European Marine Biological Resource Centre Biobank (EBB)

WP 6 ABS compliance for innovative uses of Marine Biological Resources

Action 4

D6.4. Report on application and EBBs contribution to Best Practice Guidelines

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Table of contents

Disclaimer

The following report compiles outcomes collected while implementing ABS regulations within the project (see deliverable D6.2). It is solely intended to draft the two guidance documents delivered by the EBB project:

- *D3.4: Seek, Keep and Transfer - the Step-by-Step Guide to ABS compliance when utilizing marine genetic resources*
- *D5.1: the guide to ABS compliance. Recommendations to marine biological resources collections' and users' institutions*

The content herein mostly refers to the Guidance document C(2020)8759 on the scope of application and core obligations of Regulation (EU) No 511/2014 (EU ABS Regulation) published in December 2020 by the European Commission to help users with the ABS compliance measures adopted within the European Union. The guidance document was issued after the adoption of D3.4 and D5.1 and will be taken into account in their subsequent versions.

Conclusions and opinions expressed in this report replace and / or supersede neither the abovementioned EBB guidance documents, nor official national ABS legislation and guidance documents.

Report on application and EBBs contribution to Best Practice Guidelines

Context and objectives

The Nagoya Protocol on Access and Benefit Sharing (ABS) is the global mechanism to regulate the access and utilization of genetic resources, including marine genetic resources. The agreement entered into force on October 12, 2014, as a supplementary agreement to the 1992 Convention on Biological Diversity (CBD). In April 2021, 128 countries plus the EU are parties to the Protocol (129 parties). The NP organises an international mechanism called ABS, based on the sovereignty rights of countries over their genetic resources and the fair and equitable share of benefits for their utilization, in force since the CBD. The volume of national implementing rules continues to proliferate, and this requires continuous screening of the national regulatory landscape globally.

Utilization of marine genetic resources from National waters requires providing proof that sampling and utilization of resources has been done in accordance with National ABS regulations in place. Nagoya National Focal Points need to be contacted before doing any sampling and or research.

In the EEB project we have explored a series of use cases (Deliverable 6.2) to learn the possible constraints, problems that may arise during the process and present easy to follow solutions. The lessons learned were applied to improve the EBB best practice guidelines on ABS (The guide to ABS compliance. Recommendations to marine biological resources collections' and users' institutions) produced for institutions providing ex-situ and in-situ marine genetic resources (Deliverable D5.1) and to produce a Step by Step guide towards ABS compliance for users (Deliverable D3.4). In the present deliverable, we present the learning outcomes summarised.

Learning outcomes

Nagoya landscape

- The Nagoya landscape is dynamic and changes, and this asks for a continuous screening of the situation in relation to every particular genetic resource.
The Nagoya protocol had 99 signing countries + the EU for compliance measures (100 parties) in February 2018 and has 129 parties in February 2021, with 69 countries being non-parties. In Europe many countries had not adopted an access regulation yet. In the EU Bulgaria, Croatia, France, Malta, Açores region (Portugal) and Spain have adopted access regulations. In France the initial

regulation incorporated an addendum in 2019 (French law n° 2019-486-article 129) with a moratorium of 3 experimental years on the access and utilization of microorganisms in mainland France. Such simplified access will be free for those 3 years (https://www.ecologie.gouv.fr/sites/default/files/Access%20to%20genetic%20resources%20and%20associated%20traditional%20knowledge%20and%20sharing%20of%20the%20benefits%20arising%20from%20their%20utilization%20%28ABS%29%2016%20f%C3%A9vrier%202021.pdf). Definition of genetic resources in providing countries may vary from one country to another, as it occurs with the definition of utilization, and for instance there are already 17 countries that somehow regulate access to digital sequence information (DSI). The CBD is currently discussing on the need to incorporate DSI into the Nagoya track. Access to genetic resources in the High Seas and benefit sharing for their utilisation will also be soon regulated under the Convention of the Law of the Sea (UNCLOS)."

- Reaching ABS compliance in projects implies time, specific expertise and extra costs.
Nagoya protocol ratification by European Union and European countries imposes an increase dedication and bureaucracy on non-commercial research and development (R&D) activities (dedication that goes with a cost, which is not covered in project calls).

Procedures and application for permits

-Complying with Nagoya involves planning in advance.
ABS clearance demands analysing research projects well in advance to understand their possible ABS ramifications, seeking for information in the ABSCH (ABS Clearing-House)[1] and contacting national focal points (NFPs). If permits would be necessary, time needs to be allowed for the introduction of changes or additional explanations in your request that might be imposed by the authorities, in an iterative dialogue with the pertinent NFP and once the request is consolidated for files to be analysed by the Competent National Authority (CAN) and permits to be issued. For instance, in Spain a permit for non-commercial utilization (upon a consolidated request with all information needed) needs 2 months, and for a commercial one 6 months. It must be considered that Spain is quick in responding and in many circumstances, it will be impossible to stablish contact with the NFP in the provider country of interest (because it has not been appointed, because it does not answer…).

