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Scoping industrial needs for sustainable development

D3.9 Identify specific marine biotechnology issues (non-monetary)
D3.10 Societal and sustainability issues relevant for MBT
D3.11 Access and benefit sharing

Work Package 3

Interactions with industry

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EXECUTIVE SUMMARY

Utilization of marine biological resources have environmental and societal impacts affecting costal zones and societies and business models for product and market developments. In this report the ERA-MBT project gives focus to the Nagoya protocol and the regime for access and benefit sharing (ABS) which is an open and complex regulatory framework, which needs to be developed for nations implementing it in their national jurisdiction. We draw up how this matters for the utilization of biotechnology to make value from marine resources. References to central info sources for further reading are given. In addition, the report points to societal and sustainability issues as well as non-monetary benefits to be considered in this broad area of regulatory and juridical frameworks. Other FP7-funded projects have looked into these in detail and even made practical pilot actions to test the implementation of them. Of particular interest are the results and experiences from the MicroB3 and PharmaSea projects where the report gives overviews and references.

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INTRODUCTION AND DEFINITIONS

The purpose of this delivery (D3.9, 3.10, 3.11) is to review the state of the art of the legal framework regarding the access and utilization of marine genetic resources (MGRs), particularly with respect to the issues specific to research in biological sciences and marine biotechnology including sustainability and societal matters.

Marine biotechnology and marine genetic resources

A definition of Marine Biotechnology was elaborated in D3.7, and reformulated to frame these deliveries, it can be expressed as: *"**Marine biotechnology** explores and uses marine bioresources as the target for or origin of biotechnological applications for the production of goods and/or services. **These developments can affect the natural environment positively or negatively; therefore, it is necessary to consider sustainability and societal aspects for the use of the marine environment**."*

The current potential of the fast-growing application of marine biotechnology, lies in the exploration and utilization of MGRs of which only a minor fraction (~5%) has been documented and identified. For the most part, the unknown fraction is made up of microscopic organisms (bacteria, archaea and microalgae) — whose discovery relies on efficient, high-technology methods — and, to a lesser extent, macroscopic organisms (e.g. algae, invertebrates and fish).

The Convention on Biological Diversity (CBD), which aims to protect biological diversity on Earth as well as the sovereign rights of countries providing natural resources over their genetic resources, defines biotechnology as follows:

> *"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)."*
>
> This definition is taken from Art. 2 of the Nagoya Protocol, which aims to promote *"the fair and equitable sharing of the benefits arising from the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components."*
>
> *"Biotechnology" as defined in Article 2 of the Convention means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.*
>
> Genetic resources are defined in Art. 2 CBD as follows: *"Biological resources" includes genetic resources, organisms or parts thereof, populations, or any other biotic component of*

> *ecosystems with actual or potential use or value for humanity. Genetic resources: genetic material of actual or potential value. Genetic material: any material of plant, animal, microbial or other origin containing functional units of heredity.*

The Nagoya Protocol defines the utilization of genetic resources in the following text:

> *"Utilization of genetic resources" means 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 Convention****.*
>
> This protocol, a supplementary agreement to the CBD, also provides a definition of "derivatives" in reference to the definition of "biotechnology" in the CBD:
>
> *"Biotechnology" as defined in Article 2 of the Convention means any technological application that uses biological systems, living organisms,* ***or derivatives thereof****, to make or modify products or processes for specific use.*
>
> ***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*

Although the definition of "genetic resources" is subject to debate in the scientific community, this report uses the definition laid out in the Nagoya Protocol that encompasses derivatives (see above). This definition is the most appropriate one for marine biotechnology because various types of molecules can be involved in innovative developments and commercial applications in this field: genes, RNA, proteins (including enzymes), metabolites and polymers.

Marine biological resources, either living organisms as such or extracts thereof that include the expression of heredity, are — at least initially — harvested from the natural environment. When possible and if knowledge, expertise and technology permitting, these living organisms can be cultivated, if necessary, for the production of biomass or at least enough biological material for study. Collection, harvesting and/or cultivation may constitute major scientific issues and technical challenges specific to each species. This also includes the understanding of how harvested wild and the culturing of resources impact the environment. Societies are getting more and more aware of the impacts and needs for sustainable solutions also related to how utilisation of the marine environment impacts costal societies and their use of this nature.

Within exclusive economic zones (EEZ/national jurisdictions), authorization must be obtained from sovereign States for access to and exploration of the MGRs in their maritime areas. Outside EEZ the United Nations Convention on the Law of the Sea (UNCLOS) is in effect, and for access and use of natural resources within EEZ CBD and its Nagoya Protocol comes in effect. The rights must be negotiated with the providing country when the user benefits from the use of these biological resources.

Position paper no. 15 from the Marine Board "*Marine Biotechnology, a new vision and strategy for Europe*"[1] published in 2011 already underlined the importance of international regulations on the access to marine resources for the development of marine biotechnologies and two of its recommendations were:

1- Development of a common European position on the simplification and harmonization of regulation on access and fair and equitable benefit sharing from the use of marine genetic resources to strengthen European's voice at the international level. In its analysis, Europe must take into account three territories: i) inside Europe, ii) outside Europe, and iii) international waters.

2- Simplification of access and benefit-sharing agreements throughout Europe and its territories through the development of a common template agreement. However, simplifications and harmonization of regulations on access and "fair and equitable" benefit sharing (commonly called ABS) from the use of genetic resources should not be limited to the European level but also needs to be addressed at the international level.

In 2012, the OECD organized a conference on Marine Biotechnologies in Vancouver, Canada leading to a report entitled "Marine Biotechnology Enabling Solutions for Ocean Productivity and Sustainability"[2] in 2013. A chapter of this report is dedicated to societal issues and more specifically to the challenges and opportunities regarding the conservation and sustainability of marine biological resources. It clearly indicated the importance of setting up governance over the distribution of marine bioresources and establishing a regulatory framework for the access to these resources and the sharing of the benefits. Recently (2016) the OECD published the report on "*The Ocean Economy in 2030*"[3] where for the first time the oceans role in the world's economy is analysed. Marine biotechnology is included as an enabler realizing valorisation from marine biological resources, but also raising sustainability and societal issues which are discussed in the report.

Here, this delivery examines the cases of the utilization of MGRs in areas within national jurisdiction (1), outside national jurisdiction (2), and some special cases (3).

1. USING MGRS FROM AREAS WITHIN NATIONAL JURISDICTION

1.1 Accessing the sea (UNCLOS)

UNCLOS is an international United Nations treaty that outlines the legal framework governing activities in the world's oceans, particularly in regard to the utilization of resources and the requirement to protect and preserve the marine environment and its natural resources. It was adopted in 1982 and entered into force in 1994.

The diagram below summarizes the different maritime zones as defined by UNCLOS rules.

