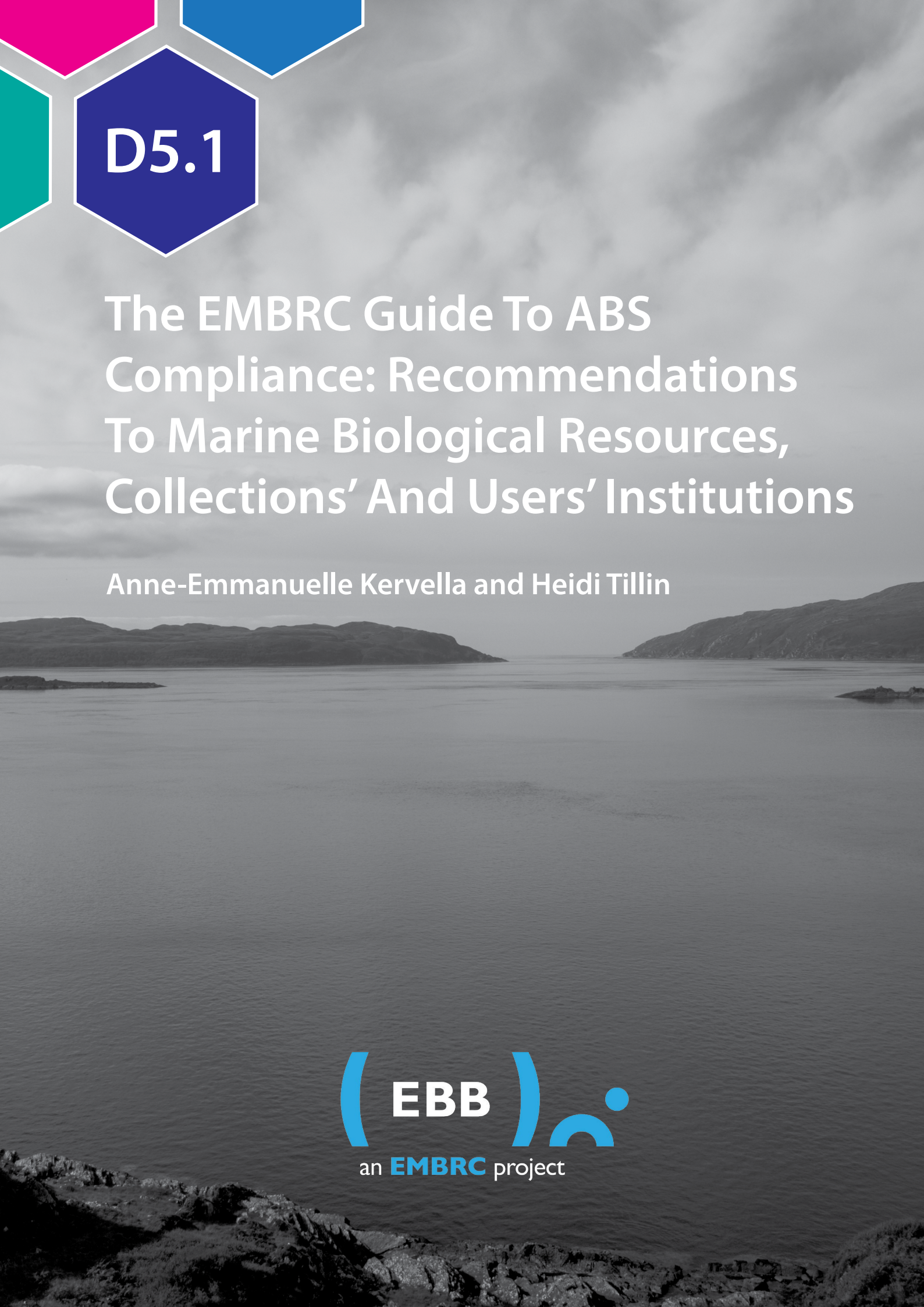


D5.1

The EMBRC Guide To ABS Compliance: Recommendations To Marine Biological Resources, Collections' And Users' Institutions

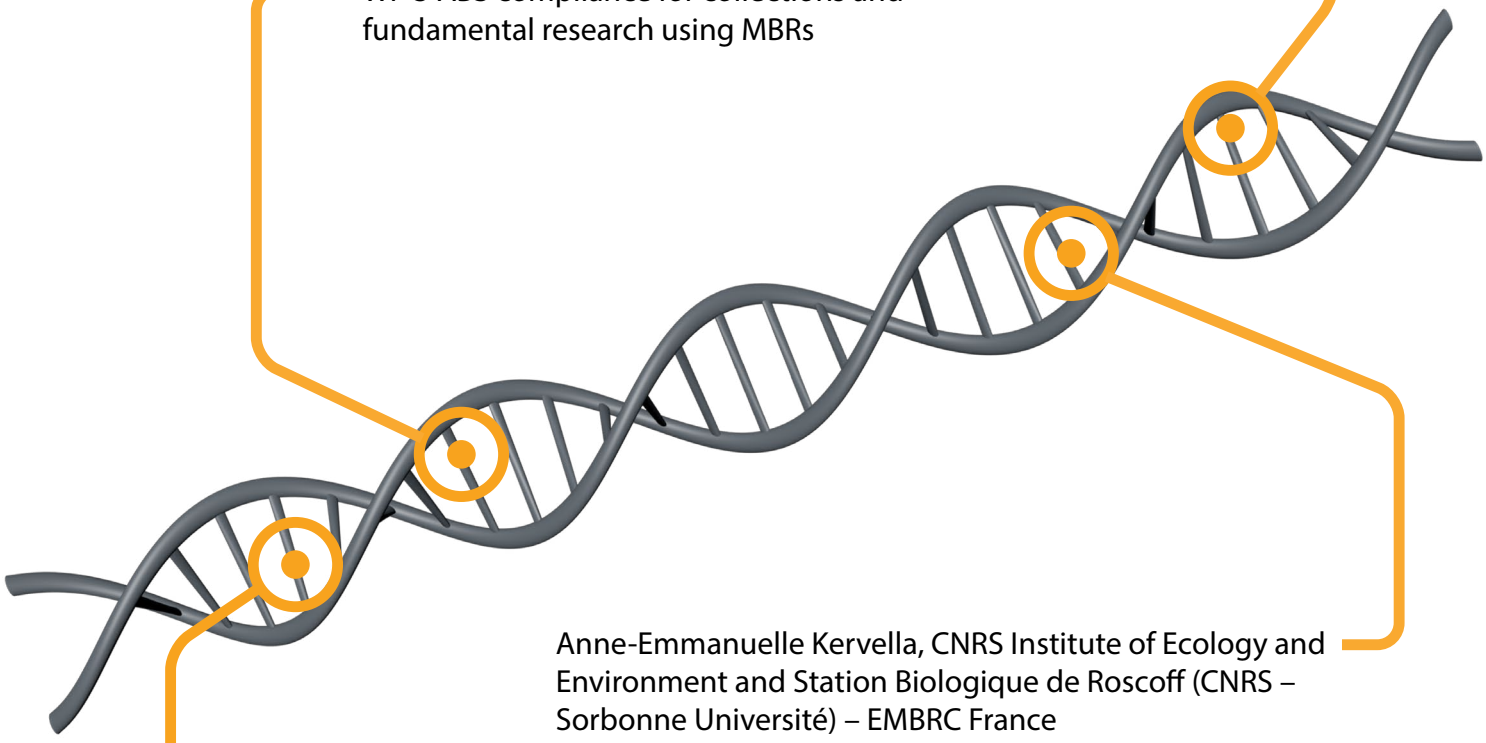
Anne-Emmanuelle Kervella and Heidi Tillin

EBB

an EMBRC project

European Marine Biological Resource Centre Biobank (EBB)

WP 5 ABS compliance for collections and fundamental research using MBRs



Anne-Emmanuelle Kervella, CNRS Institute of Ecology and Environment and Station Biologique de Roscoff (CNRS – Sorbonne Université) – EMBRC France

Heidi Tillin, Marine Biological Association, Plymouth, EMBRC-UK

European Marine Biological Resource Centre biobank – Financing programme: 2014 - 2020 INTERREG VB Atlantic Area- Grant Number: EAPA_501/2016

Interreg Atlantic Area
European Regional Development Fund

EUROPEAN UNION

EMBRC
EUROPEAN MARINE BIOLOGICAL RESOURCE CENTRE

CNRS • SORBONNE UNIVERSITÉ
Station Biologique de Roscoff

THE MARINE BIOLOGICAL ASSOCIATION

D 5.1

Kervella, A-E. and Tillin, H.M. (2020). The EMBRC guide to ABS compliance. Recommendations to marine biological resources collections' and users' institutions. A handbook produced by the European Marine Biological Resource Centre.

This Handbook has been endorsed by the EMBRC.

Acknowledgements

This handbook has developed through discussions, events and workshops in the course of setting-up of the European research infrastructure European Marine Biological Resource Centre-ERIC (EMBRC-ERIC), namely the EMBRC Preparatory Phase 2 workshop 'Practical Guidelines for Accessing and Providing Marine Genetic Resources' held in Heraklion (Crete) in June 2016, which sealed the first guidelines on access and benefit sharing issued for the EMBRC community; an EBB workshop in May 2018 'Practical steps for facilitating the use of marine biological resources for commercial R&D in the context of the new Access and Benefit Sharing (ABS) legal framework (Nagoya Protocol)', the EBB General Assembly held in Porto in March 2019 and in Bilbao in November 2019. The participants of these events are thanked for sharing their views, best practices, and for contributing in structuring and improving the handbook.

The authors would specifically like to acknowledge the following people for their useful contributions, comments and input:

Dimitra Manou and Nicolas Pade, authors of the 2016 "Best Practice Guidelines on Access and Benefit Sharing for EMBRC".

Ian Probert, Simon Berkowicz, Marta Evangelista and Tim Verstraeten for their input on this former version.

Ibon Cancio and Antonio Villanueva for the first amended draft.

Ian Probert for Annex 4.

Nathalie Kowalczyk for Annex 5.

Ana Rachel Teixeira-Cavalcante, Sarah Aubertie and Bleuenn Guilloux for Annex 6.

The ABS Competent National Authorities for their comments and valuable guidance, esp. Rob Yarlett and Katy Bird.

CETAF's ABS working group rep. Chris Lyal and Anne Nivart.

The EMBRC-ERIC ABS working-group, especially Arnaud Laroquette.

The EBB Project coordination and management team for their continuous support and editorial work: Antonio Villanueva, Belén Martín Míguez, Ibon Cancio, Fiz da Costa, María del Mar Costa and Cristina Secades.

Notes on development and version

The first iteration of this handbook was developed by the EMBRC Preparatory Phase 2 project. As part of the EBB project the handbook has been edited and technical guidelines and annexes developed. A key reference for this handbook was the Best Practice Guidelines developed by the Consortium of European Taxonomic Facilities (CETAF) that were the first Best Practice Guidelines on ABS to be registered by the European Commission under Art. 8 of the EU ABS Regulation. Finally, this handbook has been endorsed by EMBRC to implement Best Practices to support ABS compliance within its institutions.

Disclaimer

EMBRC has striven to make the information within this manual as accurate and up to date as possible. However, interpretation of the European ABS regulations may further evolve in light of experience gained in its implementation. EMBRC, the EBB project and the handbook authors are not responsible for the results of any actions taken by institutes or users on the basis of information contained neither within this manual nor for any error in or omission from this manual.

The European Commission Guidance documents on the implementation of the EU ABS Regulation may provide additional clarity to assist in the understanding and application of the EU ABS Regulation and the Implementing Regulation. Nevertheless, only the Court of Justice of the European Union is competent to authoritatively interpret Union law.

How to use this document

Recognising the needs of different users, this Handbook has two parts that are designed to be printed and used as stand-alone documents (hence the repetition of certain contents).

The Executive Summary captures the essence of the Handbook, including a condensed set of recommendations and policies that can be used as a checklist.

Part 1 EMBRC Best Practices for ABS compliance: provides the legal context and background to the development of these best practices for collections and users of genetic resources in the marine realm. It describes extensively the legal framework and derived obligations related to Access and Benefit Sharing focusing on compliance with EU Regulation 511/2014, as well as other regulations that affect marine research. It also provides valuable information and general recommendations to familiarize and meet the requirements of that legal framework.

Part 2 EMBRC Technical Guidelines for ABS compliance: gives more detailed, practical and specific information to help institutions to develop the required polices and training to implement the best practices and ensure ABS compliance. By means of a series of technical guidelines, readers can find instructions, procedures as well as specific recommendations for each of the activities where collections need to consider ABS. Part 2 also includes Annexes containing templates forms, diagrams and illustrations to aid understanding and help with compliance.

Legal specific names, concepts and acronyms are presented and widely used throughout the text. A glossary section is provided at the end of Part 2 to facilitate reading and understanding.

Contents

Executive Summary

Genetic resources (GR) of marine origin remain under explored, despite their potential value. Blue biotechnology has been identified as a promising growth area for the future of Europe. However, exploring and exploiting marine genetic resources in research and development requires complying with international frameworks for the protection of biodiversity and national regulations that scientists using marine genetic resources are usually unaware of. One of these frameworks is the Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation (Access to genetic resource and Benefit Sharing - ABS).

To support users, the European Marine Biological Resource Centre (EMBRC-ERIC) aims at facilitating access to marine genetic resource. The handbook is a deliverable of the **European Blue Biobank (EBB) Interreg Atlantic Area project**. The EBB project aims to support biobanks and their users to comply with the ABS framework. **EBB is an EMBRC-ERIC project**, with the main goal to facilitate sustainable access to marine biodiversity, its associated data, and extractable products for local and international academia and industry users, and to incentivise biodiversity conservation in coastal ecosystems by promoting compliance with ABS regulations derived from the Nagoya Protocol.

The fair and equitable sharing of benefits arising from the use of genetic resources is one of the three objectives of the Convention on Biological Diversity (CBD) and has its roots in the North-South post-colonization debate. The supplementary agreement signed in Nagoya in 2010 on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation provides a framework for the fair and equitable sharing of benefits arising out of the utilisation of genetic resources[1], **and traditional knowledge associated with genetic resources**, including research and development.

The Nagoya Protocol entered into force in 2014 and was adopted the same year by the European Union, requiring the Member States to develop measures to comply with the new obligations imposed on users of genetic resources. These rules have created considerable legal, financial and administrative burdens on scientific research exploring biodiversity, particularly in the academic sector.

The CBD's Access and Benefit Sharing (ABS) framework on utilisation of genetic resources complements other existing ABS regimes, or regulatory frameworks to protect the environment or to access the sea and its resources under national jurisdiction. In addition, other legal instruments regulate access and utilisation of marine genetic resources from locations beyond national jurisdiction. The handbook outlines these key instruments, to provide collections and users with an understanding of the background and development of ABS and the scope of implementation.

The EMBRC handbook presents a set of guidelines and recommendations to collections and users of genetic resources to familiarize and adopt best practices to comply with the ABS framework. Collections and biobanks holding resources from different origins will find in this handbook a useful set of practices to exercise due diligence and manage the ABS requirements. Scientists will be aware of any ABS requirements before undertaking any

1 Traditional knowledge associated to genetic resources (see also reference in the Glossary of the Handbook) is also protected under the Nagoya Protocol. While not specifically covered in this Handbook the reader must bear in mind that depending on local regulations, it may be necessary to negotiate access and benefits with indigenous and local communities for using their knowledge, whether used with the biological resources or independently.

fieldwork or scientific cruise collecting biomaterial. The handbook will also facilitate the collected material to be prepared for conservation, for any further use and transfer. Implementing the recommended best practices will:

- Harmonise standards/procedures within the community;
- Facilitate compliance of its users to applicable legislation;
- Reduce administrative burden and create a safety-net process for researchers (for obtaining funding and for publications);
- Increase transparency on how genetic resources and the associated traditional knowledge are utilised;
- Facilitate fair and equitable sharing of benefits arising from utilisation of genetic resources;
- Promote non-monetary benefit-sharing for non-commercial research;
- Reduce the risk of unlawful utilisation of genetic resources (and minimize the risk of legal consequences and in terms of international cooperation for researchers and their organisation);
- Increase legal certainty; and
- Attract users of bioresources to the EMBRC biobanks.

Summary of recommendations

Institutions should identify which activities they carry out will require managing and define the institutions responsibility for ABS. In some instances, current policies and procedures will be adequate and if not, modifications are required following the technical annexes.

Internal policies and procedures should identify:

- ✓ Persons with legal authority for agreeing to terms and signing ABS commitments on behalf of the institution;
- ✓ Persons responsible for providing training to staff, keeping records of training being delivered and updating relevant materials;
- ✓ Individuals with responsibility for ABS including due diligence;
- ✓ All persons the polices are relevant to e.g. employees, research associates, sub-contractors, external visitors and users of the institution's services;
- ✓ Compliance checking requirements and scheduling by the Competent National Authority (CNA); and
- ✓ Internal auditing of collections, policies and procedures to ensure compliance; and
- ✓ Processes for dealing with deliberate or accidental breaches of ABS regulations.

For acquisition of genetic resources:

- ✓ Internal policies or procedures around acquisition should include:
    - An object entry system to ensure that genetic resources entering and leaving are tracked with appropriate information and documents;
    - Training and documentation. Institutions are advised to develop or revise procedures to train and inform staff and independent or contracted individuals or organisations who collect and supply biological materials or who do fieldwork for and in the name of that institution;
    - Institutions should identify authorised persons responsible for due diligence,

negotiating terms (mutually agreed terms (MAT), material transfer agreements (MTAs) and other documents), collecting and keeping the necessary documentation at access (receipts for Internationally Recognised Certificate of Compliance (IRCC));

- Institutions should have policies on due diligence, negotiating benefit-sharing terms and other terms, including limitations and restrictions. Institutions should ensure that terms can be met and do not conflict with policies and activities;
- Staff should be aware of due diligence requirements and when they or their institution is and is not responsible for due diligence. Agreements with project co-ordinators, visitors etc. around due diligence should be agreed in writing and kept;
- The institutions should set out conditions under which in-situ (fieldwork collection) by personnel is managed, including obtaining prior informed consent (PIC) and negotiating MAT, including number of attempts over which time period to contact unresponsive national focal points (NFP) and other authorities.
- Management and archiving of key documents, including contact with NFP, including emails to unresponsive NFP;
- The institution should set out temporary loans of materials and permanent acquisition from outside the institution can be accepted including formal agreements between visitors and host institutions assigning responsibility for due diligence;
- Identify practice around contractual work on genetic resources including disposal and/or return of genetic resources; and
- Scientific cruise collected biomaterial should be prepared for ABS compliance, the collected material managed as a single collection vis-a-vis ABS for the time of scientific work and the transfer to a collection for conservation studied well in advance to comply with ABS requirements.

For depositing genetic materials in collections:

✓ Internal policies or procedures around acquisition should ensure collections only accept materials that are legally accessed and where terms and conditions can be met. Checks and procedures should include:

- Standard depositor checks to ensure material was legally accessed and depositor has the authority to deposit the resource;
- Processes for checking any data gaps;
- Processes to manage and archive key documents, including tracking of key checks;
- Terms of benefit and their feasibility/acceptability; and
- Any restrictions or requirements should be identified and evaluated for acceptability;
- Process for contacting the competent authority in the provider country and any third parties should issues arise around legality or other aspects of the resource.

For utilisation of genetic resources

✓ Institution policies should ensure:

- Utilisation of genetic resources is compliant with PIC and MAT and other terms and agreements;
- Individuals with responsibility for due diligence reporting are identified and aware of requirements and timing of declarations;
- The correct information is reported in publications;
- Terms are renegotiated with provider countries where required and signed by authorised personnel; and
- Utilisation of genetic resources is recorded and tracked in accordance with due diligence obligations.

For supply or transfer of genetic resources to third parties

✓ Institutions should have policies and procedures in place to:

- Track and record supply of genetic resources in accordance with due diligence obligations;
- Ensure biological material is supplied (temporarily or permanently) to third parties only on terms and conditions consistent with those under which it was acquired;
- Use standard MTAs to facilitate third party supply and utilisation in line with terms and conditions. MTAs should differentiate between commercial and non-commercial use as well as change in ownership (temporary vs permanent transfer) and should address ownership and intellectual property rights of any product or derivate resulting from utilisation of original samples;
- Handle inappropriate or prohibited utilisation of such material, e.g. notification of the Checkpoint or NFP of the user's country;
- Ensure third parties are aware of any restrictions or requirements; and
- Ensure that where required, third parties are aware of obligations to renegotiate terms with provider countries.

For data management linked to ABS monitoring

✓ Internal policies or procedures around acquisition should:

- Assess policies, management and record keeping protocols across collections and the institute, ensuring these are adequate and updating and harmonising where necessary;
- Ensure data management allows the tracking of:
  - Acquisition of genetic resources including associated legal documentation (PIC; MAT; IRCC; MTA; other permits and agreements), any restrictions or requirements around utilisation or transfer and the data required to fulfil due diligence;
  - Utilisation and the person, group or subcontractor utilizing them and whether this was funded by internal or external sources;
  - Any temporary or permanent supply to third parties (if permitted) and supply with required documentation; and
  - Any benefits derived from use/utilisation and shared with the provider country; and
  - When and how genetic resources exited the institution or collection, e.g. loss, disposal.

For disposal and deaccession of genetic material

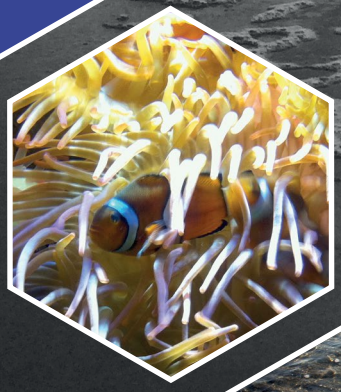
- ✓ Institutions should have policies and procedures in place to track:
    - If the original PIC, MAT or MTA requires the genetic resource to be destroyed;
    - That destruction or other disposal has taken place and the provider country informed;
    - The use of genetic resources, including complete consumption and disposal;
    - When and how specimens permanently leave the ownership/custodianship of the Institution, including permanent transfer of ownership to a third party; and
    - Loss of genetic resource by collection, staff or third parties.

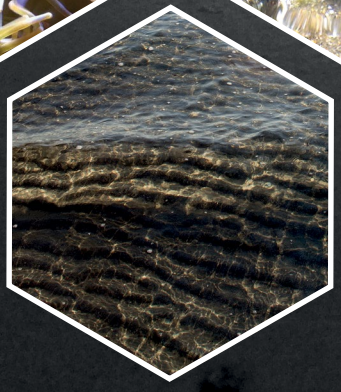
Regarding retrospective compliance to ABS framework

- ✓ Institutions are encouraged to apply best practices, as far as reasonably possible, to all biological material in their collections;
- ✓ Collections and biobanks should identify countries of origin, find out their national legislation, and where relevant, seek retrospective compliance in accordance with their legislation; and
- ✓ Establish a risk management policy with regards to non-compliant material.

D 5.1

PART 1: EMBRC BEST PRACTICES TO SUPPORT ABS COMPLIANCE





EBB
an EMBRC project

List of Tables

List of Figures

1. Introduction

The European Marine Biological Resource Centre (EMBRC-ERIC[2], hereinafter referred to as EMBRC) is a distributed pan-European research infrastructure that provides access to coastal marine ecosystems and marine biological resources for both fundamental and applied research. Providing access to marine genetic resources is one of EMBRC's primary services.

The EMBRC is committed to facilitating access to and supply of marine biological and genetic material to users in compliance with international, European and national legal frameworks regarding Access and Benefit Sharing (ABS). European Blue Biobank (EBB) project, under the umbrella of EMBRC, supports this aspiration by promoting compliance with ABS regulations derived from the Nagoya Protocol and implemented in Europe through the EU ABS Regulation[3] that came into force in 2014 as well as Member State's access legislation, where applicable. This regulatory framework, although effective in protecting the rights of the provider country, puts burden on the user to demonstrate lawful utilisation. In this context, research infrastructures, facilities, biobanks and collections may play a role by facilitating legal compliance and lawful use of the genetic resources **(and any associated traditional knowledge)** they provide.

ABS rules complement those regulating access to the sea and its resources under national jurisdiction i.e. water column and seabed under the United Nations Convention on the Law of the Sea (UNCLOS) in Exclusive Economic Zones (EEZ), Regional Seas Conventions (e.g. OSPAR), and related instruments and Marine Protected Areas. In addition, other legal instruments regulate access and utilisation of marine genetic resources from locations beyond national jurisdiction (e.g. Antarctica Treaty System, current negotiation of an International Legally Binding Instrument under the UNCLOS for biological diversity in the deep seabed and the high seas, including genetic resources). This handbook outlines these key instruments and the Nagoya Protocol and European ABS legislation to provide collections and users with an understanding of the background and development of ABS and the scope of implementation. Regardless of ABS and the mentioned frameworks, other national measures applicable to natural resources should be observed and collections and users should seek advice to ensure they comply with these.

These best practice recommendations are designed to support EMBRC partners to meet the requirements of compliance under the EU ABS Regulation in terms of collecting, transferring and using bio-resources and that users accessing bio-resources through participating institutions are confident about their origin.

2 https://embrc.eu/embrc-network has the legal status of a European Research Infrastructure Consortium (ERIC), which was awarded by the European Commission on 20 February 2018.

3 "EU ABS Regulation No 511/2014 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 Utilisation in the Union". https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32014R0511

2. Normative Framework

At the international level, different parallel or complementary legal frameworks regulate scientific research on marine biological resources:

- The international treaty applying to scientific research on genetic resources is the Convention on Biological Diversity and its Nagoya Protocol setting up the Access and Benefit Sharing (ABS) system, but specific biomaterial, i.e. influenza viruses and protected seeds, fall under specialised ABS regimes; and
- Research at sea including when the activity of collecting biomaterial for science falls under the United Nations Convention on the Law of the Sea[4] (UNCLOS) when performed within the national jurisdiction, whereas specialised treaties regulate marine research in areas beyond national jurisdiction (which predominantly cover the Antarctic, the high seas, the seabed, the ocean floor and subsoil thereof outside of nation jurisdictions, termed "the Area"). A supplementary treaty to UNCLOS will be soon adopted that covers a status for utilising the marine genetic resources from the high seas.

