IUCN Information Papers on Marine Genetic Resources

prepared by
IUCN Environmental Law Centre

International Union for Conservation of Nature

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Background

The United Nations General Assembly, in its resolution 59/24 of 17 November 2004, established the Ad Hoc Open-ended Informal Working Group to study issues relating to the conservation and sustainable use of marine biological diversity beyond areas of national jurisdiction (Working Group).

Resolution 67/78 of 11 December 2012 welcomed the first meeting of the Working Group convened in May 2012 *"within the process initiated by the General Assembly […], with a view to ensuring that the legal framework for the conservation and sustainable use of marine biodiversity in areas beyond national jurisdiction effectively addresses those issues by identifying gaps and ways forward, including through the implementation of existing instruments and the possible development of a multilateral agreement under the United Nations Convention on the Law of the Sea"*. Resolution 67/78 further recalled the United Nations Conference on Sustainable Development (Rio+20), held in June 2012, and the conference outcome document *"The future we want"* where *"States committed to address, on an urgent basis, building on the work of the Ad Hoc Open-ended Informal Working Group and before the end of the sixty-ninth session of the General Assembly, the issue of the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction, including by taking a decision on the development of an international instrument under the United Nations Convention on the Law of the Sea".*

In this context, two intersessional workshops were convened in New York, from 2 to 3 May and 6 to 7 May 2013, one focusing on the issue of marine genetic resources and the other one addressing the issue of conservation and management tools, including area-based management and environmental impact assessments. The objective of these workshops was to improve understanding of the issues and to clarify key questions as an input for the sixth meeting of the Working Group.

To inform the intersessional workshops as well as the Working Group, the IUCN Environmental Law Centre, in collaboration with the German Federal Agency for Nature Conservation (BfN) and with financial support from the German Federal Ministry for Environment, Nature Conservation and Nuclear Safety (BMU), prepared this series of information papers on different topics related to marine genetic resources. The papers are the outcomes of a fruitful collaboration between experts from different organizations who initially came together at the informal *IUCN Seminar on Marine Genetic Resources in Areas beyond National Jurisdiction – Preparing for the 2013 Intersessional Workshop*, which took place at the IUCN Environmental Law Centre from 4 to 6 February, 2013. The papers therefore do not aim to reflect the discussions held during the intersessional workshop on marine genetic resources in May.

A number of people in their personal capacities have assisted in the preparation of the information papers, not only by participating in the IUCN seminar, but also by drafting the papers and/or providing thoughtful verbal or written comments on the different drafts. All of the comments received were carefully considered by the authors in the preparation of the final text. The IUCN Environmental Law Centre would like to acknowledge all those contributions, and thank the following individuals (in alphabetical order) who came together in their personal capacity at the IUCN seminar:

Arianna Broggiato, Claudio Chiarolla, Duncan Currie, Ute Feit, Kristina Gjerde, Lyle Glowka, Thomas Greiber, Katherine Houghton, S. Kim Juniper, Evanson Chege Kamau, Christopher Lyal, Sonia Peña Moreno, Charlotte Salpin, Tullio Scovazzi, Graham Shimmield, and Johanna Wesnigk.

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Finally, it should be recognized that the views expressed in the following information papers belong solely to the authors and do not represent the views or policies of IUCN, BfN, BMU, or any organization(s) mentioned in this work.

Summary of Conclusions

This chapter summarizes the main conclusions drawn at the end of each Information Paper.

Meaning and Scope: Clarification of the meaning and scope of the terms marine genetic resources (MGR) and areas beyond national jurisdiction (ABNJ), as well as the activities in relation to them is a cross-cutting issue. This means that related decisions have considerable consequences on all other MGR issues, including access and benefit-sharing (ABS). Apart from questions about the substantive scope of MGR, questions around geographical and temporal scope should not be ignored in the discussions from the outset. While it is critical to reflect the peculiarities of the discovery and exploitation of MGR in ABNJ, the experiences gained in particular from the Convention on Biological Diversity (CBD) and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization may provide a good foundation on which to further consider the different questions of scope in relation to MGR from ABNJ.

Extent and Types of Research, Uses and Applications: With the advent of new sequencing technologies, both the microbial and macro-organisms of the oceans are now capable of being discovered and studied for their genetic resources. Costs of genetic analyses are falling exponentially, although significant skills and computational power are required to interpret the data. Typically, collaboration with scientists from developing countries in these new approaches to microbial diversity has been limited. The recognition of the value of microbial genetic resources has not been lost on entrepreneurial individuals, foundations or governments. Whilst it is questionable whether major blockbuster drug/chemical compounds will emanate from such research, the potential pervasiveness of the use of genetic sequencing technology and the use of key proteins and enzymes in industrial processes have the ability to change our current approach to biotechnological innovation.

Technological, Environmental, Social and Economic Aspects: There is little evidence of systematic commercial scale development of MGR from ABNJ to date. Furthermore, it is important not to confuse or conflate the potential of MGR from ABNJ with the more prolific evidence of commercialization of marine biodiversity from shallower waters, primarily within areas of national jurisdiction. While the potential for development has been widely stated, a more realistic appreciation of this potential awaits further studies and commercial successes (and failures). The current unequal distribution of research capabilities underlines the need for capacity development related to marine scientific research so that a greater number of countries can participate in the exploitation of MGR.

Access-related Issues: Different access types need to be differentiated: access to samples from their natural environment, versus access to samples stored in biorepositories, versus access to molecular data such as DNA sequences drawn from the research of these samples and stored in databanks. Promoting or facilitating these different types of access for researchers from developed as well as developing states would already provide a great, universal benefit. Especially open access to data is an important and growing component of biotechnological research in both developed and developing countries. Furthermore, distinction is also necessary in view of the different sectors accessing resources and their particular interests and characteristics, the sustainability of various access activities, as well as the challenges of monitoring.

Types of Benefits and Benefit-sharing: Benefit-sharing obligations are inherent in UNCLOS. However, the extent to which these obligations are applied with regard to MGR from ABNJ is currently not clear. Furthermore, their implementation in relation to MGR from ABNJ could benefit from a more elaborated/detailed policy and regulatory framework creating an enabling environment for pure, applied and commercial research on the one hand (e.g. by setting standards for the deposit and exchange of samples, data and related metadata), and ensuring equity in the sharing of benefits from such research on the other hand. Issues that require closer consideration include how to overcome the general problems in accessing data and samples when they have not been made publicly accessible, and how to address the existing inefficiencies in finding data and samples. Furthermore, the possible contribution of benefit-sharing from MGR in ABNJ for the conservation and sustainable use of marine biodiversity in ABNJ could be further explored.

Intellectual Property Rights Issues: The appropriate management of intellectual property assets that arise from marine scientific research needs to be considered carefully in the context of promoting research, innovation and their widest possible dissemination for the benefit of society as a whole. Patents can provide incentives for private sector investments in research and development on MGR, and – through licensing – they can also promote the transfer and commercialization of relevant marine technologies. However, newly discovered MGR may also be *locked up* by patent monopolies which could eventually provide a research barrier, in particular for non-profit research on these resources. The management of intellectual property assets arising from marine scientific research under a regime of confidentiality or trade secrecy could contradict the requirement under the United Nations Convention on the Law of the Sea to provide for the publication and dissemination of information and knowledge related to marine scientific research. By contrast, researching the patent literature helps disclose knowledge on technologies and processes, which can be in the public domain in many jurisdictions (other than those where patent protection has been sought and granted). The application of open access to research and data, and open source licensing of MGR-based inventions might therefore hold potential for promoting benefit sharing.

Global and Regional Regimes on Genetic Resources, Experiences and Best Practices: Multilateral approaches aiming to ensure equitable access to and use of genetic resources have been undertaken in different sectors. These may provide interesting experiences to address critical issues in the management of MGR in ABNJ. Global regimes on genetic resources indicate some innovative instruments dealing with intellectual property rights and the public domain approach; benfit-sharing obligations; and the building of common pools of resources. Regional frameworks provide interesting steps toward harmonizing policies and fostering cooperation among the member countries, but some of them are lacking in terms of implementation or in terms of effectiveness. The best practices adopted by the scientific community are important efforts towards awareness-raising and voluntary standard setting (e.g. concerning the origin of genetic resources, including from ABNJ).

Exchange of Information on Research Programs Regarding Marine Biodiversity in Areas beyond National Jurisdiction: Binding and non-binding rules, guidelines and practices already exist at global and regional levels with regard to international cooperation in, and promotion of, scientific research, as well as the exchange of information on research programs regarding marine biodiversity in ABNJ. While these rules and guidelines may not necessarily apply only to the collection of, and research on, MGR from ABNJ, they still provide an interesting source of information for policy-makers to consider. Although the current rules and practices facilitate the exchange of information to a certain extent, a comprehensive and authoritative system/regime for exchanging information is still lacking, in particular for MGR from ABNJ.

Current cooperation and information exchange systems tend to be linked to geographical locations or types of research involved. Many of these efforts do not distinguish between MGR originating within or beyond areas of national jurisdiction. Furthermore, differences exist with regard to rules of confidentiality as well as protection of intellectual property rights. As a consequence, information is scattered and cooperation is lacking efficiency.

Meaning and Scope

Author: Thomas Greiber[1] [2]

1. Introduction

A necessary step in the discussions around marine genetic resources (MGR) in areas beyond national jurisdiction (ABNJ) will be clarifying the precise meaning and scope of these terms and the activities in relation to them. In general, three different types of scope are distinguishable: substantive scope; geographical scope; and temporal scope. This paper aims to raise several critical points that could be considered. It reviews experiences from other policy fora related to genetic resources which can inform the ABNJ process in this regard. However, the paper does not intend to provide solutions or concrete recommendations on how to address the different issues, as the definition of scope is clearly a political decision for which States have a wide discretion.

2. Substantive Scope

The substantive scope determines the actual resources and activities that are under discussion. Their precise definition is important to ensure clarity regarding when access to MGR in ABNJ occurs, when the utilization of such resources takes place, and also when benefit-sharing obligations might be triggered. The United Nations Convention on the Law of the Sea (UNCLOS) does not provide a specific definition of (marine) genetic resources. Indeed, the term "resources" is only defined in Article 133(a) UNCLOS as *"all solid, liquid or gaseous mineral resources in-situ in the Area at or beneath the seabed, including polymetallic nodules"*, which refers only to non-living resources and therefore does not include MGR.