[1] http://www.marineboard.eu/science-strategy-publications

[2] http://www.oecd-ilibrary.org/science-and-technology/marine-biotechnology_9789264194243-en

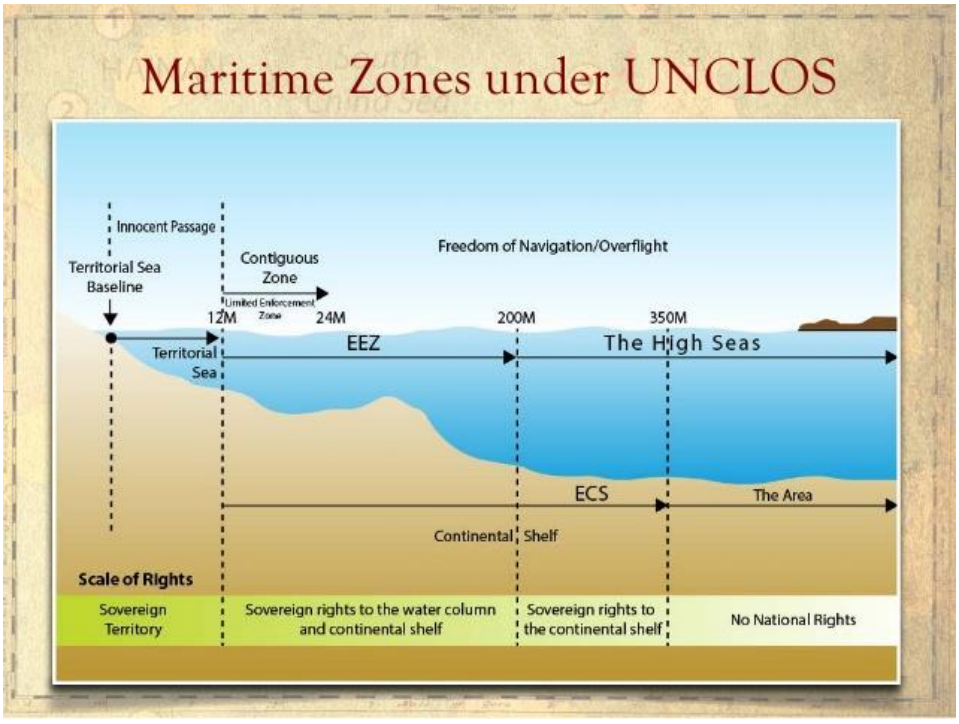
[3] http://www.oecd-ilibrary.org/economics/the-ocean-economy-in-2030_9789264251724-en

Territorial seas: The sovereignty of a coastal State extends, beyond its land and territory and internal waters and, in the case of an archipelagic State, its archipelagic waters, to an adjacent belt of sea, described as the territorial sea. The breadth of its territorial sea must not exceed a limit of 12 nautical miles.

Exclusive Economic Zone (EEZ): An area beyond and adjacent to the territorial sea, subject to a specific legal regime established, under which the rights and jurisdiction of the coastal State and the rights and freedoms of other States are governed by the relevant provisions of the Convention.

The High Seas: All parts of the sea that are not included in the Exclusive Economic Zone (EEZ), in the territorial sea or in the internal waters of a State, or in the archipelagic waters of an archipelagic State.

The Area: The seabed and ocean floor and subsoil thereof, beyond the limits of national jurisdiction. *The Area's boundaries are different from* High Seas *boundaries, which start at 200 nm where* Exclusive Economic Zones *have been claimed (e.g. at 12 nm in the Mediterranean).*



Access to and utilization of marine genetic resources is covered by this framework for access to waters under national jurisdiction. The users of marine bioresources must apply for authorization ex-ante to enter in a State's territorial waters and must provide information on their project, as well as scientific results obtained from the used resources.

The project also falls under the Access and Benefit-Sharing (ABS) principles that have been implemented in some countries since the CBD, and then extended to Nagoya Protocol signatory countries since 2015.

1.2 Exploring its biodiversity (CBD and Nagoya Protocol)

The Convention on Biological Diversity (CBD) entered into force in 1993 and enhanced in 2010 by the **Nagoya Protocol**, sets the regulatory framework for the utilization of genetic resources and associated traditional knowledge. The Nagoya Protocol requires CBD parties in particular to fulfil legal obligations to obtain access to genetic resources and to ensure the fair and equitable sharing of the benefits arising from their utilization. Although marine biodiversity is found in all maritime zones around the world, the CBD and the Nagoya Protocol are only applicable to the EEZ and the continental shelf of coastal countries and do not cover areas located beyond national jurisdiction (Areas Beyond National Jurisdiction – ABNJ). Until now, marine resources found in ABNJ could be used by all and for any use, with no legal restrictions. The absence of a legal framework causes serious problems in the interpretation of the law, particularly in regard to access to MGRs and the sharing of benefits. Moreover, marine organisms, both planktonic and benthic, have motile stages and can move vertically and horizontally across EEZ borders, the continental shelf and the High Seas. Therefore, according to location where they are collected, they may or may not fall under a specific legal framework.

The Nagoya Protocol & Access and Benefit Sharing:

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization entered into force on 12 October 2014 and has thus far been ratified by 73 countries. The European Parliament and the Council adopted the new ABS on 16 April 2014. It entered into force on 9 June 2014 and all of its provisions have been applied since 12 October 2015.

There is abundant literature on ABS, the implementation of the Nagoya Protocol and the impact of this new regulatory framework on the scientific community and private businesses. The object of this report is not to provide a detailed description of the subject, but to review the subject, provide a snapshot of the current state of affairs and highlight the current issues for marine biotechnology.

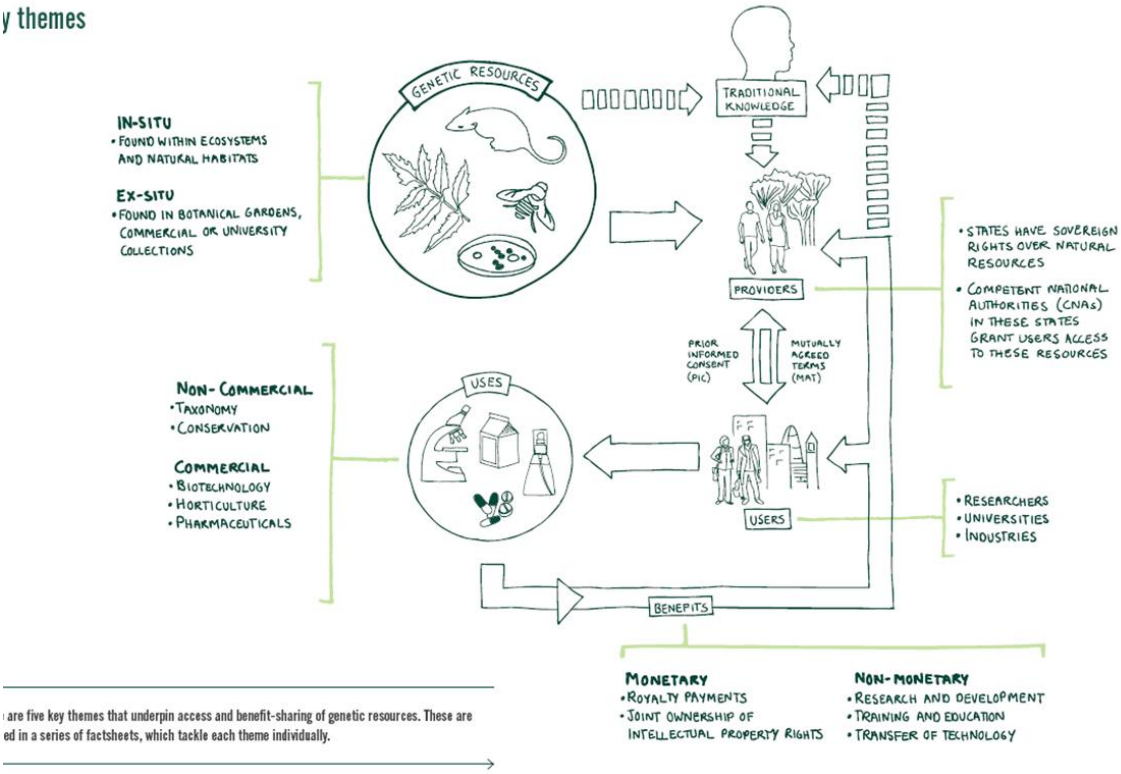
The article by Lallier et al (2014) is a very interesting and useful overview of the legal framework related to marine scientific research and provides valuable information on ABS and MGRs. In addition, the CBD hosts a highly useful website for searching detailed information on the Nagoya Protocol and its implementation (https://www.cbd.int/abs/).