2.1 Scientific research on genetic resources

Scientific activity using genetic resources is regulated by different frameworks depending on the activity performed (research and development over the genetic or biochemical activities of the resource, agriculture or health research) or the type of resources (human or non-human genetic resource, protected genetic resource or international health threat).

The ABS framework developed within the Convention on Biological Diversity covers the utilisation of non-human genetic resources in R&D, but said utilisation could also fall under the World Health Organisation Pandemic Influenza Preparedness Framework or the Food and Agriculture Organisation International Treaty on Plant Genetic Resources for Food and Agriculture.

2.1.A The Convention on Biological Diversity and the Nagoya Protocol

The discussion on accessing and using genetic resources in a fair and equitable way has its roots in the North-South debate [5], which goes back as far as the decolonization era. The developing countries (including newly industrialized) have long demanded respect of their sovereign rights over their resources and equitable sharing of benefits.

The North-South debate, brewing for years in the field of international law, has led to new principles, such as the principle of Common but Differentiated Responsibilities and the principle of the states' sovereignty over their natural resources. This was included in the Convention on Biological Diversity (CBD)[6] in 1992 and was reaffirmed in the Nagoya Protocol [7] (NP) in 2010.

One of the three pillars of the CBD, along with the conservation of biodiversity and the

4 http://www.un.org/depts/los/convention_agreements/texts/unclos/unclos_e.pdf

5 The North – South debate (North – South dialogue) is the term used to describe the process through which the "third world countries" engaged the rich Northern countries (North America and Western Europe) in negotiations over changes to the international economic system during the 1970s (New International Economic Order). This process had serious impacts on the development of international environmental law.

6 http://www.cbd.int

7 https://www.cbd.int/abs/

sustainable use of biodiversity, is "the fair and equitable sharing of the benefits arising from the utilisation of genetic resources" (CBD Art. 15, see Figure 1.1). With regard to this latter pillar, the Convention provides us with four major axioms:

- States have sovereign rights over their natural resources in areas within their jurisdiction;
- States shall facilitate access to genetic resources for environmentally sound uses and shall not impose restrictions that run counter to the objectives of the CBD;
- Parties to the Convention have the authority to determine access to genetic resources in areas within their jurisdiction by developing national legislation. Access is subject to prior informed consent and, when granted, utilisation shall be on mutually agreed terms; and
- Parties to the Convention shall take appropriate measures for sharing the benefits derived from the use of genetic resources.

There is no specific definition of marine genetic resources in either the CBD or any other international or regional document. CBD Art. 2 defines "genetic resources" as "genetic material of actual or potential value". In the same article, "genetic material" is defined as "any material of plant, animal, microbial or other origin containing functional units of heredity".

The 6th Conference Of the Parties (COP-6) to the CBD adopted the 'Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilisation[8]'. This non-binding document was developed to assist parties to the Convention in the implementation of relevant provisions of the CBD when establishing legislative, administrative or policy measures on ABS and/or when negotiating contractual arrangements for ABS.

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation (ABS) to the Convention on Biological Diversity ("Nagoya Protocol" signed on 29 October 2010 and entered into force on 12 October 2014) reaffirms the sovereign rights of the states over their natural resources and the principles of prior informed consent (PIC) and mutually agreed terms (MAT), and establishes, for the first time, obligations to support ABS compliance. In addition, Art. 8 of the Nagoya Protocol calls for states to promote and encourage non-commercial research by using simplified measures, taking into account the need to address any change of intent.

The Nagoya Protocol defines a set of three obligations for its Parties:

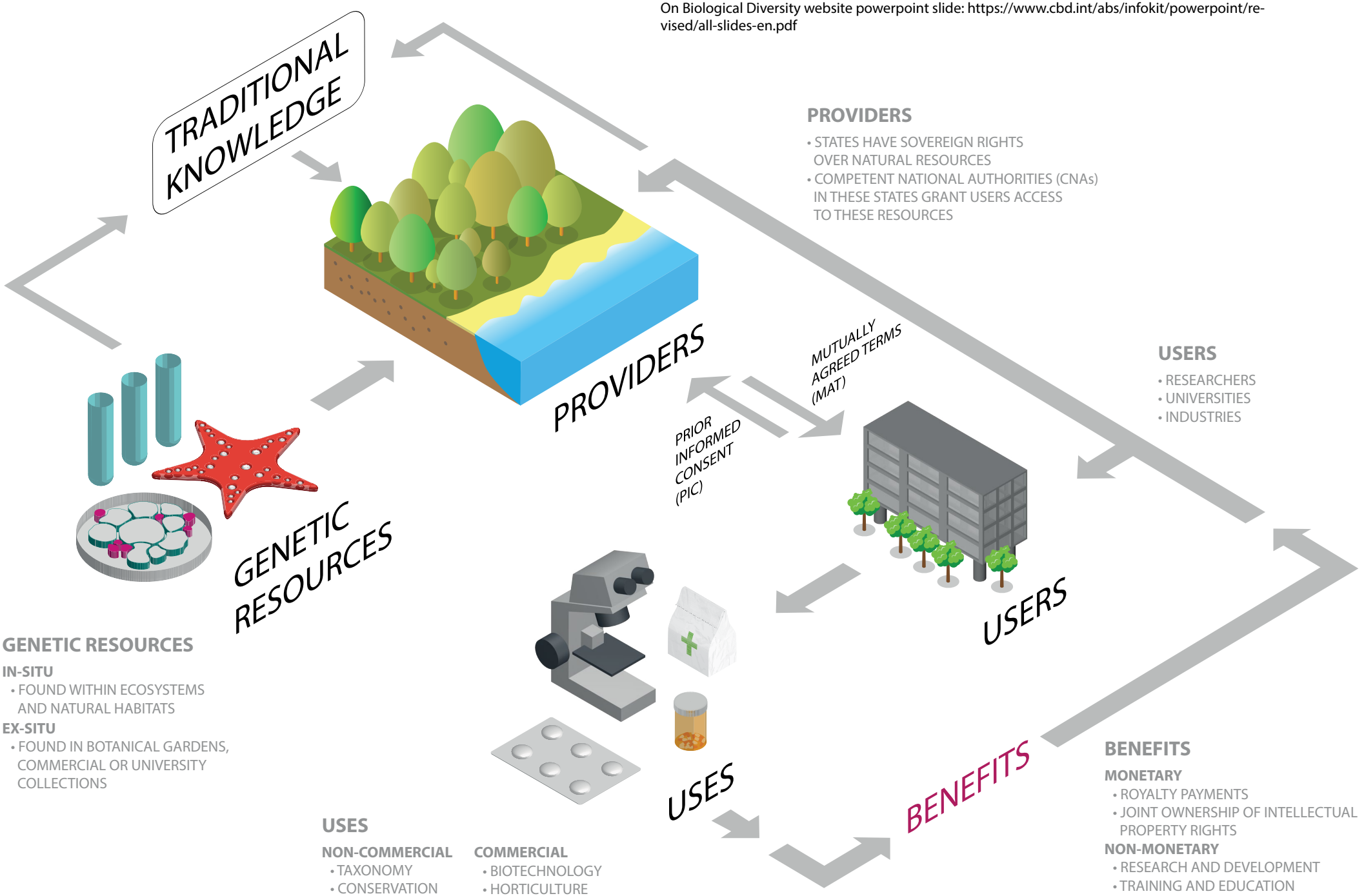
- Access whereby a country establishes clear rules for accessing and using its natural resources, including deciding whether the access is granted or not;
- Benefit-sharing measures that are fair and equitable; and
- Compliance obligations, meaning measures taken to insure that genetic resources utilised in their jurisdiction have been accessed in accordance to ABS requirements and to monitor ABS on non-domestic genetic resources.

The issue of "digital sequence information on genetic resources" [9] (i.e. sequence data) is at present under the scrutiny of the CBD's COP. A specific regime is expected to be adopted in the forthcoming years. It is worth mentioning that some countries have already regulated on digital sequence information (DSI) or have included DSI in the definition of their genetic resources.

8 Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilisation, https://www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf

9 https://www.cbd.int/dsi-gr/

Figure 1.1. Access and benefit sharing in a nutshell. Redrawn by © Rufus Wood 2021 from the Convention On Biological Diversity website powerpoint slide: https://www.cbd.int/abs/infokit/powerpoint/revised/all-slides-en.pdf



2.1.B International specialised ABS regimes

Existing international agreements are not affected by the entry into force of the Nagoya Protocol in 2014. This includes other specialised ABS agreements governing the utilisation of specific genetic resources, namely in health or agriculture and food.

2.1.B.1 The Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines or other benefit (WHO PIP Framework)

The UN World Health Organisation adopted in 2011 a framework to facilitate the exchange of influenza viruses between laboratories and relevant stakeholders in an attempt to implement a global approach to pandemic influenza preparedness and response. It is conducted by a Global Influenza Surveillance and Response System (GISRS) with international influenza laboratories organised as a network working under standard methods and material transfer agreements. The GISRS acquire the necessary biomaterial and transfer it to the relevant users.

According to article 8 of the Nagoya Protocol, the EU has also established another public health emergency preparedness for pathogens within the compliance measures. Art. 4.8 of the EU ABS Regulation allows for users acquiring "genetic resource that is determined to be, or is determined as likely to be, the causing pathogen of a present or imminent public health emergency of international concern" to fulfil the due diligence obligations at the latest:

- One month after the imminent or present threat to public health is terminated; or,
- Three months after commencement of utilisation of the genetic resource;
  whichever is the earlier.

2.1.B.2 The International Treaty on Plant Genetic Resources for Food and Agriculture (FAO Seed Treaty)

The ITPGRFA (or FAO Seed Treaty) has been adopted in 2004 under the UN Food and Agriculture Organisation. It constitutes a specialised international ABS instrument that is not be affected by the rules implementing the Nagoya Protocol. The Seed Treaty set up an ABS regime whereby 64[10] of the worlds most important crops comprise a pool of genetic resources that are accessible to everyone in a multilateral system that links genebanks and collections worldwide and puts the crops and collections in the public domain under the direct control of the Parties to the Treaty.

The Multilateral System facilitates the access, the transfer and the benefit-sharing on the 64 crops by standardized procedures and MTAs. The utilisation of the crops under ITPGRFA is limited to R&D for food and agriculture, and excludes R&D in chemical, pharmaceutical, cosmetics, bioenergy, etc.

A user is considered to have exercised due diligence under the EU ABS Regulation when acquiring in a country that is a Party to the Nagoya Protocol, a Plant Genetic Resources for Food and Agriculture (PGRFA) not listed in the ITPGRFA but subject to the the ITPGRFA standard material transfer agreement.

10 The list of the 64 food and forages crops covered under the Multilateral System: http://www.fao.org/3/a-bc084e.pdf

2.1.C The ABS framework in the European Union

The European Union adopted the Nagoya Protocol on 14 April 2014. With sovereignty over their natural resources, each member State remains solely competent over the decision to regulate the access to their genetic resources and the European Union's scope of intervention is limited to ensuring the application of ABS due diligence on its territory. In March 2020[11], Italy, Cyprus, Ireland, Poland, Latvia, Lithuania had not signed the Nagoya Protocol and France, Spain, Malta and Bulgaria were regulating access to their genetic resources.

The EU Regulation No 511/2014 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 Utilisation in the Union" (EU ABS Regulation) was adopted on 16 April 2014 to implement the mandatory elements of the Nagoya Protocol, i.e. the compliance measures.

According to EU ABS Regulation No 511/2014. Art. 4:

"Users shall exercise due diligence to ascertain that genetic resources […] have been accessed in accordance with applicable ABS legislation or regulatory requirements, and that benefits are fairly and equitably shared upon mutually agreed terms, in accordance with any applicable legislation or regulatory requirements."

2.1.D Assessing if genetic resources are in scope

A user must first determine whether access and use of genetic resources and/or traditional knowledge are within the scope of the EU ABS Regulation. This must be done on a case-by-case basis and must be examined each time a genetic resource and/or traditional knowledge is accessed for its utilisation. The European Commission has provided guidance[12] on the scope of the application and this is summarized in Figure 1.2 and Table 1.1 (below). Further guidance on implementing core obligations on the EU ABS Regulations has also been developed and is currently under development[13]. It is important to note that countries may have access measures that cover a broader scope than the EU compliance measures, the Nagoya Protocol, or the Convention on Biological Diversity. These should be observed regardless of if they are out of scope of the EU compliance measures.

11 According to the ABSCH: https://absch.cbd.int/countries/EU

12 Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52016XC0827%2801%29

13 Ibid

To help users of genetic resources assess whether resources are in scope based on the conditions above, the EC has edited the following chart (Figure 1.2)

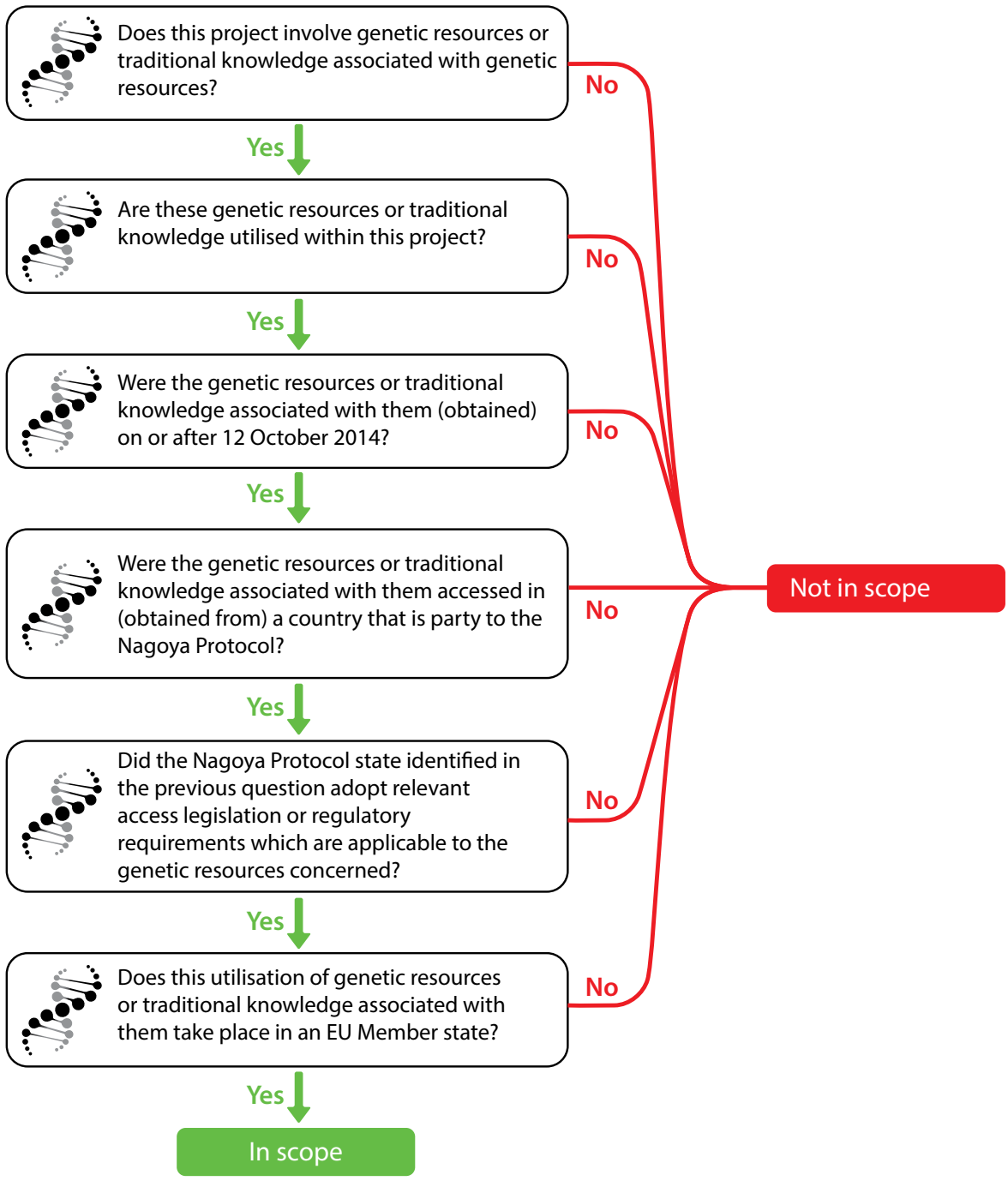


Figure 1.2 Decision support flow chart to assess whether genetic resources are in scope of EU ABS Regulations. (© European Commission. Redrawn by © Rufus Wood 2021 from the Horizon 2020 online manual[14]). Table 1.1 provides more detail.

The following elements are of importance when deciding if a resource falls within the scope of the EU ABS Regulation: geographic area, access by the user (in-situ, i.e. date of sample collection or ex-situ, i.e. acquisition from collection or biobank), type of material and intended use. All elements must be fulfilled for the EU ABS Regulation to apply.

14 https://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/ethics_en.htm

Some basic points and clarifications regarding the scope of the EU ABS Regulation are summarized as follows (see also Figure 1.2 above and Table 1.1 below):

- In cases where genetic resources are obtained by the user indirectly (e.g. from culture collections) the national legislation or other requirements (including national environmental protection law) of the country which has jurisdiction over the genetic resource still apply (together with the country's collection, for the collection's activity); and
- In cases of indirect access to genetic resources through collections located in the country that has jurisdiction over these genetic resources, given the country in question has in place access rules for such ex-situ genetic resources and if they are accessed from the collection after the entry into force of the Nagoya Protocol, this falls within the scope of the EU ABS Regulation, regardless of when the resources were collected.

Table 1.1 Overview of conditions for applicability of the EU ABS Regulation[15] to genetic resources (GR).

		Within scope (cumulative conditions)*	Outside of scope
Geographic scope (provenance of genetic resource)	Access in-situ or ex-situ in…	Area within a country's jurisdiction	Area beyond national jurisdiction e.g. high seas or covered by Antarctica Treaty System
	Provider country / country of origin of the GR is...	Party to the Nagoya Protocol	Not a party to the Nagoya Protocol
	Provider country / country of origin of the GR has...	Applicable access legislation	No applicable access legislation
Temporal scope	Access by the user	On or after 12 October 2014	Before 12 October 2014
Material scope	Genetic Resources (GR)	Not covered by a specialised ABS instrument**	Covered by a specialised ABS instrument**
		Non-human	Human
		Obtained as commodities but subsequently subject to R&D	Used as commodities
	Utilisation	R&D on genetic and/or biochemical composition	No such R&D
Personal scope		Natural or legal persons utilising genetic resource	Persons only transferring genetic resource or commercializing products based on it
Geographic scope (utilisation)	R&D	Within the EU	Exclusively outside of the EU

* To be within scope, all conditions must be fulfilled.

** Use and transfer of influenza viruses are covered by a specialised international ABS instrument: the WHO PIP Frameworkgenetic resources for agriculture and food listed in Annex 1 of the ITPGRFA (the FAO Seed Treaty) fall under a different ABS regime. (See B. Specialised regimes). Pathogens out of the scope of the PIP Framework are covered by the Nagoya ABS regime, but the procedure is facilitated in case of international or transnational public health emergency (Art. 4.8 EU ABS Regulation). The EU ABS Regulation allows users acquiring with the ITPGRFA standard material transfer agreement, a Plant Genetic Resources for Food and Agriculture (PGRFA) not listed in the ITPGRFA in a country that is a Party to the Nagoya Protocol is considered to have exercised due diligence.

15 Adapted from Guidance document on the scope of application and core obligations of EU ABS Regulation - Commission Notice (2016/C 313/01). https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52016XC0827%2801%29

2.2 Scientific research at sea

Marine scientific research on biological material falls under different legal regimes depending on the place where the research is performed and / or the material collected (see Figure 1.3):

- Within the national jurisdiction, i.e. on the territorial sea, the Exclusive Economic Zone or the extended continental shelf; and
- Beyond national jurisdiction, i.e. in the high seas, the seabed, the ocean floor and subsoil thereof outside of nation, in Antarctica or in the Poles.

2.2.A Marine scientific research in areas within national jurisdiction

According to UNCLOS, all states have the right to conduct marine scientific research[16] (Art. 238) and shall promote and facilitate the conduct of research (Art. 239).

Coastal States have the right to regulate marine scientific research in their territorial sea, Exclusive Economic Zone (EEZ) and continental shelf, so their consent is needed to carry out marine scientific research, including sampling biological material, in these areas under their jurisdiction (Arts. 245 and 246). Besides, there is an obligation to comply with certain conditions as stated in Art. 249, such as to "ensure the right of the Coastal State, if it so desires, to participate or be represented in the marine scientific research project, especially on board research vessels and other craft or scientific research installations" and to "undertake to provide access for the Coastal State, at its request, to all data and samples derived from the marine scientific research project".

In addition, the following information should be made available to the Coastal State at least six months in advance (Art. 248):

- The nature and objectives of the project;
- The method and means to be used, including name, tonnage, type and class of vessels and a description of scientific equipment;
- The precise geographical areas in which the project is to be conducted;
- The expected date of first appearance and final departure of the research vessels, or deployment of the equipment and its removal, as appropriate;
- The name of the sponsoring institution, its director, and the person in charge of the project; and
- The extent to which it is considered that the Coastal State should be able to participate or to be represented in the project.

These conditions are well established within the marine research community and are generally already being followed by researchers involved in exploratory campaigns at sea. As detailed below, there are many similarities in the conditions which need to be fulfilled by the user to demonstrate due diligence with the abovementioned conditions included in UNCLOS.

The UNCLOS requirements and compliance overlap and somehow undermine the ABS framework and it happens that the collection of material at sea is performed without ABS due diligence due to the complexity of superimposing very similar but different systems.

16 Part XIII of UNCLOS refers to Marine Scientific Research without providing a definition. http://www.un.org/depts/los/convention_agreements/texts/unclos/unclos_e.pdf

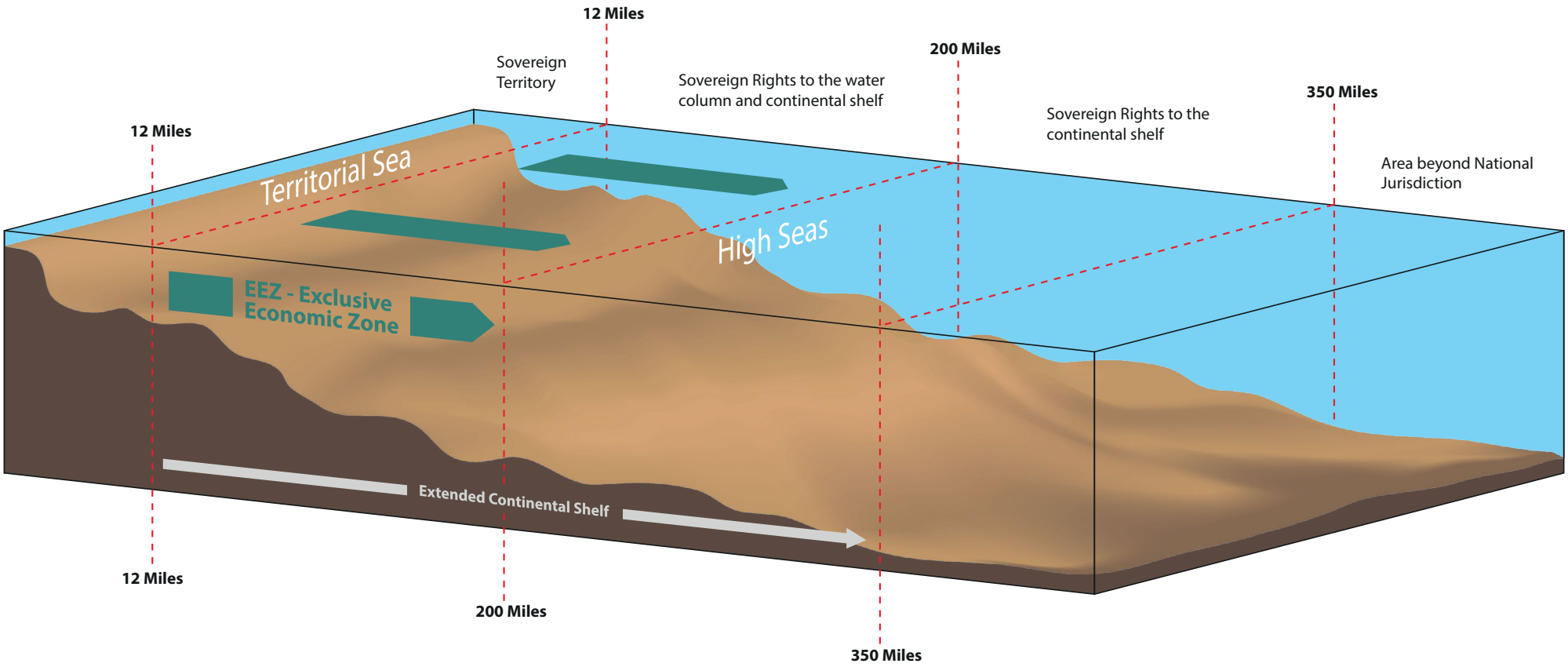


Figure 1.3. Marine areas within and beyond national jurisdictions (redrawn by Rufus Wood). See also Annex 5 (PART 2 of the Handbook)

Annex 6 provides recommendations to prepare exploratory campaigns at sea with the objective to address both legal frameworks when collection of material and to lawfully manage the collection under the UNCLOS and the ABS requirements of the Coastal State, if any.

2.2.B Beyond national jurisdiction

The Nagoya Protocol only covers areas within the jurisdiction of a State. Areas Beyond National Jurisdiction (ABNJ) predominantly cover the Antarctic, the high seas, the seabed, the ocean floor and subsoil thereof outside of nation jurisdictions (termed "the Area") (UNCLOS, Art. 1).