Defining what genetic resources are concretely has been a difficult exercise practiced by a large number of experts from international organizations, countries and nongovernmental organizations over the last 20 years. The controversial discussions held in different policy fora, such as the Convention on Biological Diversity (CBD), the FAO Commission on Genetic Resources for Food and Agriculture, the World Intellectual Property Organization (WIPO), or the World Health Organization (WHO) show that there is not a single ordinary, scientific, or technical meaning of the term genetic resources. Different ways of understanding biological resources, genetic resources, derivatives and products exist which have led to a variety of definitions of the term genetic resources at international and national level. However, it is important to note that these definitions are to large extent adaptations trying to address *inter alia* the following critical issues:

[1] The views expressed in the following information paper belong solely to the author and do not represent the views or policies of IUCN, BfN, BMU, or any organization(s) mentioned in this work.

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Biological resources vs. genetic resources

A first distinction that should be made is between biological resources and genetic resources. The CBD provides definitions of the terms “biological resources”, “genetic resources”, and “genetic material”. It is interesting to note that the International Treaty on Plant Genetic Resources for Food and Agriculture has adopted the distinction between genetic resources and genetic material, and has defined these terms similarly to the CBD’s understanding. The CBD definitions might therefore also serve as a useful starting point for a better understanding of MGR in ABNJ. This is even more so, as the CBD definitions do not only apply to terrestrial genetic resources but also to MGR within the limits of national jurisdiction.

Under the CBD, biological resources are defined as including genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity. Biological resources are thus specimens or parts thereof, as well as organic material. In contrast, genetic resources are defined as genetic material of actual or potential value, with genetic material referring to any material of plant, animal, microbial or other origin containing functional units of heredity. This means a resource may qualify as a genetic resource if it

- Is contained in biological material, which can be a plant, an animal, parts thereof, but also a microorganism;
- Contains functional units of heredity, that is DNA (a molecule encoding the genetic instructions used in the development and functioning of all living organisms) and RNA (an ubiquitous family of large biological molecules that perform multiple vital roles in the coding, decoding, regulation, and expression of genes); and
- Has actual or potential value, which is the case when a use can or is likely to be ascribed to its genetic characteristics (Glowka *et al*., 1994, 22).

According to the CBD, genetic resources are thus a subset of biological resources (UNEP/CBD, 2008, 6).

Utilization of resources

It is important to understand that the (potential) utilization of a resource may play a critical role in its determination as a biological or genetic resource. Functional units of heredity can be found in virtually all cells and cell types and in many other parts of organisms (UNEP/CBD, 2008, 6). A biological resource can therefore be accessed for different “purposes”, namely to use it as a commodity (i.e. a basic good for direct use or consumption), or to undertake research on its genetic resources. In each case, different international norms and rules may apply. For example, krill and sponges contain DNA and could therefore be considered MGR as well as marine biological resources/commodities, depending on their use. In the same way, fish that was primarily harvested as seafood may also provide fish waste that can be used downstream for research on its MGR (examples mentioned during the 2013 MGR seminar organized by the IUCN Environmental Law Centre). The difference is thus the intended or declared use (Cabrera and López Silva, 2007, 10).

Focusing on the use of genetic resources could have the advantage that “utilization” is an action, and as such may be externally verifiable (Tvedt and Young, 2007, 66). This raises, however, the question about typical criteria that might help identifying a particular use as utilization of genetic resources. Possible ways to categorize utilization of genetic resources may include identification by

- Sector: pharmaceutical, neutraceutical, cosmetics, *ex-situ* collections, etc.;
- Objective: health and medicine, commerce, conservation, etc.;
- Specific genetic-related activity; and
- Developmental stage and/or type: pure research, applied research (research and development), or commercialization (Tvedt and Young, 2007, 67).

The following is a non-exhaustive list of activities that may constitute possible uses of genetic resources (see UNEP/CBD, 2008, 7-8):

- Genetic modification, i.e. development of new variations within non-human species through genetic modification techniques (e.g. transfer of a genetic trait out of one species and put into another);
- Biosynthesis, i.e. use of genetic material as a "factory" to produce organic compounds (e.g. antibodies, hormones, enzymes, active compounds);
- Breeding and selection, i.e. creating new varieties, breeds, or strains of non-human species with particular characteristics through sexual or asexual reproduction (e.g. selection of microorganisms or algae with specific traits);
- Propagation and cultivation of the genetic resource in the form received (e.g. cultivation of microorganisms or plants; production of plant, animal and microbial products);
- Conservation, i.e. preservation of non-human organisms for conservation of genetic diversity, genetic resources or reintroduction purposes (e.g. deposition in genebanks);
- Characterization and evaluation (e.g. sequencing genes or genomes);
- Production of compounds naturally occurring in genetic material (e.g. screening and extraction of metabolites from genetic material).

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (Nagoya Protocol) defines the term "utilization of genetic resources" in order to determine the scope of application or trigger of the main operational provisions of the Protocol. Accordingly, 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"*, which in turn is defined as *"any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use"*. While the definition does not contain a list of specific uses to be covered, it is considered comprehensive enough to cover all possible uses of genetic resources, allowing for rapidly evolving techniques and the changing uses of genetic resources occurring with advances in knowledge and technology (Greiber *et al.*, 2012, 64). Furthermore, it avoids a clear distinction between sectors of users and/or development stages, which is difficult to make due to the discontinuous paths from the collection of samples in the field through to commercialization (see also Information Paper 3 on *Technological, Environmental, Social and Economic Aspects*). Finally, it clarifies that the Protocol does not apply to biological resources traded as commodities (Glowka and Normand, 2012, 29).

Genetic resources vs. derivatives and products

Another issue to be considered in the identification of genetic resources is the possible need to differentiate between genetic resources and so called derivatives and products. The basis for such a distinction, which was one of the most controversial and confusing topics throughout the negotiations of the Nagoya Protocol (see Glowka and Normand, 2012, 32), would be a definition of genetic material as material containing functional units of heredity (as is the case under the CBD). Accordingly, it could be questionable whether biochemical compounds derived from genetic resources (i.e. being the result of metabolic processes orchestrated by them) should be covered by the substantive scope of the MGR discussions. For example, within the CBD process it was discussed whether naturally occurring materials which form the basis for a wide range of products, such as aromas, gums, resins, or snake venoms, but which can be accessed without also accessing the genetic resource at the same time, should be included in ABS.

Despite difficulties in agreeing on a common understanding of the concept of derivatives throughout the negotiations of the Nagoya Protocol (UNEP/CBD, 2008, 10), States were able to agree on a definition of "derivatives" in the final Protocol text. Here it means *"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"*. As this definition is linked to the Nagoya Protocol's definition of "utilization of genetic resources" (which refers to research and development on the biochemical composition of genetic resources), derivatives are at least covered by the Protocol's access and benefit-sharing obligations.

Samples vs. related data

Finally, it is important to note that not only samples of MGR might fall under the substantive scope of comprehensive ABS discussions, but also related data (see also the Information Papers 4-5 on *Access-related Issues*, as well as *Types of Benefits and Benefit-sharing*). Under the CBD and its Nagoya Protocol, the focus has been mainly on regulating ABS with regard to samples of genetic resources. In contrast, data gained from their research and analysis has mainly been referred to in the context of benefit-sharing. However, data-processing, -integration, -visualization, and -accessibility are recognized as critical in order to manage the huge amount of data on marine ecosystems, as well as to improve the ability of researchers worldwide to take a holistic approach to data and thereby increase their chances of making major discoveries (see for example www.microb3.eu).

A challenge in this context might be a clear distinction between data, information and knowledge, as well as a decision what to include or exclude in ABS. For example, the first analysis of a sample of MGR that is taken from ABNJ can be considered (just) data – mostly generated automatically. Information is gained from the integration of such data with other data. Knowledge again could be understood as facts, information and skills gained after further processing the data with more information about the ecosystem or potential functions of enzymes. While the creation of information and knowledge need human intervention, it is important to understand that such intervention is not "non-programmable" (based on communications between partners involved in the EU funded research project MicroB3). The issue would therefore be how to distinguish clearly the different levels/degrees of human intervention and where to draw a line from an ABS perspective.

3. Geographical Scope

The geographical scope refers to the question which maritime zones are covered. The term "areas beyond national jurisdiction" refers to the high seas and the Area. Both maritime zones are outside of the geographical scope of the CBD and its Nagoya Protocol which only apply to MGR over which States have jurisdiction (i.e. MGR found in the territorial sea, the exclusive economic zone, and on the continental shelf).

A critical issue to consider with regard to the geographic scope is the management of straddling/transboundary MGR. Two situations can be distinguished here:

- Horizontal transboundary situations: MGR moving between areas within and beyond national jurisdiction; and
- Vertical transboundary situations: MGR moving between the benthic zone (the Area) and the pelagic zone (the water column above).

It is good standard practice amongst marine scientists to geo-reference the exact location and depth where the collection of an MGR sample took place (see the Information Paper 2 on *Extent and Types of Research, Uses and Applications*). Under normal circumstances, it should therefore be unproblematic to determine whether an MGR was taken within or beyond national jurisdiction and from the water column or the seabed. However, ABS discussions also need to reflect that in practice, the metadata containing this information is often fragmented (see also the Information Papers 6 and 8 on *Intellectual Property Rights Issues* and *on Exchange of Information on Research Programs Regarding Marine Biodiversity in Areas beyond National Jurisdiction*).

Furthermore, it needs to be considered whether ABS loopholes exist/are created which might provide an unintended incentive for users to falsify their geo-references. This could become a problem, if it gave users of MGR a possible way to avoid the obligations of a particular ABS regime, may it be the regime of a particular State for accessing MGR within its jurisdiction, or a potential ABS regime for MGR in ABNJ. The same problemat could arise if ABS discussions were limited to MGR either from the Area, or the water column above only. Such a limitation and distinction would also not reflect scientific realities, as experiences and practices show that MGR from both (vertical) zones, i.e. the Area and the water column, are of great interest for pure, applied and commercial research.

4. Temporal Scope

Finally, the temporal scope refers to the question from which point in time MGR-related activities should be considered in the ABS discussions. During the negotiations of the Nagoya Protocol the issue of temporal scope was another critical point, as States held different positions whether the Protocol should apply retroactively or not. Retroactivity means that norms and obligations are imposed *ex post facto*, i.e. they apply also to situations in the past when no such norms and obligations yet existed. With regard to the Nagoya Protocol, it was thus discussed whether its provisions should only apply to the utilization of genetic resources after entry into force of the Protocol, or also to the utilization of those resources which were accessed before the entry into force of the Protocol for a Party or even to pre-CBD acquisitions.