In particular, the ABS Clearing House (ABSCH) is an information-sharing platform on the access and the sharing of benefits set up by article 14 of the Protocol (https://www.cbd.int/abs/theabsch.shtml). The page dedicated to raising awareness on ABS (https://www.cbd.int/abs/awareness-raising/) provides informative factsheets, brochures and other materials.

ABS in a nutshell (based on information extracted from the CBD/ABS web site)

ABS refer to the way in which genetic resources may be accessed, and how the benefits that result from their use are shared between people or countries using the resources (users) and the people or countries that provide them (providers).

The diagram below summarizes the key themes that underpin ABS (excerpted from the ABSCH).



How does ABS work?

ABS is based on prior informed consent (PIC) being granted by a provider to a user and negotiations between parties to develop mutually agreed terms (MAT) that ensure the fair and equitable sharing of genetic resources and associated benefits.

Prior Informed Consent (PIC) is 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.

Mutually Agreed Terms is an agreement reached between the providers of genetic resources and users on the conditions of access and use and the benefits to be shared between both parties.

Who is involved?

Users of genetic resources

The user is deemed an individual. These individuals are part of a diverse group, including botanical gardens, industry researchers such as pharmaceutical, agriculture and cosmetic industries, collectors and research institutes. They seek access for a wide range of

purposes, from basic research to the development of new products. Users are responsible for sharing the benefits derived from genetic resources with the providers

Providers of genetic resources

Providers are the States. States have sovereign rights over natural resources under their jurisdiction. They are obligated to set up conditions that facilitate access to these resources for environmentally sound uses. Providers agree to terms, which include PIC and MAT, for granting access and sharing benefits equitably. Laws within the providing country determine rights over genetic resources at the national level, who has the authority to grant access to genetic resources and who should be involved in the negotiation of MAT with potential users (e.g. private land-owners, indigenous and local communities).

Providers may also be intermediaries, i.e. collections.

National Focal Points (NFPs):

NFPs role is to facilitate access. Users need a clear and transparent process that details who to contact and what the requirements and processes are in providing countries in order to gain access. They are responsible for providing information on ABS.

Competent National Authorities (CNAs):

CNAs are bodies established by governments and responsible for granting access to users of their genetic resources, on behalf of providers on a local or national level.

NFP and CNA details from all countries can be found on the ABSCH web site (https://absch.cbd.int/countries).

Traditional knowledge

The ABS agreements of the Nagoya Protocol also take into account **traditional knowledge** held by local or indigenous communities that do not have the same capacities for research and development as industrialized countries. Traditional knowledge includes "Knowledge, know-how, skills and practices developed, sustained and passed on from generation to generation within a community, often forming part of its cultural or spiritual identity, and found in varied contexts, including agricultural, scientific, technical, ecological and medicinal" (http://www.wipo.int/tk/en/tk). This traditional knowledge relies on historical ancestral of use of genetic resources which frequently inspires, initiates or guides research that may eventually lead to a commercial application of genetic resources. The objective is to ensure that holders of traditional knowledge — who often live in developing countries — are not ignored or, unfairly dispossessed of future economic benefits. PIC and ABS agreements ensure that indigenous or local populations are implicated in the authorization to use genetic resources when traditional knowledge is involved. The agreements also guarantee that these populations are involved in MAT negotiations to reach a consensus on how to share the benefits. Until now, traditional knowledge associated with genetic resources dealt mainly with terrestrial environments and little with marine biodiversity.

However, with the increasing number of exploration and sampling expeditions/cruises in the marine environment, and the emergence of marine biotechnologies, this ratio can change rapidly.

Capacity building initiatives:

The **ABS Capacity Development Initiative** is an international organization, established in 2006, to support the development and implementation of national regulations on ABS. The ABS Initiative brings together experts from all over the globe to train relevant stakeholders and create platforms for mutual exchange with the aim to discuss ABS issues, improve cooperation among countries, support partnerships between relevant stakeholders and negotiate related agreements (http://www.abs-initiative.info/).

The ABS Capacity Development Initiative organizes many events (e.g. stakeholder workshops), publishes documents (e.g. working papers, factsheets and outreach materials, etc.) and closely observes traditional knowledge associated with genetic resources. A factsheet entitled "Relevance of Marine Bioprospecting for ABS frameworks" published in 2014 reviews the research and development of marine natural products that have applications in medicine or cosmetics. Three of the ten marine molecules that have been marketed rely on traditional Arctic or Asian uses: omega-3 polyunsaturated fatty acids in fish oils (Lovaza® and Omacor®) and a polysaccharide extracted from red seaweed (Carragelose®).

IDLO *(*International Development Law Organization, http://www.idlo.int *)* is an intergovernmental organization exclusively devoted to promoting the rule of law. Governments, multilateral organizations, private foundations and the private sector support our work. Together with the CBD Secretariat, ABS Capacity Development Initiative and the Centre for International Sustainable Development Law (CISDL), IDLO offers new capacity building opportunities for national lawyers and policy officers to act as legal leaders in their own countries. For instance, capacity-building courses entitled "Establishing legal frameworks to implement the Nagoya Protocol" including e-learning sessions and workshops and designed to build the capacity of lawyers and policy officers actively involved in designing and implementing domestic frameworks or advising on national processes to implement the Nagoya Protocol was organized in 2016.

WIPO (World Intellectual Property Organization, http://www.wipo.int/) is a global forum for intellectual property services, policy, information and cooperation. The WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore negotiates international legal instrument(s) on intellectual property (IP) and Genetic Resources, Traditional Knowledge and Traditional cultural expressions. WIPO has developed a portal dedicated to indigenous peoples and local communities that provides various documents, cases studies, fellowships and reports and also organizes practical workshops.

2. USING MGRS BEYOND NATIONAL JURISDICTION (HIGH SEAS)

Agreement on the conservation and use of marine biodiversity in ABNJ

As mentioned above, the Nagoya Protocol does not cover the Areas Beyond National Jurisdiction (ABNJ) and there are currently no regulatory frameworks for the access and utilization of MGRs in this large marine space that covers roughly two-thirds of the world's oceans and 60% of the seafloor. Some countries consider that the biological resources of the ABNJ belong to the Common Heritage of Humanity and the benefits from their use must be shared among all countries. Other countries advocate applying the precautionary principle and establishing marine protected areas in ABNJ. However, to mention but one case, most deep-sea hydrothermal ecosystems are located in the ABNJ. These ecosystems harbour highly original microbial flora and fauna that are little documented but undoubtedly hold high promise for biotechnology applications (thermostable enzymes, new polymers, antibiotics, etc.). Moreover, the international community has become more and more aware of the growing threats that loom over ABNJ ecosystems. Considering these growing interests and the lack of a legal framework, the United Nations began to tackle the issue of natural resources located in ABNJ more than 10 years ago to propose concrete actions for the definition of an international legally binding instrument under UNCLOS to safeguard the conservation and sustainable use of ABNJ marine biodiversity.