The high seas are defined as the sea not included in the EEZ, in the territorial sea or in the internal waters of a State, or in the archipelagic waters of an Archipelagic State, according to UNCLOS (Art. 86).

Although the Antarctic is not covered by a single nation jurisdiction, it is governed by its own treaty system (Antarctic Treaty System) and is thus not covered by the Nagoya Protocol.

In all of these areas, research is not restricted for all States under the condition that it is for peaceful purposes only. Access to genetic resources is not regulated, although there are currently ongoing discussions on this issue within relevant United Nations forums.

The United Nations have opened an Intergovernmental Conference on an International Legally Binding Instrument under UNCLOS on the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction (General Assembly Resolution 72/249).
One of the four topics under discussion is the legal regime of the ABS from marine genetic resources in these areas. An agreement was expected to be reached for mid-2020 at the 4th Inter-Governmental Conference, but the latter was postponed due to the COVID-19 pandemic.

In conclusion, the basic premises of the international treaties impacting the scientific research on marine biological resources can be summarized as follows:

- States have sovereign rights over their own natural resources;
- States have rights over scientific research, data and samples in the remit of their territory (EEZ included);
- States party to the Nagoya Protocol may or may not choose to adopt access measures to their genetic resources;
- Users in the European Union must show evidence of compliance to the Nagoya Protocol when using genetic resources for scientific activities;
- Users must check if PIC from the provider country is required for using genetic resources, in addition to the other research permits from the State to access biological material for marine scientific research; and
- Benefit sharing may be monetary or non-monetary and should be agreed in MAT between the competent authority of the country providing the genetic resources and the user of the genetic resources.

The following Best Practice Guidelines have been developed to help EMBRC institutions and scientists in their activity of sampling biological material in territorial seas and EEZ, for the purpose of using it for genetic or biochemical activities, transferring it to be utilised, conserving it in collections. A template to support implementation is provided below in Figure 1.4.

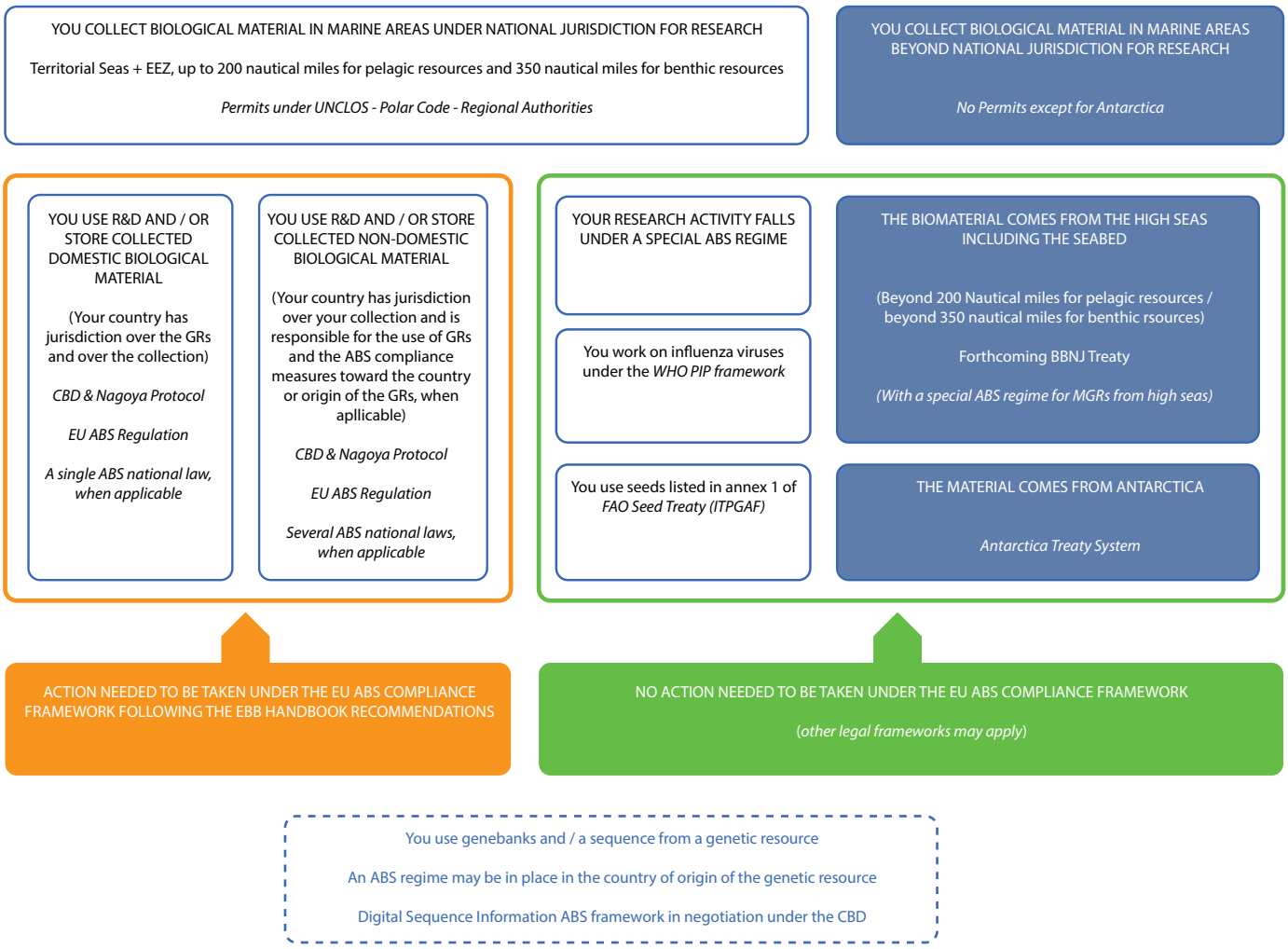


Figure 1.4. Template to implement the EMBRC Handbook (with applicable legal frameworks).

3. Best Practice Guidelines

"Best practices" in the sense of the EU ABS Regulation (Art. 8) are procedures, tools or mechanisms, developed and overseen by associations of users or other interested parties, which – when effectively implemented – help users of genetic resources to comply with the obligations of the EU ABS Regulation[17].

The Commission Implementing Regulation[18] lays down detailed rules for the implementation of the EU ABS Regulation and sets out the procedural requirements for the recognition of best practices.

This section sets out two sets of best practice guidelines (BPG):

- BPGs for collections aimed at ensuring compliance with ABS obligations, preparing them for entry into the EU register of collections by harmonising procedures (see 3.I.A) and facilitating the due diligence obligations of collections' users and depositors (see 3.2.fixed B below and Background section from the PART 2 of the Handbook); and
- BPGs for accessing marine genetic material aimed at clarifying due diligence obligations and harmonising procedures, contributing to minimize administrative burden on users.

3.1 Best practice guidelines for EMBRC institutions

The BPGs laid out in this document have been developed for the EMBRC institutions to support registration of their collections and to ensure that collections that are not registered comply with ABS regulations. Further technical information and discussion on each of the guidelines are provided in PART 2 of this Handbook.

3.1.A Internal policies and procedures to implement best practice

To implement best practices, institutions will require policies, implementation and training. A checklist of these is provided in the Executive Summary of this document. Activities or points in workflows, where decisions have to be taken – which have an ABS implication, which are governed by ABS legislation, or where ABS concerns have to be managed are indicated in the flowchart below (Figure 1.5). The flowchart indicates the relevant accompanying Technical Guidelines (PART 2).

3.1.B The European Register of Collections

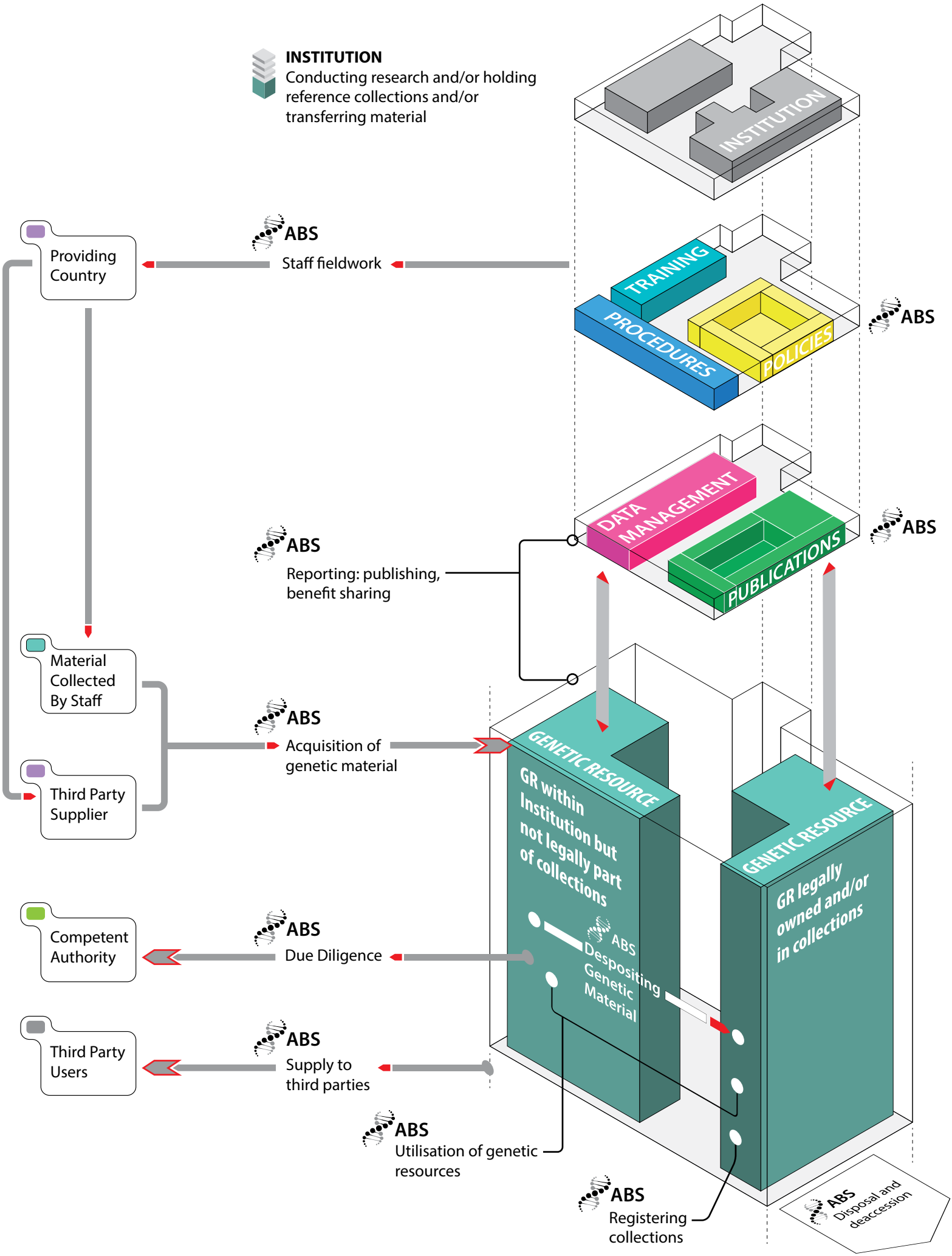
The preamble of the EU ABS Regulation sets out the requirements for a voluntary register of trusted collections which apply measures ensuring the supply of resources with documentation on their legal access. The intention is that registered collections minimise the risk that a genetic resource which is not accessed in accordance with a national law or regulation is utilised in the European Union and contribute to a reduction in administrative and compliance requirements.

A collection is defined in the EU ABS Regulation as *"a set of collected samples of genetic resources*

17 http://ec.europa.eu/environment/nature/biodiversity/international/abs/legislation_en.htm

18 Commission implementing Regulation (EU) N° 2015/1866 http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32015R1866

Figure 1.5. Workflow points at which ABS must be considered (redrawn and modified by © Rufus Wood 2021 from Chris Lyal's Natural History Museum ABS workflow with permission). This same image with links to the relevant technical guidance is provided in Part 2 of this document.



and related information that is accumulated and stored, whether held by public or private entities". The procedural requirements for the registration of collections of genetic resources are set out in the Implementing Regulation. A registered collection (Art. 5 of the EU ABS Regulation) refers to a collection which has demonstrated the capacity to apply standardised procedures for exchanging and supplying samples of genetic resources (and related information).

The European Commission is responsible for establishing and maintaining the Register of collections within the Union, whereas the CNAs of the EU Member States are responsible for verifying that the collection meets the criteria set out in the EU ABS Regulation and granting the status of registered collection. According to EU ABS Regulation (Art. 5, par.3), in order for a collection or a part of a collection to be included in the register, it shall demonstrate its capacity to:

- Apply standardized procedures for exchanging samples of genetic resources and related information with other collections, and for supplying samples of genetic resources and related information to third persons for their utilisation in line with the Convention on Biological Diversity and the Nagoya Protocol (see Technical Guideline 4 and 5, PART 2 of the Handbook);
- Supply genetic resources and related information to third persons for their utilisation only with documentation providing evidence that the genetic resources and the related information were accessed in accordance with applicable access and benefit-sharing legislation or regulatory requirements and, where relevant, with MAT (Technical Guideline 4);
- Keep records of all samples of genetic resources and related information supplied to third persons for their utilisation (Technical Guideline 4 and 5);
- Establish or use unique identifiers, where possible, for samples of genetic resources supplied to third persons (Technical Guideline 5); and
- Use appropriate tracking and monitoring tools for exchanging samples of genetic resources and related information with other collections (Technical Guideline 5).

Users obtaining a genetic resource from a registered collection would be considered to have exercised due diligence as regards the seeking of information[19].

3.1.C Recommendations

The following recommendations 1 to 6 set the ABS compliance minimum standards for acquiring and distributing genetic resources, irrespective of the registration as a trusted collection under EU ABS Regulation Art. 5. They are supported by the Technical Guidelines (PART 2 of the Handbook).

3.1.C.1 Acquisition of genetic material by institute personnel (Technical Guideline 1)

Technical Guideline 1 (PART 2 of the Handbook) sets out guidance and steps with flow charts to be followed for direct acquisition of genetic resources by institution personnel. In order to meet the due diligence requirements laid out in the EU ABS Regulations (Art 4. par. 3), the following obligatory information is recorded every time a resource that is destined for distribution is collected by staff. The steps for acquiring genetic resources through field work is laid out below

19 EU ABS Regulation No 511/2014 Article 4. Paragraph 7. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32014R0511

in section 3.2.A as this is the process recommended for institute staff and other users.

- Name/affiliation of the collector;
- Date and geographical location of sample from which the material originates;
- Collector's identifier;
- Description of the material;
- Information on any rights and obligations related to ABS;
- Information on the source from which material was directly obtained (person or department approving permit/collection or person/company from which the resource was obtained); and
- Access permits and any other legal documentation accompanying the material including IRCC, PIC and/or MAT, where applicable. Where not applicable, for example because there is no access regulation in the country of origin, or because the regulations of access exclude the genetic resources or the specific utilisation it is advised to keep track of the rationale and evidence justifying this.

This information is recommended to be kept for all material collected in areas within national jurisdiction (territorial waters and Exclusive Economic Zone) as well as for areas beyond national jurisdiction (beyond 200 miles for pelagic species, and beyond 350 miles for benthic species) which do not fall under the Nagoya Protocol.

Any collected material destined for distribution must be identified by a unique reference number.

3.1.C.2 Depositing material in collections (Technical Guideline 2)

It is recommended that a Material Accession Form (also referred to as a Material Deposit Form) is used by institutions to be filled in by the depositor that will include at least the following obligatory information in order to meet the due diligence requirements laid out in Art. 4 par 3: (see Background Section and Annex 1 of accompanying technical guidelines and annexes, PART 2 of the Handbook):

- Name/affiliation/contact details of the depositor;
- Date and geographical location of sample from which the material originates;
- Depositor's identifier;
- Description of the material;
- Information on the source from which material was directly obtained;
- Information on any rights and obligations related to ABS; and
- Access permits and any other legal documentation accompanying the material including IRCC, PIC and/or MAT, where applicable. Where not applicable, it is advised to keep track of the rationale and evidences justifying so.

This information is recommended to be kept for all material collected in areas within national jurisdiction (territorial waters and Exclusive Economic Zone) as well as for areas beyond national jurisdiction (beyond 200 miles for pelagic species, and beyond 350 miles for benthic species) which do not fall under the Nagoya Protocol.

It is recommended that the Material Accession Form includes a declaration by the depositor that to the best of his/her knowledge there is no infringement with any third party rights (as in the template provided in Annex 1 from the annexes (see Technical Guidelines Document, PART 2 of the Handbook)). It is recommended that any deposited material is identified by a unique reference number specific to the institution.

3.1.C.3 Defining and communicating availability of resources to be "utilised in compliance with ABS regulations" (Technical Guideline 3)

The institutions catalogue of resources (which is recommended to be available on-line), should ensure that the utilisation status of each resource is clear to potential users. Resource status is either:

- Available to be used without restrictions in compliance with ABS regulations;
- Available to be used in compliance with ABS regulations with restrictions; and
- Not available to be used in compliance with ABS regulations.

If the MAT allows for any type of utilisation by any user (or if no MAT is required), the resource is considered available to be used without restrictions in compliance with ABS regulations. In some cases, a genetic resource may be "available to be used in compliance with ABS regulations with restrictions" depending on the project and the activity undertaken, for example taxonomic activity performed on a Spanish genetic resources does not require a renegotiation of PIC / MAT whereas another utilisation would not be allowed under Spanish law without renegotiating PIC / MAT.

Genetic resources for which a MAT has been obtained (when necessary) may be available to be used in compliance with restrictions imposed by the provider country. In this case users must be clearly informed that the resource is available to be used with restrictions and a summary of the utilisation conditions must be provided. In some instances, the genetic resource can only be utilised if the user obtains the necessary ABS permits (which could include MAT) for its utilisation. Restrictions imposed by the provider country must be accessible on the documentation available with the genetic resources (ABS resource passport (see section below 3.1.C.6) with conditions set in the MAT).

In general, only resources available to be used in compliance with EU ABS Regulations (with or without restrictions imposed by the provider country) should be distributed for non-commercial and commercial research that falls under the scope of the EU ABS Regulations. Resources that are not available to be used in compliance with EU ABS Regulations, can however be distributed under certain circumstances if the Terms and Conditions/ MTA explicitly inform that the accessed resource can only be utilised for activities that fall out of the scope of ABS regulations and that the responsibility of unlawful use falls entirely on the user.

3.1.C.4 Supplying material and transferring to third parties (Technical Guideline 4)

For supplying material to users for research purposes, the minimum recommendation is that the genetic resource is supplied with an ABS resource passport, an Order Form accompanied by publicly available Terms and Conditions (see model forms in Annex 1, PART 2 of the Handbook). If the MAT does not allow the transfer to a third party, the collection must acquire an authorization from the competent national authority prior to the supply. If the utilisation falls under the scope of EU ABS Regulations, the obligations of the user should be clearly flagged to:

- To seek authorization from the CNA of any deviation from the original utilisation (since any change in intended use may require renegotiation of MAT with the country of origin) unless the original MAT allows for it; and
- Eventually to seek authorization from the CNA for a transfer of material to a third party.

It is recommended that the Terms and Conditions for acquiring biological material from the collection are available online.

The Order Form should contain at least the following information:

- Recipient's name/affiliation/contact details;
- Date of access;
- The collection identifier(s) of material ordered;
- Country of origin;
- Short description of intended use;
- Detail of any fees;
- Recipient's declaration that he/she accepts the Terms and Conditions; and
- Recipient's signature.

Order Form Recommendations
It is recommended that the following paragraphs are added to Order Forms "(name of the institute) will supply the material to the recipient in accordance with the following Terms and Conditions. In order to be valid, the order form must be signed and sent to (name of the institute)." In addition, the institution's collections and biological resource centres websites should inform users in its Terms and Conditions that it is the user´s responsibility to lawfully use the provided resources by the following disclaimer: "Utilisation of the material is subject to the sovereign rights of the country of origin with respect to accessing the material and sharing the benefits of its utilisation. The user may be requested to negotiate the rights to use the material with the country of origin if the intended utilisation is not included in the existing MAT. The user will be solely responsible for unlawful use of provided material."

3.1.C.5 Minimum and recommended database requirements (Annex 4)

Institutions are required to ensure long-term traceability of data relating to the acquisition, maintenance and distribution of genetic resources. Data should be stored in a structured database for 20 years, preferentially in an electronic form.

Annex 4 provides a list of obligatory and recommended data fields for institution databases. Harmonization of data field labels according to the list is preferable, but it is not obligatory to have exactly the name proposed in the list as long as there is an equivalent field name for which the content fits the description given in the list.

Databases may contain as many additional (optional) data fields as required by the institution. Whenever possible, accessory documents (including all permits) that are linked to the main record of the material should be digitized and saved in an accessible on-line repository.

All institutions are recommended to define, document and implement a strategy to ensure that genetic resource databases are secure and regularly backed-up in order to minimize the risk of loss of data.

3.1.C.6 Resource passport

To support compliance with EU ABS Regulations, institutions are required to provide a "resource passport" (in addition to a MTA) with every genetic resource that is supplied to any user. The resource passport should: 1) allow the user to comply with due diligence 2) demonstrate that the genetic resource was legally accessed and 3) provide information on the terms of use (e.g. PIC and MAT and other relevant permits or documentation).

As a minimum requirement the resource passport should contain the following information:

- Unique identifier of the resource;
- Country of origin of the resource;
- Date of collection (day/month/year);
- Name of person who collected resource;
- Name of institute of person who collected the resource;
- Country of institute of person who collected the resource;
- Name of person who deposited resource (if applicable);
- Name of institute of person who deposited resource (if applicable);
- Country of institute of person who deposited resource (if applicable);
- Identity of the resource (at least genus / species - can be "unidentified" if no information available);
- Sample permit identifier (if applicable);
- Other info on sample permit (if applicable);
- ABS status (available to be used without restrictions in compliance with ABS regulations / available to be used in compliance with ABS regulations with restrictions / not available to be used in compliance with ABS regulations); and
- ABS remarks (explanation of ABS status).

The passport can contain any other information the institute deems relevant.

3.2 Best practice guidelines for users

3.2.A Guidelines for accessing material in-situ

Any institution or user intending to directly collect genetic resources in-situ should follow the steps laid out in the Technical Guideline 1 (PART 2 of this Handbook) in order to ensure compliance with CBD, Nagoya Protocol and EU ABS Regulations and to be able to prove that the material was accessed legally and in line with the national legislation (please see also Annex 1 in PART 2 for template documentation).

In summary these steps are:

- Step 1. Identify and follow ABS legislation in the country where collecting the material, if applicable;
- Step 2. Contact national focal point to check access requirements of countries and permit requirements;
- Step 3. Seek collaboration with local scientists;
- Step 4. Contact the competent national authority of the country of origin of the genetic resource for advice before starting the fieldwork and to obtain PIC and MAT if required or other permits; and
- Step 5. Collect material and keep proof of all permits / documentation (or of efforts to acquire them).

Please note that sampling at sea also requires sampling permits under UNCLOS or Antarctic Treaty Secretariat, which is a different – parallel – procedure to that described above on ABS.

The Ocean Sampling Day organized by the FP7 MicroB3 project details the documents required (see Figure 1.3, Figure 1.6 and Annex 6 in PART 2) and set up protocols and a handbook for sampling (von Kries et al. 2015, ten Hoopen et al. 2016), which provides a useful overview of sampling requirements and could be followed[20].

3.2.B Due diligence obligations for users

3.2.B.1 Due diligence: information required

Art. 4 par. 3 of the EU ABS Regulation requires certain information to be sought and kept in order for the users to prove that they have exercised their due diligence obligation and to be submitted to the competent authorities of the country where utilisation is taking place. The competent national authority in the State in which the utilisation is carried out, can advise users on the competent authorities to which due diligence declarations should be made and how to do this and the specific number and identity of checkpoints. For the purpose of due diligence, the following information (Table 1.2) should be kept by the user or collection (for 20 years) and transferred to subsequent users[21] where applicable and in accordance with PIC and MAT.

