or funding agencies to get information on European and national platforms for ABS compliance control.

Declare due diligence once Steps 1 to 4 have been completed.

TIPS

Familiarise yourself with the ABS compliance control mechanism and the sanctions for non-compliance in your country.

STEP 6. Keep trace => ABS documentation management

In the EU, ABS compliance documentation (IRCC or Step 1 list with Step 4 permits) must be kept for 20 years after the last utilisation and transferred to any subsequent users.

It is recommended to develop an ABS documentation management system (spreadsheet or database) that contains all ABS necessary information for each genetic resource used in the project, including for those not impacted by ABS at the time of utilization.

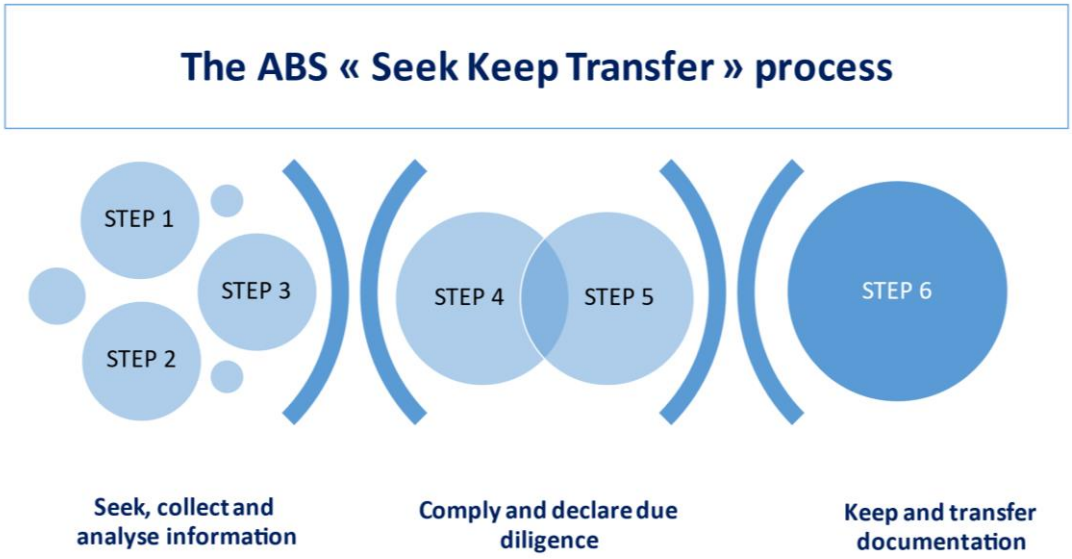
ACTION

Implement a secure data management system for ABS documentation of all of the resources used in your project.

TIPS

To avoid long-term ABS data management on genetic resources used in your project, you may choose to deposit the resources in a collection / biorepository with a clear ABS (and/or quality) management system.

You may be allowed to store the resource, but note that subsequent uses usually require to reiterate the step-by-step process.



FOR FURTHER INFORMATION

- The EMBRC guide to ABS compliance. Recommendations to marine biological resources collections' and users' institutions.
- 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 (ABS Guidance document C(2020)8759):

  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