In 2004, the United Nations General Assembly set up an Ad Hoc Open-Ended Informal Working Group to study issues relating to the conservation and sustainable use of marine biological diversity in ABNJ (the BBNJ working group). A paper by Broggiato et al. (2014) details the state of the art and the international processes that aim to establish a legal framework for the management of genetic resources, taking into account both monetary and non-monetary benefit sharing.

The BBNJ working group has met nine times since 2006 (mention IDDRI Issue Brief), all the reports and studies of this WG are available on the following web page:

http://www.un.org/depts/los/biodiversityworkinggroup/biodiversityworkinggroup.htm

The first "Oceans and the law of the sea" report, presented to the UN General Assembly (UNGA), and published on 15 July 2005, outlined the WG's objectives, which involve "study[ing] issues relating to the conservation and sustainable use of marine biological diversity beyond areas of national jurisdiction" to provide "information on the scientific, technical, economic, legal, environmental, socio-economic and other aspects of the conservation and sustainable use of marine biological diversity beyond areas of national jurisdiction, including key issues and questions where more detailed background studies would facilitate consideration by States of these issues and, where appropriate, possible options and approaches to promote international cooperation and coordination in this area". It also presents information on past and present activities of the United Nations and other relevant international organizations.

After 10 years of informal discussions, before the final 6th session held in January 2015, the BBNJ WG issued final recommendations to the UNGA "to address, on an urgent basis, building on the work of BBNJ WG, the issue of the conservation and sustainable use of marine biological diversity of ABNJ, including by taking a decision on the development of an international instrument under the UNCLOS, before the end of the 69th session of the Assembly". In June 2015, UNGA adopted a Resolution to develop a legally binding Instrument on the Conservation of Marine Biological Diversity in ABNJ under UNCLOS.

The key messages of the Resolution as summarized in *IDDRI Issue Brief* No. 04/16 (Wright and Rochette,2016; http://www.iddri.org/Publications/Collections/Syntheses/IB0416_GW%20et%20al._high%20seas.pdf) are:

"ABNJ represent nearly half of the planet's surface and a significant amount of its biodiversity, but there are significant gaps that hinder effective conservation and sustainable use."

"The first meeting of a newly created Preparatory Committee will be held in March-April 2016, during which States will begin to navigate the complex issue at stake and discuss the elements of a new agreement, including the "Package Deal" namely: marine genetic resources; area-based management tools; environmental aspects impact assessments; capacity building and the transfer of marine technology. Institutional arrangements, including issues regarding the relationship with existing organizations and agreements, will be also discussed."

Complete study: G. Wright, J. Rochette, E. Druel, K. Gjerde (2015) The long and winding road continues: Towards a new agreement on high seas governance Studies, n°1, Study No. 01/16, IDDRI, Paris, France, 50 p.

The Preparatory Committee (Prep Com) has already held one session in 2016 (28 March – 8 April 2016), in order to make recommendations to the UNGA on the elements of a draft text of an international legally binding instrument under UNCLOS, taking into account the various reports of the Co-Chairs on the work of the BBNJ WG. During the first session, the PrepCom's members agreed on a road map and addressed a number of issues related to the elements of the Package Deal such as the objective, scopes, definitions, guidelines and relationships to other instruments and frameworks. The second session of the PrepCom will be held at the end of Summer 2016 (26 August – 9 September 2016).

Thus, by the end of 2017, via UNCLOS, the UNGA should agree on a legally binding instrument analogous to the Nagoya Protocol for EEZ to bridge the existing legal gaps and provide clear guidelines on benefit sharing for access to genetic resources in ABNJ.

Read more: http://nr.iisd.org/news/unga-adopts-resolution-to-develop-legally-binding-instrument-on-the-conservation-of-marine-biological-diversity-in-abnj/

IUCN position paper "Recommendations for the elements of a draft text of an internationally binding instrument under UNCLOS"

http://cmsdata.iucn.org/downloads/iucn_statement_to_the_unga_69292_first_prepcom.pdf

3. PRACTICAL ISSUES

3.1 Complying with ABS in Europe: the "due diligence" obligation

The EU regulation of ABS compliance

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 was adopted on 16 April 2014. Implementing the mandatory elements of the Nagoya Protocol in the European Union, it entered into force on 9 June 2014 and is applicable as of the date the, i.e. 12 October 2014.

The ABS rules apply when genetic resources, and the traditional knowledge associated with them, are used in research and development for their genetic properties and/or biochemical composition, including through the application of biotechnology.

The EU ABS Regulation organizes the way users will comply with the Nagoya Protocol in EU territory.

According to 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."

Thus, 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.** The following elements are of importance when deciding if a resource falls within the scope of the Regulation: geographic area, date of sample collection, type of material and intended use. All elements must be fulfilled for the EU ABS Regulation to apply[4].

"Due diligence" checkpoints:

The **first checkpoint** (defined in Article 7(1) of the Regulation) concerns the research stage, when a research project involving utilization of genetic resources and traditional knowledge associated with genetic resources is subject to external funding in the form of a grant. The EU ABS Regulation does not make a distinction between public and private funding. Both types of funding for research are covered by the obligation to declare due diligence as provided for in Article 7(1). For instance, researchers must declare "due diligence" when applying for a H2020 grant.

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[4]Guidance on the EU Regulation implementing the Nagoya Protocol, http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetailDoc&id=21409&no=1

The **second checkpoint** at which a due diligence declaration is to be submitted by users is the stage of final development of a product developed via the utilization of genetic resources or traditional knowledge associated with genetic resources. The Implementing Regulation (Article 6) refers to five different instances but also clarifies that the declaration is to be made only once, at the first (i.e. the earliest) event occurring.

Guidelines:

A guidance document on the scope of the EU ABS Regulation was adopted on 22 August 2016 and published in the French Official Journal on 27 August 2016. A report on utilization practices among upstream actors (collections, researchers at universities, etc.), prepared by a contractor, was one of the many elements that fed into this guidance document. The issues raised in the guidance document were discussed in the Consultation Forum, the first meeting of which was held in January 2016.

Additional sectorial guidance documents on cosmetics, animal breeding, plant breeding, biocontrol, pharmaceuticals, food and feed, biotechnologies and upstream actors are being developed.

3.2 Science and ABS: sharing non-monetary benefits

It is relatively straightforward to define the monetary benefits for the access and utilization of genetic resources; the Nagoya Protocol (Article 36) provides a detailed but non-exhaustive list:

- Access fees/fee per sample collected or otherwise acquired;
- Up-front payments;
- Milestone payments;
- Payment of royalties;
- License fees in case of commercialization;
- Special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity;
- Salaries and preferential terms where mutually agreed;
- Research funding;
- Joint ventures;
- Joint ownership of relevant intellectual property rights.

There are currently few known examples of commercial use of MGRs that have an ABS agreement. One of the rare examples is Gorgonian Extract®, which is used in cosmetics (Relevance of marine bioprospecting for ABS frameworks, ABS Factsheet, The ABS Capacity Development Initiative).