20 https://www.microb3.eu/sites/default/files/osd/OSD_HandbooK_2016.pdf

21 EU ABS Regulation No 511/2014. Art. 4. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32014R0511

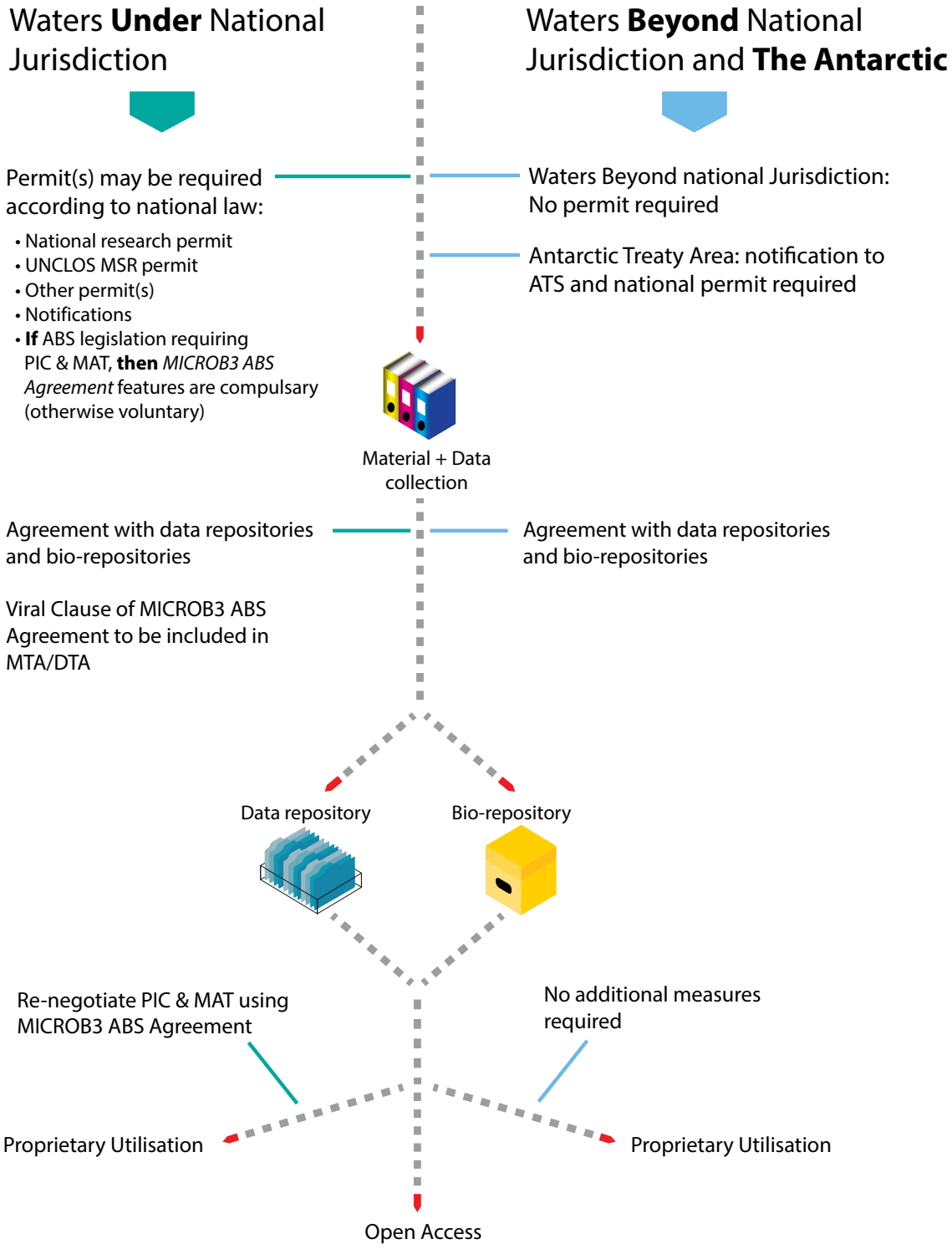


Figure 1.6. Overview of legal documents needed prior to sampling as requested by national and international laws.

Table 1.2 Information required for due diligence under Art. 4 of the EU ABS Regulations (Regulation (EU) No 511/2014).

Genetic resources with IRCC	Genetic resources without IRCC
The IRCC, as well as information on the content of the mutually agreed terms relevant for subsequent users.	Where no internationally-recognised certificate of compliance is available, information and relevant documents on:
	(i) the date and place of access of genetic resources or of traditional knowledge associated with genetic resources; (ii) the description of the genetic resources or of traditional knowledge associated with genetic resources utilised; (iii) 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; (iv) the presence or absence of rights and obligations relating to access and benefit-sharing including rights and obligations regarding subsequent applications and commercialisation; (v) access permits, where applicable; (vi) mutually agreed terms, including benefit-sharing arrangements, where applicable.

3.2.B.2 Due diligence: checkpoints

Due diligence declarations should be submitted by users to at least two "checkpoints" (at the stage of research funding and at the stage of final development) as defined in the EU ABS Regulation and the Commission Implementing Regulation[22] (see below and discussed further in the Background section of PART 2). Additional due diligence reports may be required by states.

EU states may use systems such as DECLARE (see below and Background section, PART 2) or others[23]. The EU ABS Regulation provides two templates (Annex II and III)[24] to submit due diligence declarations to the relevant competent authority, which will then transmit the information to the ABS Clearing-House (ABSCH).

If the user is part of a project team, typically the project co-ordinator should undertake due diligence declarations and it is advised that users who are part of project teams should confirm responsibility for submitting due diligence declarations and to keep these agreements. Further information on responsibility for institutions and users in submitting due diligence declarations is provided in the Background section (PART 2 of the Handbook).

22 Commission Implementing Regulation (EU) N° 2015/1866 Art. 5 http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32015R1866

23 Certain countries like Spain or France impose their own system to declare due diligence.

24 EU ABS Regulation No 511/2014 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32014R0511

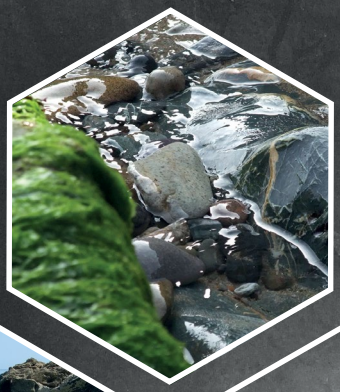
1. Due diligence declaration at the stage of research funding
   According to the Commission Implementing Regulation (Art. 5 par. 2), the timing for filing such a declaration is after the first instalment of funding has been received and all of the genetic resources and traditional knowledge associated with 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 report, at the project's end).
2. Due diligence declaration at the stage of final development
   According to the Commission Implementing Regulation (Art. 6)[25] the second checkpoint at which a due diligence declaration is to be submitted is the stage of final development of a product developed via the utilisation of genetic resources or traditional knowledge associated with genetic resources.

The Background section (PART 2 of the Handbook) provides more information on due diligence requirements and the process for making a declaration.

25 Commission Implementing Regulation (EU) N° 2015/1866 http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32015R1866

D 5.1

PART 2: TECHNICAL GUIDELINES TO IMPLEMENT EMBRC BEST PRACTICES



EBB
an EMBRC project

Contents

List of Tables

List of Figures

Introduction

The European Marine Biological Resource Centre (EMBRC-ERIC[26], hereinafter referred to as EMBRC) is a distributed pan-European research infrastructure that provides access to coastal marine ecosystems and marine biological resources for both fundamental and applied research. Providing access to marine genetic resources is one of EMBRC's primary services and the EMBRC is committed to facilitating access to and supply of marine biological and genetic material to users in compliance with international, European and national legal frameworks regarding Access and Benefit Sharing (ABS).

The EMBRC, European Blue Biobank (EBB) project supports this aspiration by promoting compliance with ABS regulations derived from the Nagoya Protocol and implemented in Europe through the EU ABS Regulation[27] that came into force in 2014. This regulatory framework, although effective in protecting the rights of the provider country, puts the burden on the user to demonstrate lawful utilisation. In this context, research infrastructures, scientific facilities, biobanks and collections can play a role by facilitating legal compliance and lawful use of the genetic resources they provide. Activities or points in workflows, where decisions have to be taken which have an ABS implication, are governed by ABS legislation, or where ABS concerns have to be managed are indicated in the flowchart below (Figure 2.1).

To support implementation of the EU ABS Regulation, EMBRC has produced a handbook that includes these technical guidelines to help institutions develop the required policies, implementation and training.

By implementing recommended best practices, EMBRC partners will be able to:

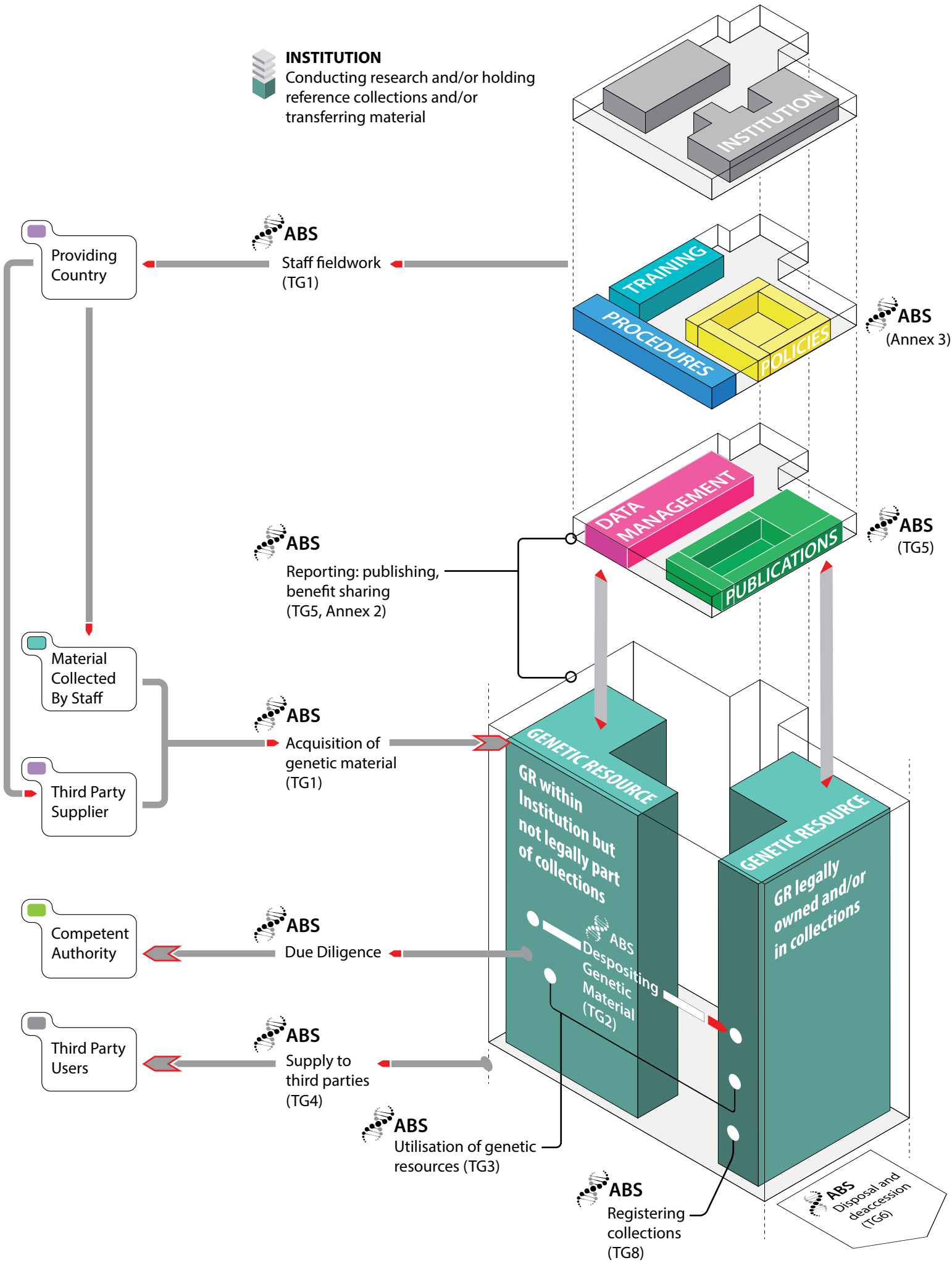
- Harmonise standards/procedures within the infrastructure and within its community;
- Facilitate compliance of its users to applicable legislation;
- Reduce administrative burden and create a safety-net process for researchers (for obtaining funding and for publications);
- Increase transparency on how genetic resources and the associated traditional knowledge are utilised;
- Facilitate fair and equitable sharing of benefits arising from utilisation of genetic resources;
- Promote non-commercial research and non-monetary benefit-sharing;
- Reduce the risk of unlawful utilisation of genetic resources (and minimize the risk of legal consequences and in terms of international cooperation for researchers and their organisation);
- Increase legal certainty; and
- Attract users.

The technical guidelines and annexes, refer to the use of genetic resources. However, ABS also regulates access to traditional knowledge associated with genetic resources. While not specifically covered in this Handbook, the reader must bear in mind that depending on local regulations, it may be necessary to negotiate access and benefits with indigenous and local communities for using their knowledge, whether used with the biological resources or independently.

26 http://embrc.eu/ EMBRC has the legal status of a European Research Infrastructure Consortium (ERIC), which was awarded by the European Commission on 20 February 2018.

27 "EU ABS Regulation No 511/2014 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 Utilisation in the Union". https://eur-lex.europa.eu/legal-content/ES/TXT/PDF/?uri=CELEX:32014R0511&from=EN

Figure 2.1 Workflow points at which ABS must be considered and linked to the Technical Guidelines (TG) and Annexes in the handbook (image redrawn and modified by © Rufus Wood 2021 from Chris Lyal's Natural History Museum ABS workflow with permission)



Technical guideline and annex overview

The technical guidelines and annexes provide guidance to support institutions and their staff to comply with the ABS framework by putting training, procedures, and policies in place (Background section) to ensure that they exercise due diligence and manage the ABS requirements:

- Technical Guideline 1: Acquire genetic resources legally, whether through in-situ or ex-situ acquisition;
- Technical Guideline 2: Deposit genetic resources in collections with full data for subsequent tracking, utilisation and transfer, if allowed;
- Technical Guideline 3: Use genetic resources in compliance with mutually agreed terms (MAT) or other terms and conditions under which they were provided and acquired, or renegotiate these if required;
- Technical Guideline 4: Supply genetic resources to third parties only on terms and conditions under which they were acquired and with relevant documentation and to track this utilisation;
- Technical Guideline 5: Manage data to ensure all material and its use is traced and documented and that documentation is easily accessible and available to facilitate due diligence, utilisation and supply;
- Technical Guideline 6: Dispose of material in accordance with MAT or other terms and conditions and tracked;
- Technical Guideline 7: Seek retrospective compliance in accordance with ABS national legislations; and
- Technical Guideline 8: Qualify to be included in the European register of collections.

To support implementation these technical guidelines also include:

- Annex 1: Model templates for "Terms and Conditions for academic use" "Material Transfer Agreement" and "Material Accession Forms" (to be adapted as needed);
- Annex 2: Share benefits with the provider as agreed in negotiated MAT or other agreements;
- Annex 3: Summary of the recommendations outlined in the technical guidelines;
- Annex 4: List of obligatory and recommended fields to be included in databases to comply with EU ABS Regulations;
- Annex 5: Training and communication materials 'Don't be a Biopirate', that can be used to inform institution members and others on ABS Regulations; and
- Annex 6: Recommendations to prepare exploratory campaigns at sea with the objective to address both legal frameworks when collection of material and to lawfully manage the collection under the UNCLOS and the ABS requirements of the Coastal State, if any.

Background: Key resources and recommendations for institutions.

This Background Section provides some information on key resources and mechanisms; the ABS Clearing-House (ABSCH); prior informed consent (PIC); mutually agreed terms (MAT) and due diligence and provides some recommendations for institutions to manage resources. A description of the scope of ABS regulations is summarised in Figure 2.1 and Table 2.1, further guidance is available on-line[28].

Assessing whether genetic resources are in scope

To help users of genetic resources assess whether resources are in scope based on the conditions above, the EC has edited the following chart (Figure 2.2). Table 2.1 outlines the conditions in more detail. Some additional, basic points and clarifications regarding the scope of the EU ABS Regulation are summarized as follows:

- In cases where genetic resources are obtained by the user indirectly (e.g. from culture collections) the national legislation or other requirements (including national environmental protection law) of the country which has jurisdiction over the genetic resource still apply (together with the country's collection, for the collection's activity); and
- In cases of indirect access to genetic resources through collections in the country of origin of these genetic resources: If the country in question has in place access rules for such ex-situ genetic resources and if they are accessed from the collection after the entry into force of the Nagoya Protocol, this falls within the scope of the Regulation, regardless of when the resources were collected.

28 Commission Notice (2016/C 313/01): Guidance on the EU Regulation implementing the Nagoya Protocol https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2016.313.01.0001.01.ENG&toc=OJ:C:2016:313:TOC

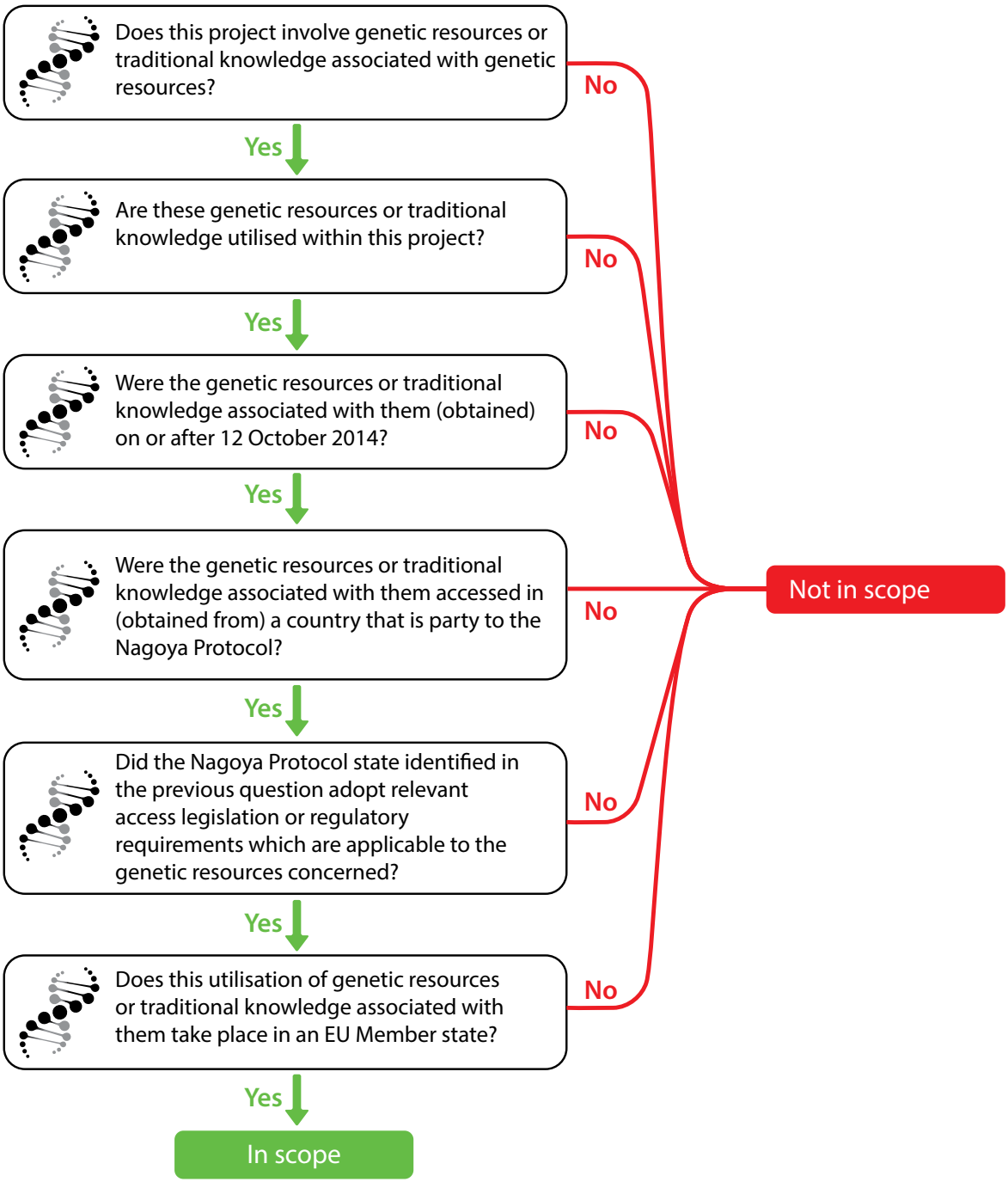


Figure 2.2 Decision support flow chart to assess whether genetic resources are in scope of EU ABS Regulations. (© European Commission. Redrawn by © Rufus Wood 2021 from the Horizon 2020 online manual[29]). Table 2.1 provides more detail.

29 https://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/ethics_en.htm

Table 2.1 Overview of conditions for applicability of the EU ABS Regulation[30]

		Within scope (cumulative conditions)*	Outside of scope
Geographic scope (provenance of GR)	Access in-situ or ex-situ in…	Area within a country's jurisdiction	Area beyond national jurisdiction e.g. high seas or covered by Antarctica Treaty System
	Provider country / country of origin of the GR is…	Party to the Nagoya Protocol	Not a party to the Nagoya Protocol
	Provider country / country of origin of the GR has...	Applicable access legislation	No applicable access legislation
Temporal scope	Access by the user	On or after 12 October 2014	Before 12 October 2014
Material scope	Genetic Resource	Not covered by a specialised ABS instrument**	Covered by a specialised ABS instrument**
		Non-human	Human
		Obtained as commodities but subsequently subject to R&D	Used as commodities
	Utilisation	R&D on genetic and/or biochemical composition	No such R&D
Personal scope		Natural or legal persons utilising genetic resource	Persons only transferring genetic resource or commercializing products based on it
Geographic scope (utilisation)	R&D	Within the EU	Exclusively outside of the EU

* To be within scope, all conditions must be fulfilled.

** Use and transfer of influenza viruses are covered by a specialised international ABS instrument: the WHO PIP Framework genetic resources for agriculture and food listed in Annex 1 of the ITPGRFA (the FAO Seed Treaty) fall under a different ABS regime. (See B. Specialised regimes). Pathogens out of the scope of the PIP Framework are covered by the Nagoya ABS regime, but the procedure is facilitated in case of international or transnational public health emergency (Art. 4.8 EU ABS Regulation). The EU ABS Regulation allows users acquiring with the ITPGRFA standard material transfer agreement, a Plant Genetic Resources for Food and Agriculture (PGRFA) not listed in the ITPGRFA in a country that is a Party to the Nagoya Protocol is considered to have exercised due diligence.

30 Commission Notice (2016/C 313/01) https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2016.313.01.0001.01.ENG&toc=OJ:C:2016:313:TOC

ABS Clearing-House

The Access and Benefit Sharing Clearing-House (ABS Clearing-House)[31] is a website, administered by the CBD Secretariat and established by Art. 14 of the Nagoya Protocol. It is designed to make information relevant to ABS available in a standardized, open and organized global repository.

The ABS Clearing-House provides reliable information regarding national procedures and requirements on ABS. It supports countries to help users of their genetic resources and associated traditional knowledge understand and follow ABS rules and facilitate users' compliance with national legislation.

In accordance with Articles 14 and 17 of the Nagoya Protocol, information is submitted to the ABS Clearing-House as part of the internationally-recognised certificate of compliance (IRCC) process. The publishing of an IRCC is not compulsory for the provider country, but it is very helpful if they do publish it. Collection and user interactions with the ABS Clearing-House are outlined below. Due diligence declarations at the two project checkpoints (see below) are made to the ABS Clearing-House by competent authorities and published as checkpoint communiqués.

Prior informed consent (PIC)

Prior informed consent (PIC) or free prior informed consent is a direct consequence of the countries' sovereignty over their natural resources and is issued by each country's competent authorities (unless otherwise determined by that party). It is the state's relevant CNA[32] responsibility to draft the PIC. PIC should be sought by users and issued by CNAs adequately in advance of accessing genetic resources. The Bonn Guidelines[33] provide a useful outline of PIC and the information that may be required by a CNA in order to determine if PIC can be awarded.

Mutually agreed terms (MAT)

Mutually agreed terms (MAT) are a key mechanism by which ABS is negotiated and tracked, to allow the legal acquisition, deposition and subsequent transfer of genetic resources between provider countries, collections and users. This section describes what MAT are and some recommendations around negotiating these. Subsequent annexes on the acquisition of genetic material (Technical Guideline 1), deposition (Technical Guideline 2) and transfer (Technical Guideline 4) will refer back to this section. Recording, managing and archiving of MAT are discussed in Technical Guideline 5 (Data management and publications).

MATs are usually laid down in a contract established between the providers and users of genetic materials. The MAT defines the conditions governing access to genetic resources and grants permission for their use and the sharing of the benefits arising from the utilisation.

Indigenous and local community customary laws and protocols should be taken into consideration and reflected in MAT, even if this is not required by national legislation.

31 ABS Clearing-House https://absch.cbd.int/

32 Note: a state may appoint more than one CNA: see glossary for definition.

33 Secretariat of the Convention on Biological Diversity (2002). https://www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf

MATs are signed by authorised personnel with legal authority and only if the institution is able to meet the agreed terms.

The Bonn Guidelines[34] (CBD) set out the basic principles and elements of MAT, which should describe:

- Type and quantity of genetic resources, and the geographical/ecological area of activity;
- Any limitations on the possible use of material;
- Whether the genetic resources can be transferred to third parties and under what conditions;
- Recognition of the sovereign rights of the country of origin; and
- Capacity-building in various areas to be identified in the agreement.

When negotiating MAT (and PIC) the purposes for which the material is to be used should be clear. Consideration should also be given to research requirements to deposit material in collections, for example to allow publication of new molecules. The purpose of the utilisation of a genetic resource may change. While a researcher may require a genetic resource for basic non-commercial research purposes, the associated institution may wish to deposit this material in a collection and supply it to third parties for commercial purposes. To support future utilisation, it is recommended that the MAT considers and covers potential future research and uses beyond current research projects. For example, permission should be sought to deposit any genetic materials acquired in a collection, with permission to transfer the material to third parties for further research or commercial purposes. Agreeing MAT to accommodate this should ensure delivery of benefits resulting from commercialization, are set out. Where possible, the use of specific techniques should be avoided in favour of using broader descriptions and definitions, to avoid triggering new negotiations due to the use of new analytical techniques or advances.

However, the above considerations need to be balanced with the need for competent authorities to have sufficient detailed information on the purpose of the access and utilisation of a genetic resource, as well as on the user and the detailed activities to be carried out in the utilisation. Therefore, it is likely that it will not be possible to obtain a broad authorisation with PIC and MAT covering a wide range of future potential utilisations. These circumstances need to be carefully considered, and interested users should be informed of the procedures and requirements applicable for negotiating the MAT and obtaining the PIC.

Negotiations should make clear whether the acquisition includes ownership or only change in custodianship and whether the change confers intellectual property rights on products and derivatives arising from utilisation.

Any restrictions placed by the provider should be set out in writing in the agreement or permit.

The MAT should record all benefits that are to be delivered and institutions should be aware of the need, and have procedures in place, to record all benefits being delivered. Only benefits that can be realistically achieved should be agreed.

For basic non-commercial science research, the benefits laid out in the MAT may be non-monetary. Possible monetary and non-monetary benefits are shown in Annex 2 but this list that was appended to the Nagoya Protocol is not exhaustive. For example, joint publications as

34 Secretariat of the Convention on Biological Diversity (2002). https://www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf

an example of a non-monetary benefit are not included. Where possible, fieldwork should be conducted as part of a collaborative venture with partners within the provider country such as other research scientists, institutes or museums. Such collaboration can be included in the MAT as a direct benefit arising from the fieldwork.

