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Best practice procedures for harmonized access

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Abstract

Facilitating the access to bioresources for research purposes is one of the principal foci of the EMBRIC cluster. This deliverable will outline a harmonised “passporting” system for all marine genetic resources to be supplied through EMBRIC partners, ensuring materials are accompanied by the appropriate information and the various permits and documentation related to the samples origin and conditions of use. As part the passporting system unique identifiers to all organisms and strains will be implemented based on existing systems in place across the partners. Crucially, the identifiers must be suitable to track the utilisation of the resources and to access the permits on the EMBRIC website. The passporting system will help to reduce the burden of compliance of the user with due diligence, reduce the risk of companies and researchers of legal action due to non

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1 Introduction

Marine bioresources are fundamental requirements for scientific research and biotechnological R&D and thus accessing them has to be easy and provide the user with all the necessary information to successfully and legally utilise the resource (i.e. Material Transfer Agreement (MTA) and Terms & Conditions (Ts&Cs)). This has been further complicated in recent times by the introduction of new legislation related to the use of genetic material and the sovereign rights of the countries over their natural resources and traditional knowledge (Convention on Biological Diversity – CBD). New rules designed to reduce instances of biopiracy and ensure the sharing of benefits arising from the genetic resources with the country of origin (Nagoya Protocol - NP) have severely confused users over their rights and what they can and cannot do legally with samples obtained from other countries, or third party provides, such as culture collections (CCs). In addition, these new frameworks are making it possible to bring criminal charges against researcher and companies who do not comply with the regulations, potentially stifling research out of concern of legal prosecution. Furthermore, due to its complicated nature, the frameworks are likely to have the undesired effect of making researchers either avoid accessing particular countries and resources or to not comply with the law. It is thus becoming crucial for researchers and companies to be able to easily access material that can be traced and with the necessary paperwork making it clear what work is permitted under the conditions of use that accompany a particular sample.

Within the EMBRIC cluster there are a number of research infrastructures (RIs) supplying marine biological resources for both applied and fundamental research: EMBRC, AquaExcel, and MIRRI. It is in their interest to facilitate the supply of material for use in research and are thus looking to support the research community in complying and accessing marine genetic resources (MGRs) in an easy and legally compliant manner. As part of improving and aiding in the access to marine genetic resources, users must be able to use materials with full confidence of their legality and the access and benefit sharing (ABS) agreement stipulated by the country of origin. This is particularly pertinent in cases where researchers or companies wish to utilise MGR for R&D or commercial purposes as usually this will require renegotiating the terms of use with the country of origin.

This deliverable will outline a harmonised “passporting” system to be implemented across the EMBRIC partners to ensure that all users of MGR obtained through the participating RIs is accompanied by the appropriate information regarding the material requested but also, crucially, the various permits and documentation related to the samples origin and conditions of use (e.g. Prior Informed Consent (PIC), Mutually Agreed Terms (MAT)). As part of the passporting system a system for assigning unique identifiers to all organisms and strains provided by EMBRIC resource centres will be harmonised so as to betrack the utilisation of the resources and to access all relevant permits through the EMBRIC website. There is a need to ensure the different research infrastructures across EMBRIC address their legal responsibilities associated with supply of marine resources. Hence the EMBRIC “passporting” system which will ensure that the systems implemented by partners in the partner Research Infrastructures are compliant and provide legal clarity for the use of the provided biological material.

2 EMBRIC Bioresource Passport

EMBRIC partners will provide a passport that will accompany all biological resources and materials supplied by the participating RIs, and will in effect be a certificate of origin. The passport will provide information on (a) collection and culturing conditions (provenance, environmental impact, ethics, etc.); (b) degree of legal compliance with the Nagoya Protocol (NP) of the Convention for Biological Diversity, with member state, and EU regulations.

2.1 Passport Section A: Collection and Culturing Conditions

A nominal amount of information should be included physically with the material shipped to ensure that the recipient has the necessary information at hand on delivery, such as order number, strain/species identifier and storage conditions. Further, more detailed information will be available online via the EMBRIC data portal using the unique identifier of the material.

The following information is recommended by the Organisation for Economic Co-Operation and Development (OECD) to be included with the shipped sample:

- Biological material identifier, accession number and batch number.
- An estimate of shelf-life, storage conditions, storage instructions and if appropriate, conditions of growth.
- Instructions for opening ampoules or vials (when appropriate and in all cases where materials are being provided to new users).
- A safety data sheet including the containment level required for handling the biological material, disposal measures and measures to take in case of spillage.
- A Material Transfer Agreement: an essential requirement to protect IPR and mandatory where they are required by national law. They are used to relay the depositor's and/or country of origin requirements on use of the biological material.
- Fax-back sheet to acknowledge receipt of materials may be desirable.

It is recommended that all EMBRIC partners supply, as a minimum, the first five pieces of information with their shipped samples. The sixth recommendation should be replaced with an email asking for confirmation of receipt.

2.2 Passport Section B: Legal Compliance with Nagoya Protocol and Relevant Permits

The primary function of section B will be to ensure that any genetic resource obtained through EMBRIC has been obtained and used in a lawful manner. This section of the resource passport recommends a physical and a virtual component. The physical component will provide information on the available legal documentation through a traffic light system:

- Red: no permits available. User must contact the country of origin to establish terms of use
- Yellow: some permits available/material obtained prior to 1993

- Green: all relevant documentation present.

In addition, the passport will provide basic information on the scope of use of the material, e.g. “fundamental research permitted; industrial R&D subject to ABS agreement”, or “country of origin not signatory to NP and CBD – all use permitted”.