[1] It is a website designed to make information relevant to ABS available in a standardized, and open and organized repository, allowing providers to share information on contacts, procedures and requirements for access to the GR and associated traditional knowledge. (https://absch.cbd.int)

-Be explicit in your request.
When available use the ABS related information post-boxes to request information, but in such cases make very specific questions for the problem willing to solve, as answers very often can be very generic. Users of genetic resources should include information on the type of sample they want to collect, describe briefly the aims of your research and the methodology that you will use.

-What happens when the provider country does not answer?
EBB recommends to try to contact the national focal point as in the ABSCH through e-mail at least three times, with intervals of one month after each mail, and to cc. the ABS Competent National Authority (CNA) for research in your country at the third attempt. Keep trace of such communication, so this can used as proof of your due diligence.

- I forgot, or did not consider the need, to obtain ABS permits and I have already sampled or even utilized the genetic resources.
Remember access and collection (keeping *ex-situ*) are out of scope under the EU regulation 511/2014 (national regulations might be broader), and it is the moment of access to the resource for utilization (for instance from an ex-situ collection) that marks the need to request permits, so apply ABS permits to access and utilize genetic resources in collection.

- Extra checkpoints.
The EU REG 511/14 includes two checkpoints to guarantee due diligence and ensure that all users from European countries comply with ABS regulations. The first checkpoint is at the stage of research funding and the second one is at the stage of final development of a product. ABS regulations of some countries impose other checkpoints, as at the stage of requesting a patent in Spain or France. For that, it is important to check the national legislation in advance.

In addition to the previous checkpoints, certain institutions may request for additional documentation and audits, thus acting as extra checkpoints in order to ensure that all the samples incorporated to their institutions are in compliance with ABS regulations (Ethic bodies). For instance, and initial International Certificate of Compliance (IRCC) awarded to an institution or researcher, might not be accepted by a third institution where the researcher may wish to carry out his/her research with the genetic resource. This may ask for a need to modify initial permits to incorporate yet another research institution.

Registered collections in the EU which have been transferred compliance obligations may serve as ABS checkpoints to accept or refuse a GR. For instance, the DSMZ (German Collection of Microorganisms and Cell Cultures Gmbh) does not allow deposit of a microorganism if it does not come with the pertinent ABS clearance documentation. In the same way, the registered collection only allows the deposit of new species when they can be supplied to

their users without any restriction, including ABS, according to the international practices for publication of new organisms. This applies to the microorganism coming from France where there is a moratorium on ABS requirements for their access and utilization but with an annual declaration on utilization. Users who access to French genetic resources cannot use the initial declaration associated to genetic resources

- Indecisions about at what point permits should be requested.
When users request a permit, they can do so for commercial or non-commercial purposes, depending on whether the final marketing of a product is proposed or not. This creates uncertainty for researchers, mainly for industrial sector, who do not know what option suits them best.

Applying for a permit with non-commercial purposes provides legal certainty, but it implies an investment of money and time, which may not be recovered if the product does not reach the market. Companies also find it a waste of money, to request an initial permit, when they know that they will have to request a second one if they want to commercialise their products. Unlike researchers from academia, it is unlikely that they need this non-commercial permit to participate in a public-funded project or to publish a paper, although they will soon be required to give evidence like academia (EC new guidance). Even if they can afford that investment, when R&D is at a very exploratory phase, companies find it very difficult to define sufficiently the type of product and potential benefit you expect (in order to request for the PIC and MAT).

For this reason, some companies opt to operate without a permit, and wait until they have the product and they are in the position of marketing it. However, this has a serious drawback, as there is always a risk that the permit will not be granted by the origin country, which would imply that the developments made to obtain the product will not bring about any benefit.

- GRs as tools or model/indicator/sentinel organism.
When an organism is used to validate a tool, protocol or hypothesis this activity does not constitute utilization.

- Language barrier on communications and application.
Some official websites are designed in the official language of the country of origin and thus, this is a constraint for the users of genetic resources that are non-speakers of that language. It would be advisable that applications were designed in a common language, preferably in English, that the application can be done online and made available for foreign citizens.

- Collaboration with local partner could be decisive.
In some countries access to their genetic resources will be only possible through collaboration with national researchers or institutions (a local partner), and in

some cases, it could be advisable for practical reasons to incorporate them in the team of users.