This example involves the use of pseudopterosin (a diterpene glycoside) extracted from the sea whip (a soft coral) *Pseudopterogorgia elisabethae* harvested each year in the Bahamas. The ABS agreement covers the initial part of its value chain. In 1982, researchers from the University of California discovered anti-inflammatory properties of pseudopterosins extracted from specimens sampled in the Bahamas and a patent was filed in 1988. Later that year, the Estée Lauder company started to use the coral extract in its Resilience product line. The patent

license fees paid by Estée Lauder to the University of California in 1995 and 1996 alone amounted to USD 1.5 million.

The Nagoya Protocol also provides a non-exhaustive list of non-monetary benefits:

- Sharing of research and development results;
- Collaboration, cooperation and contribution in scientific research and development programmes, particularly biotechnological research activities, where possible in the Party providing genetic resources;
- Participation in product development;
- Collaboration, cooperation and contribution in education and training;
- Admittance to *ex situ* facilities of genetic resources and to databases;
- Transfer of knowledge and technology to the provider of the genetic resources 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 utilization of biological diversity;
- Strengthening capacities for technology transfer;
- Institutional capacity building;
- Human and material resources to strengthen the capacities for the administration and enforcement of access regulations;
- Training related to genetic resources with the full participation of countries providing genetic resources, and where possible, in such countries;
- Access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies;
- Contributions to the local economy;
- 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;
- Institutional and professional relationships that can arise from an access and benefit-sharing agreement and subsequent collaborative activities;
- Food and livelihood security benefits;
- Social recognition;
- Joint ownership of relevant intellectual property rights.

In 2014, as part of a project on "Access and Benefit-sharing in Latin America and the Caribbean: A science-policy dialogue for academic research", the Regional Office for Latin America and the Caribbean (ROLAC) and the ICSU (International Council for Science) contributed to a report that includes many practical examples of non-monetary benefits (falling into four main categories: capacity building and knowledge, scientific benefits, sharing information and results and providing infrastructures) all based on cases studies. Those examples complement and illustrate the non-exhaustive list of the Nagoya Protocol.

Ref: http://www.icsu.org/latin-america-caribbean/what-we-do/priority-areas/biodiversity/access-benefit-sharing/ICSUROLACABSINLAC_English.pdf

Whether part of the Nagoya Protocol for the EEZ or ABNJ marine zone, capacity building and technology transfer constitute basic non-monetary benefits geared towards non-industrialized countries so that they can also gain from the benefits of applications developed from MGRs found in their waters. Many experts agree that although the non-monetary benefits mentioned in the Nagoya Protocol are useful guidelines, they are nonetheless relatively vague. It is necessary and very useful to define standards, guidelines and best practices in terms of non-monetary benefits as well as carry out case studies to guide future and current users of genetic resources and increase their awareness on this topic.

Note: best practices in scientific communities can be recognized in application of EU ABS regulations ("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[5]).

3.3 Collections & biological resource centres as facilitators to ABS

National and international collections of biological resources managed by natural history museums, botanical gardens or research institutes are important stakeholders in the implementation of the Nagoya Protocol and ABS. Other than holding highly specialized knowledge in taxonomy, they are providers and users of genetic resources (organisms, tissues, DNA, etc.). These collections accept new specimens from sampling expeditions around the world's seas, identify them with respect to current taxonomic knowledge, archive them and supply them for basic or applied research.

The EU ABS Regulation acknowledges the importance of collections for the compliance of ABS in Europe by setting up a registration of trusted collections. When using a trusted collection, users do not need to provide evidence of "due diligence".

Under the EU ABS Regulation, the main characteristic of registered (i.e. 'trusted' under the EU ABS Regulation) collections is that they 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 parties for their utilization in line with the CBD and the Nagoya Protocol (See Regulation (EU) No. 511/2014, Art 5). "If collections fulfil specific requirements, they may be included in the register of collections. Users obtaining resources from such a registered collection are considered to have exercised due diligence as regard the seeking of information listed I Art. 4(3)." Establishing this type of register is clearly important because registered collections guarantee users that the genetic resources that they are accessing comply with regulations.

In addition, registered collections do not supply genetic resources and related information to third persons for their utilization without documentation of evidence that the genetic

[5] http://ec.europa.eu/environment/nature/biodiversity/international/abs/legislation_en.htm

resources and the related information were accessed in accordance with applicable ABS legislation or regulatory requirements and, where relevant, under mutually agreed terms.

For a collection or a part of a collection to be included in the register, a collection shall demonstrate its capacity to:

(a) 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 utilization in line with the Convention and the Nagoya Protocol;

(b) supply genetic resources and related information to third persons for their utilization 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;

(c) keep records of all samples of genetic resources and related information supplied to third persons for their utilization;

(d) establish or use unique identifiers, where possible, for samples of genetic resources supplied to third persons; and

(e) use appropriate tracking and monitoring tools for exchanging samples of genetic resources and related information with other collections.

Culture collections in Europe are thus applying for admission to the register (i.e. MIRRI).

Research infrastructures (RI) may benefit from a negotiating mandate in compensation for know-how transfer. Nonetheless, not all collections or RIs are completely aware of the Nagoya Protocol rules and regulations or how they affect their operational procedures and practices (e.g. the requirement of complete traceability of genetic resources from sampling and attribution of an accession code to publication, filing for a patent or commercial use). This ignorance is primarily due to the lack of information on the subject. However, some collections or consortia of collections have begun to tackle this issue.

For example, the Consortium of European Taxonomic Facilities (CETAF) (http://cetaf.org/) has developed a "Code of conduct and best practice for access and benefit sharing". This document is available on the CBD site (https://www.cbd.int/abs/submissions/icnp-3/EU-Taxonomic-practices.pdf, see also Neumann et al. 2014, SPNHC collections, Watanabe 2015, Bioscience). In addition, the pan-European ESFRI Microbial Resources Research Infrastructure (MIRRI, www.mirri.org), which provides access to a large collection of microorganisms, has developed a Policy statement on ABS and a Best Practice Manual that provides guidance for their partners in implementing their ABS institutional policies in order to comply with the Nagoya Protocol (ref Best practice manual May 2016/ MIRRI-ERIC policies, January 2016).

The World Federation for Culture Collections (WFCC) (http://www.wfcc.info) anticipated (prior to any EU legislation) and accompanied the entry into force of the Nagoya Protocol. The WFCC-MOSAIC initiative established a voluntary Code of Conduct, a tool to support the

implementation of the CBD at the microbial level, in accordance with other relevant rules of international and national laws. "*Access to microbial genetic resources (MGRs) is a prerequisite for the advancement of microbiology. Furthermore, monitoring the transfer of MGRs is necessary to identify the individuals or groups that are entitled to be scientifically or financially rewarded for their contribution to the conservation and sustainable use of the MGRs. MOSAICC combines the need for easy transfer of MGRs and the need to monitor the transfer of MGRs.*" (http://bccm.belspo.be/projects/mosaicc#code)

WFCC has also developed a pioneering database system by registering its members through a unique acronym and numerical identifier in its official directory. Combining the WDCM (World Data Centre for Microorganisms) system and the use of electronic markers called "Globally Unique Identifiers (GUIDs)", the WFCC set up a system to organize transfers of microbiological items, tracking the flow of resources and related information. This system also facilitates the application of ABS since it can potentially retrieve all kinds of information about microbiological resources, including information related to the location and movements of the resource.