Like in the negotiations on the Nagoya Protocol, limiting the temporal scope of the MGR discussions to future activities might in practical terms exclude large reservoirs of samples and data already collected in the past and held in *ex-situ* collections (public and private). In this context it would also need to be considered that UNCLOS already contains certain provisions on exchange of information related to marine scientific research which applied to past research activities and therefore could be interpreted as (non-monetary) benefit-sharing obligations (see also the Information Paper 5 on *Types of Benefits and Benefit-sharing*).

At the same time, it needs to be recognized that retroactivity might compromise legal certainty leading to severe difficulties in its practical application. A fine balance is therefore necessary between the interests of temporal flexibility on the one hand, and stability of the system on the other hand.

5. Conclusions

Clarification of the meaning and scope of MGR is a cross-cutting issue in the ABNJ discussions. This means that scope-related decisions have considerable consequences on all other MGR issues, such as access and benefit-sharing.

While the focus might currently be on the substantive scope of MGR, questions around geographical and temporal scope should not be ignored in the discussions from the outset. Important lessons with regard to potential pitfalls can be learned from the CBD process and the negotiations of the Nagoya Protocol. Furthermore, although not all scope-related questions were resolved in the final Protocol text, practical approaches, for example on how to understand the utilization of genetic resources, or how to deal with derivatives, can be found here.

The following Information Papers indicate that it is critical to reflect the peculiarities of MGR in ABNJ in order to come up with practical concepts that facilitate rather than hamper future research, as well as the creation of real global benefits. However, it is equally important to note that the experiences gained in particular from the CBD and its Nagoya Protocol may provide a good foundation on which to further consider the different questions of scope in relation to MGR from ABNJ. It can therefore be concluded that copy pasting the CBD approach is not possible, while reinventing the wheel is not necessary either.

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Extent and Types of Research, Uses and Applications

Author: Graham Shimmield[1] [2]

1. Introduction

The focus of this paper is on microbial marine genetic resources[3] (MGR) found in open ocean waters where the water depths exceed 200m, much of which lie beyond areas of national jurisdiction, rather than microorganisms found in extreme environments (such as mid-ocean ridges) and abyssal sediments which also offer the potential of MGR. The new power of genetics, and particularly metagenomics, has revolutionized the opportunity for searching for novel genes and compounds within the microorganisms of the open ocean. Such sampling requires only a few milliliters of seawater providing the opportunity for collecting to be carried out over broad spatial scales. This opens the possibility of investigating open water MGRs, in contrast to those organisms found on the deep sea floor, in ways that were not possible even five years ago.

The following paper aims to describe the new genomic approaches, and to explore the extent and novelty of research and applications being carried out with regard to microbial MGR found in the high seas, i.e. the water column in marine areas beyond national jurisdiction (ABNJ).

2. Focus of Research

Biological oceanography is primarily a science of discovery. Since the earliest days of ocean exploration scientists have been conducting voyages of discovery to search and explore for new organisms in the deepest ocean depths. Such voyages include the world's first oceanographic expedition conducted aboard *HMS Challenger* (1884) led by Dr James Murray and Charles Wyville Thomson. In 1831 a young Charles Darwin, aboard her Majesty's ship *HMS Beagle,* circumnavigated the world's oceans over three years collecting new organisms leading Charles Darwin to later write his book *On the Origin of Species* in 1859. Over the intervening years there have been many such global expeditions, but particularly over the last ten years there has been a radical new approach. Dr Craig Venter, the scientist who pioneered methods for decoding the human genome, set out aboard *Sorcerer II*, his private 32m sailboat, on a global oceanographic mission to sample and reveal microbial genetic diversity around the world. The voyage of the *Sorcerer II* started from the east coast of the United States through the Sargasso Sea across the Pacific and Indian Oceans and returned

[1] The views expressed in the following information paper belong solely to the author and do not represent the views or policies of IUCN, BfN, BMU, or any organization(s) mentioned in this work.
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[3] Marine microbes primarily comprise organisms found in the ocean less than around 1 mm in size, and are dominated by the prokaryotic bacteria. The descriptive term used here also encompasses the eukaryotic protists, and archaea, found in ocean waters and sediments.

to Florida. The early results from this cruise revealed an enormous wealth of genetic information described in the paper by Venter *et al*. (2004). In 2010, a new approach to global genetic ocean sampling commenced under the auspices of the Tara Oceans expedition. Between 2009 and 2012, using the 40m schooner *Tara,* the expedition, covered higher latitudes than Venter's work, including the Southern Ocean and the South Pacific. The results from these cruises are starting to flow into the public domain, which means that they become available to everybody (e.g. Rusch *et al.,* 2007; www.sorcerer2expedition.org; http://oceans.taraexpeditions.org).

Most maritime nations have conducted voyages on the high seas over the years for public, private and semi-commercial use (see below). In this case, semi-commercial use is where national agencies have sponsored the studies with industry partners under cost and intellectual property-sharing arrangements. There have been decade long studies involving the international scientific community in global partnerships with common objectives such as the Census of Marine Life (CoML) and the International Census of Marine Microbes (ICOMM). Over recent years there has been a significant trend towards the study of genetic diversity (metagenomics) rather than just taxonomic diversity.

The world's ocean microorganisms represent significant diversity. However, we have been able to culture less than 2% of them. Part of the reason for this low culturability is the wide range of environmental conditions, such as light, temperature, pressure (depth), nutrients and essential trace elements, and symbioses, that comprise the necessary requirements for microbial life found in the oceans. We are simply unable to identify, understand and replicate all these features in the laboratory. Indeed, when we have, we do notice that some microorganisms have changed their metabolism to adjust to being in culture, for example no longer producing toxic compounds.

Their genetic diversity and metabolic pathways are accessible either through culture-dependent (traditional) or culture-independent approaches. The latter embraces the new power of genomics technologies and supercomputers (bioinformatics) taking a "metagenomic" approach. For this all the DNA of marine microbes obtained from filtering seawater is sequenced in a generic sample, or a single cell approach can be taken, which relies on advanced cell sorting techniques to isolate a single identified microbe, followed by DNA extraction and massive DNA amplification under stringent clean condition to avoid contamination (e.g. Woyke *et al.*, 2009; see below for further details). These newer methods are complementary to traditional culturing techniques, as they remove the necessity to learn how to culture marine organisms (the "vast un-culturable") providing access to the remaining 98% of marine microbes that do not exist in culture collections.

Much of the marine microbial diversity that has been collected and cultured is stored in publicly accessible culture collections, though non-public collections associated with for example research institutions and universities, curate a significant portion as well. Many of the publicly accessible collections are associated with the World Federation for Culture Collections (www.wfcc.info; see Table 1 with internet links, below). Culture collections have many roles the most prominent of which is to promote the international sharing and exchange of microbial cultures and associated information for basic and applied research, including preservation of biodiversity. Some collections also explore the biotechnological potential of marine organisms including genetic composition, biochemically-active compounds and even their skeletal structure. It is vital that culture collections store and manage the metadata associated with the specimens, particularly the methodology and location of collection. The lack of such metadata including missing location and contextual environmental information for the case of high-seas samples, makes the provenance and value of the sample difficult to track.

Forty-one collections are also registered as “international depositary authorities” (IDAs) under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, which makes provision for the curation of microorganisms that have patent filings. The Budapest Treaty seeks to establish a uniform regime for the establishment and operation of IDAs and as such provides a uniform regime for recognition of deposit in order to avoid the patent seeker having to deposit specimens in multiple states. Furthermore, many collections individually and through the WFCC are starting to review their procedures and operations to ensure they support implementation of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity when developing their own informal joint codes of conduct for culture collections. Such codes of conduct can have several principles, namely sustainability; an ecosystem-based approach; integrated management; the precautionary principle; stakeholder participation; transparency for all stakeholders; and, compatibility with international and domestic legislation (e.g. the Nagoya Protocol and the Convention on Biological Diversity).

Table 1: Network of World Microbial Resource Centers (Including Marine Organisms)

Federations, Societies and Networks of Microbial Resource Centers	
ABRCN	Asian Biological Resource Centers Network
BCCM	Belgian Co-Ordinated Collections of Microorganisms, Belgium
CCRB	French Comité Consultatif des Ressources Biologiques
CTCCCAS	The Committee on Type Culture Collection of Chinese Academy of Sciences
ECCO	European Culture Collections' Organisation
FCCM	Federation of Czechoslovak Collections of Microorganisms
FELACC	Culture Collections Federation for Latin America and The Caribbean
FEMS	Federation of European Microbiological Societies
FORKOMIKRO	Indonesia - Communication Forum for Indonesian Culture Collection Curators
GBRCN	Demonstration Project for a Global Biological Resource Centre Network
HPACC	UK Health Protection Agency Culture Collections
IUMS	International Union of Microbiological Societies
JSCC	Japanese Society for Culture Collections database
KFCC	Korean Federation of Culture Collections
MICRO-NET	Microbial Information Network of China
MIRCEN	UNESCO Microbial Resource Centers
PNCC	Philippines National Culture Collections
SBMCC	Brazil - Sociedade Brasileira de Microbiologia Coleções de Culturas
SCCCMOMB	Cuban Culture Collection and other Biological Materials Section
TNCC	Thailand Network on Culture Collection
UKFCC	UK Federation for Culture Collections

UKNCC	UK National Culture Collection
USFCC	United States Federation of Culture Collections, USA
Useful Links	
CABRI	Common Access to Biological Resources and Information
CBD	Internet site of the Convention on Biological Diversity
EFB	European Federation of Biotechnology
EMbaRC	European Consortium for Microbial Resource Centres
GRIN	The Germplasm Resources Information Network, USA
MSDN	Microbial Strain Data Network, UK (site is no longer supported)
MycoBank	The fungal web site
StrainInfo	Navigator for locating strains in distributed culture collections

3. Objectives of Research

In very general terms, the objective of research into oceanic microorganisms considers their role in biodiversity, ecosystem functioning, and opportunities for biotechnological applications. Marine genetic diversity is very important. We seek to understand and untangle the genetic “tree of life”, as we recognize that microorganisms maintain:

- Ecosystem function through resiliency (allowing functions to persist under stress),
- Redundancy (the depth of the ecologic pool from which niche organisms may flourish), and
- Stability (the predictability of the ecosystem to maintain itself).

Genetic diversity is also important for providing a vast pool of biotechnological potential such as in the areas of

- Pharmaceuticals,
- Cosmetics,
- Food and nutraceuticals, and
- Microbial biofuels.