Institutions signing MAT should be satisfied they can meet the conditions and that these can be accommodated within the existing legal framework governing institution and collections. Where appropriate, institutions may develop framework agreements with competent national authorities that cover multiple specimens and samples.

Due diligence

Institutions and users must demonstrate that they have exercised 'Due diligence': reasonable care to ensure that the material is legally accessed in accordance with applicable ABS legislation and that its utilisation and supply (if applicable) is within agreed terms. The minimum requirements for exercising due diligence for biological material that enters an institute in accordance with Art. 4 of EU ABS Regulations are outlined below in Technical Guideline 1 (Table 2.2). Specific obligations relate to some pathogens to support public health emergency preparedness and Art. 4 should be consulted.

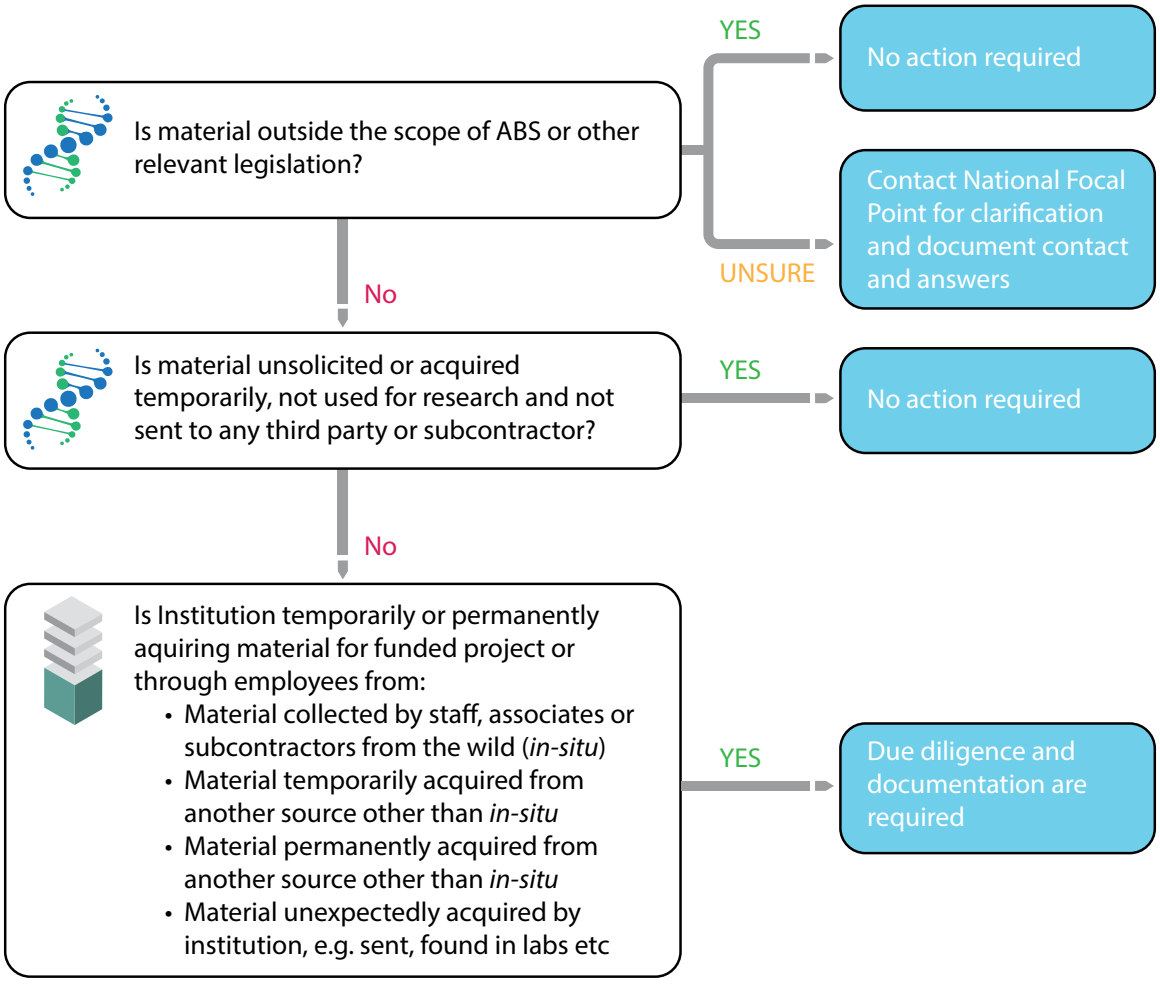


Figure 2.3 Flowchart showing situations where due diligence and documentation are required. (© Rufus Wood 2021)

Where genetic resources have been obtained from a registered collection (see Technical Guideline 8) the institute or user of the resource would be considered to have exercised due diligence regards information seeking. Figure 2.3 (above) outlines when due diligence is required.

Due diligence: information required

For the purpose of due diligence, the following information (Table 2.2) should be kept by the user or collection (for 20 years from the utilisation or transfer) and transferred to subsequent users[35]. EU ABS Regulation requires that this information should be submitted for due diligence declarations at the stage of research funding and final development of a product (see due diligence checkpoints below). Institutions will require this information to support due diligence, the information should be kept and transferred to new users, where applicable and in accordance with PIC and MAT.

Table 2.2 Information required for due diligence under Art. 4 of the EU ABS Regulations (Regulation (EU) No 511/2014) (see also Table 2.3, Technical Guideline 1 for a simplified description of information required).

Genetic resources with IRCC	**Genetic resources without IRCC**
The IRCC, as well as information on the content of the mutually agreed terms relevant for subsequent users.	Where no internationally-recognised certificate of compliance is available, information and relevant documents on:
	(i) the date and place of access of genetic resources or of traditional knowledge associated with genetic resources; (ii) the description of the genetic resources or of traditional knowledge associated with genetic resources utilised; (iii) 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; (iv) the presence or absence of rights and obligations relating to access and benefit-sharing including rights and obligations regarding subsequent applications and commercialisation; (v) access permits, where applicable; (vi) mutually agreed terms, including benefit-sharing arrangements, where applicable.

Competent authorities: Due diligence and compliance monitoring

European Member states designate competent authorities who are responsible for the application of ABS regulation. These competent authorities receive due diligence declarations at the checkpoints designated by the EU ABS Regulations (and any additional reporting required nationally) and monitor collection and user compliance (see below). The competent authority that receives the due diligence declaration is responsible for transmitting the information to the ABSCH and where appropriate to the competent national authorities referred to in Art. 13(2) of the Nagoya Protocol or forwarding it to the competent authority responsible for such

35 EU ABS Regulation No 511/2014. Art. 4. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0511

transmission. The competent national authority (CNA) in the state in which the utilisation is carried out can advise on how due diligence declarations should be made, i.e. through DECLARE (see below) or other systems.

Competent authorities should take account of confidentiality of commercial or industrial information where this protects legitimate economic interests.

The following should be submitted at the same time as the due diligence declaration:

- The relevant information from the IRCC; or
- The related information as referred to Table 2.2 (above) and an access permit or its equivalent and MAT.

Due diligence checkpoint 1: Declaration at the stage of research funding

Due diligence declarations should be made by recipients of research funding to the competent authority of the EU Member State in which they are established or, if they are not established in the EU, to the competent authority of the EU Member State in which the research is carried out.

A declaration made by recipients of research funding may cover more than one genetic resource. The due diligence declaration is made after the first instalment of funding has been received and all the genetic resources that are going to be utilised have been obtained and no later than the final report or if there is no final report, the end of the project. National authorities or research funders may further specify the timing or number of due diligence submissions and users should ask for clarification and be aware of requirements. Annex II of the Commission Implementing Regulation[36], provides a template for the due diligence declaration. Only information which is essential for the identification of genetic resources is exchanged at this checkpoint[37]. Only the country of origin is mandatory, all other information could be confidential.

Where the research project is funded from more than one source or involves more than one recipient, the recipient(s) may decide to make only one due diligence declaration. This should be submitted by the project co-ordinator to the competent authority of the Member State in which they are established. If the project co-ordinator is not established in the EU and the research is carried out in the EU, the due diligence declaration should be made to one of the member states in which the research is carried out. The competent authority receiving the declaration submitted by a project co-ordinator is responsible for exchanging information with other competent authorities with its counterparts in other member states.

Due diligence checkpoint 2: Declaration at the stage of final development of a product

At the stage of final development of a product developed by the utilisation of genetic resources, users should declare that they have complied with ABS obligations and exercised due diligence[38]. Annex III of the Commission Implementing Regulation (EU) 2015/1866[39], provides a template for the due diligence declaration.

36 Commission Implementing Regulation (EU) N° 2015/1866 Art. 5 http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32015R1866

37 Par. 3. Commission Implementing Regulation (EU) No 511/2014. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32015R1866

38 EU ABS Regulation No 511/2014. Art. 7 and Commission Implementing Regulation (EU) No 2015/1866 Art. 6. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0511

39 Commission implementing Regulation (EU) N° 2015/1866 http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32015R1866

As described in Article 6 of the Implementing Regulation (EU) 2015/1866[13] the due diligence declaration shall only be made once, prior to the first of the following events occurring:

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

Using the DECLARE system to report due diligence

DECLARE[40] is an EU-wide, web-based tool which enables users of genetic resources to submit the required due diligence declarations to the relevant competent authorities responsible for their implementation. The competent authorities also use DECLARE to transfer non-confidential information from the due diligence declarations to the ABSCH. In order to use DECLARE an EU Login is required (DECLARE, will re-direct to EU Login on first use).

It should also be noted that the use of DECLARE is not mandatory and some members states use their own declaration system (i.e. users in Spain as well as users in France are required to use the national system instead of DECLARE for the purpose of submitting the declaration at the research stage).

Monitoring user compliance

The competent authorities are responsible for monitoring user compliance with due diligence obligations[41]. Checks may be planned or carried out in response to concerns that the users are not complying with regulations; special consideration would be given to concerns raised by provider countries. The competent authority will issue a notice of remedial action or measures to be undertaken by the user if needed. Checks may include[42]:

- Measures taken by a user to exercise due diligence;
- Documentation and records that demonstrate the exercise of due diligence;
- Instances where a user was obliged to make due diligence declarations; and
- On-the-spot checks where appropriate.

40 https://webgate.ec.europa.eu/declare/

41 EU ABS Regulation No 511/2014. Art 4 and Art. 7. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0511

42 EU ABS Regulation No 511/2014. Art. 9. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0511

Benefit sharing

Institutions should share benefits from their utilisation of genetic resources fairly and equitably with the provider country and appropriate stakeholders, as agreed in PIC and MAT. Benefits may include any of those listed in the Annex to the Nagoya Protocol (see Annex 2 for list of monetary and non-monetary benefits). Where genetic utilisation is undertaken on a not-for-profit basis, benefits are most likely to be non-monetary, e.g. collaboration, training and joint publication.

Benefit sharing is most likely to be agreed by:

- Signing PIC or MAT which may require agreement of standard terms and conditions, such as return of specimens;

Benefit sharing may also be supported by additional mechanisms such as:

- Agreeing a Memorandum of Cooperation with a partner institution; and
- Informal discussions and correspondence with collaborators.

Benefit sharing recommendations

Institutions should ensure that they:

- Can deliver the benefits agreed and make sure that agreements are met;
- DO NOT agree to things that cannot be done, or are against the institutions practices and policies;
- Document agreements to enable delivery to be managed, reporting on benefits providing evidence that the institution is a good partner and conditions have been met; and
- Are aware of all benefits agreed in a larger project and ensure that there are no conflicts between PIC and MAT and other agreements such as a Memorandum of Understanding. Conditions agreed in the PIC and MAT should always be adhered to, so it is important that conflicts are avoided.

Recommendations for institutions and staff

Institutions should identify which activities require managing and where policies and procedures will need to be updated or modified. Where possible, policies should echo wording in accepted legal frameworks, including the EU ABS Regulation, Commission Implementing Regulation46[43] and any national implementing regulation.

Institutions should be clear on their due diligence obligations, when and how these apply to staff, project teams and visitors and the checkpoints and processes for submitting due diligence declarations.

Internal policies and procedures should identify:

- Persons with legal authority for agreeing to terms and signing MAT and PIC agreements on behalf of the institution;
- Persons responsible for providing training to staff, keeping records of training being delivered and updating relevant materials;
- Individuals with responsibility for ABS including due diligence;
- Internal checkpoints for due diligence and reminders to submit, for example at internal checks for submission for research funding etc.;
- All persons the polices are relevant to e.g. employees, research associates, sub-contractors;
- Compliance checking requirements and scheduling by the CNA;
- Internal auditing of collections, policies and procedures to ensure compliance; and
- Processes for dealing with deliberate or accidental breaches of ABS regulations.

43 Commission Implementing Regulation (EU) 2015/1866: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32015R1866

Technical Guideline 1: Acquisition of genetic material

Summary: This guideline refers to the acquisition of genetic resources either by collection in the field (in-situ) or temporary or permanent acquisition from ex-situ sources e.g. from other collections. Material may also enter an institution by unsolicited donation. This Annex addresses only the requirements for ensuring the initial entry of genetic resources to an institution is compliant with ABS legislation. Key tools, such as MAT, PIC and due diligence are described in more detail in the Background section as these are relevant to all the technical guidelines.

It should be noted that water and sediment samples may be collected that carry genetic resources. Agreement should be reached with the provider country if these are to subsequently be utilised.

Best practice requires that institutions ensure that:

- Acquisition by in-situ conditions is compliant with the provider country's access laws, and where required (PIC) and (MAT) in addition to other relevant permits or conditions are obtained from the Government and other stakeholders of the providing country;
- Biological material acquired from ex-situ collections, should be accessed under agreed terms;
- When biological material is received through other routes, e.g. donation, transfer from visitors etc., steps are taken to ensure that as far as reasonably possible the available documentation is evaluated and other steps taken as required to ensure the material is acquired in accordance with applicable law;
- Institutions that acquire genetic resources should exercise due diligence to ascertain that these have been legally accessed in compliance with ABS regulations, and the required information is retained for 20 years (see Table 2.3 and Technical Guideline 5).

Table 2.3 Simplified description of information required for due diligence as set out in Art. 4. Regulations (EU) No 511/2014 (see also Table 2.2).

Required Information to assess if material is in scope of ABS	**Notes**
Taxonomic information if available (Scientific name)	Compulsory
Depositors Identifier for the material	Compulsory
Date of original collection	Compulsory
Place of original collection (indicate if collected in area outside national jurisdiction e.g. high seas).	Compulsory
Name of collector and institution they were employed by	Compulsory
Required information to collect proof of legal access in the country of origin and information on agreed terms	
Internationally recognised certificate of compliance; prior informed consent, mutually agreed terms and material transfer agreements or other legal documents	If available, copies should be provided
To be completed by institution	
Unique strain identifier	By collection

Types of acquisition:

I. Acquisition by in-situ (fieldwork)

This section addresses the acquisition of genetic resources by institution personnel in the wild (in-situ) in the territory of the provider country. Step-by-step guidance for the steps involved is described and outlined in the flow chart below (Figure 2.4). Sufficient time should be allocated to contacting the national focal point (NFP), local partners and competent national authorities (CNA) and negotiating terms. Where resources have already been collected and are provided to an institution by a collection, other institution or individuals such as visitors, this is referred to as ex-situ acquisition, as described in later sections.

I.A. Step 1 Assess national requirements under ABS regulations

Assess whether material and intended utilisation or other purpose for collection is in scope (see main PART 1 of the Handbook and Table 1.1). Through the ABSCH[44]:

- Check whether the country has ratified the Nagoya Protocol or not and if there are alternate regulations around ABS;
- Identify the NFP and CNA. If these are not listed seek other appropriate contacts within the country;
- Check access requirements of countries and permit requirements. If information is not available contact the NFP / seek information through other means, e.g. internet search; and
- If there are no access requirements this should be documented.

Note: additional permits or agreements may be required to access biological material. The status of access requirements should be checked again immediately before starting fieldwork to check there has been no updates.

I.B. Step 2 Contact national focal point

If there is no response from the NFP it could be that there is no legislation in place. However, unless this can be confirmed by finding the information elsewhere, the NFP should be repeatedly contacted until they respond or the institution policies are satisfied that due diligence has been exercised. Due diligence could be considered to be satisfied by sending a number of regular emails over an extensive time period- the length and number of which should be decided on a case by case basis or by institutional policy e.g. 3 times (3 e-mails) 1 month between attempts. 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.[45]

Nevertheless, if it is subsequently established that the Regulation actually is applicable to genetic resources previously believed to be outside of the scope, and it becomes clear that the genetic resources have not been accessed in accordance with applicable access legislation, the user will be required to obtain an access permit or its equivalent and establish mutually agreed terms, or discontinue utilisation. It is therefore recommended to make best efforts when establishing the existence of applicable access legislation.

44 Access and Benefit Sharing Clearing-House https://absch.cbd.int

45 Commission Notice (2016/C 313/01) https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2016.313.01.0001.01.ENG&toc=OJ:C:2016:313:TOC

Where countries provide unrestricted access and permits are not required this should be documented in the Material Accession Form (see Annex 1) and details of correspondence kept. Depending on the provider country's legislation, other offices may need to be contacted for example, for export or research permits.

I.C. Step 3 Involve local partner

Where possible, fieldwork should be conducted as part of a collaborative venture with partners within the provider country such as other research scientists, institutes or museums. Such collaboration can be included in the MAT as a direct non-monetary benefit arising from the fieldwork (see Annex 2 for further information on monetary and non-monetary benefits).

I.D. Step 4 Contact the competent national authority

To negotiate and obtain PIC and MAT (if required) the CNA must be contacted and informed of the planned research as part of the application process. The researcher must provide a full explanation of the purposes for which biological material will be used and how genetic resources will be utilised and ensure that the government or other responsible authority obtains this information in accordance with the requirements and procedures foreseen under the relevant national access measures or legislation (see the Background section, PART 2 for more details on PIC and negotiating MAT).

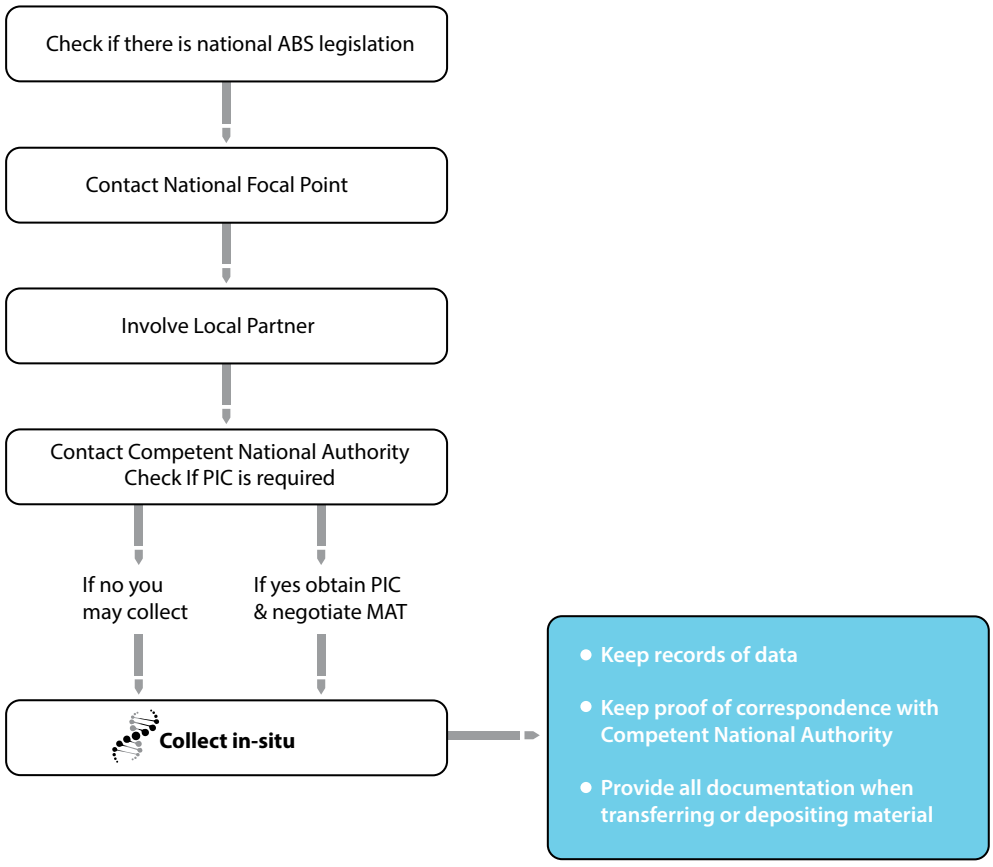


Figure 2.4. Guide to in-situ acquisition of genetic resources.

I.E. Step 5: Collect samples and store information for due diligence obligations

Fieldwork should not be started until required permits are agreed and finalised or appropriate written guarantees received. Staff should be aware of and act in accordance with laws and regulations of that country.

II. Temporary acquisition

Summary: Temporary acquisition refers to instances where material is not transferred into the ownership of the institution and/or is not accessioned into its collections. This scenario covers situations where visiting scientists bring material into the institute or where material is provided to the institute for processing, e.g. gene sequencing.

II.A. Temporary acquisition to carry out contracted studies

When the host institution is sequencing or providing other services such as taxonomic identification on request for an external user and has no involvement in the research, and the relationship between the host and the legal person carrying out the research is governed by contract, the legal person contracting the work is the user, not the host institution.

The contract between this legal person and the host institution should make clear who is legally responsible to exercise due diligence to ensure that the material is legally accessed in accordance with ABS legislation and submit due diligence declarations if required for compliance with the Nagoya Protocol under user country regulations. The contract should also specify that there is no transfer in rights to the host institution and state whether any material the study should be returned or destroyed.

II.B. Temporary acquisition for research

Genetic resources may be acquired by researchers through temporary transfer for use in their own projects or as part of joint research. The institution should have in place policies to establish who is responsible for making a due diligence declaration for joint projects and that this is recorded in project agreements.

II.C. Temporary acquisition resulting from visitors bringing in scope material for utilisation

Where visitors bring in-scope material into an institution for utilisation, the host institution should ensure that due diligence is carried out either through staff members or through a written agreement with the visitor that obliges them to meet all necessary legal ABS requirements when utilising genetic resources in the institution. The responsibility for submitting a due diligence declaration regarding utilisation must also be agreed (see Background Section, PART 2). Further discussion of due diligence requirements in this instance is described in Technical Guideline 3 (Utilisation of genetic resources).

III. Permanent acquisition

Summary: This covers all cases where material is not collected in the wild (in-situ) by institution personnel, but is transferred from other collections or any other ex-situ sources into the ownership or custodianship of the institution, by means such as purchase, donation, bequest, or exchange. Institutions will need to ensure their policies and procedures address management

of documentation associated with acquisition of material from ex-situ sources (Technical Guideline 5 and Annex 4).

The institution will need documents covering requirements and permissions associated with the material and demonstrating its provenance e.g. the number of an IRCC, and/or PIC and MAT (or a statement as to why they were not required if they are not provided). These might usefully be attached to a document confirming transfer of title to the institution, including any conditions. Standard Material Accession Forms for use with any material not collected by staff will facilitate this and should contain all information required for due diligence (see Annex 1 for template). These are also of use in cases where material is offered to the institution and a commitment to accept the material is required prior to its donation.

Institutions should seek confirmation of proof of origin through the ABSCH by verifying IRCC/ permit numbers.

IV. Unsolicited acquisition

Summary: Unsolicited acquisition of genetic materials may occur where material is sent for identification, donated by other researchers or left by visitors. If the institution wishes to retain an unsolicited donation, clarity must be sought on their legal status and appropriate documentation acquired or if documentation is not required this should be clarified and documented.

If material is unsolicited and acquired temporarily, for example to perform identification, and is not used for research purposes or sent to any third party or subcontractor, it is outside the scope of the regulation. The material should be returned to the source or destroyed after the end of the work.

Genetic sequence or other data from unsolicited donations, including those for received for identification purposes, should not be published without clarifying legal status and whether this is appropriate.

Material left by visitors should be returned or clarity on legal provenance sought.

Recommendations for institutions and staff

Activities that involve in-situ collecting specimens or samples by staff and associates, and any other individuals using the name of the institution, should be carried out only for and in the name of the institution responsible for the fieldwork. Any additional acquisition of biological material for private or other use, including on behalf of or for sale to third parties, should be prohibited by the institution.

An object entry system to ensure that genetic resources entering and leaving (Technical Guideline 6) are tracked with appropriate information and documents.

In regards to training and documentation, institutions are advised to develop or revise procedures to train and inform staff and independent or contracted individuals or organisations who collect and supply biological materials or who do fieldwork for and in the name of that institution. Internal policies or procedures around acquisition should include:

- Institutions should identify authorised persons responsible for negotiating terms and

signing PIC, MAT, Material Transfer Agreements (MTA) and other documents;

- Institutions should have policies on negotiating PIC and MAT and other terms, including limitations and restrictions;
- Institutions should ensure that terms can be met and do not conflict with policies and activities;
- Staff or other associates should be aware of due diligence requirements and when they or the institution are responsible, or not, for due diligence; Agreements with project co-ordinators, visitors etc. around due diligence should be agreed in writing and kept;
- Institutions should set out conditions under which in-situ (fieldwork collection) by personnel is managed. This should include the negotiation of PIC and MAT and the number of attempts over which time period to contact unresponsive NFP/this has been fixed already?;
- Management and archiving of key documents, including contact with national focal point or competent national authority, including emails which have not been responded to (see Technical Guideline 5);
- The institution should set out how temporary loans of materials and permanent acquisition from outside the institution can be accepted including formal agreements between visitors and the host institution assigning responsibility for due diligence; and
- Identify practice around contractual work on genetic resources including disposal and/or return of genetic resources.