Ref: WFCC newsletter No. 53, Dec 2014: www.wfcc.info/pdf/WFCC-NL-DECEMBER-2014-SC.pdf

The European Marine Biological Resource Centre (**EMBRC**[6]) 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 MGRs is one of EMBRC's primary services. Therefore, legal issues concerning the collection of samples, access to genetic resources, and transfer and utilization of resources are of utmost importance for EMBRC.

One aim of the EMBRC preparatory phase 2 project is to facilitate access to and use of marine biological resources by ensuring EMBRC-user compliance with this framework in areas within and beyond national jurisdiction.

To do so, the EMBRC issued Best Practice Guidelines (BPG) for EMBRC culture collections (CCs) to comply with the applicable international framework for accessing and using marine bioresources (UNCLOS, CBD and its Nagoya Protocol on Access to Genetic Resources & Benefit Sharing, EU ABS Regulation) for approval by the European Commission under the EU ABS Regulation (Regulation (EU) No. 511/2014[7]).

The EMBRC community used MicroB3, MIRRI and Pharmasea and the French programme OCEANOMICS (http://www.oceanomics.eu/en/project/project-overview) as case studies.

[6] http://embrc.eu/

[7] "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 Utilization in the Union"; http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32014R0511 (applies from 12 October 2014, which is the date of entry into force of the Nagoya Protocol for the EU)

For example, the OCEANOMICS practical recommendations include:

- a multidisciplinary approach, combining science and law, to prepare international sampling & bio-discovery campaigns;
- protocols to sample, deposit, and/or transfer genetic material;
- a track-and-trace mechanism that assigns a legal tag to each MGR to be transferred from users to users and to monitor the use of the genetic material.

By developing Best Practice Guidelines (BPGs) and having them registered under the EU ABS Regulation, EMBRC will be able to ensure compliance of its users with the Nagoya Protocol, the associated EU Regulation and other applicable legislation on ABS. This will greatly facilitate access for users by allowing them to easily exercise due diligence of their lawful use of genetic resources provided by EMBRC.

The culture collection guidelines (EMBRC BPGs for CCs) cover material accession forms, terms and conditions for supplying materials to third parties, and tracking of resources. BPGs for accessing material (EMBRC BPGs for users) deal with accessing genetic material *in situ*, due diligence, and the information that must be retained by the user prior to collection and the transfer procedure.

The guidelines have not yet been formally adopted by the EMBRC Implementation Board (EIB). They will be presented and discussed with various stakeholders including other research infrastructures and the European Commission DGs RTD, ENV, MARE at a workshop organized on 13 September 2016 in Brussels.

3.4 From research to exploitation of MGRs: the industrial point-of-view

It is difficult to find information in the grey or academic literature on the stance and the action of industry professionals with regard to the Nagoya Protocol and ABS. The private sector is nonetheless directly affected by these conventions because any economic use of genetic resources, in particular in the bioprospecting sector, is required to comply with ABS regulations. As a rare counter-example, there is a position paper written by the European Federation of Pharmaceutical Industries and Associations (EFPIA), which aims to be the representative voice of pharmaceutical industry research operating in Europe, in conjunction with the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). This two-page document, dating from 2013 thus before the Nagoya Protocol came into force, recognizes the value of the Nagoya Protocol and ABS and supports its implementation. It nonetheless expresses reservations as to the obligation for due diligence and the risk to giving disproportionate power to competent national authorities in controlling the enforcement of the regulations.

However, manufacturers in the marine biotechnology sector are for the most part small and medium-sized enterprises (SMEs) or very small enterprises (VSEs) that do not have the means or the time to remain abreast of the new rules and regulations relating to ABS. Helping these

businesses in updating their regulatory intelligence by providing access to practical and educational materials and information packs is thus an important goal.

3.5 Accessing the sea & using its biodiversity: a single national focal point

MGRs considered in the Nagoya Protocol may come from sampling in the natural environment (*in situ*) or from public or private collections (*ex situ*).

The necessity for the user to prove that these genetic resources were acquired legally (i.e. to demonstrate due diligence) and that ABS agreements were set up between the provider and the user are legal obligations that, if violated, can have dire consequences, in particular when patents or market applications are filed.

Users of MGRs are currently from the academic realm such as research institutes and national public collections (museums, conservatories, research institutes). These users are frequently also providers. In this case, the shared benefits from the use of genetic resources are non-commercial and can have an impact in terms of production of new knowledge (research) for which the added value is generated in the form of scientific publications, taxonomic expertise to identify unknown species or conservation activities (preservation of the environment). However, the line between commercial and non-commercial use of genetic resources is very fine and can shift. For instance, a non-commercial result in academic research can be used by the private sector several years later, and eventually generate unforeseen economic profits. It is thus essential to make provisions for sharing benefits throughout the value chain that connects providers to users and that can include many players.

Although the situation is improving, scientists who use or provide genetic resources appear to be insufficiently aware of their legal obligations. For example, a study conducted as part of an ERC Starting Grant at the University of Edinburg that combined a literature review and interviews of upstream actors (collections and research institutes) demonstrates that most providers are unaware or little aware of the concept of "use" of genetic resources as set out in the Nagoya Protocol and the European ABS regulations. The report on this subject underscores the necessity to better inform and educate researchers on this issue and provide them with precise indications on the practices to set up to comply with current regulations without necessarily increasing the related administrative burden.

http://ec.europa.eu/environment/nature/biodiversity/international/abs/pdf/ABS%20Final%20Report%20upstream%20users.pdf

In summary, all stakeholders have to be educated to comply with ABS legislation.

- The authorities involved in ABS procedures should acquire a working understanding of the goals and mechanisms of academic research.
- National Focal Points need to provide guidance to researchers on how to comply with ABS regulations.

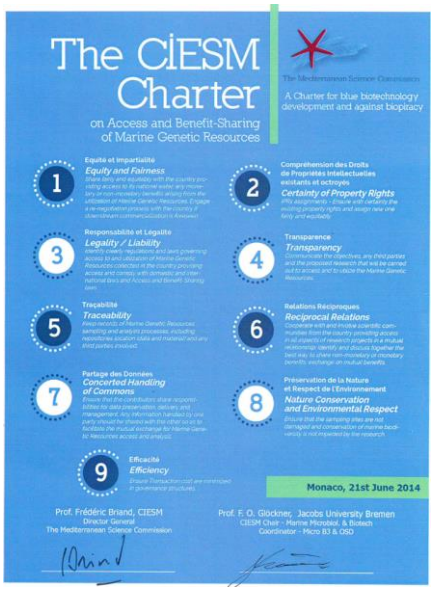
3.6 The scientific community and ABS

The European scientific community of marine biologists wishes to contribute to the implementation of best practices and anticipate the implementation of ABS principles in Europe by developing appropriate solutions for scientific activities. Accordingly, it did not wait for the ratification and implementation of the Nagoya Protocol to address the subject of legal and political obligations that affect MGR users. Several FP7/H2020 European projects have tackled the issue to anticipate the potential restrictions, to inform researchers and to provide them with advice and tools so that they can use MGRs in marine biotechnologies in full compliance with the law. The documentation and recommendations from these projects has also provided valuable material for debates on European ABS regulations and the rules for the application of the Nagoya Protocol in European countries. They will be useful for future debates on the high seas.