Within each milliliter of ocean water there are over 10^5 cells providing over 1 terabyte of microbial genetic information! Probing these microbial communities using their 18S rRNA genes[4] has shown a wide variety of “phylotypes” (a proxy for species). Their relative abundance varies significantly from those that are abundant, comprising the majority of the microbial biosphere, to many that are few in number, which are termed the “rare biosphere”. This probing, or phylotyping, of protein coding and rRNA sequences is termed “metagenomics” and was pioneered by Craig Venter during the Global Ocean Sampling program (Venter *et al.,* 2004). This study revealed 7.7 million DNA sequences equal to 2,000 microbial genomes, or 10% of the total accessions to GenBank in 2006. Of the 1,800 genomic species identified, 148 were unique (novel bacterial phylotypes) and 1.2 million previously

[4] 18S ribosomal RNA is the structural RNA of a small part of the cytoplasm found in eukaryotic organisms, and is therefore a basic component of all eukaryotic cells. In prokaryotes the nuclear equivalent is 16S ribosomal RNA.

unknown genes reported. As Venter *et al.* said, *"it is likely that no two sequenced cells contained identical genomes"*.

The application of the metagenomics approaches has now developed into two main objectives:

- *Sequence-based metagenomics* tries to determine what genes and metabolic pathways are present and thus allows us to ask questions of "who, what and why?" in the microbial community. This approach requires screening against reference libraries.
- In comparison *function-based metagenomics* allows screening to identify functions of interest such as vitamin or antibiotic production. This enables us to find the genes that code for functions of interest and usually requires an unambiguous assignment of gene function.

In a third approach, researchers have started to apply cell sorting techniques to develop the field of single cell genomics (Woyke *et al.*, 2009, 2011). This technique avoids some of the pitfalls of shotgun (metagenomic) sequencing in that vital information on the physiology and environmental factors of a single cell (organism) can be linked to their genetic makeup, and hence can address microbial diversity and function in the ocean. Recent examples of this approach include the discovery of dark ocean autotrophy where cells from a variety of oceans below the euphotic zone have been shown to have RuBisCO and sulfur oxidation genes. This suggests that these bacteria may be significant players in the global carbon cycle (Swan *et al.*, 2011). Assembling and storing all this genetic data is a huge task. As well as the international GenBank, in the United States the Department of Energy's Joint Genome Institute has started the Genomic Encyclopedia of Bacteria and Archaea (www.jgi.doe.gov/programs/GEBA).

Marine biotechnology seeks to identify novel products from marine species to be used in commercial applications. Arrieta *et al.* (2009) have shown recently that the rate of natural product description and subsequent patenting exceeds significantly the rate of new species discovery. Roughly 10% of all natural products known are derived from the marine world (around 18,000 products; Dunkel *et al*, 2006). Typically the eukaryotic organisms dominate natural products discovery, whereas prokaryotes dominate the gene sequences.

A wide range of industries use genes from marine organisms (Arrieta *et al.,* 2009). Most dominant are the fields of human health and genetic engineering/molecular cell biology, whereas new technologies such as bioremediation and biofuels are also just starting the search for useful genes from marine organisms. Looking at marine algae and the industries that use algal products shows a wide range in potential market value (see Table 2 below). One important caveat to all these studies is that there is no distinction made concerning marine organisms in general, compared to the organisms of actual or potential commercial value from ABNJ.

Table 2: Overview of Potential Market Value per Industrial Sector

Industrial Sector	Potential Market Value in USD/Year
Health and food	2.5 billion
Aquaculture	700 million
Animal feed additives	300 million

Omega-3 fatty acids (e.g. Docosahexaenoic acid)	1.5 billion (e.g. Martek Biosciences Corp products)
Anti-oxidants (e.g. Beta-carotene)	400 million
Coloring substances (e.g. Astaxanthin)	160 million
Fertilizers/soil conditioners	5 billion

Source: Wilson, personal communication

4. Structure of Research

Ocean research, and particularly in the field of marine genetic discovery, is an international venture. The Tara Oceans expedition, for example, lists over 50 sponsors and partners ranging from government research agencies, such as CNRS (Centre National de la Recherche Scientifique) and the EMBL (European Molecular Biology Laboratory), through to nongovernmental and intergovernmental agencies such as UNESCO and the International Union for Conservation of Nature – IUCN (http://oceans.taraexpeditions.org). One foundation, the Gordon and Betty Moore Foundation, has specifically targeted marine microorganism diversity through their Marine Microbial Genetic Sequencing Project, which has allocated over USD 50 million to individual investigators (www.moore.org/init-grants-awarded). In Europe, there are consortia based projects such as MicroB3 (www.microb3.eu) and PharmaSEA (www.pharma-sea.eu). Typically, research funding agencies in developed countries focus on hypothesis-driven research objectives that are quite narrowly-focused with specific outcomes in mind. Occasionally, such projects become aggregated into consortia under a broader objective. Programs, such as the Census of Marine Life, specifically attempted to renew the objectives of discovery, description and enumeration. Foundations also wish often to be associated with "discovery", or generally to tackle high-risk science objectives outside the scope of the funding agencies.

As mentioned in the introduction, semi-commercial and private sector involvement has been limited. In some cases there are national programs involving the private sector using a cost-sharing approach with associated intellectual property agreements. These programs have been targeted at the living and non-living resources found within the states' maritime zones within national jurisdiction (see below). The private sector has had a long-standing interest in sea floor polymetallic sulphides (mineral deposits) which has driven aspects of biodiversity research in the deep sea and at hydrothermal centers. In the pelagic realm, the private sector has essentially focused on capture fisheries, although attention on zooplankton, such as krill, for oils, antioxidants and pigments has been increasing.

Taking a more international view, the engagement with scientists from developing countries is still evolving. Other than a few specific programs aimed at bi-lateral "capacity-building", longer-term, sustained ocean discovery has eluded funding agencies. There is one organization, the Partnership for Observation of the Global Ocean (POGO, www.ocean-partners.org), that involves selected *research institutions* in global oceanography, but hitherto has focused on ocean and climate change and the implementation of the Global Ocean Observing System (GOOS). However, POGO has strong involvement in capacity-building and sharing or research vessel opportunities, and a major training program for scientists and scholars from developing countries. Its involvement in marine genetic discovery and training is minor, to date, but this would be one platform from which to build international expertise between developed and developing countries, and to use the significant ocean-going infrastructure and analytical capabilities that exist.

5. Mechanisms of Funding and Associated Obligations

The vast majority of marine genetic discovery being conducted in ABNJ is funded through research agencies and councils at a national level, using research vessels from the national fleets. Most of this publicly-funded research places obligations on the researchers to deposit their taxonomic and genetic discoveries in public databases, which make them available to other researchers around the world, usually within one year of the completion of a project. There are many such databases but selecting a few would include the World Register of Marine Species (WoRMS; www.marinespecies.org), the Ocean Biogeographic Information System (OBIS; www.iobis.org), and the Encyclopedia of Life (EOL; www.eol.org). Genetic data is commonly deposited in GenBank, and in the United States an initiative known as the Community Cyberinfrastructure for Advanced Microbial Ecology Research and Analysis (CAMERA; www.camera.calit2.net). Unfortunately, it remains comparatively difficult to link existing databases, or indeed have a portal, or "one-stop-shop" for all genetic resources from the oceans. However, one example with a strong emphasis on the terrestrial biosphere, is StrainInfo (www.straininfo.net). This Bioportal currently integrates data from 55 Biological Resource Centres (BRCs) that cover all earth's continents and range from small niche-specific research collections to large general-purpose service collections into an integrated strain database that underpins the Bioportal (www.oxfordjournals.org/nar/database/summary/1182). Part of the problem involves funding which is only available for national initiatives, rather than international cooperation, and particularly access by developing nations. This remains a significant challenge and should be high on the agenda for international cooperation.

Understanding the obligations on the researchers is a complex business. Already the distinction between "pure research", "applied research" and "commercialization" is becoming blurred. Usually, public funding as well as publication requirements of scientific journals requires deposition of the data in a publicly accessible repository. However, the standards for metadata (the geographic and environmental data associated with a collected sample) are fragmentary. Unfortunately publication in journals usually precludes detailed methodology describing sample collection and analysis.

6. Workflow for Collecting and Studying MGR

Many of the larger pharmaceutical companies and energy companies are returning to marine natural product research. In part this is driven by the need to reinforce the pipeline of novel compounds as the original patents are expiring. There is the opportunity provided by the new technologies described above, such as metagenomics, which is opening the door to unlimited genetic diversity from small sample sizes collected also by vessels of opportunity (meaning small private vessels or sampling from commercial and passenger ships following regular cruise tracks). New techniques, such as single cell genomics, remove the necessity to learn how to culture marine organisms providing access to the remaining 98% of marine microbes that do not exist in culture collections. Screening and pyrosequencing technologies are evolving rapidly driving down the costs of genetic sequencing to levels that are within reach of researchers the world over.

Finally, the new field of "synthetic biology" (e.g. Schmidt, 2012 and www.jcvi.org/cms/research/projects/first-self-replicating-synthetic-bacterial-cell/faq) will use the proteins and genes discovered in the marine environment to engineer new organisms capable of carrying out commercial processes, although such work is very much in its infancy.

7. Conclusions

With the advent of new sequencing technologies, both the microbial and macro-organisms of the oceans are now capable of being discovered and studied for their genetic resources. The sheer diversity of the microbial world, and the comparative ease by which it may be sampled especially in the upper water column of the open oceans, makes understanding the marine microbial world and marine genetic discovery much easier. Costs of genetic analyses are falling exponentially, although significant skills and computational power are required to interpret the data. Typically, collaboration with scientists from developing countries in these new approaches to microbial diversity has been limited.

The recognition of the value of microbial genetic resources has not been lost on entrepreneurial individuals, foundations or governments. At this point, studies are still in the ”discovery” mode, essentially describing the diversity and understanding some of the ecosystem functions performed by the vast biomass of microbes in the ocean. Soon, however, such information will find its way to new areas of applied research. Whilst it is questionable whether major blockbuster drug/chemical compounds will emanate from such research, the potential pervasiveness of the use of genetic sequencing technology and the use of key proteins and enzymes in industrial processes, have the ability to change our current approach to biotechnological innovation. It is for these reasons, that increased awareness on microbial marine genetic resources is now warranted.