Supporting documentation

- A standard Material Accession form example has been provided (Annex 1) which can be adopted. This form collects all the information required for due diligence when genetic resources enter an institution. The information should be kept and transferred to subsequent users (see Technical Guideline 4); and
- Table 2.3 above sets out all the information required for due diligence as outlined in Art.4 of EU ABS legislation. The information should be kept for a minimum of 20 years and transferred to subsequent users (see Technical Guideline 4 and 5).

Technical Guideline 2: Depositing genetic material in collections

Summary: This technical guideline describes the deposition (or accession) of genetic resources to a collection. At the point of entry to an institution, checks should be carried out to ascertain whether the genetic resource is in scope of ABS regulations and to document information to meet due diligence obligations (Background section, PART 2). A tool to record the relevant information is a Material Accession Form (see Annex 1) which contains the required information for due diligence and determining whether material is in scope.

The depositor should be able to demonstrate that the material was legally accessed in-situ and provide relevant documentation including PIC and MAT and subsequent agreements. Terms of benefit sharing may need to be agreed and these could be non-monetary (see Annex 2).

The institution should make reasonable efforts to track the origin of the material and any intermediary transfers before accepting the genetic resources. The collection should be satisfied that the documentation shows that the material was legally accessed and can be deposited in accordance with ABS regulations and that information is available to satisfy the due diligence requirements laid out in the Background Section (PART 2). The collection should ensure that the depositor has the authority to deposit the resource by cross-checking with documentation e.g. IRCC, PIC, access permits.

If the depositor wishes to restrict use of the genetic resource this should be recorded at the time of deposit. Material associated with onerous conditions may be rejected by collections.

Documentation checks should include:

- If the material has an IRCC it should be cross-checked on the ABSCH;
- If the material has an IRCC the institution should add the certificate's unique identifier to the Material Accession Form;
- In the absence of an IRCC other relevant documents issued by the competent national authority should be checked (PIC, MAT, access permits). In the absence of a competent authority listed on the ABSCH the national focal point should be contacted to confirm legality of documents;
- If there are any concerns these should be discussed with the depositor before acceptance. If questions around legality or documentation emerge after acceptance the institution should raise these with the depositor. The competent authority in the provider country and any third parties provided with the resource should be notified. Appropriate measures should be agreed with the competent authority; and
- Additional documents should be archived with the Material Accession Form, including PIC and MAT (see Technical Guideline 5 for more on data management). These include correspondence with the depositor.

Recommendations for institutions and staff

Institution policies should identify the documentation required IRCC, PIC, MAT, Material Transfer Agreement (MTA), depositor correspondence, etc.) and how these are managed. The individual responsible for authorising deposits should also be clear.

Internal policies or procedures around acquisition should ensure collections only accept materials that are legally accessed and where terms and conditions can be met. Checks and procedures should include:

- Standard depositor checks to ensure material was legally accessed and depositor has the authority to deposit the resource;
- Processes for checking any data gaps;
- Processes to manage and archive key documents, including tracking of key checks;
- Terms of benefit and their feasibility/acceptability;
- Any restrictions or requirements should be identified and evaluated for acceptability; and
- Process for contacting the competent authority in the provider country and any third parties should issues arise around legality or other aspects of the resource.

A standard Material Accession Form will facilitate recording and tracking the required information (see Annex 1). It is recommended that the Material Accession Form include a declaration by the depositor that to the best of their knowledge there is no infringement with any third party rights.

Technical Guideline 3: Utilisation of genetic resources

Summary: Utilisation refers to research and development on the genetic and/or biochemical composition of genetic resources[46]. Institutions and individual users must ensure that they only utilise genetic resources in accordance with the terms and conditions under which they were acquired or otherwise accessed. PIC and MAT must be renegotiated to utilise genetic resources in a different way to those sent out in the original agreements. Utilisation may result in complete consumption and Technical Guideline 6 should be referred to. Where users are uncertain of the legality of utilisation or there is insufficient evidence to exercise due diligence, users should obtain an access permit or equivalent or discontinue use.

Activities outside of utilisation

Utilisation does not refer to maintenance and management, such as storage of material, investigations to identify material and quality checks.

Visitors to institutions bringing genetic resources for utilisation

Visitors to institutions may bring genetic resources to the institute as described above in Technical Guideline 1 for utilisation. It is important that visitors are made aware that if the utilisation happens inside the EU, their utilisation may be within scope of the EU ABS Regulation and, if so, they are legally bound to carry out due diligence and submit a due diligence declaration if required.

If the host institution (i) has no collaborative interest in the research and has not received research funding for it, or (ii) the guest researcher is not employed via external funding by the host institution or its agents, the host institution can reasonably take the view that due diligence obligations in relation to the research carried out and any submission of a due diligence declaration is the responsibility of the visitor. However, this needs to be supported by a formal agreement.

If the utilisation is part of a collaborative project involving the institution, the host institution should ensure that due diligence is carried out either through staff members or through a written agreement with the visitor that obliges them to meet all necessary legal ABS requirements when utilising genetic resources in the institution.

There should in all cases be a formal agreement between the visitor and the host institution setting out:

- The individual who has the responsibility to ensure that due diligence has been done in regard to the material being utilised; and
- The individual who has responsibility to submit a due diligence declaration, if required. It should also specify what is to happen to any material left by the visitor (see also Technical Guideline 1 above "Unsolicited acquisitions"). The submission should be made by either:
    - The host or supervisor within the institution;
    - The Project Co-ordinator, for collaborative projects if based in another EU institution; or
    - The visitor, as appropriate

46 Including through the application of biotechnology as defined in Article 2 of the Convention (EU ABS Regulation No 511/2014 Art. 3) https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0511

Recommendations for institutions and staff

Institution policies should ensure:

- Individuals with responsibility for due diligence reporting are identified and aware of requirements and timing of declarations;
- Collections and users should also be satisfied that utilisation of genetic resources is compliant with PIC and MAT and other terms and agreements, otherwise MAT and transfer agreements must be renegotiated with the provider country in order to use the genetic resource or the use of the genetic resource stopped[47];
- Genetic resources should not be utilised if the original permit conditions or circumstances of collection are unclear. When acquiring genetic resources in-situ, negotiations should avoid creating very narrow terms around MAT if possible (see Background Section);
- Data management and curation procedures should document and track utilisation in accordance with due diligence obligations;
- The correct information is reported in publications; publications or reporting resulting from utilisation of genetic resources (including electronic publications and online databases) should:
    - Acknowledge the providing country; and
    - Include an identifier of the permit or other agreement where these exist, e.g. IRCC.

47 EU ABS Regulation No 511/2014, Art. 4 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0511

Technical Guideline 4: Supply to third parties

Summary: Material may be loaned (temporary transfer) or permanently transferred. Material should only be transferred to third parties if this is permitted by PIC and MAT.

Material should always be supplied under relevant terms laid out in a Material Transfer Agreement (MTA). Genetic resources should only be transferred to third parties under an appropriate MTA, at least as restrictive as the MAT signed with the provider. By this MTA the third party would undertake to use the biological material only in a manner compliant with the original PIC and MAT. Any restrictions or requirements should be made clear and information required for due diligence transferred (see Table 2.3 in Technical Guideline 1). The use of standard MTAs facilitates supply; model examples are provided in Annex 1.

The requirement for institutions to retain for 20 years information on utilisation for reporting should be made clear to third parties. Material Transfer Agreements for supply of material from collections should not allow further third party transfer.

Transfer to subcontractors for research

Institutions should only supply genetic resources for subcontracted work with a contract excluding utilisation not in compliance with the terms and conditions under which they were acquired.

Permanent transfer to third parties

To support the institutions to meet due diligence obligations records should be maintained of specimens or samples transferred permanently to third parties.

Third party obligations

Where third parties wish to utilise the genetic resource in a manner different from the conditions set out in the original PIC and MAT or Material Transfer Agreement, the institute may deny the request or ask the third party to obtain PIC and MAT from the original provider country, or partner with the third party in renegotiating terms with the provider country. Where the institution is not party to negotiations, the third party should provide documentation that this has taken place.

Any commercial facility to which samples are sent as a part of research (e.g. for DNA sequencing) should be required to return or destroy material following completion of the work (see Also Technical Guideline 6).

Recommendations for institutions and staff

Institutions should record all transfers of material in fulfilment of due diligence obligations, which require that information on subsequent users is kept. Tracing of further transfers is not required but collections may choose to specify in the MTA that no further transfer of genetic resource is allowed. third parties should be provided with copies of the documentation showing agreements with the provider country, where applicable, including PIC, MAT or other relevant documents.

Institutions should have policies and procedures in place to:

- Track and record supply of genetic resources in accordance with due diligence obligations;
- Ensure biological material is supplied (temporarily or permanently) to third parties only on terms and conditions consistent with those under which it was acquired;
- Use standard MTAs to facilitate third party supply and utilisation in line with terms and conditions. Material transfer agreements should differentiate between commercial and non-commercial use as well as change in ownership (temporary vs permanent transfer) and should address ownership and intellectual property rights of any product or derivate resulting from utilisation of original samples;
- Handle inappropriate or prohibited utilisation of such material, e.g. notification of the Checkpoint or NFP of the user's country;
- Ensure third parties are aware of any restrictions or requirements; and
- Renegotiate terms with provider countries where required.

Technical Guideline 5: Data management and publications

Summary: Data management underpins compliance with EU ABS Regulations regarding the acquisition, utilisation and transfer of genetic resources. Recommendations in this annex are supported by the supplied model documents (Annex 1). Institutional policies and procedures should cover ABS where necessary and support the compilation of resource passports (the documents and information required to supply a genetic resource).

Record keeping and data management

Institutions should manage collections to ensure that the legal requirements of ABS legislation around acquisition, utilisation and supply of genetic resources are met as laid out in Articles 4 and 5 of the EU ABS Regulation. Collections must be able to demonstrate that genetic resources have only been used in a way consistent with the terms and conditions of the providing country and must ensure that due diligence has been undertaken. Collections should provide collection specific unique identifiers that will allow genetic resources to be tracked from acquisition to use, transfer or disposal.

The following information is required (see Annex 4, Table 2.6 for field list):

- Acquisition records including: terms and conditions under which genetic resources are acquired (PIC, MAT and associated due diligence see Background section);
- Records of relevant utilisation (including the person or entity utilising them and whether this was funded by internal or external sources);
- Records of benefit sharing in accordance with PIC and MAT (see also Technical Guideline 3);
- Records of supply of genetic resources to third parties, either temporarily or permanently including the terms and conditions (see also Technical Guideline 4); and
- Records of how and when biological material passes permanently out of the collection, including complete consumption of samples or disposal (see also Technical Guideline 6).

Data management systems adopted must support the recording of this key information and allow institutions to track material to ensure compliance with terms and conditions. The data management system should enable the following to be linked to the genetic resource:

- Legal documents, conditions and restrictions that can also be provided to users;
- Provision of unique identifier;
- Data and information resulting from utilisation; and
- Publications.

Publication and reporting

Publications resulting from the utilisation of genetic resources should acknowledge the provider country and should reference the IRCC and could also include other information such as an identifier referring to respective documents (permits or equivalent) on file at the Institution. Publication includes paper and electronic publications, as well as online databases in the public domain.

Archiving

All relevant records and legal information should be kept for at least 20 years after end of utilisation in compliance with ABS Regulation.

The EBB project will deliver a joint database of the genetic resources held by EBB partners. The following table shows obligatory and recommended database fields for ABS archives and MTAs and the EBB joint database (Annex 4, Table 2.6) that will be developed as part of the EBB project. Table 2.7 shows information that is not held in the EBB joint database but is added automatically when material is transferred.

Recommendations for institutions and staff

Internal policies or procedures should:

- Assess policies, management and record keeping protocols across collections and the institute, ensuring these are adequate and updating and harmonising where necessary;
- Ensure data management allows the tracking of:
    - Acquisition of genetic resources including associated legal documentation (PIC; MAT; IRCC; other permits and agreements), any restrictions or requirements around utilisation or transfer and the data required to fulfil due diligence;
    - Utilisation and the person, group or subcontractor utilizing them and whether this was funded by internal or external sources;
    - Any temporary or permanent supply to third parties (if permitted) and supply with required documentation;
    - Any benefits derived from use/utilisation and shared with the provider country; and
    - When and how genetic resources exited the institution or collection, e.g. loss, disposal (see also Technical Guideline 6).

Technical Guideline 6: Disposal and deaccession of genetic material

Summary: Mutually agreed terms (MAT) may lay out requirements for destruction or disposal and genetic resources should be managed according to these. It is recommended that institutions have a process to manage destruction of genetic resources in line with PIC, MAT or Material Transfer Agreement, including tracking of specimen and the archival of relevant information (Technical Guideline 5).

Recommendations for disposal of genetic material

Genetic resources should only be disposed of (including complete consumption) in agreement with PIC, MAT or MTA. Mutually agreed terms may require that specimens be destroyed following use (e.g. DNA sent for sequencing to a third party laboratory) or returned to the provider country. Institutions are recommended to have policies in place to track the use of genetic resources, including complete consumption and disposal, including to a third party for permanent deposit. Where the original PIC, MAT or MTA requires the genetic resource to be destroyed, institution procedures should be capable of tracking this has been done and confirmed with the provider country.

Deaccessioning and loss

Institutions should have policies in place to track when specimens permanently leave the ownership/custodianship of the Institution, which may be governed by a MAT or a MTA. Genetic material may be lost by a third party while on loan and procedures should be in place to track this and report as necessary to the provider country.

Recommendations for institutions and staff

Institutions should have policies and procedures in place to monitor:

- If the original PIC, MAT or MTA requires the genetic resource to be destroyed;
- That destruction or other disposal has taken place and the provider country informed;
- The utilisation for which the authorization has been provided, including complete consumption and disposal;
- When and how specimens permanently leave the ownership/custodianship of the Institution, including permanent transfer of ownership to a third party; and
- Loss of genetic resource by collection, staff or third parties.

Technical Guideline 7: Retrospective compliance

European ABS regulations apply to biological material accessed after the entry into force of the Nagoya Protocol (12 October 2014). The protocol is not retrospective but some countries have interpreted regulations in a way that may require retrospective compliance. For example, Spain as a provider country considers that the date of acquisition of a Spanish genetic resource within a collection in Spain refers to the date of transfer to a user, NOT the date of sampling. Therefore, the compliance status of some Spanish genetic resources will vary depending on whether they are held inside or outside of Spain. France as a provider country takes into account the date of use of a French genetic resource, regardless of whether it was collected in situ before or after the entry into force of the French ABS law. Collections and users should be aware of these state variations in interpretation when assessing whether genetic resources are compliant with ABS regulations.

Countries may have access measures that cover a broader scope than the EU compliance measures. Genetic resources may be compliant with regards to European ABS regulations but not the national access requirements of the provider country. Not all countries are party to the Nagoya Protocol, and some have their own legislation on access and benefits sharing of their genetic resources. Some do require retrospective compliance for all resources (e.g. Brazil). The national measures should be observed regardless of if the resource is out of scope of the EU compliance measures. This may mean that further retrospective work is required collecting data and permit details for genetic resources that are compliant with EU ABS regulations.

Materials collected in areas beyond national jurisdiction are not covered under the Nagoya Protocol. An international legal instrument is currently being negotiated under the auspices of the UNCLOS which will include a specific and different ABS regime for marine genetic resources sampled in the high seas.

Recommendations for institutions and staff

Institutions are encouraged to apply best practices, as far as reasonably possible, also to all other biological material in their collections.

Collections and biobanks should identify countries of origin, find out their national legislation, and where relevant, seek retrospective compliance in accordance with their legislation.

Technical Guideline 8: Registering collections

Summary: a registered collection is one that can effectively apply measures (best practices) as described in the previous technical guidelines. The characteristics of registered collections are described below. A collection may implement best practice but may choose not to register or may choose to register only part of the collection.

In order for a collection, or a part of a collection, to be included in the European register of collections it (the collection) shall demonstrate its capacity to meet the conditions described below in Table 2.4[48]:

Table 2.4 Conditions which collections must meet in order to be included in the European register (from Art 5 ABS Regulation (EU) No 511/2014 with some edits to text). Changes in the capacity of a registered collection to comply with these should be notified to the national competent authority.

Condition	Relevant Annex within this report
Apply standardized procedures for exchanging samples of genetic resources and related information with other collections, and for supplying samples of genetic resources and related information to Third Persons for their utilisation in line with the Convention and the Nagoya Protocol.	Technical Guideline 1, 2, 3 & 4
Supply genetic resources and related information to Third Persons for their utilisation only with documentation providing evidence that the genetic resources and the related information were accessed in accordance with applicable access and benefit-sharing legislation or regulatory requirements and, where relevant, with mutually agreed terms. Tracking if the original PIC, MAT or MTA requires the genetic resource to be destroyed	Technical Guideline 4, 5 & 6
Keep records of all samples of genetic resources and related information supplied to Third Persons for their utilisation. Monitoring when and how specimens permanently leave the ownership/custodianship of the Institution, including permanent transfer of ownership to a third party and tracking loss of genetic resource by third parties	Technical Guideline 4, 5 & 6
Establish or use unique identifiers, where possible, for samples of genetic resources supplied to Third Persons.	Technical Guideline 5
Use appropriate tracking and monitoring tools for exchanging samples of genetic resources and related information with other collections.	Technical Guideline 5 & Annex 4

Registering networks of collections

Applications for registering collections are made by the collection holder to the Member State in the jurisdiction in which the collection is held. Following the inclusion in the register of a collection or a part thereof, the collection holder shall notify the competent authority of any significant changes that influence the collection's capacity to comply with the criteria in Art. 5(3) of Regulation (EU) No 511/2014 (as set out in Table 2.3).

48 EU ABS Regulation No 511/2014. Art. 5. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0511

Annex I of Implementing Regulation (EU) 2015/1866[49] details the information that should be provided to request inclusion in the register:

- Information on the holder of the collection (name, type of entity, address, e-mail, telephone number);
- Information on whether the application concerns a collection or part of a collection;
- Information on the collection or the relevant part thereof;
    - Name;
    - Identifier (code/ number);
    - Address(es);
    - Website, where available; and
    - Link to the collection's online database of genetic resources (where available)
- A brief description of the collection or the relevant part thereof. Where only part of a collection is to be included in the register, details on the relevant part(s) and its (their) distinctive features should be provided;
- Collection category. The application should provide information on the category to which the collection or part thereof belongs; and
- Where an applicant is a member of a network of collections, the applicant may inform the competent authorities about any other collections or parts thereof from the same network that were or are the subject of an application in other Member States for inclusion in the register.

Collection verification by Member States

Applications for registered status are made by collections to the Member State in whose jurisdiction they are held. The Member State will award the status of registered collection and will regularly verify that the collections continue to meet the criteria set out in Table 2.4. When applications from a network of collections have been made, the state's competent authority would consider exchanging information with the competent authorities of other Member States in which applications have been or are being made.

✓ Verification may include the following:

- On-the-spot checks;
- Examination of selected documentation and records of a collection or part thereof, which are relevant for demonstrating compliance with Art. 5(3) of Regulation (EU) No 511/2014;
- Examination of whether selected samples of genetic resources and related information of the collection concerned has been documented in accordance with Art. 5(3) of Regulation (EU) 511/2014;
- Examination of whether the collection holder has the capacity to consistently supply genetic resources to Third Persons for their utilisation in accordance with Art. 5(3) of Regulation (EU) No 511/2014; and
- Interviews with relevant persons, such as the collection holder, staff, external verifiers, and users obtaining samples from that collection.

49 Commission Implementing Regulation (EU) 2015/1866, Art. 3 http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32015R1866

After verifying that the collection meets the criteria for registry the Member State shall notify the Commission of the name and contact details of the collection and its holder.

Information held by the collection register

✓ The collection register details the following information[50] for each collection:

- Registration code assigned by the commission;
- Name given to the collection;
- Name and contact details of the holder;
- Category of the collection;
- Link to database (where available);
- Information on the collection or the relevant part thereof (website, link to the collection´s online database of genetic resources); and
- Brief description of the collection.

Collection compliance

Where there is evidence, on the basis of information provided pursuant to paragraph 3 from Article 5 ABS Regulation (EU) No 511/2014[51] (are laid out in Table 2.4), that a collection or a part of a collection included in the register does not meet the criteria set out in paragraph 3, the Member State concerned shall, in dialogue with the collection holder concerned and without undue delay, identify remedial actions or measures.

A Member State which determines that a collection or a part of a collection within its jurisdiction no longer complies with paragraph 3 shall inform the Commission thereof without undue delay. Upon receipt of that information, the Commission shall remove the collection or the part of the collection concerned from the register.

Benefits of including a collection in the EU register for users

For users: a registered collection will reduce administrative burden and ensure legal certainty that they have complied with obligations. Users which obtain genetic resources from a registered collection should be considered to have exercised due diligence as regards the seeking of information on the legality of access of the acquired genetic resource. Registration will provide an additional benefit of raising the collection profile to users.

50 https://ec.europa.eu/environment/nature/biodiversity/international/abs/pdf/Register%20of%20Collections.pdf

51 Regulation (EU) No 511/2014. Art. 5. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32014R0511

Annex 1: Document templates[52]

The authors recommend users of genetic resources not to engage in an ABS negotiation without the competent department in their institution.

To help in the negotiation, the handbook suggests using the following guidance documents:

- To negotiate ABS with a providing country when no commercial use is envisaged: The ABS Contract Tool https://absch.cbd.int/api/v2013/documents/B1C6A46D-5EC6-E5BA-45A2-2F3E406DCB49/attachments/ABS_Contract-Tool_EN_ANSICHT.pdf
- To negotiate ABS with commercial use and involving IP: The WIPO Guide to Intellectual Property Issues in Access and Benefit-sharing Agreements: https://www.wipo.int/edocs/pubdocs/en/wipo_pub_1052.pdf
- To supply a genetic resource from a collection, in compliance with ABS: https://www.eccosite.org/ecco-core-mta/

The handbook also provides below model templates as basis of negotiation. Disclaimer: these models are to be used by legal professionals and experienced contract negotiators.

52 These templates are taken from EMBRC Practical Guidelines for Accessing and Providing Marine Genetic Resources (EMBRC PP2 project)

Model for sample Terms and Conditions for academic use

1. Use of Material:
The Recipient
a. Will use the material and its derivatives solely for research or/and academic purposes;
b. Will not use the material in human subjects, in clinical trials, or for diagnostic purposes, involving human subjects;
c. Will use the material only at the Recipient's organization and only in the Recipient's working premises;
Any use of material for commercial purposes and/or by private entity is subject to a separate written material transfer agreement negotiated between the (name of collection) and the Recipient.
The Recipient will, unless the (name of collection) agrees otherwise, promptly return to (name of the collection) or destroy the material and its derivatives

2. Transfer to Third Parties:
Recipient shall not make the material available to any third party without written permission from the (name of the collection). Upon written permission thereof, Recipient shall pass on the same obligations under this Agreement to the third party recipient(s).

3. Ownership and Intellectual Property Rights:
a. The material and its derivatives remain the property of (name of the collection);
b. This Agreement does not transfer ownership of any intellectual property rights in the material or its derivatives.

4. Acknowledgement:
The Recipient agrees to cite the unique identifier in all publications and patent applications that reference the material and acknowledge the (name of collection) as the source of the material. The Recipient is kindly requested to provide the (name of collection) with details of the related publications.

5. Payment:
On receipt of the material and subject to invoice, the Recipient will pay (name of the collection) the Fees.

6. Warranties:
(name of the collection):
a. does not warrant that the use of the material does not or will not infringe any patent;
b. is under no obligation to obtain or provide licenses that may be required for the use of the material by the Recipient.

7. Liabilities:
The delivered material is experimental in nature and may have hazardous properties, and is provided by (name of the collection) with no warranties, express or implied, including any warranty of merchantability, title, or fitness for a particular use. Except to the extent prohibited by law, Recipient agrees to assume all liability for damages that arise from Recipient's use, storage or disposal of the material. (name of the collection) is not liable for any losses, damages, claims or liabilities, which are caused by the transfer to and/or the use, storage and disposal of the material by Recipient, except to the extent such loss, claim, damage or liability is the direct result of (name of the collection)'s gross negligence or wilful misconduct.

8. Disclaimer:
The utilisation of the material therein is subject to the sovereign rights of the country of origin with respect to accessing the material and sharing the benefits of its utilisation.
The User may be requested to negotiate the rights to use the material with the country of origin if the intended utilisation is not included in the existing MAT.
The User will be solely responsible for unlawful use of provided material.
The collection and / or database should not be held responsible for unlawful use of provided material.

9. Dispute Resolution:
The parties will negotiate in good faith to resolve any dispute that arises between them. Any dispute which cannot be settled amicably will be submitted to the Courts of (place of collection)

10. Agreement:
a. (name of the collection) may end this Agreement by giving notice in writing to the Recipient if the Recipient does not pay the Fees within 7 days of those Fees becoming due.
b. Either party may end this Agreement by giving 90 days of notice in writing to the other party.
c. After this Agreement ends: the Recipient will, unless the parties agree otherwise, promptly return to (name of the collection) or destroy the material and its derivatives.

I have read and agree with the TERMS & CONDITIONS

(* create a tickbox to be checked online)

Model for sample Material Transfer Agreement

COLLECTIONS - SUPPLYING MATERIAL FOR FOR-PROFIT PURPOSES

The **PARTIES** to this agreement are:

a).....(hereinafter referred to as **PROVIDER**) and

b) …*please add name of the organization*.....(hereinafter referred to as **RECIPIENT**) and the **RECIPIENT's PRINCIPAL INVESTIGATOR**.....*please add name* …….(hereinafter referred to as **PRINCIPAL INVESTIGATOR**)

Whereas the PROVIDER holds the MATERIAL as described in ANNEX 1, PROVIDER is willing to supply the RECIPIENT with the MATERIAL under the terms and conditions as set forth hereinafter and RECIPIENT agrees to the following before RECIPIENT receives the MATERIAL:

1. The RECIPIENT shall use the MATERIAL for the following specific purpose:……..……

2. The RECIPIENT shall obtain written prior permission from the PROVIDER for the usage of the MATERIAL for any other purposes than the purpose specified above.