Finally, the passport will inform users of their obligation status:

- Due diligence exercised (when obtained from an EMBRIC partner registered with the European Register of Collections)
- All documentation available to demonstrate due diligence (when all permits are present)
- User must seek relevant documentation from country of origin.

The virtual part of the passport will comprise all the documents and permits relevant to the use of the material supplied. EMBRIC partners will harmonise across its CCs and BRCs a system of digital identifiers for each strain and species available for supply. Systems for tracking and complying with CBD and NP outlined by the World Data Centre for Microorganisms (WDCM), OECD, and MIRRI (i.e. Access and Benefit Sharing Manual DOI: https://doi.org/10.5281/zenodo.284881) will be explored and adapted as necessary to conform with existing systems already in place. Of importance is that the code should enable access to all available permits (i.e. PIC, MAT, and any other relevant documentation) through the EMBRIC portal. All participating partners will retain records of permits and supply for a minimum of twenty (20) years.

It should be noted that this information is only of relevance to fundamental research. All other types of research will have to negotiate access and benefit sharing arising from any commercial value generated using the genetic material.

Compliance with Nagoya Protocol will be a major challenge for biological resource centres (BRCs) and the research community over the next decade. Indeed, various initiatives are underway to help users and to facilitate access to resources. Both MIRRI and EMBRC have developped best practice guidelines for users and CCs (MIRRI manual accessible through ABS Clearing House: https://absch.cbd.int/database/modelContractualClause/F1C80F1C-1EB7-F02A-CEED-E7D523F17079). It will take time for these mechanisms and procedures to be fully in place. The BRCs are now under pressure to produce significant quantities of f new information for their users to help them be able to pass their check-points for due diligence as quickly as possible. However, the passporting system, along with other material developed within the RIs should greatly facilitate this.. Initiatives within the EMBRIC partners include the registration of collections in the European Register of Collections, standardisation of protocols, production of best practice guidelines for the RIs and users of genetic material.

3 Compliance with Nagoya Protocol

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3.1 Bioresource use for fundamental research

Currently, a large number of countries permit fundamental research on their bioresources without any special arrangements. The passporting system will facilitate the passing of check-points when receiving funding or applying for patents by first of all providing a certificate of origin as well as access to all the permits required to fill out the necessary form to demonstrate due diligence from the user. Once collections have successfully been registered, obtaining material from RIs and BRCs will in itself constitute exercising due diligence and greatly facilitate users compliance at check points.

3.2 Bioresource use for applied science and industrial R&D

BRCs and RIs will also support and supply applied research and R&D. However, it will not be possible for researchers and companies working on applied projects to demonstrate due diligence purely by obtaining their material from a registered RI or BRC. For applied science and industrial R&D research the available documentation is of value but only to inform the user of origin and who to contact to negotiate access and benefit sharing. The documentation will also be helpful in informing the user when the material originated from areas beyond national jurisdictions (ABNJs) or when the country of origin has no rules in place and/or are not signatories to the CBD and NP. In these instances, the users are more or less free to use the material as they please.

To facilitate the negotiation of this legal mine-field, best practice guidelines to help commercial users with what to do when accessing marine biological resources for commercial or close-to-market research, which is being developed in a parallel project for EMBRC and already established for MIRRI (also see EMBRIC Deliverable D2.2 Best practice methods for Biological Resource Centres). This will provide a step-by-step guide for commercial and applied users on the steps they need to take when working on MGRs.

4 Implementation

It will require time and adaptation to put these new measures in place. The standard passport template needs to be prepared and agreed upon, as do the databasing issues.

Section A is already in place for CCs but this procedure will need to be extended to BRCs. A template based on those used in the EMBRIC CCs will be developed that can be extended for macroorganisms as well.

Section B will require a much longer time frame for full implementation due to the fact that the relevant documents related to CBD and NP are not currently held and must be sought retrospectively in many cases. What must be put in place now is the digital and database frameworks necessary to allow this to work in the future. Specifically what is required is the adoption of the identifiers and the mapping of depositories for documentation for the bioresources.

Finally, more effort is required to device a common approach to help and support commercial companies and applied researchers in complying with ABS legislation to ensure that these frameworks do not become insurmountable barriers to research and innovation.
A workshop will be organised at the EMBRIC GA, bringing together the relevant WP2 partners and WP4 data warehouse designers to discuss agree on the specificities of the passport, specifically the template and the exact information to be included. Furthermore, in order to address the virtual part of Section B of the passport an agreement must be reached on the implementation of the digital identifiers for the bioresources, as well as the virtual space for storing and accessing the documentation related to the organisms. Finally, the proposed best practice guidelines for commercial use of bioresources and the step-by-step guide to working on MGRs need to be validated by the EMBRIC consortium.

5 Conclusion

Facilitating the access to bioresources for research purposes is one of the principal foci of the EMBRIC cluster. The marine biotechnology sector is heavily dependent on these and need materials which they know are of high quality, have good traceability, and that can be used with confidence. The EMBRIC Bioresource Passport harmonised system will provide a certificate of origin and basic information on collection and husbandry, as well as the information required for companies to understand what they can and cannot do under the various permits accompanying marine bioresources. In a first instance, this will help to solidify the RIs as the CCs & BRCs to support applied and commercial research. Secondly, it will help to reduce the burden of compliance for users with due diligence and reduce the risk of companies and researchers inadvertently breaching international law and be liable for prosecution. Thirdly, it will raise awareness and generally encourage compliance with ABS regulation, as well as generally encourage compliance with the framework. Finally, from a practical perspective, this initiative will further push the RIs to work together in a more coordinated manner as well as harmonising procedures based on common standards for accessing bioresources. This in turn will ensure a high standard of service and support for applied and fundamental research communities from RIs across Europe.