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Technological, Environmental, Social and Economic Aspects

Author: S. Kim Juniper[1 2]

1. Introduction

The natural environment has long been a source of inspiration for new drugs and other products of biotechnology. Until relatively recently, the terrestrial environment, in particular, has been the primary source of genetic material and natural products at the center of major new developments in biotechnology, including new drugs. Examples of natural products that have been used in drug development include the anti-malarial drug quinine isolated from the bark of the *Chinchona*, the analgesics codeine and morphine from *Papaver somnifetum* latex and antibiotics such as penicillins and tetracyclines from fungal strains of *Penicillum* sp. and *Streptomyces* sp. The terrestrial environment contains far more known species of plants and animals than are presently known in the oceans, and has contributed greatly to the development of new biotechnologies, and new drugs in particular. Yet there are many reasons to expect that the marine environment should represent a rich reservoir of novel genetic material and natural products, particularly those derived from animals. Covering more than 70% of the planet, the oceans are home to a greater diversity of major animal groups (phyla) than the terrestrial environment (34 of 36 known phyla are found in the oceans versus 17 found on land). Marine areas beyond national jurisdiction (ABNJ) tend to be far from coastal waters where marine biodiversity is best known, and where marine organisms are most abundant. Yet the sheer size and largely unknown nature of this portion of the biosphere inspires speculation about the potential of its genetic material and biomolecules/natural products. This paper will focus on several aspects related to the discovery and exploitation of marine genetic resources (MGR) in ABNJ. It is based on personal research by the author and draws from a recent publication by Leary and Juniper (in press).

2. Technological Capacities Needed to Access, Use and Apply MGRs

The first step in the process of accessing MGR is the collection of samples in the field. In ABNJ, sampling requires an offshore capable ship (defined here as greater than 60m in length) and in most cases requires a specialized research vessel. At first glance, this basic capability appears to be fairly widespread among nations. The International Research Vessel database lists 271 vessels greater than 60m in length, belonging to more than 40 countries. However, the majority of these vessels belong to a small number of developed countries, as shown in Figure 1. Smaller vessels, even sailing vessels can be used to sample water column organisms. For example, the recent Sorcerer and Tara expeditions used privately owned

[1] The views expressed in the following information paper belong solely to the author and do not represent the views or policies of IUCN, BfN, BMU, or any organization(s) mentioned in this work.

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sailing yachts to conduct ocean basin scale surveys of planktonic microorganisms (see also the Information Paper 2 on *Extent and Types of Research, Uses and Applications*).

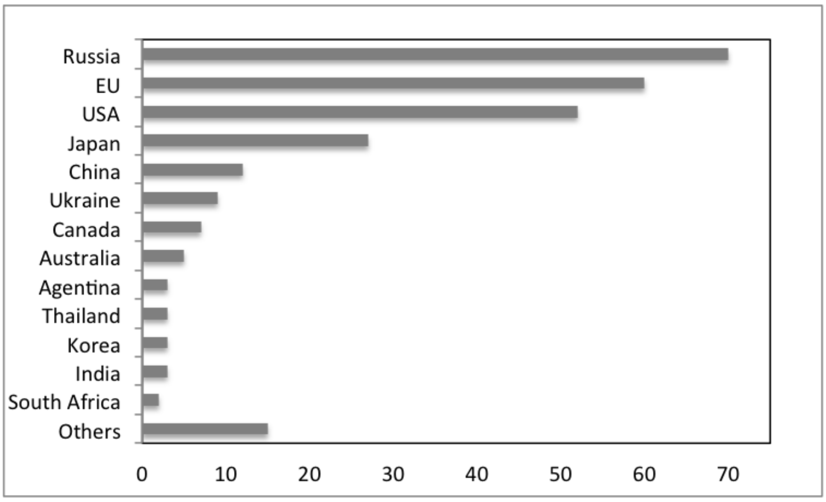

Figure 1. Geographic distribution of offshore research vessels (60 m or greater in length). Source: International Research Vessel Database.

At sea, most biological specimens are collected by lowering or towing sampling devices from the vessel, including water sampling bottles, nets and coring devices. Heavier gear in the way of winches, cable and dredges and corers is required to sample the seabed where more than 90% of known marine species are found. This latter requirement reinforces the importance of larger, motorized research vessels for accessing biodiversity at depths of several kilometers in ABNJ. Some sampling devices are highly specialized and not all research vessels have the same collecting capacity. This is especially true for remotely-operated vehicles (ROVs), which are used to locate and sample hydrothermal vent ecosystems, which are a source of novel species adapted to extreme conditions. Hydrothermal vent sites are very small in area, usually 10's to 100's of square meters, and cannot be easily sampled or even located by lowering standard sampling devices from ships. They require precisely navigated diving with ROVs or human occupied submersibles although the latter are used less frequently than ROVs. These vehicles are capable of diving to depths many times deeper than military submarines, and are equipped with robotic arms, video cameras and various sampling devices. The list of states possessing and operating deep diving scientific submersibles is limited to a subset of the developed countries currently leading marine scientific research efforts globally, such as Canada, France, Japan, the Russian Federation, the United Kingdom, the United States of America, and most recently China, India and South Korea. ROVs can also be chartered from commercial firms that provide support for the offshore petroleum industry, but most of these vehicles are limited to depths of less than 2000 meters.

Another important capacity related to accessing and deriving value from marine biodiversity is the specialist knowledge required to identify species, either known species or those new to science. Marine biodiversity specialists are mostly trained in developed countries, where there has been a long history of botanical and zoological scholarship in universities and museums. One way to measure the worldwide distribution of marine biodiversity expertise is to examine the level of publication activity in the scientific literature in relation to the country of affiliation of the lead author on these publications. A recent review of the literature revealed that the majority of publications in the field of marine biodiversity were issuing from a relatively small

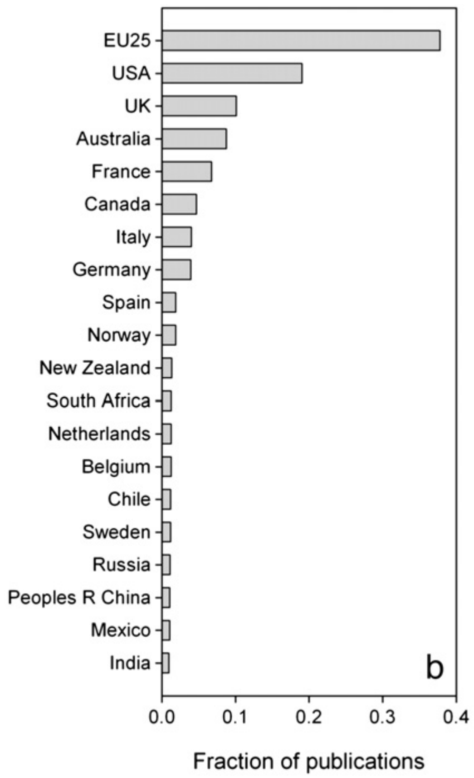

Figure 2. Geographic distribution of marine biodiversity publications for the period 1990-2004, by affiliation of first author. From Hendriks and Duarte (2008).

number of developed countries (see Figure 2). These specialists are experts in the morphological identification of specimens and, increasingly, the interpretation of DNA sequence information that is used to identify marine plants, animals and microbes. It could be argued that this scientific expertise is of greater importance to the usage and application of MGR than is access to laboratories that can produce gene sequence and biochemical composition information from field samples. There are many countries with commercial sequencing and biochemical analysis facilities that serve national and international government, academic and private clients. The raw data produced by these facilities require expert interpretation before they can be used to identify species, genes and biochemical compounds of interest.

Table 1 illustrates the dominance by a small number of developed countries in recent patent claims for genes of marine origin (see also the Information Paper 6 on Intellectual Property Rights Issues). It would be interesting to extend this analysis to patented biomolecules and other natural products. The top ten countries own 90% of deposited gene patents, with 70% owned by the top three. The data do not permit the separate evaluation of the percentage of patent claims originating from MGR in ABNJ. Relatively new approaches such as microbial metagenomics also require sophisticated bioinformatics tools and training and these are most accessible in developed countries (see also the Information Paper 2 on Extent and Types of Research, Uses and Applications). Nevertheless some capabilities in bioinformatics and genomics exist in developing countries, particularly in the health and agricultural science sectors, and these skills could be adapted and applied to the exploitation of MGR.

Table 1: Geographic distribution of patent claims for genes of marine origin

Country	Marine Organism Patent Claims
USA	199
Germany	149
Japan	128
France	34
United Kingdom	33
Denmark	24
Belgium	17

Netherland	13
Switzerland	11
Norway	9

Sources: Arnoud-Haond et. al. (2011).

3. Potential Environmental Impacts related to MGR Discovery and Exploitation

Marine scientific research (MSR) has a long history in ABNJ, beginning with the Challenger expedition of 1872-1876 that laid the foundation for modern oceanography and proved that animal life existed in the deepest depths of the ocean. The basis of MSR is the collection of ocean data and imagery and the collection of samples from the water column and seabed. Most scientific instruments and cameras cause negligible disturbance to marine habitats. Two notable exceptions are active acoustics (sonars, seismic soundings) that can locally disturb marine mammals, and the introduction of artificial light to normally dark areas of the deep ocean by submersibles and cabled observatories that could result in local photo-sensitive responses by fish and crustaceans. The latter effect has been little studied.

The collection of scientific samples in the water column by water bottles and nets deployed from research vessels is a negligible source of disturbance in ABNJ considering the relatively small size of scientific sampling devices. Even sampling of the seabed by coring or scientific trawling is a very minor source of disturbance compared with the impact of trawl fisheries, or future extraction of seabed minerals. Nonetheless there are some areas of the seabed where scientific sampling is concentrated in relatively small areas, such as at well-studied hydrothermal vent fields. There, use conflicts have arisen between researchers requiring physical samples (biological or geological) and researchers wishing to observe the natural evolution of local ecosystems. Such use conflicts have led to the adoption of codes of best practices by international organizations such as InterRidge (see www.interridge.org/IRStatement).

While there is still the possibility of direct extraction of natural products from marine biomass, such as the extraction of oils from Sargassum or krill, future exploitation of MGR in ABNJ for purposes of developing the genetic resource is unlikely to involve substantial large-scale harvesting of marine organisms and the resultant destruction of habitat and depletion of species populations that we have seen caused by fisheries. Instead, if recent trends can be used as a guide, most of this exploitation will occur in laboratories and larger facilities where genes and biomolecules will be discovered, and then incorporated into industrial processes that may involve the artificial synthesis of biomolecules, or the insertion of desired genes into microbes that then produce the desired molecule(s). However, there is potential for habitat damage in collection of samples, particularly in vulnerable marine ecosystems such as cold water corals or sponges or hydrothermal vents, underlining the need for a precautionary approach. As well, the success of nutraceutical extraction from fish waste (see below) could lead to the large scale harvesting of stocks that have little or no food value but are attractive as sources of nutraceuticals.