3. The RECIPIENT shall not use the MATERIAL for diagnosis or treatment of humans or other direct applications to human bodies or as food source for humans.

4. The RECIPIENT shall not make the MATERIAL available to any third party without written permission from the PROVIDER. Upon written permission thereof, the RECIPIENT shall pass on the same obligations under this Agreement to the third party recipient(s).

5. The RECIPIENT acknowledges that the MATERIAL is or may be the subject of intellectual property right protection. No express or implied licenses or other rights of any form of intellectual property or other proprietary rights of the PROVIDER are provided to the RECIPIENT.

6. The PROVIDER does not warrant that the use of the MATERIAL does not or will not infringe any patent. The PROVIDER is under no obligation to obtain or provide licenses that may be required for the use of the MATERIAL by the RECIPIENT.

7. The RECIPIENT agrees to provide appropriate acknowledgement of the source of the MATERIAL in all publications and presentations, reporting on RECIPIENT's use of the MATERIAL.

8. The RECIPIENT will use the MATERIAL in compliance with all laws and regulations both nationally and internationally, including but not limited to, the use of human and animal subjects. The RECIPIENT shall bear full responsibility also for any other legal obligations including, but not limited to, the Paris Convention for the Protection of Industrial Property, the Convention on Biological Diversity (CBD) and its Nagoya Protocol, the Cartagena Protocol on Biosafety (CPB). The RECIPIENT shall, if necessary, take all steps or procedures to comply with legal requirements for handling of the MATERIAL.

9. The RECIPIENT shall be responsible for negotiating in advance of the use and in good faith the terms of any benefit sharing with the appropriate body of the country of origin of the MATERIAL.

10. The delivered MATERIAL is experimental in nature and may have hazardous properties, and is provided by the PROVIDER with no warranties, express or implied, including any warranty of merchantability, title, or fitness for a particular use. Except to the extent prohibited by law, the RECIPIENT agrees to assume all liability for damages that arise from the RECIPIENT's use, storage or disposal of the MATERIAL. The RECIPIENT will defend, indemnify and hold the PROVIDER harmless from any losses, damages, claims or liabilities, which are caused by the transfer to and/or the use, storage and disposal of the MATERIAL by the RECIPIENT, except to the extent such loss, claim, damage or liability is the direct result of the PROVIDER's gross negligence or wilful misconduct.

11. This Agreement will terminate on the thirty (30) days written notice by either party to the other. The PROVIDER reserves the right to terminate this agreement where the RECIPIENT fails to perform its obligations under this Agreement.

12. Articles 4, 5, 6 and 7 shall survive termination.

13. Upon termination of this Agreement, the RECIPIENT will discontinue its use of the MATERIAL and will, upon direction of the PROVIDER, return any remaining MATERIAL.

14. This Material Transfer Agreement will be governed and interpreted in accordance with the …… law. Any disputes in relation with the interpretation or execution of the present agreement, which cannot be settled amicably, will only be submitted to the Courts of ……..

15. The RECIPIENT shall be responsible for the upfront fee of …… for each Material (VAT inclusive), and the royalty fee for commercial use or license of the MATERIAL, according to the Fees Conditions.

To confirm agreement with the above terms, please have an authorized representative sign and date the agreement below in two originals. Please return this document in two originals to the PROVIDER. The PROVIDER will return one fully executed agreement to the RECIPIENT and forward the MATERIAL.

Model for sample Material Accession form

<table>
<tr><td colspan="4">(fields marked with * are compulsory to fill in)

(Name of collection)

(Address/Tel. of collection)</td><td>For the (name of CC) only</td></tr>
<tr><td colspan="4">I. General Information</td><td></td></tr>
<tr><td colspan="3">a) Scientific name of organism Authors Type</td><td></td><td>Registration Number *:</td></tr>
<tr><td colspan="3">b) Strain/Sample origin (Project)* Date of Sampling * Geo-coordinates*

Sampling by (name and institution)*</td><td></td><td></td></tr>
<tr><td colspan="2">c) Isolated by (name, affiliation and address)*</td><td colspan="2">Identified by</td><td></td></tr>
<tr><td colspan="3">d) Source of Isolation/Country Date of Isolation Time of Isolation</td><td></td><td></td></tr>
<tr><td colspan="2">e) Description of strain/sample</td><td colspan="2">Application of strain/sample</td><td></td></tr>
<tr><td colspan="4">f) Strain/sample code used by Depositor</td><td>Strain Code Identifier:</td></tr>
<tr><td>g) References (please attach reprints if available)</td><td>Original isolation</td><td>Original description</td><td>Other appropriate documentation</td><td>Reprints attached:
Yes
No
☐
☐</td></tr>
<tr><td colspan="4">h) History since original isolation

Depositor <—</td><td></td></tr>
<tr><td colspan="4">i) Is sequence data available?
☐ Yes
☐ No</td><td></td></tr>
</table>

II. Preservation and maintenance				
a) Recommended medium and growth method	Medium	Incubation temperature	Other specified growth condition	
b) Recommended method for long-term preservation	(a) Freeze-drying:	(b) Cryopreservation: (specify recommended cryoprotectant(s)	(c) Other (please specify):	
III. Health and Safety Information				
a) Is this strain/ sample known to be or likely to be pathogenic	☐ For man ☐ For animals ☐ For plants ☐ For the environment ☐ Unknown			
IV. Information on origin of the strain for compliance to Nagoya Protocol (Please complete as far as possible)				
a) Country or location of origin* Collected on high seas beyond national jurisdiction.				
b) Date of transfer from country of origin to recipient*				
c) Sampling Permit*	Sought ☐ Yes ☐ No	Agreed ☐ Yes ☐ No	Documentation Attached ☐ Yes ☐ No	Permits attached: ☐ Yes ☐ No
c) Prior informed consent (PIC)*	Sought ☐ Yes ☐ No ☐ Not required	Agreed ☐ Yes ☐ No	Documentation Attached ☐ Yes ☐ No	Permits attached: ☐ Yes ☐ No
d) Name and address of the person or organisation who issued the PIC:				
e) Details of any agreed benefit sharing or other form of agreement between originator and contracting parties relevant to the end use of this organism such as MAT. Please supply Internationally Recognised Certificate of Compliance (IRCC) if relevant.				MAT attached: ☐ Yes ☐ No
f) Is Traditional Knowledge associated with the material? ☐Yes ☐No If yes, please provide documentation that the material can be made publicly available.				Permits attached: ☐ Yes ☐ No
Any further comments.				

V. Deposit conditions			
☐ Free	☐ Restricted	☐ Confidential	Acceptance ☐ Yes ☐ No
DEPOSITOR* Name*: Institution*: Address*: Tel.*: Fax*: E-mail*: I declare that all the information above is accurate and true and that to my best knowledge there is no infringement of any third parties' rights or any terms of MTAs to which the material is subject. Signature*:			Received by Date: Name: Signature

Annex 2: Benefit sharing: Monetary and non-monetary benefits

Summary: As listed in the Annex (Table 2.5) to the Nagoya Protocol 29 October 2010 on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their utilisation the Convention on Biological Diversity (CBD). Benefits arising from scientific research should involve non-monetary benefits, agreed benefits should be documented within the MAT and institutions should document realisation of these.

Table 2.5 Monetary and non-monetary benefits from Annex to the Nagoya Protocol.

Monetary benefits may include, but not be limited to:	**Non-monetary benefits may include, but not be limited to:**
(a) Access fees/fee per sample collected or otherwise acquired;	(a) Sharing of research and development results;
(b) Up-front payments;	(b) Collaboration, cooperation and contribution in scientific research and development programmes, particularly biotechnological research activities, where possible in the Party providing genetic resources;
(c) Milestone payments;	(c) Participation in product development;
(d) Payment of royalties;	(d) Collaboration, cooperation and contribution in education and training;
(e) License fees in case of commercialization;	(e) Admittance to ex-situ facilities of genetic resources and to databases;
(f) Special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity;	(f) Transfer to the provider of the genetic resources of knowledge and technology under fair and most favourable terms, including on concessional and preferential terms where agreed, in particular, knowledge and technology that make use of genetic resources, including biotechnology, or that are relevant to the conservation and sustainable utilisation of biological diversity;
(g) Salaries and preferential terms where mutually agreed;	(g) Strengthening capacities for technology transfer;
(h) Research funding;	(h) Institutional capacity-building;
(i) Joint ventures;	(i) Human and material resources to strengthen the capacities for the administration and enforcement of access regulations;
(j) Joint ownership of relevant intellectual property rights.	(j) Training related to genetic resources with the full participation of countries providing genetic resources, and where possible, in such countries;
	(k) Access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies;
	(l) Contributions to the local economy;
	(m) Research directed towards priority needs, such as health and food security, taking into account domestic uses of genetic resources in the Party providing genetic resources;
	(n) Institutional and professional relationships that can arise from an access and benefit-sharing agreement and subsequent collaborative activities;
	(o) Food and livelihood security benefits;
	(p) Social recognition;
	(q) Joint ownership of relevant intellectual property rights.

Annex 3: Summary of recommendations and policy checklist

Summary: Institutions should identify which activities they carry out will require managing and define the institutions responsibility for these. In some instances, current policies and procedures will be adequate to manage these activities and if not modifications will be required.

✓ Internal policies and procedures should identify:

- Persons with legal authority for agreeing to terms and signing MAT and PIC agreements on behalf of the institution;
- Persons responsible for providing training to staff, keeping records of training being delivered and updating relevant materials;
- Individuals with responsibility for ABS including due diligence;
- Internal checkpoints for due diligence and reminders to submit, for example at internal checks for submission for research funding etc.;
- All persons the polices are relevant to e.g. employees, research associates, sub-contractors;
- Compliance checking requirements and scheduling by the competent national authority;
- Internal auditing of collections, policies and procedures to ensure compliance; and
- Processes for dealing with deliberate or accidental breaches of ABS regulations.

Acquisition of genetic resources (Technical Guideline 1)

✓ Internal policies or procedures around acquisition should include:

- An object entry system to ensure that genetic resources entering and leaving (Technical Guideline 6) are tracked with appropriate information and documents;
- Training and documentation. Institutions are advised to develop or revise procedures to train and inform staff and independent or contracted individuals or organisations who collect and supply biological materials or who do fieldwork for and in the name of that institution;
- Institutions should identify authorised persons responsible for negotiating terms and signing PIC, MAT, MTA and other documents;
- Institutions should have policies on negotiating PIC and MAT and other terms, including limitations and restrictions. Institutions should ensure that terms can be met and do not conflict with policies and activities;
- Staff should be aware of due diligence requirements and when they or their institution is responsible for due diligence. Agreements with project co-ordinators, visitors etc. around due diligence should be agreed in writing and kept;
- The institutions should set out conditions under which in-situ (fieldwork collection) by personnel is managed, including negotiation of PIC and MAT, including number of attempts over which time period to contact unresponsive NFP and other authorities;
- Management and archiving of key documents, including contact with NFP, including emails to unresponsive NFP (see Technical Guideline 5);
- The institution should set out temporary loans of materials and permanent acquisition from outside the institution can be accepted including formal agreements between visitors and host institutions assigning responsibility for due diligence; and
- Identify practice around contractual work on genetic resources including disposal and/or return of genetic resources.

Depositing genetic materials in collections (Technical Guideline 2)

✓ Internal policies or procedures around acquisition should ensure collections only accept materials that are legally accessed and where terms and conditions can be met. Checks and procedures should include:

- Standard depositor checks to ensure material was legally accessed and depositor has the authority to deposit the resource;
- Processes for checking any data gaps;
- Processes to manage and archive key documents, including tracking of key checks;
- Terms of benefit and their feasibility/acceptability;
- Any restrictions or requirements should be identified and evaluated for acceptability; and
- Process for contacting the competent authority in the provider country and any third parties should issues arise around legality or other aspects of the resource.

Utilisation of genetic resources (Technical Guideline 3)

✓ Institution policies should ensure:

- Utilisation of genetic resources is compliant with PIC and MAT and other terms and agreements;
- Individuals with responsibility for due diligence reporting are identified and aware of requirements and timing of declarations;
- The correct information is reported in publications;
- Terms are renegotiated with provider countries where required and signed by authorised personnel; and
- Utilisation of genetic resources is recorded and tracked in accordance with due diligence obligations.

Supply or transfer to third parties (Technical Guideline 4)

✓ Institutions should have policies and procedures in place to:

- Track and record supply of genetic resources in accordance with due diligence obligations;
- Ensure biological material is supplied (temporarily or permanently) to third parties only on terms and conditions consistent with those under which it was acquired;
- Use standard MTAs to facilitate third party supply and utilisation in line with terms and conditions. MTAs should differentiate between commercial and non-commercial use as well as change in ownership (temporary vs permanent transfer) and should address ownership and intellectual property rights of any product or derivate resulting from utilisation of original samples;
- Handle inappropriate or prohibited utilisation of such material, e.g. notification of the Checkpoint or national focal point of the user's country;
- Ensure third parties are aware of any restrictions or requirements; and
- Renegotiate terms with provider countries where required.

Data management (Technical Guideline 5)

- ✓ Internal policies or procedures around acquisition should:
  - Assess policies, management and record keeping protocols across collections and the institute, ensuring these are adequate and updating and harmonising where necessary;
  - Ensure data management (see Annex 4) allows the tracking of:
    - Acquisition of genetic resources including associated legal documentation (PIC; MAT; IRCC; other permits and agreements), any restrictions or requirements around utilisation or transfer and the data required to fulfil due diligence;
    - Utilisation and the person, group or subcontractor utilizing them and whether this was funded by internal or external sources;
    - Any temporary or permanent supply to third parties (if permitted) and supply with required documentation; and
    - Any benefits derived from use/utilisation and shared with the provider country; and
    - When and how genetic resources exited the institution or collection, e.g. loss, disposal.

Disposal and deaccession of Genetic Material (Technical Guideline 6)

- ✓ Institutions should have policies and procedures in place to track:
  - If the original PIC, MAT or MTA requires the genetic resource to be destroyed;
  - That destruction or other disposal has taken place and the provider country informed;
  - The use of genetic resources, including complete consumption and disposal;
  - When and how specimens permanently leave the ownership/custodianship of the Institution, including permanent transfer of ownership to a third party; and
  - Loss of genetic resource by collection, staff or third parties.

Retrospective compliance (Technical Guideline 7)

- ✓ Institutions are encouraged to apply best practices, as far as reasonably possible, also to all other biological material in their collections; and
- ✓ Collections and biobanks should identify countries of origin, find out their national legislation, and where relevant, seek retrospective compliance in accordance with their legislation.
- ✓ Establish a risk management policy with regards to non-compliant material.

Annex 4: Genetic resource database fields required for internal ABS management and fields used for the EBB project joint database

Table 2.6 The obligatory and recommended database fields that are required in order to comply with EU ABS Regulations for internal archives and third party supply of genetic resources and the information that will be held in the EBB project joint database on the genetic resources of the EBB project partners. GR=Genetic resource, O= Obligatory, R= Recommended. The description refers to the EBB project database fields and is not proscribed by EU ABS Regulations.

Database field	Description	ABS MTA/ Archive	For EBB joint database
Sample date	DD/MM/YYYY	O	O
Sample location: country	Country (includes EEZ) or "international waters" if outside all EEZs	O	O
Sample location: long degrees		O	O
Sample location: long minutes	Max 60 (do not use decimal system)	O	O
Sample location: long NS	N or S	O	O
Sample location: lat degrees		O	O
Sample location: lat minutes	max 60 (do not use decimal system)	O	O
Sample location: lat EW	E or W	O	O
Sample location: ocean	Atlantic Ocean, Pacific Ocean, Mediterranean Sea, Black Sea, Arctic Ocean, Southern Ocean	O	O
Sample location: region	Regional sea e.g. North Sea (open list)	O	O
Sample location: site	Specific site e.g. Villefranche Bay	O	O
Sample habitat type	Marine pelagic, marine benthic, brackish, freshwater, terrestrial	R	O
Sample cruise	Name of cruise during which samples collected (if applicable)	R	
Sample station	Number/name of sampling station during cruise from which samples collected (if applicable)	R	
Sample depth	Depth (in metres) at which sample taken (round number, 0 for surface water)	R	
Sample project	Name of project in which samples collected (if applicable).	R	
Sample remark	Any extra info on sampling location	R	
Sampled by person	Name of person who sampled genetic resource	R	
Sampled by institute	Name of institute of person who sampled GR	O	
Sampled by institute country	Country of institute of person who sampled GR	O	
Isolated by person	Name of person who isolated GR (if applicable)	R	
Isolated by: institute	Name of institute of person who isolated GR (if applicable)	R	

Database field	Description	ABS MTA/ Archive	For EBB joint database
Isolated by: institute country	Country of institute of person who isolated GR (if applicable)	R	
Deposited by: person	Name of person who deposited GR in CRB (if applicable)	R	
Deposited by: institute	Name of institute of person who deposited GR in CRB (if applicable)	O	
Deposited by: institute country	Country of institute of person who deposited GR in CRB (if applicable)	O	
Deposit: date	Date of deposit in BRC	O	
Sample batch type	Live/dead	R	O
Sample batch treatment	Fixed/ frozen/ dried/ filtered/ no treatment/other	R	O
Strain code OR sample batch id	Unique identifier for GR	O	O
Lost	Has strain been lost? Yes/no	O	O
Taxonomy: species	Use XXX system: name of lowest known taxonomic rank followed by one X for each unknown level (division/ class/order/ family/ genus/ species)	O	O
Taxonomy: clade	Intra-specific group (if applicable)	O	O
Taxonomy: WORMS id	ID of species (or higher) in WORMS database	O	O
Strain name	For cultures only: strain code(s) of equivalent strain in other collection(s); code(s) given to strain before inclusion in CC catalogue	O	O
Image link	Link to location of image on server	R	O
Authentic culture	Nomenclatural type strain or material?	R	O
Mutant	Type of mutant if strain is mutant		O
Biohazard class	International biohazard classification (1 to 4)	R	O
Sample permit: id	Internal unique identifier for permit	R	
Sample permit: reference	Reference code for permit (provided by issuer of permit)	R	
Sample permit: date	Date permit issued	R	
Sample permit: type	PIC/MAT/IRCC/other…	R	
Sample permit: from organization	Organization that delivered permit (e.g. Ministry of Environment)	R	
Sample permit: from country	Country of organization that delivered permit	R	
Sample permit delivered to: organization	Organization of person to whom permit delivered (e.g. CNRS)	R	
Sample permit delivered to: country	Country of organization of person to whom permit delivered	R	
Sample permit: link	Web link to where document is stored	O	
Sample permit: remarks	Additional info (including summary of terms and conditions of permit)	R	

Database field	Description	ABS MTA/ Archive	For EBB joint database
ABS status	Compliant without conditions / compliant with conditions / Non-compliant	O	O
ABS status remarks	Explanation of why GR is compliant or non-compliant (fixed list)	O	O
Order: id	Internal unique identifier for each order	O	
Order: batch prepared by	Staff member who prepared order	R	
Order: batch type	Form of supply (liquid culture, solid culture, preserved sample, frozen sample, etc.)	O	
Order: batch quantity number	How many	O	
Order: batch quantity unit	Kg/ml/individuals, etc.	O	
Order: sent date	date order sent	O	
Order: sent waybill number		R	
User: name	Name of user	O	
User: address institute	Institute of user	O	
User: address department	Department of user	R	
User: address city	City of user	R	
User: address country	Country of user	O	
User: email	Email of user	O	
User: project description	Short description of intended use (minimum requirement: distinction between fundamental / applied research)	O	
MTA T&Cs link	Link to electronic version of MTA or T&Cs	O	
Order remark	Any extra info on order	O	
Maintenance: culture medium	Culture medium used to maintain strain		R
Maintenance: temperature	Temperature at which strain/sample maintained (°C)		R
Maintenance: light intensity	Light intensity at which strain/sample maintained (microEin/m2/s)		R
Cryopreserved only	Is strain/sample maintained only as cryopreserved stock that can be successfully reanimated (yes/no)		O

Table 2.7 EBB joint Database, information added automatically at point of transfer.

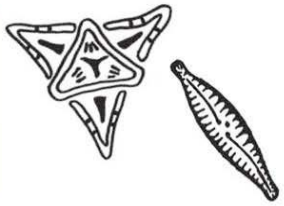
Field	Description
Resource: provider	Name of marine station
Resource: type	Wild / Cultured
Resource: availability	On-site and/or remote
Resource: item	List of formats provided (e.g. 30ml, 1kg, 10 individuals etc.

Annex 5: ABS Poster - Don't be a biopirate[53]

DON'T BE A BIOPIRATE

Tips for marine basic scientists to lawfully access marine genetic material & use it in Europe

Your work involves using genetic resources?
You are going abroad and want to bring back samples in Europe?
You have learned the properties of an algae from local fishermen and want to use it for your research?
You are using strains from a collection that is not ABS registered by the EU?
Your research might fall under the Nagoya Protocol on Access and Benefit Sharing!



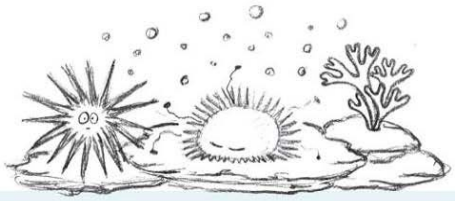
What you need to do first!

1. TRACK your samples

date + place of collection
description
providing source
previous users

2. SEEK information

visit absch.cbd.int
check providing country status
contact National Focal Point



!!! DO NOT !!!
transfer

unless you have a MTA, which can be negotiated during MAT, or separately

...then, if relevant, there is some paperwork

3. COMPLY

with a PIC and a MAT, you agree with the providing country on benefits and get the permission to sample

4. KEEP

you must keep proof of compliance 20 years after the use end

5. DECLARE
due diligence

Two EU checkpoints:
- Research funding
- Final development of a product designed for the EU market

For samples from EU registered collections, due diligence is covered

GLOSSARY

GR – genetic resources
it includes all biological material, from an organism to a molecule produced by or contained in an organism (DNA, RNA, protein, metabolite, etc.)

ABS – access and benefit sharing
the way GR may be accessed and how the benefits resulting from their use are shared between the users and providers (country or people)

MAT – mutually agreed terms
agreement reached between providers and users of GR, on the condition of access, use and benefit sharing between both parties

PIC – prior informed consent
permission given by the provider country to a user, **prior** to accessing GR

MTA – material transfer agreement
contract containing the sample's tracking information

DDD – declaration of due diligence
the proof that the user of a GR has verified if the access or use of the GR falls within the scope of EU ABS regulation and collected requested information

NFP – national focal point
contact that provide all information related to ABS for each country

ABSCH – ABS clearing house
ABS information portal, including contacts of NFPs.

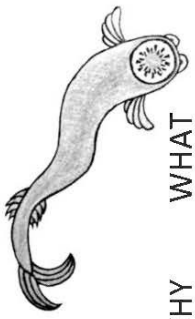
ABNJ – Area beyond national jurisdiction

What is out of the scope of ABS?

- handling and storage of a GR, without any research
- describing of a phenotype
- GR as a tool and not the object of the research (enzyme, bacteria as a vector)
- GR as a reference/control material
- publicly available DNA sequence
- GR collected in ABNJ

In case of doubt
check with the legal experts of your institution

53 Figure adapted from © Nathalie Kowalczyk, COLUMBUS Marine Biological Resources node fellow, Station Biologique de Roscoff.



Access and Benefit Sharing

WHAT

THE LEGAL FRAMEWORK OF ABS
Following the Convention on Biological Diversity (1992), the Nagoya Protocol on Access and Benefit Sharing (2010) adds a new legal frame to the utilisation of all genetic resources and is complementary to the coastal state rights over their maritime territories (UNCLOS).

WHY

It aims at **protecting biodiversity** and the sovereign rights of the countries over their **natural resources** and the rights of indigenous and local communities over their **traditional knowledge**. These rules and regulations are here **to avoid biopiracy** on genetic resources and ensure that any benefits derived from the utilisation of national genetic material is passed back to the providing country.

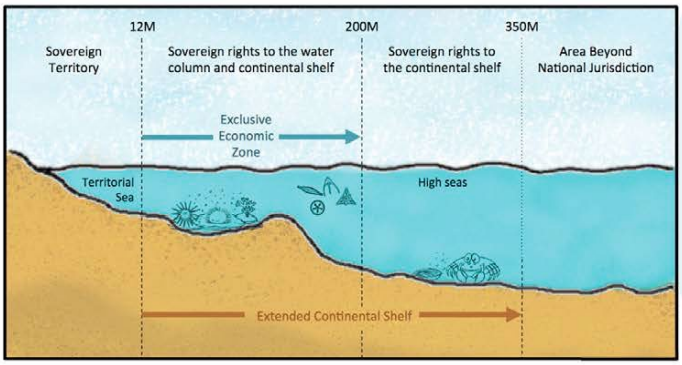
WHEN

Since 12 October 2014, a new European regulation applies to all research activities **carried out in the European Union**. It asks all users to comply due diligence, that is to make sure that access to genetic resources and traditional knowledge is done according to the ABS rules in effect.

!

- The non respect of the EU regulation can lead to severe penalties, in addition to the penalties of the providing country (i.e. in France: up to 1 year of prison and 150k€ of fine or 1M€ if case of commercial use).
- A country can have its own ABS regulation, independent of the Nagoya Protocol.

WHAT IS UNCLOS?
It is the United Nations Convention on the Law Of the Sea. It outlines the regulation of activities in the world's ocean, particularly the **utilisation** of its **natural resources**. It defines zones with a **scale of rights**.



Sampling in the Sea is regulated by the adjacent country, up to:
- **200M** for **planctonic** species,
- **350M** for **benthic** species.

Beyond 350M, there is no national rights... Yet! (2016).