3.6.1 Code of conduct:

The Mediterranean Science Commission (**CIESM**) developed a charter on Access and Benefit-Sharing for access to knowledge for all and for the prevention of misuse of the global ocean commons. The CIESM Charter favours the sharing of scientific knowledge with collaborative handling of data, traceability, nature conservation and environmental stewardship. The Charter, which was developed after extensive consultation with scientists and legal experts, lists nine ethical guidelines for providers, applicants and end-users regarding the use of marine resources. It emphasizes essential core values, such as fair and equitable sharing of benefits, transparency and reciprocal relations. The CIESM Charter goes beyond biological approaches and extends beyond the strict perimeter of the Mediterranean/Black Sea region. It is applicable to large scientific initiatives such as oceanographic cruises in the world oceans.

http://ciesm.org/marine/charter/index.php



InterRidge

InterRidge statement of commitment to responsible research practices at deep-sea hydrothermal vents (2006):

https://www.interridge.org/IRStatement

OSPAR Commission

OSPAR (http://www.ospar.org/) is the mechanism by which 15 Governments & the EU cooperate to protect the marine environment of the North-East Atlantic. The OSPAR convention for the protection of the Marine Environment in the North-East Atlantic issued in 2009 a document "setting out advice concerning the legal basis on which the OSPAR Commission may decide to take forward the designation of Marine Protected Areas (MPAs) in Areas Beyond National Jurisdiction (ABNJ) within the OSPAR Maritime Area". This document is a code of conduct for responsible marine research in the deep seas and high seas within the OSPAR maritime area [OSPAR commission, OSPAR 08/24/1, Annex 6, 2008].

3.6.2 FP7/H2020 projects with ABS:

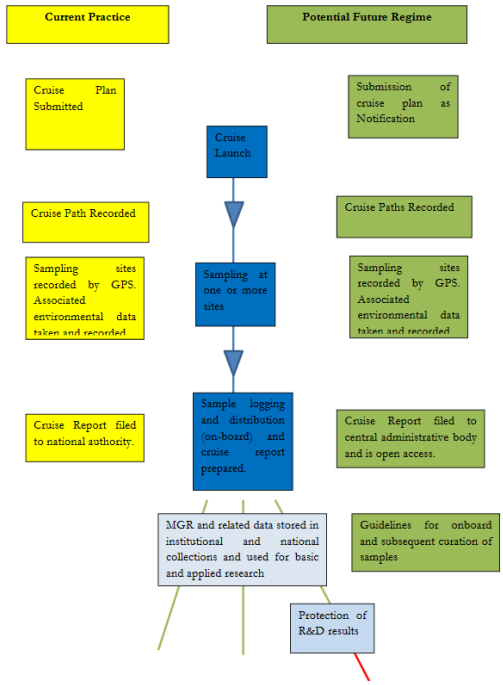
PharmaSea "Exploring the hidden potential: Novel bioactive compounds"

(http://www.pharma-sea.eu/)

The EU-funded FP7 project PharmaSea focuses on the biodiscovery and the development and commercialization of new substances from marine organisms. Its primary goal is to collect samples from the oceans, home to some of the hottest, deepest and coldest places on the planet. These samples are being screened to uncover marine microbes and new bioactive compounds to evaluate their potential as novel drug leads, and antibiotics. PharmaSea dedicated a workpackage (WP) to "Ethics, Policy and Legal Aspects of Access and Use of Marine Genetic Resources" whose aim was to provide clear recommendations and practical solutions to address critical policy and legal barriers that impede the access and sustainable use of marine bioresources for European biotechnological research, development and commercialization.

As part of this WP, a stakeholder workshop was held in 2014. The discussions have been condensed in a richly documented report on the sourcing of *in situ* and *ex situ* MGRs and on monetary and non-monetary benefit-sharing. This document also includes recommendations for the BBNJ WG — which at that time was studying the issue — such as the necessity to provide marine scientific research with guidelines and standard formats for the collection and conservation of MGRs as well as educational materials and tools.

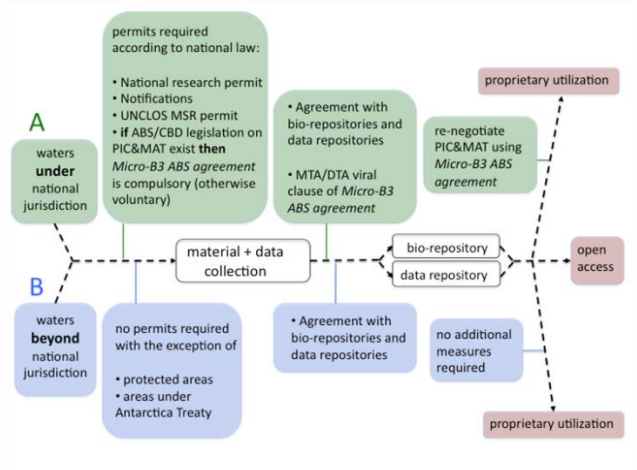
In particular, to lay down the foundation for a future ABS scheme in ABNJ, PharmaSea drafted a diagram the BBNJ WG illustrating areas warranting modification of current practices in the R&D sector for access to MGRs.



MicroB3 "Microbial biodiversity, bioinformatics, biotechnology" 2011-2016 (https://www.microb3.eu/).

The objectives of the FP7 project MicroB3were to develop new bioinformatics approaches to analyse, integrate and visualize marine molecular and environmental data jointly. From the outset, this was done in close collaboration with field scientists providing ecosystems expertise as well as their small and large-scale datasets. MicroB3 devoted a workpackage (WP8) to "Intellectual Property (IP) Management for Marine Bioprospecting". This WP fostered extensive work that lead to proposals of solutions to the many obstacles related to the access and utilization of MGRs in compliance with the Nagoya Protocol.

In particular, MicroB3 designed a workflow diagram that sketches out and summarizes all the steps involved in the access to and the use of MGRs in a legal framework.



MIcroB3 WP8 also finalized model agreements for pre-competitive and competitive research on access to marine microorganisms and benefits sharing:

- "Micro B3 Model Agreement on Access to Marine Microorganisms and Benefit-Sharing" was designed as a model agreement intended for the R&D sector to adapt according to the situation at hand. This model agreement has also been adopted by the scientific community and is now a recognized reference.
  https://www.microb3.eu/sites/default/files/deliverables/MB3_D8_3_PU.pdf
- "IP Model Agreements for Pre-Competitive Access to Large-Scale Microbial Genomic Research Databases"
  https://www.microb3.eu/sites/default/files/deliverables/MB3_D8_2_PU.pdf

Through its workpackage on **Standards and Interoperability** (WP4), MicroB3 also developed standard protocols for sampling marine microbial diversity. In particular, the Ocean Sampling Day handbook is a best practices guide describing the procedures and directives relating to the collection of marine samples as well as the logistics and the analysis and storage of bioinformatics data. This handbook is mainly intended for marine research stations and sampling expeditions that participate in the sampling event of the MicroB3 project Ocean Sampling Day (OSD).