4. Social Benefits of Research, Utilization and Application of MGR

Benefits to all humankind arising from MGR research include improved knowledge of marine biodiversity and its role in the provision of ecosystem services and in the maintenance of ocean health. Marine natural products research is also resulting in more efficient, value-added exploitation of marine resources, for example through the manufacture of nutraceuticals and beauty products from fish processing waste (e.g. collagen from fish skins, fish oils), although the market for such products is primarily in developed countries. As illustrated by the above statistics, developed countries are also most likely to directly benefit from any accelerated growth in the MGR research sector, any profits from marine pharmaceuticals, or health or other social benefits from access to the pharmaceutical or other products themselves.

5. Role of State and Private Sectors in Research, Utilization and Application of MGR

MSR field research in ABNJ is primarily funded by state agencies in developed countries, although there have been a few recent, highly publicized biodiversity expeditions funded by combinations of private, public and nongovernmental organization support. There are also some examples of private foundations funding MSR (e.g. Gordon and Betty Moore Foundation, Schmidt Ocean Institute), and industry supporting MSR through arms-length foundations (e.g. Fondation Total). While MSR field programs receiving foundation funding are relatively few in number compared to state-sponsored studies, they can be of very high impact and attract funding from other sources. For example, the Alfred P. Sloan Foundation was the founding sponsor of the highly successful Census of Marine Life, a 10-year program involving 80 nations that was completed in late 2010. State funding is also critical to early laboratory studies that document marine biodiversity and identify genes, organisms and biomolecules that may be of future interest for exploitation by the biotechnologies.

There are few examples of a direct developmental path from field collections of marine organisms through to the commercialization of marine natural products or genes from marine organisms. MSR field research is primarily led by academic or government scientists and is aimed at increasing our knowledge of the ocean and the organisms that it supports. It is this knowledge base that may be later exploited by laboratory-based scientists in academia, industry and government in research more directly related to the eventual use of MGR for commercial purposes. There are surprisingly few direct connections between these basic and applied research sectors. Nevertheless, the Vent Polymerase enzyme, described further below, is one example of a rapid transition from the discovery of a new microorganism in the field to the commercialization of a biomolecule.

Figure 3 illustrates the various steps along the mostly discontinuous path from the collection of samples in the field through to the commercialization of a drug, and the unclear transition from state to private sector funding. Even under the best of conditions, this process is long (15-20 years) and the Industry–involved steps are extremely costly (estimated at USD 900 million for one drug) and subject to rigorous regulatory and testing regimes.

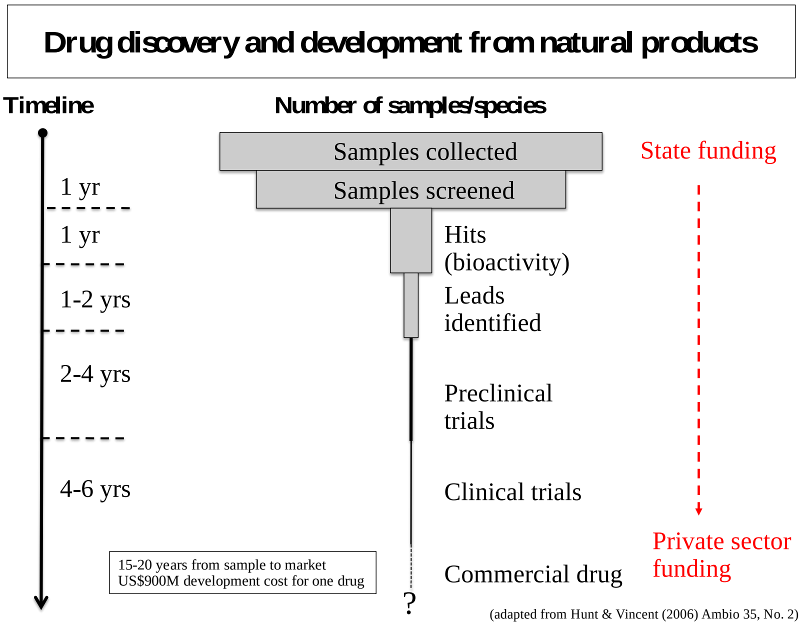

Figure 3. The drug development pipeline, illustrating the various, but usually not connected steps between the collection of samples in the field and the eventual commercialization of a new drug.

Chances of success are also extremely low. A review by the journal Nature (Macilwain, 1998) concluded that there are tens to hundreds of thousands of failed prospects for every example of a commercially successful natural product. One measure of our success at extracting drugs from the sea is the number of drugs from marine organisms that have been approved for commercialization by the US Food and Drug Administration (USFDA). As of January 2013 there were only 7 drugs from marine organisms that had received USFDA approval, with approximately twice that number in clinical trials. Mayer *et al.* (2010) notes that the pre-clinical pipeline *"continues to supply several hundred novel marine compounds every year and those continue to feed the clinical pipeline with potentially valuable compounds."*

6. Commercial Interest in MGR vs. Actual Use and Application

The growing appreciation of the diversity and novelty of life in the oceans that has emerged from efforts by conservationists and programs such as the Census of Marine Life has fuelled interest in the commercial possibilities of MGR. Despite repeated waves of enthusiasm and much early promise, examples of the successful development of commercial products to date are very few, and there are no data permitting the separate evaluation of the success of MGR from ABNJ. Nonetheless, marine biodiversity in theory has enormous potential. Biochemists are often effusively enthusiastic about the diversity of biomolecules produced by marine organisms, compared to their terrestrial counterparts. To date, the realization of this potential has been slow. In the early 1950s the first marine bioactive compounds, spongouridine and spongothymidine were isolated from the Caribbean sponge *Cryptotheca crypta*. The 1970s saw the beginning of basic scientific research in chemistry and pharmacology of marine natural products and directed efforts in drug development. However, it has only been in the last decade that these research efforts have resulted in the production of a first generation of drugs from the sea into clinical trials. It was not until 2004 that the first drug from the sea (developed from a neurotoxin produced by a tropical marine cone snail) was finally approved for sale on the market under the name Prialt. Prialt is used in the treatment of chronic pain associated with spinal cord injuries. More recently, in 2007, a second drug, the anti-tumour compound trabectedin (known as Yondelis) was approved for the treatment of soft-tissue sarcoma in the European Union. And as mentioned above, there are now 7 USFDA approved drugs on the market that are derived from marine organisms.

Molinski *et al.* (2009) noted that beginning in the mid-1990s there was a decline in the interest of large pharmaceutical companies in the development of “drugs from the sea”. There are some hints of a recent resurgence but it will be several years before it can be determined if this is a sustainable trend. In parallel with “Big Pharma” reducing activity in this sector, there has been an increased activity in smaller scale academic-industry partnerships in developed countries, and the resultant emergence of small-scale start-up companies. New developments in analytical technologies (gene sequencing, biomolecule characterization) have helped drive this new trend. Further evidence of increased interest in MGR is found in an analysis by Arrieta *et al.* (2010) who noted rather spectacular growth over the past decade in the accumulation of marine organism gene patent claims (currently increasing by 12% per year) and identified marine natural products.

In contrast to the more limited development of new drugs from marine organisms, the nutraceutical industry in Europe and Asia is undergoing significant growth. Marine and algal omega-3 products alone accounted for USD 1.5 billion in sales in 2009, and the nutraceutical industry as a whole is estimated to grow to a USD 180 billion business by 2017. As noted above, this rapidly growing industry often makes use of marine biomass, such as fish waste or harvested algae, to produce health food products and restorative cosmetics. This gives rise to the question of the role of the commercialization of nutraceuticals in the MGR debate. Is this biomass-based industry simply another form of living resource extraction similar to agriculture, aquaculture, fisheries and forestry? Or does it involve the development of MGR that relies at least in part on research and development, and related intellectual property? If the latter, then it must be included in discussions of the impact of MGR exploitation since purposeful harvesting of marine biomass for nutraceutical extraction, if it occurred in the future, could result in greater environmental impact than is anticipated from other uses of MGR that are expected to be based on laboratory and industrial scale synthesis of biomolecules following initial discovery in natural samples.

7. Potential Economic Value of MGR from ABNJ

There are a few successful and exciting examples of products commercialized from ABNJ. One of those is the Fuelzyme™ enzyme sold by Verenium Corporation. The Fuelzyme™ enzyme is a thermostable enzyme that is effective over an exceptionally wide temperature and pH range, which is useful in ethanol production, developed from samples from hydrothermal vents. Another example is the polymerase enzymes derived from hydrothermal vent bacteria. Polymerase enzymes from various sources are used in applications such as DNA fingerprinting. Two polymerase enzymes coming from vent organisms, Vent Polymerase and pfu DNA, are known for their particularly high fidelity in copying small amounts of sample DNA, and together account for around 30% of a USD 500 million annual industry.

However, these few examples aside, it is difficult to identify accurately the extent of actual commercialization of MGR from ABNJ. Some commercial products have been developed from deep-sea organisms, but the actual proportion coming from ABNJ is as yet unsubstantiated. In part, this may be because of a lack of requirements to identify the location of collected organisms (see also the Information Paper 6 on *Intellectual Property Rights Issues*). In analyzing what information is available it is very important to distinguish between products actually on the market or in the development phase, and speculation about their theoretical potential and diversity of uses. There are many optimistic statements about possibilities in the academic literature and policy debates, but there are few examples available of products from ABNJ currently on the market, since there have been no detailed or comprehensive studies of the full extent and scope of commercialization.

8. Conclusions

A recent review by Leary and Juniper (in press) concluded that there was little evidence of systematic commercial scale development of MGR from ABNJ to date. They also point out that it is important not to confuse or conflate the potential of MGR from ABNJ with the more prolific evidence of commercialization of marine biodiversity from shallower waters, primarily within areas of national jurisdiction, such as in territorial seas or exclusive economic zones. It would be helpful if researchers could, where possible, distinguish new MGR discoveries from within national jurisdictions from those in ABNJ. While the potential for development has been widely stated, a more realistic appreciation of this potential awaits further studies and commercial successes (and failures). The current unequal distribution of research capabilities underlines the need for MSR capacity development so that a greater number of countries can participate in the exploitation of MGR.

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Access-related Issues

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1. Introduction

The issue of access to genetic resources within national jurisdiction has been the subject of long and intensive discussions in different policy fora, such as the Convention on Biological Diversity (CBD), the Commission on Genetic Resources for Food and Agriculture of the Food and Agriculture Organization of the United Nations (FAO), the World Health Organization (WHO), or the World Intellectual Property Organization (WIPO). The issue of access to marine genetic resources (MGR) from areas beyond national jurisdiction (ABNJ), i.e. the high seas and the Area, has emerged more recently in the international policy arena. Advancements in knowledge of MGR and technology to collect and analyze them have unlocked the potential of MGR. The United Nations Convention on the Law of the Sea (UNCLOS) does not provide for a specific ABS regime with regard to MGR in ABNJ.