What is utilization of genetic resources in the context of EBB

- Storing or collecting in a public or private collection is not utilization of GRs.
Permits for sampling in the sea still apply under UNCLOS. Collections act as repositories of biological resources, but only keeping in collection does not imply utilization under Nagoya protocol and ABS regulations. Even if the holdings are characterised molecularly such activity does not entail utilization of genetic resources.

- Taxonomy is out of scope in Europe, but…
Taxonomic studies (even if using molecular phylogenetic tools) where they do not look into genetic properties (functionality), are not within scope of the EU ABS Regulation. The same applies for instance in the Spanish ABS regulation. This is not necessarily the case in other regulations such as the French one. It is always important check the local regulations. There is no need to exercise and declare due diligence for such activities in the European Union

Definition of genetic resources (GRs)

- GR vs commodity, where is the boundary?
According European Commission glossary, commodities are defined as goods sold for production or consumption just as they were found in nature. With this definition, sometimes it is difficult to discern when our samples are considered commodities and when they are genetic resources. In Spain, even if the genetic resources were obtained in the market or with an intermediary, this genetic material may fall in the scope of the Spanish regulations. In other countries the interpretation of the competent authorities or what is defined in their regulations may be different. The recently published (December 2021) new guidance document of the EU on ABS Regulation[2] it suggests that utilization of genetic reocurces obtained as commodities is in scope.

- Wild taxon vs cultured bioresource, where is the boundary?
Sometimes, differentiating where a wild resource is collected from the natural environment or is collected in a place dedicated to the culture or breeding can be difficult. This is the case of the culture of molluscs in rafts or beaches, where, despite being the natural environment, they have been placed there for breeding and fattening. The need for a permit for access to this type of genetic resources will depend on the country where they are collected and what its domestic

[2] 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

legislation dictates. For instance, in Spain, the access is to bivalve species from culture production is included in the Spanish ABS regulations, so a permit is required.

- Environmental sample vs taxon.
The sampling of a single and unique environmental sample can involve the presence of more than one genetic resource. Water or sediment samples usually contain microorganisms, algae and other small invertebrates corresponding with various genetic resource. In Spain, for example, the domestic legislations regulate that access to environmental samples is also in scope because several taxa are included in them.

Delimiting who is the user and utilization

- Personal vs Institutional request.
Each country has its own permit request system. In some cases, it is done electronically, while in others it is necessary to get in touch through other systems. In some countries, there is no qualified mechanism to make institutional requests, unless the legal representative of the institution does. In this context, sometimes it is difficult differentiate between a personal and an institutional request. A possibility to minimize this problem would be to standardize the systems and, if requested on a personal level, validation by a legal representative may be required.

- Retrospectivity when accessing genetic resources ex-situ.
This issue is especially important for those genetic resources obtained from a collection, and interpretation would depend on the country of origin. In some countries like Spain, it is the moment of access to a Spanish genetic resource from a Spanish culture collection for utilization that triggers the process no matter that the resource was sampled in the wild in Spain prior to Nagoya Protocol ratification.

- Specificity of utilization and constraints for framework utilization permits.
The need to request permits for accessing genetic resources depends on what each country has established. Even for those countries that have regulated access, the same activity may require permission in one country and not in another. This is the case, for example, of the use of genetic resources for taxonomic purposes. In Spain it falls out of scope, while in France it is within (if the particular project falls within the French definition of utilization). Since the EC 2020 guidance document clarified that taxonomy is out of scope for compliance measures, a new doctrine is expected in France.

- Is large scale screening of environmental samples, screening of ex situ collections in scope?
As per the guidance document of the EU on ABS it is out of scope in no utilization of genetic resources is taking place, but companies may be interested in obtaining non-commercial ABS permits to ensure R&D investment in the light of possible future developments towards a commercial product resulting from positive hits during the screening. Thorough due diligence is recommended for this activity and potential checks, i.e. monitoring the screening activity and the transfer to research activities.

- Seek the best provider.
When accessing genetic resources users should be addressing biological resource centres either with registered collections or ABS practice guidelines put in place. This is a bidirectional recommendation as it is in the interest of Biological Resources Centres (BRCs) to seek registration or adoption of best practice guidelines to gain the confidence of their users and gain clients.

Conclusions

All the learning outcomes summarised above, result of the use cases tested during the life of this project by EBB partners and mainly by WP6 and WP1 leaders. They were shared as they were learned with WP5, and incorporated into the best practices delivered to the EBB community in “The guide to ABS compliance. Recommendations to marine biological collections’ and users’ institutions”. After the adoption of these BPGs in EBB the learning outcomes were the main drivers of the “Seek Keep & Transfer, a step-by-step guide to ABS compliance when utilizing marine genetic resources” that was produced to users.