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

MaCuMBA "Marine Microorganisms: Cultivation Methods for Improving their Biotechnological Applications" (2012-2016).

http://www.macumbaproject.eu

> The objective of the MaCuMBA KBBE FP7 project was to uncover the untold diversity of marine microbes using cultivation-dependent strategies. Furthermore, MaCuMBA aimed to improve the isolation rate and growth efficiency of marine microorganisms from conventional and extreme habitats by applying innovative methods and using automated high-throughput procedures. MaCuMBA did not dedicate a specific workpackage to intellectual property and the legal aspects of access to MGRs. However, as part of its dissemination activities, one of the consortium partners, ECoast Marine Research, addressed the issue and published an article in its August 2015 newsletter entitled "The Nagoya Protocol – What scientists need to know" which reviews the legal developments regarding the access and utilization of MGRs for scientific research purposes.
>
> http://www.macumbaproject.eu/images/MACUMBA/Media/Newsletters/MaCuMBA%20Newsletter%20Issue%2012.pdf

SeaBioTech "From sea-bed to test-bed: harvesting the potential of marine biodiversity for industrial biotechnology" (2012-2015).

http://spider.science.strath.ac.uk/seabiotech/index.php

SeaBioTech is a KBBE-FP7 project designed and driven by SMEs to create innovative marine biodiscovery pipelines as a means to convert the potential of marine biotechnology into novel industrial products for the pharmaceutical (human and aquaculture), cosmetic, functional food and industrial chemistry sectors. To achieve its goals, SeaBioTech brings together complementary and world-leading experts, integrating biology, genomics, natural product chemistry, bioactivity testing, industrial bioprocessing, legal aspects, market analysis and knowledge exchange. SeaBioTech dedicated a workpackage to "Marine policy, legal and ethical issues related to marine biodiscovery pipelines" and developed a community of stakeholders interested & committed to marine bio-discovery and other initiatives on issues involving UNCLOS, CBD & the Nagoya Protocol.

COLUMBUS "Monitoring, managing and transferring marine and maritime knowledge for sustainable blue growth" (2015-2018)

http://columbusproject.eu/

COLUMBUS is a BG11-H2020 project, that aims to ensure that applicable knowledge generated through EU-funded science and technology research is accessible and effectively transferred to end-users: policy, industry, science and wider society. The project's activities are to capture, organize, assess and transmit knowledge, skills and competence from those who generate them to those who will utilize them.

COLUMBUS will ensure measurable value creation from research investments contributing to sustainable Blue Growth within the timeframe of the project.

Columbus is closely following the matter of access and benefit sharing of genetic resources, especially how it has been handled in past and current EU-funded projects. Based on the work of these projects, and in the frame of a Knowledge Transfer action, COLUMBUS will shortly produce a factsheet summarizing best practice guidelines and checklists, in order to raise awareness of researchers using marine biological resources to the ABS legal framework and facilitate its understanding and application.

3.6.3 Workshops and events related to NP and ABS implementation

The growing interest in the scientific community for MGRs and ABS and the wish to better prepare and educate themselves in legal issues that are far removed from their usual everyday preoccupations is also evident by the number of workshops held as part of various programmes or projects.

- 15-16 October 2015 (Concarneau, France), 7th Edition of "Rendez-vous de Concarneau : where Industry meets Science in Marine Biotechnology" with a half-day session on Laws in Marine biotechnology in Europe.

- 4-5 April 2016 (Naples, Italy) Euromarine Workshop: Exploitation and legal aspects on Marine Genetics and Chemical resources
  http://euromariqt.cluster003.ovh.net/activities/exploitation-and-legal-aspects-marine-genetic-and-chemical-resources

- 12-15 June 2016 18th Genomics Standard Consortium, workshops with a dedicated session on "The Nagoya protocol: Responsible and Ethical Global Sampling".
  http://wiki.gensc.org/index.php?title=GSC_18

- 29-30 June 2016 (Iraklion, Crete), EMBRC workshop on Practical Guidelines for Accessing and Providing Marine Genetic Resources
  http://www.embrc.eu/ws-practical-guidelines-accessing-and-providing-marine-genetic-resource

- 13 September 2016 (Brussels, Belgium) EMBRC workshop "Assessing the Sea and its Biodiversity for Science: what role for European infrastructures". The workshop focused on facilitating access to marine biological resources under the new rules and procedures for accesses from the Convention on Biological Diversity (CBD), Access and Benefit Sharing (ABS), the associated Nagoya Protocol and the United Nations Convention on the Law of the Sea (UNCLOS). The meeting will explore the role RIs can play to reduce the burden on the users and identify common and shared solutions and future collaborations on accessing biodiversity. Topics to be explored will include interoperability, data as a genetic resource, accessing areas not governed by CBD and the Nagoya Protocol (Antarctica, deep sea and high seas), and meeting the needs of the private sector.

CONCLUSION

- The legal framework and complex regulatory requirements have changed considerably. The regulations regarding intellectual property and ABS in the EEZ are now well-established through the implementation of the Nagoya Protocol. However, there is currently a legal gap in benefit sharing for access to MGRs in ABNJ. For ABNJ, the UNCLOS plans to develop a legally binding instrument analogous to the Nagoya Protocol for the EEZ.
- Intellectual property relating to MGRs and the ABS principle are major issues to tackle for the application of marine biotechnology, which relies for the most part on the utilization and the commercial use of these marine bioresources.
- The scientific community is not yet well informed or educated on these issues. However, awareness of the topic is growing and actions to promote awareness are burgeoning. In addition, Research and education institutes need real incentives to promote and utilise non-monetary benefits.
- SMEs do not have the capacity to mobilize human or financial resources to comply with this new regulatory framework.
- There is a need for outreach to stakeholders. Building awareness should be organized for specific groups so that they can participate in debates, produce guidelines, clarify points that can have different interpretations, and benefit from education and outreach actions illustrated with real-life case studies. Setting up incentives to promote non-monetary benefits is another avenue for fostering awareness.

- Intermediary parties have an important role to play in enhancing the practices of academic research (registered collections, research infrastructures) to facilitate and accompany the implementation of this complex and constantly evolving regulatory framework.
- Multidisciplinary scientific projects are valuable ambassadors for this field. For example, the application of international conventions can greatly benefit from knowledge in the field of geopolitics, whose stakes must be addressed in conjunction with diplomats, legal experts, economists, etc.
- According to the CBD and the Nagoya Protocol, genetic resources are defined as the "genetic material contained in functional units of heredity" and this extends to the derivatives of these resources as well (metabolites, enzymes, etc.). However, uncertainty persists, according to the interpretation of texts and definitions, as to what is and is not considered a genetic resource, particularly data (e.g. DNA sequences and metagenomics libraries) and databases. The potential ambiguity of regulatory texts on this point can have a very negative and restrictive impact on the scientific community. Scientists therefore must remain vigilant and actively participate in debates and discussions.

APPENDIX

GLOSSARY

ABNJ: Areas Beyond National Jurisdiction
ABS: Access and Benefit Sharing
CBD: Convention on Biological Diversity
CETAF: Consortium of European Taxonomic Facilities
CNA: Competent National Authorities
EEZ: Exclusive Economic Zone
EMBRC: European Marine Biological Resource Centre
ICSU: International Council for Science
IDDRI: Institute for Sustainable Development and International Relations
IDLO: International Development Law Organization
IUCN: International Union for Conservation of Nature
MAT: Mutually Agreed Terms
MGR: Marine Genetic Resources
MIRRI: Microbial Resources Research Infrastructure
NFP: National Focal Point
NP: Nagoya Protocol
OECD: Organization for Economic Co-operation and Development
PIC: Prior informed Consent
UNCLOS: United Nations Convention on the Law of the Sea
UNGA: United Nations General Assembly
WDCM: World Data Centre for Microorganisms
WFCC: World Federation for Culture Collections
WIPO: World Intellectual Property Organization