The following paper therefore aims to raise a number of access-related issues that need to be taken into consideration when discussing the potential need for and content of a future access regime for MGR in ABNJ, in particular the different types of access and access approaches/concepts, the sustainability of access, the management of transboundary/straddling resources, the facilitation of access to technology, as well as potential monitoring of compliance and enforcement.

2. Different Types of Access

Different types of access need to be distinguished when considering ABS related to MGR from ABNJ. The CBD, though not applicable in this context, provides for an interesting approach when referring to three types of access:

- Access to genetic resources;
- Access to relevant technology, including biotechnology; and
- Access to benefits ultimately gained from the use of genetic material in the development of biotechnology.

Access to benefits from the utilization of genetic resources, as well as access to technology are basically issues to be considered in the context of benefits and benefit-sharing. In the context of access-related issues it is nevertheless important to note that many countries especially in the developing world do not yet have the capacity in terms of the technology

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needed to collect and/or exploit MGR from ABNJ. Such countries are disadvantaged in that although all states legally have free access to such resources, they are not able to benefit from them. Since the 1992 Rio Declaration on Environment and Development there has been widespread recognition that the development, transfer, adaptation, and diffusion of technology and the building of related capacity are crucial for achieving sustainable development. Access to technology generally comprises the following two main elements: technological cooperation (i.e. collaboration and cooperation in technical and scientific research and development programs), and transfer of technology (which does not necessarily mean shifting machinery or equipment but rather a flow of goods and knowledge that opens opportunities for learning and capacity-building). One of the critical issues to consider with regard to implementation of technology transfer is intellectual property rights (see also the Information Paper 6 on *Intellectual Property Rights Issues*).

With regard to access to genetic resources, three types may be distinguished:

- Access to *in-situ* resources;
- Access to *ex-situ* resources; and
- Access to *in-silico* analysis.

Access to *in-situ* resources can be understood as access to/collection of samples of marine organisms (containing MGR) within their natural surroundings, such as ecosystems and habitats in the high seas or the Area. Biodiversity in ABNJ is still largely unexplored hence discovery and analysis of MGR especially from extreme environments continue to be of great interest despite advances in genomic sciences and technology (see also the Information Papers 2-3 on *Extent and Types of Research, Uses and Applications*, as well as *Technological, Environmental, Social and Economic Aspects*).

Access to *ex-situ* resources means access to MGR outside of their natural habitats, which involves transfer of samples previously collected from ABNJ that have been analyzed and kept in biorepositories. Such biorepositories have the purpose to maintain biological specimens, and associated information, for future use in research, and therefore manage their collection, processing, storage or inventory, and distribution. As the collection of *in-situ* resources is very costly, access to samples from collections plays an important role for cost-efficient research around the world, and in particular for developing countries which might not have sufficient technological capacities to conduct their own research *in-situ*.

Access to *in-silico* analysis refers to access to information, data and research results for *in silico* testing and the results therefrom. *In-silico* testing are methods of testing biological models, drugs and medical interventions using sophisticated computer models rather than expensive laboratory (*in-vitro*) and animal (*in-vivo*) experiments.

3. Different Access Approaches/Concepts

Apart from different access types, two access approaches/concepts can be distinguished – a bilateral and a multilateral approach.

Bilateral approach

A bilateral approach is well established in the CBD-system, including its Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of the Benefits Arising from their Utilization. Here, a relationship is established between a provider and a user (of genetic resources) based on sovereign rights of States over their natural resources. The sovereign rights give States the authority to determine access to their genetic resources based on their national laws and upon their prior informed consent (PIC) and the establishment of mutually agreed terms (MAT) between the participating parties. Upon utilization of genetic resources, the party on the user side is required to share with the provider the benefits that arise therefrom in a fair and equitable manner.

In the context of access to MGR in ABNJ a bilateral approach might be difficult to apply, as states do not have sovereign rights or jurisdiction over such geographical areas and the resources found therein. In regard to the high seas, UNCLOS clearly states that "*No State may validly purport to subject any part of the high seas to its sovereignty*" (Article 89). Concerning the Area it further states that *"No State shall claim or exercise sovereignty or sovereign rights over any part of the Area or its resources …"* (Article 137.1). Furthermore, the mandate of the International Seabed Authority does not cover MGR in ABNJ (see the limited definition of "resources" in Article 133(a)). Consequently, no State or intergovernmental authority is currently in a position to grant its consent or negotiate terms of access to MGR from ABNJ in a bilateral setting.

Multilateral approach

The multilateral system (MLS) established under the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) is a known example of a multilateral approach for exchanging genetic resources and sharing benefits from their utilization. It is a system agreed upon by the contracting Parties of the ITPGRFA for access to plant genetic resources for food and agriculture of 60 crops. These crops have been selected based on specific criteria, *inter alia*, due to their importance for food security (and hence to humankind) and the fact that their existence has been and continues to be dependent on global effort and open exchange of plant genetic resources. Therefore, to foster their conservation and sustainable use as well as to share fairly and equitably the benefits arising from their utilization, the contracting Parties have agreed to facilitate access by not requiring bilateral PIC and MAT, but rather executing exchange through a standard material transfer agreement (SMTA). Access, however, is only allowed for specific purposes, namely the utilization and conservation for research, breeding, and training for food and agriculture. In addition, no claims of intellectual property rights over the material accessed from the MLS in the form received are allowed. Benefits arising from the utilization of the material of the MLS are shared according to the criterion of need for conservation and sustainable use and not bilaterally with the source country or country of origin of the material (for details on the functioning of the MLS see Kamau, 2013).

The MLS of the ITPGRFA cannot simply be copied for MGR in ABNJ, but some aspects of its organization and functionality could provide useful inspiration. Under the MLS, access is considered as a trigger for recognizing the obligation to share benefits, whether monetary or non-monetary. Access takes place with the understanding that generated results and benefits are public domain, i.e. they become available to everybody, unless significant development has taken place. Standard terms and conditions are used in executing exchange and transfer thus putting aside the need for bilateral PIC and MAT or variation of terms and conditions. A mechanism of tracking downstream transfer of material and obligations is established according to which a recipient of material notifies any transfer to a subsequent recipient to the Governing Body (the highest organ) of the Treaty after which the transferor has no obligations *vis-à-vis* actions of subsequent recipients (Article 6.4 SMTA).

4. Sector-specific Access Characteristics

Both pure scientific and commercial sectors participate in activities involving access to MGR from ABNJ. The pure scientific sector accesses the resources with an intention to study and increase humankind's knowledge about their role in biodiversity and ecosystem functioning, as well as opportunities for biotechnological applications. The majority of the results of studies conducted by this sector are put in the public domain (see also the Information Paper 2 on *Extent and Types of Research, Uses and Applications*). The commercial sector, on the other hand, accesses genetic resources in order to unlock their commercial potential. The information and inventions of the studies conducted by the latter sector are normally protected by intellectual property rights (see also the Information Paper 6 on *Intellectual Property Rights Issues*). What differentiates the two sectors essentially is what their research aims at (intention) and what happens to their results. However, that is not to say that a clear line can be drawn between the two in terms of the outcome of their research as the results of scientific research might have a commercial potential and feed into downstream commercial applications. In addition, access and research activities are at times undertaken through public-private partnerships or joint research initiatives, for example through joint research cruises or programs.

At the same time, it is important to consider potential impacts that access regulation may have on these two sectors. Experiences from national access regulations indicate that restrictive control can cause a drastic increase in transaction costs due to delays caused by bureaucratic (access) procedures, multiple permits and fees etc., and might also create a certain level of legal uncertainty (Kamau and Winter, 2009). Under the CBD-system, it has been noted that very restrictive control on access (to genetic resources within national jurisdiction) impacts negatively on both public and private sectors, but in varying intensity. Especially is the pure scientific sector readily impeded because it mostly relies on public funds and does not aim at commercial gain.

Of importance likewise is the difference between the sectors regarding access to technology, skills necessary for collection and analysis of MGR, as well as knowledge resulting therefrom. As mentioned at the beginning, some countries, especially the developing ones, do not possess the capacity to directly participate in the discovery and exploitation of MGR in ABNJ. Nevertheless, the pure scientific research sector is often more open with regard to engaging developing countries through the promotion of a wide collaboration of scientists. In contrast, the private sector, having often invested heavily in the research with the aim of achieving results that will produce a commercial gain, has normally a greater interest in keeping its operations secret and protecting its inventions using intellectual property rights.

5. Sustainability of Access

Access to *ex-situ* resources and access to *in-silico* analysis have no direct negative impacts on the marine environment, as the collection of material has already taken place in the past. Thus, in these cases the marine ecosystems in ABNJ hosting MGR are not accessed.

Access to *in-situ* resources requires the collection of biomass, but generally only very limited amounts (e.g. a tube of water containing microorganisms) for the initial step of gene or product discovery. Thus, threats to biodiversity from access to *in-situ* MGR are usually not comparable to those related to harvesting of marine resources for food (Hunt and Vincent, 2006). However, a concrete threat to biodiversity may arise when for example a promising drug candidate is found, and an additional, more substantial harvest is required to collect the several grams needed to test the drug in clinical studies (Arrieta *et al.*, 2009).[3] Furthermore, it needs to be considered that although synthesis of substances may be possible, it may be deemed economically unviable, thus triggering again the need for large collections of wild biomass (Proksch *et al.*, 2003) (see also the Information Paper 3 on *Technological, Environmental, Social and Economic Aspects*).

This indicates a need for differentiation when assessing the potential environmental impacts of access to *in-situ* MGR. In particular, the following aspects need to be taken into consideration:

- Access activity/procedure: The type of activity or procedure of access can involve for example collection of MGR, exploration by drilling the seabed, or bringing light to areas of eternal darkness. Different environmental impacts are possible, depending on the equipment or technology used, and the level of diligence applied (e.g. with regard to the introduction of invasive organisms).
- Accessed habitat: Access activities can target the water column, but also highly fragile ecosystems (e.g. hydrothermal vents). In particular, the frequency of accessing fragile habitats matters.
- Accessed species: Target species may be rare or common, known or unknown, and also more or less sensitive to interference.
- Purpose for access: The purpose of access may also determine how much resources are taken and how often they are taken.

The role of Environmental Impact Assessment (EIA) and Strategic Environmental Assessment (SEA) may be key in this regard. However, for this a number of questions need to be answered, such as: Which procedural mechanisms can be introduced to evaluate the environmental impact of activities in ABNJ prior to their commencement, especially when target species or habitats are yet unknown? How can States exchange information, notify, and consult one another on activities that are likely to significantly affect adversely the biological diversity in ABNJ? In case of imminent or grave danger or damage to biological diversity, who should be notified? Which action should be initiated to prevent or minimize such danger or damage?