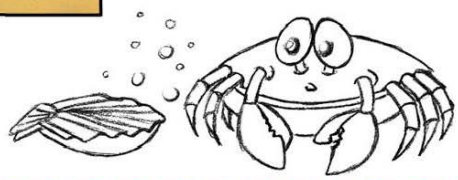
Exception for protected areas and areas under Antarctica Treaty System.

For more information

check the **ABS Clearing House**
absch.cbd.int

More info on ABS
www.abs-initiative.info

EU ABS Regulation FAQ
ec.europa.eu/environment/nature/biodiversity/international/abs/



Nathalie Kowalczyk, COLUMBUS Marine Biological Resources node fellow

Station Biologique Roscoff
COLUMBUS
KNOWLEDGE TRANSFER FOR BLUE GROWTH

Annex 6: Recommendations based on the experience of the Tara Oceans scientific cruise[53]

GENERAL RECOMMENDATIONS ON BEST PRACTICES FOR USING MARINE GENETIC RESOURCES ACQUIRED *IN-SITU* OR *EX-SITU* WITH REGARDS TO COMPLIANCE WITH INTERNATIONAL CONVENTIONS.

WP6

OCEANOMICS is a national *Investments for the Future* project in "Biotechnology & Bioresources". Its name derives from the English title *"wOrld oCEAN biOresources, biotechnology and Earth-SysteM ServICeS"* which refers to *"Biotechnology & Bioresources for the valorization of marine planktonic ecosystems"*.

In its exploratory phase, the OCEANOMICS project builds on the success of the Tara Oceans expedition, a public / private initiative that collected samples and eco-morpho-genetic data in 11 fractions of organismic sizes covering all planktonic communities - from viruses to animals - over more than 150 sites and 3 depths across the global oceans.

Part of the project consists in exploring the Tara Oceans collection. The new knowledge is also used as part of collaborations with private partners to:

- transfer new technologies and methods of high throughput sequencing / imaging to case studies in aquatic bio-monitoring,
- conduct phenotyping of environmental samples and strains of choice to analyze their lipids, secondary metabolites and exo-metabolomes,
- screen high quality strains for their bioactive compounds of interest in the pharmaceutical and nutraceutical fields, as well as in aquaculture, cosmetics, agriculture and environment.

The project served as a case study on the implementation in France of the Nagoya Protocol for marine genetic resources. Its recommendations helped supporting the research communities in the debate around the ratification of the Nagoya Protocol in France in the law for biodiversity due to be adopted by the French Parliament. A specific WP delivered a report on the legal framework, with the help of an advisory committee composed of 4 biologists and 2 lawyers.

The following practical recommendations emerge from lessons learnt in the project, following the different steps of utilization of genetic resources for scientific research, from sampling in the field to transferring the resource in a material and immaterial form.

53 These recommendations were drafted by Anne Emmanuelle Kervella, with Dr Ana Rachel Teixera-Cavalcante, Sarah Aubertie and Dr Bleuenn Guilloux, and they are issued from the OCEANOMICS project report: Teixera-Calvacante A.R. et al. (2015), Cadre juridique applicable à l'accès et à l'utilisation des bioressources planctoniques marines, Oceanomics, Programme Investissement d'avenir. (www.oceanomics.eu)

I – Recommendations for projects sampling and using *in situ* bioresources for scientific purposes

Collecting marine bioresources in their environment in the frame of a scientific project requires to follow rules under the UN Convention of the Law Of the Sea (scientific research at sea[1]), the Convention on Biological Diversity and its Nagoya Protocol on Access and Benefit Sharing (research and development using biodiversity[2]) and the Antarctica Treaty System (freedom of scientific research (observation/investigation) in Antarctica[3]). Moreover the EU regulation on ABS[4] requires users to keep track of information.

A. Sampling at sea and collecting material

In general, when preparing a project, it required to:

- Collect information on the legal framework(s) in place and identify competent authorities ;
- Plan the project with legal experts to prevent any flaws and prepare PICs and MATs ;
- Request authorizations beforehand to allow negotiations on the scope and terms of use ;
- Sample in the respect of the agreement from the coastal state and providing country ;
- Create an ID card for each sample linked to the bioresource DOI and a track and trace scoreboard to monitor the use of each bioresource and the reporting to the local authorities ;
- Set up a system to collect the necessary information for a report of utilization to the coastal state and the providing countries and a follow-up.

In order to fill in the required information and prepare the project, the following check-list may be used:

Table 1 – EX-ANTE CHECK-LIST TO COORDINATOR OF A PROJECT USING GENETIC RESOURCES

You are contributing in a scientific project using genetic resources:

1. *What is the project about?*
2. *Do you know where the resource will come from?*
    a. *Geo-tracking?*
    b. *Name of Project?*
    c. *Name and Type (private or public) of Collection?*
3. *How do you intend to get hold of it?*
    a. *From a consortium partner within the project?*
    b. *By sampling?*
    c. *Transferred from a third-party with an MTA?*
4. *Will you collect it at sea?*
    a. *Whereby?*
    b. *When?*
    c. *Where will the samples be stored?*
5. *Do you have the permits to access and use the genetic resource?*
    a. *From the providing country?*
    b. *From a scientific partner (MTAs)?*

⇨ *The information and documents regarding necessary permits and authorizations must be produced before the project starts and collected by the coordinator.*

[1] http://www.un.org/depts/los/convention_agreements/convention_overview_convention.htm Marine Scientific Research (Part XIII)
[2] The conservation of Biodiversity, the sustainable use of its components and the access and the fair and equitable sharing of the benefits resulting out the utilization of genetic resources (art. 1: Objectives) - https://www.cbd.int/abs/
[3] Art. 2 and 3 of the Antarctic Treaty - http://www.ats.aq/e/ats.htm
[4] http://ec.europa.eu/environment/nature/biodiversity/international/abs/legislation_en.htm

The following template may be used by the coordinator to compile the information for each sample, ideally identified by a Digital Object Identifier (DOI)[5]. The Sample ID (or when possible DOI) provides information on geo-tracking, date of sampling, project name & coordinator, location of the sample and a link to the legal tag. The content of legal information refers to what a user of genetic material in the European Union would need to keep according to the EU ABS Regulation.

Table 2 - SAMPLE ID CARD & LEGAL TAG

Sample ID *(Geo-tracking - Date of sampling – Project Name & Coordinator – Location of sample)*	*Sampling at sea*	*Competent authority*	*Status of authorization*	*Authorized utilisation*	*Associated obligations*	*Restrictions*	*Follow-up on implementing obligations*
Access to marine resources at sea *(UNCLOS and ATS)*	Territorial sea/ ZEE / continental shelf/ Protected Area YES – NO		*YES / NO If YES reference number*			*duration of use / nature of use / transfer of material*	
	Antarctica YES – NO		*YES / NO If YES reference number*			*duration of use / nature of use / transfer*	
Access and Benefit Sharing *(CBD & Nagoya Protocol)*	YES - NO		*YES / NO If YES reference number*			*duration of use / nature of use / transfer*	
Status of legislation	*Applicable ABS*	*Competent authority*	*Status of Authorization (Prior Informed Consent - PIC)*	*Authorized utilization (Mutually Agreed Terms – MAT)*	*ABS measures (MAT)*	*Limits of utilization and transfer (MAT)*	*Follow-up on implementing obligations and timeframe*

[5] https://www.doi.org/hb.html

B. Managing the collected resources in a project

Considering the consequences of rights infringements or misconduct for scientists and the project, we recommend that the consortium designate a partner responsible for monitoring the respect of UNCLOS / AST / ABS obligations and the project defines a WP dedicated to the topic with allocated budget. Obtaining the authorization(s) to sample and complying with their obligations may be time consuming and could impair the overall project. Depending on the providing countries, the obligations may include: reporting regularly to the coastal states and providing countries, informing of any results in the project, sharing information and data with local communities informing and/or requesting authorization(s) before publishing, monitoring the mentioning of origin of the resource in any publication or work, and sharing the commercial benefits.

Each partner must be aware of the obligations and restrictions existing on the bioresource it will use in the project. The following check-list could be filled in by each participant when using MGR and collected by the dedicated WP[6].

Table 3 - CHECK-LIST TO PARTICIPANTS IN A PROJECT USING GENETIC RESOURCES

You are using genetic resources for scientific purposes:

1. *Description of the resource*
2. *Description of the utilization of the resource*
3. *Do you know the "scientific context" in which the resource was accessed?*
    a. *Collected in the project?*
    b. *Outside of the sampling campaign in the project?*
4. *How did you get hold of it?*
    a. *From a consortium partner within the project?*
    b. *Transferred from a third-party with an MTA?*
5. *Do you have the permits to access and use the genetic resource?*
    a. *From the State of origin?*
    b. *From a scientific partner (MTA)?*

An on-line IT system for the project should be to set up whereby each used resource will get a reference (DOI) linked to its sample ID CARD. The system should also be interlinked with the ABS Clearing House[7]. Each participant using this IT system will be aware of the rights and obligations linked to the resource and will be able to inform the coordinator / partner in charge of ABS in the project of the type of use of the resource. The IT system would guarantee a track and trace mechanism within the project and facilitate further use for cultured, modified, synthesized (?) or transferred resources.

[6] See also Annexes to Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices
[7] https://absch.cbd.int/

Table 4 - TEMPLATE FOR A TRACK AND TRACE SCOREBOARD WITHIN A PROJECT.

Reference of the bioresource	*Unique identifier – ideally a Digital Object Identifier (DOI)*[8]

	Project / Consortium *Coordinator*	*Name of user* *Organization* *Contact*	*Material Transfer Agreement* *Reference* *Dates*	*Outcome of utilization* *Publication* *Database / Collection* *IP protection measures :* - *Patents* - *Licenses* - *Copyrights* - *Others*	*Contact*
Bioresource DOI					

[8] The bioresource ID must be linked to the sample ID CARD.

Furthermore, the users' institutions in the project which are ultimately liable for any breach will be informed by signing the following provision included in the project's consortium agreement:

Table 5 – DISCLAIMER FOR CONSORTIUM AGREEMENTS

"Any use of bioresource outlined in the project is subject to the rights of the providing country under Article 6 of Nagoya Protocol, with respect to access and benefit sharing, and to Article 4 of EU Regulation on ABS compliance (Regulation 511/2014 of 16 April 2014) and its Implementing Regulation (EU) 2015/1866 of 13 October 2015 with respect to the due diligence"

When the project decides to deposit the resources in a collection and / or the information related to the resource in a database, it is recommended to use a similar disclaimer on the collection and / or database webpage (see Table 7).

The consortium must ensure that the coastal State is informed of the project results and any new utilization (deposit, transfer, etc…).

It is highly recommended that each transfer of resource is subject to a MTA (material transfer agreement) with standard provisions for ABS. A model may be chosen by the consortium amongst the following list:

Table 6 – MODEL MATERIAL TRANSFER AGREEMENTS (MTAs)

World Intellectual Property Organisation	*Model provision for ABS and examples of ABS MTAs on the WIPO database*	*http://www.wipo.int/tk/en/databases/contracts/search_results.jsp* *http://www.wipo.int/tk/en/databases/contracts/*
European Culture Collections Organization	*Core Material Transfer Agreement for the supply of samples of biological material from the public collection*	*https://www.eccosite.org/ecco-core-mta/*
Microbial Resources Research Infrastructure	*Guidelines to MTAs provisions in case of transfer to third party*	*http://www.mirri.org/fileadmin/mirri/media/Dokumente/generalDocs/MIRRI_ABS_Manual_web.pdf*

The transfer of material must comply with the prior authorization and be declared to the providing country, or be authorized when not foreseen in the prior authorization (PIC & MAT). All the documents related to the resource (ID CARD & LEGAL TAG and TRACK & TRACE SCOREBOARD infos) must be transferred to the new user.

II – Recommendations for consecutive utilizations of the resource

Any new utilization of the resource out of the scope of the project and any transfer of the material, to a scientist, in a collection and in a database must be declared and agreed upon by the providing country / the coastal State.

Since the entry into force of the EU ABS regulation[9] in 2014, users in the European Union are responsible for exercising *"due diligence"* or *"reasonable care"* by collecting information regarding the right to use genetic resource. They are liable for any misuse of resource towards the providing country, whether accessed *in-situ* or *ex-situ*.

It is therefore in the interest of the scientific community and science that the supplier helps the consecutive user of the resource to exercise his/her duties. The information collected in project must therefore be handed / available to the following users.

1. A protocol to deposit the genetic resource/bioresource in a culture collection and / or information on/related to the genetic resource/bioresource in a database

When a participant to the project decides to deposit the resource in a collection and / or the information related to the resource on a database, it is recommended:

- to follow a standardized protocol. The protocol could be built on the Microbial Resource Research Infrastructure (MIRRI)'s best practices[10]
- to interconnect the collection / database to the IT system referring to the sample ID CARD and bioresource track and trace scoreboard
- to insert a disclaimer on the collection's website and / or the database or for the future users.

Table 7 – DISCLAIMER FOR COLLECTION / DATABASE

"The utilization of resources and / or data therein is subject to the rights of the providing country, under Article 6 of Nagoya Protocol with respect to access and benefit sharing, and to Article 4 of EU Regulation on ABS compliance (Regulation 511/2014 of 16 April 2014) and its Implementing Regulation (Regulation (EU) 2015/1866 of 13 October 2015 with respect to the due diligence. The collection and / or database should not be held responsible for unlawful use of provided material."

It is also recommended to deposit the resource and / or publish the data after the coastal State has been informed, to allow a new negotiation if needed and avoid any future claims.

For the management of the deposited resource, please refer to the recommendations published in MIRRI.

B. A protocol to transfer the material to third party utilization

A resource lawfully collected and used in a project may be transferred for a new utilization to a third party. Before the resource leaves the project (the first user), the supplier may use the following check-list to assess the rights:

TABLE 8 – CHECK-LIST FOR A TRANSFER OF GENETIC MATERIAL

[9] Regulation (EU) No 511/2014 of the European Parliament and of the Council 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 & its Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices

[10] Box 1 – Deposit of material in a public collection – Accession Form and Material Accession Agreement (MAA) minimal requirements, due diligence steps and recommendations: http://www.mirri.org/fileadmin/mirri/media/Dokumente/generalDocs/MIRRI_ABS_Manual_web.pdf

1. Description of the resource (unique identifier – ideally DOI)
2. Description of utilization of the resource
3. Duration of utilization
4. Name of user (person + institution)
5. Is there an agreement between supplier and user? (collaboration agreement? consortium agreement? research contract? MTA? Etc…)
6. Are there third party rights on the resource? (access rights in consortium ? license? exclusive rights? IP ?…) (see TRACK and TRACE SCOREBOARD)
7. Does the utilization conform with the providing country / coastal state authorizations (see Sample ID CARD) ?

Unless the terms of utilization are set in another written agreement, a material transfer agreement must be negotiated between the supplier and the new user (see Table 6) and the documents collected within the project (see Tables 2 and 3) should be made available to the new user. The user will check on the Sample ID CARD whether this new utilization requires an authorization and / or if it is covered in the previous authorizations from the providing countries / coastal States. If so, the new user must inform said countries. If not and depending on the utilization and the location of sample, a new permit must be sought before using the resource and an agreement on conditions of use is to be negotiated for the new utilization.

CONCLUSIONS

Accessing and using genetic resource for research & development is a complex matter that requires specialized expertise. The risk at stake is for a scientific project or results to be refrained by a country. Along with a bad reputation, a research institution or a research community may also loose trust from providing countries, making scientific collaboration very difficult.

It is therefore in the interest of science that a community shows its good faith by adopting a code of conduct engaging towards implementing the ABS framework. It also reinforces the integrity of research and research and ethics. According to the EU ABS regulation, best practices may be registered at EU level.

Managing ABS could be part of quality management and ethical management in life sciences. Developing standard and realistic best practices require however human resources and funding.

Providers of genetic resources (collections, infrastructures) have an interesting positioning in that respect and may contribute to simplifying the system. Their role is recognized in the EU ABS Regulation and when using a registered, a used is deemed to have performed “due diligence”.

A provider, a collection, a database able to transfer the genetic material together with the legal information attached to it would bring a valuable service to scientists in that respect and to the CBD. Such a service may favor such provider over others, leading eventually to attracting more users, especially SMEs.

Glossary and Acronyms

ABS national focal point: Parties to the Nagoya Protocol should designate a national focal point on access and benefit-sharing. The national focal point is responsible for liaison with the CBD Secretariat and to make available to users, information on procedures for accessing genetic resources and establishing mutually agreed terms, including information on competent national authorities, relevant indigenous and local communities and relevant stakeholders (Article 13, Nagoya Protocol).

ABS Clearing-House: 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 genetic resource and associated traditional knowledge. (https://absch.cbd.int).

Access: the acquisition of genetic resources or of traditional knowledge associated with genetic resources from a geographical region under the jurisdiction of a Party to the Nagoya Protocol (EU ABS Regulation N° 511/2014. Art. 3).

Biotechnology: any technological application that uses biological systems, living organisms, or derivatives thereof to make or modify products or processes for specific use (Art. 2 CBD).

Checkpoints: Entities designated by Parties to effectively collect or receive relevant information related to prior informed consent, to the source of the genetic resource, to the establishment of mutually agreed terms and/or to the utilisation of genetic resources, as appropriate (Article 17. NP).

Checkpoint Communiqués: A summary of the information collected or received by a checkpoint related to prior informed consent, to the source of the genetic resource, to the establishment of mutually agreed terms and/or to the utilisation of genetic resources and registered in the ABSCH (Article 17. Nagoya Protocol).

Collection: means a set of collected samples of genetic resources and related information that is accumulated and stored, whether held by public or private entities (EU ABS Regulation N° 511/2014. Art. 3).

Competent national authority: A country may decide to establish one or more competent national authorities. The competent national authority or authorities may be responsible for granting access to genetic resources and for advising on, among other things, the negotiating process, requirements for obtaining PIC, and entering into MATs and mechanisms for the effective participation of indigenous and local communities (ILCs).

Country of origin: the country that possesses those genetic resources in-situ conditions (Art. 2 CBD).

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 (Art. 2 CBD), see also provider country and provider below.

Derivative: 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 (Art. 2 Nagoya Protocol).

DECLARE: an EU-wide web-based tool which enables users of genetic resources to submit the due diligence declarations required by EU REG 511/14 (Article 7).

Due Diligence: reasonable care to ensure that the material is legally accessed in accordance with ABS legislation and that its utilisation and supply (if applicable) is within agreed terms.

EU ABS Regulation: Throughout this document the term refers to: Regulation (EU) No 511/2014 of the European Parliament and of the Council 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 Utilisation in the Union.

Ex-situ conservation means the conservation of components of biological diversity outside their natural habitats (Art. 2, CBD).

Genetic material: any material of plant, animal, microbial or other origin containing functional units of heredity (Art. 2 CBD).

Genetic resources: genetic material of actual or potential value (Art. 2 CBD).

In-situ conditions: means conditions where genetic resources exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties (Art. 2 CBD).

Internationally Recognised Certificate of Compliance (IRCC): A record generated when the competent national authority of a provider country publishes a permit or equivalent (e.g. PIC and MAT) on the ABS Clearing-House. This is given a unique identifier by the Clearing-House and provides legal surety of the genetic resources covered and assists monitoring of utilisation. It may also be used to simplify reporting.

Material Accession Form (sometimes referred to in wider literature as **Material Accession Agreement** or **Material Deposit Form**): A document setting out the required information for due diligence and other supporting information and links to documentation for a genetic resource that is being transferred (deposited) to an institute or collection.

Material Transfer Agreement (MTA): An agreement between two institutions stipulating the terms and conditions for transferring specimens or samples, including genetic material.

Marine genetic resources (MGR): No specific definition of Marine Genetic Resources (MGRs) in either the CBD or any other international or regional document. CBD Art. 2 defines "genetic resources" as "genetic material of actual or potential value". In the same article, "genetic material" is defined as "any material of plant, animal, microbial or other origin containing functional units of heredity".

Mutually Agreed Terms (MAT): The contractual arrangements concluded between a provider of genetic resources, or of traditional knowledge associated with genetic resources, and a user, that set out specific conditions for the fair and equitable sharing of benefits arising from the utilisation of genetic resources or of traditional knowledge associated with genetic resources,

and that may also include further conditions and terms for such utilisation as well as subsequent applications and commercialisation (EU ABS Regulation).

National focal point (NFP, see ABS national focal point)

Prior informed consent (PIC): The permission given by the competent national authority of a provider country to a user prior to accessing genetic resources, in line with an appropriate national legal and institutional framework. The PIC sets out the conditions around use.

Provider country: also referred to as country provider genetic resources (see above), means the country of origin of the genetic resources or any (other) Party to the Protocol that has acquired the genetic resources in accordance with the Convention (see Articles 5 and 6 of the Protocol and Article 15 CBD).
(Guidance document on the Scope of EU ABS Regulation).

Provider of genetic resources: States have sovereign rights over their natural resources and can decide to establish access legislation. Within the exercise of their sovereignty, states will determine who holds rights over genetic resources in their domestic legal order and who has the authority to grant access to genetic resources or traditional knowledge associated with genetic resources and who should be involved in the negotiation of mutually agreed terms with potential users etc. The possibilities range from public ownership over genetic resources, to a system where the rights over genetic resources follow the private property rights over the land. Even in case of public ownership over genetic resources, a national government will typically delegate the authority to grant prior informed consent to a sub-national (e.g. regional authority) or non-state entity (e.g. a reference collection). (Glossary to the EU ABS Regulation).

Registered collection: a collection included in the European Register that has demonstrated the capacities outlined in Technical Guideline 8 (Part 2 of the Handbook).

Traditional knowledge (associated with genetic resources): 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 (Guidance Document on the Scope of EU ABS Regulation).

Resource passport: Within EMBRC, 'resource passport' refers to the documents and information accompanying a genetic resource supplied to a third party that would: 1) allow the user to comply with due diligence, 2) demonstrates that the genetic resource was legally accessed and 3) indicates the terms of use (e.g. PIC and MAT and other relevant permits or documentation). The resource passport is separate from the MTA.

Research and development: Refers to 'creative work undertaken on a systematic basis in order to increase the stock of knowledge, including knowledge of man, culture and society, and the use of this stock of knowledge to devise new applications' (OECD's 2002 Frascati Manual, cited in the Guidance Document on the Scope of the EU ABS Regulation).

User: a natural person or legal entity that utilises genetic resources or traditional knowledge associated with genetic resources (EU ABS Regulation. Art. 3).

Utilisation of genetic resources: 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 CBD (EU ABS Regulation Art. 3).

Key References

Legal Texts

Convention on Biological Diversity Rio de Janeiro, 5 June 1992. https://treaties.un.org/doc/Treaties/1992/06/19920605%2008-44%20PM/Ch_XXVII_08p.pdf

European Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015 laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32015R1866

Food and Agriculture Organisation International Treaty on Plant Genetic Resources for Food and Agriculture, Rome, 3 November 2001: http://www.fao.org/plant-treaty/overview/en/

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. Nagoya, 29 October 2010. https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf

Regulation (EU) No 511/2014 of the European Parliament and of the Council 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 Utilisation in the Union Text with EEA relevance. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32014R0511

United Nations Convention on the Law of the Sea, Montego-Bay, 10 December 1982: https://www.un.org/depts/los/convention_agreements/texts/unclos/unclos_e.pdf

World Health Organisation Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefit, 24 May 2011: https://www.who.int/influenza/resources/pip_framework/en/

Guidelines

European 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 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. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016XC0827(01)&from=EN

Secretariat of the Convention on Biological Diversity (2002). Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilisation. Montreal: Secretariat of the Convention on Biological Diversity. https://www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf

Best Practices

Consortium of European Taxonomic Facilities (CETAF) Code of Conduct and Best Practices (https://cetaf.org/sites/default/files/final_cetaf_abs_coc.pdf)

MIRRI best practice manual on access and benefit sharing, microbial resource research infrastructure, 2016. Available at: https:// www. mirri. org/ fileadmin/ mirri/ media/ Dokumente/ MIRRI_ ABS_ Manual__ web. pdf

Publications

Guilloux, B. 2018. Marine Genetic Resources, R&D and the law, vol. 1, ISTE/Wiley eds, London.

ten Hoopen, P., Cochrane, G., & Micro B3 Consortium. 2016. Ocean Sampling Day Handbook. Available on-line at https://www.microb3.eu/sites/default/files/osd/OSD_HandbooK_2016.pdf

von Kries, C., Broggiato, A., Dedeurwaerdere, T., and Winter, G. 2015. "Micro B3 model agreement on access to marine microorganisms and benefit-sharing. Text and commentary". In Chege Kamau, E., Stoll, P.-T., and Winter, G.(eds.) Research and Development on Genetic Resources. Public Domain
Approaches in Implementing the Nagoya Protocol. Routledge: 330–362.

Lallier, L.E., McMeel, O., Greiber, T., Vanagt, T., Dobson, A.D. and Jaspars, M., 2014. Access to and use of marine genetic resources: understanding the legal framework. Natural product reports, 31(5), pp.612-616.

Movilla Pateiro, L. 2020. Advances and uncertainties in compliance measures for users from the Nagoya Protocol in the European Union. RECIEL. 29: 282– 290. https://doi.org/10.1111/reel.12320

Smith, D., Hinz, H., Mulema, J., Weyl, P. and Ryan, M.J., 2018. Biological control and the Nagoya Protocol on access and benefit sharing–a case of effective due diligence. Biocontrol science and technology, 28(10), pp.914-926.

5.1 A handbook produced by the European Marine Biological Resource Centre

Interreg
Atlantic Area
European Regional Development Fund

EUROPEAN UNION

EMBRC
EUROPEAN
MARINE
BIOLOGICAL
RESOURCE
CENTRE

CNRS • SORBONNE UNIVERSITÉ
Station Biologique
de Roscoff

EBB
an EMBRC project

THE MARINE BIOLOGICAL ASSOCIATION

Design, illustration and photography by Rufus Wood 2021 rufuslwood@gmail.com