6. Access to Transboundary/Straddling Resources

Biodiversity follows natural boundaries and not political borders. Some of the target resources do not only constantly move between the Area and the high seas (i.e. between the seabed and the water column above), but also between areas within national jurisdiction and ABNJ. In the latter case, the current location of a straddling MGR decides if its access is subject to the rights of a particular state or the freedom of the high seas.

Exact geo-referencing of accessed MGR is thus important with regard to access requirements and potential benefit-sharing obligations. Furthermore, it is critical in terms of monitoring compliance and enforcement, as discussed below.

[3] Here, different examples of needs for large biomass collections are cited: the anticancer drug ecteinascidin 743, obtained from the tunicate Ecteinascidia turbinate (1 g in 1,000 kg wet weight), the cytostatic halichondrin B from Lissodendoryx sp. (300 mg in 1,000 kg), or the bryostatins from the bryozoan Bugula neritina (1.5 g in 1,000 kg).

7. Tracking and Monitoring, Compliance and Enforcement

Tracking and monitoring, as well as compliance and enforcement are further issues that need to be considered in the context of access. Tracking and monitoring can be described as a mechanism of establishing and maintaining the link between access and utilization of genetic resources as well as the conditions of access and adherence thereto, including outside the geographical or jurisdictional area of the physical access of genetic resources. The two terms are closely related but "tracking" has more to do with following the movement of genetic resources (and their derived products) along the research and development chain, while "monitoring" refers to verifying that the uses being given to these resources (and products) are permitted by the access and benefit-sharing (ABS) terms and conditions under which research and development are undertaken (Ruiz Muller and Lapeña, 2007, 111). Tracking may imply identifying what institutions are actually doing research on collected genetic resources while monitoring may imply verifying if research by these institutions is permitted in the light of ABS obligations or whether the initial intent has changed (Ibid.). In contrast, compliance involves the undertaking of concrete measures in order to ensure that originally agreed ABS conditions and requirements are adhered to whereas enforcement aims to effect compliance at times through coercive measures.

Research and development chains can be long and complex. After being taken from its *in-situ* conditions, a collected sample may become accessible to multiple users through transfer/exchange (including *ex-situ* collections). Through this process, a genetic resource may also continuously change its nature, partly because the process might involve combing a number of genetic resources of different origins and genetic makeup. Consequently, the ratio of a particular genetic resource in the final product might be minimal. In addition, technology has made it possible to grow organisms in laboratory conditions, analyze their genetic makeup and turn it into data, use sophisticated computer models to test biological models, drugs and medical interventions, etc. All this can complicate tracking and monitoring and hence compliance and enforcement.

A prerequisite is therefore transparency and traceability which may be enhanced by taking specific measures including, *inter alia*:

- Establishing who has access to MGR in ABNJ and who uses them;
- Identifying and making known all third parties involved in discovery and exploitation;
- Identifying and communicating about the scientific objectives and the processes that will be carried out (in particular whether the intent of access is to conduct pure scientific, applied or commercial research);
- Identifying biorepositories and databases holding MGR and information on MGR respectively;
- Having clear policies and written agreements setting out the terms and conditions for access and transfer of material and data from biorepositories and databases respectively;
- Consistently following the flow of collected materials and related research data (including metadata);
- Establishing checkpoints in any stage of research, development, innovation, pre-commercialization, commercialization or marketing in order to collect any information that is relevant to the access and utilization of MGR from ABNJ.

8. Conclusions

It can be concluded that the issue of access to MGR from ABNJ requires a much differentiated approach. First of all it is important to distinguish different access types, i.e. access to samples from their natural environment, versus access to samples stored in biorepositories, versus access to molecular data such as DNA sequences drawn from the research of these samples and stored in databanks. Promoting or facilitating these different types of access for researchers from developed as well as developing states would already provide a great, universal benefit.

Especially open access to data is an important and growing component of biotechnological research in both developed and developing countries. However, it must also be recognized that the ability to extract information from data is shifting rapidly, which makes it almost impossible to anticipate what kind of data can and shall be extracted in 25 years from now.

Furthermore, distinction is also necessary in view of the different sectors accessing resources and their particular interests and characteristics, the sustainability of various access activities, as well as the challenges of monitoring.

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Types of Benefits and Benefit-sharing

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1. Introduction

Marine expeditions are being undertaken at an increasing pace in all oceans (in areas within national jurisdiction as well as beyond areas of national jurisdiction (ABNJ)) in order to find and collect marine organisms, as well as to isolate and analyze their various compounds and properties. Such collection of marine organisms and the analysis of the marine genetic resources (MGR) contained in them can be part of pure research (having no direct commercial intent), applied research (i.e. research and development), or commercial research (having a commercial intent). Research results may lead to increased scientific knowledge about the marine environment and its functioning, as well as to applications, both leading to greater socio-economic benefits for all humankind. The following provides a general overview of various types of benefits that can be shared, different benefit-sharing approaches, examples of existing benefit-sharing practices, potential obstacles to benefit-sharing, as well as the existing legal framework.

2. Different Benefit-sharing Approaches

Two broad categories of benefit-sharing approaches can be distinguished:

- Bilateral benefit-sharing; and
- Multilateral benefit-sharing.

A bilateral benefit-sharing approach is envisaged under the Convention on Biological Diversity (CBD) and its Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization. Here access and benefit-sharing (ABS) transactions are foreseen between a country where a genetic resource can be found within its jurisdiction (i.e. one provider), and an individual or entity that requests access to this resource in order to conduct pure, applied, or commercial research on its genetic and/or biochemical composition (i.e. one user). The provider is to facilitate access to genetic resources found within its national jurisdiction, but has the sovereign right to make such access subject to the granting of prior informed consent (usually a permit) and mutually agreed terms (the conditions identified in an ABS contract). In return, the user must share benefits with the provider in an equitable and fair way, based on the mutually agreed terms established between the two parties. It is important to note in this context that such bilateral transactions under the CBD are not necessarily between two states, but can be between a government

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entity (i.e., a competent national authority) and a private entity (e.g. an individual researcher, a research institute, or a private company).

An example of a multilateral benefit-sharing approach can be found in the FAO International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). The ITPGRFA establishes a Multilateral System for ABS which is designed to facilitate access to genetic resources listed in its Annex I and ensure the fair and equitable sharing of the benefits arising from the utilization of these resources, pursuant to a standard material transfer agreement. This standard agreement requires recipients who commercialize products that are plant genetic resources for food and agriculture and that incorporate materials accessed from the Multilateral System to pay an equitable share of the benefits arising from the commercialization of the product into an international fund. Such payment is mandatory where restrictions are placed on the availability of the product for further research and breeding. Where no such restrictions are applied, the recipient is not under any obligation to make a payment but is encouraged to do so voluntarily (see also the Information Paper 7 on *Global and Regional Regimes on Genetic Resources, Experiences and Best Practices*).

The Multilateral System automatically includes only the crops for which plant genetic resources for food and agriculture are both under the management and control of the Contracting Parties and are in the public domain. All other holders of plant genetic resources for food and agriculture are only encouraged to include them into the system, and Contracting Parties are to take appropriate measures to encourage those inclusions. In addition, the Multilateral System includes plant genetic resources for food and agriculture listed in Annex I and held in the *ex-situ* collections of the International Agricultural Research Centres of the Consultative Group on International Agricultural Research. The ITPGRFA thus establishes a multilateral benefit-sharing approach which is non-transactional, based on multilaterally agreed terms and conditions, stipulates elements of mandatory as well as voluntary access and benefit-sharing, and uses a fund to direct benefits toward conservation of plant genetic resources for food and agriculture.

Another multilateral benefit-sharing arrangement is established under the Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits which was adopted by the World Health Assembly. This framework brings together Member States, industry, other key stakeholders and the World Health Organization (WHO) to implement a global approach aiming for more equitable access to affordable vaccines and, at the same time, guaranteeing the flow of virus samples into the WHO system so that the critical information and analyses needed to assess public health risks and develop vaccines are available. Two types of standard material transfer agreements are foreseen: one establishes the conditions which apply to transfers of biological materials covered by the framework among members of the WHO Global Influenza Surveillance and Response System (GISRS); the other establishes the conditions which apply to transfer of such biological materials from a GISRS laboratory to a party outside of the GISRS. According to the latter standard agreement, manufacturers of influenza vaccines, antiviral medicines and diagnostic materials who use GISRS, notably because they receive biological materials, will contribute annually to the so called Partnership Contribution which is to be used for improving pandemic preparedness and response (see also the Information Paper 7 on *Global and Regional Regimes on Genetic Resources, Experiences and Best Practices*).

A legal basis for considering the need for and modalities of a future global multilateral benefit-sharing mechanism can also be found in Article 10 of the Nagoya Protocol which addresses situations where ABS requirements cannot be met through a bilateral approach. Article 10, which is an enabling clause to consider the possible development of a future mechanism, applies where genetic resources are located in transboundary situations, or where it is not possible to either grant or obtain prior informed consent for genetic resources. Furthermore, it is interesting to note that according to Article 10, (potential) benefits shared through a global multilateral mechanism (in case it is established) *"shall be used to support the conservation of biological diversity and the sustainable use of its components globally"*.

3. Different Types of Benefits

Two broad categories of benefits that can be possibly shared need to be distinguished: monetary and non-monetary benefits. The Annex of the Nagoya Protocol includes a non-exhaustive list of both types of benefits. While the Protocol envisages an exchange of benefits in a bilateral relationship between a provider and a user – a situation that does not apply to MGR in ABNJ as there is no such provider – some of the concepts reflected in the Annex may help to better understand potential types of benefits that could also be considered in the ABNJ context.

Paragraph 1 of the Nagoya Protocol Annex suggests different monetary benefits. First of all, it envisages the payment of money at different stages in the chain of access and utilization of genetic resources:

- Payments at the outset of research and development, i.e. before research has even started and progress has been made;
- Payments after certain milestones have been reached, i.e. after a certain phase in the research and development chain, or after a certain deliverable was completed; and
- Payments in case a product is placed on the market in the form of royalties, i.e. a certain percentage of the income generated, or license fees.

Furthermore, monetary benefits are envisaged in the form of different financial arrangements related to research undertakings, namely:

- Preferential salaries in research and development collaborations;
- Provision of funding to support research activities; and
- Engagement in joint ventures, i.e. the development of new enterprises/partnerships sharing revenues, expenses and assets which may also include joint ownership of relevant intellectual property rights.

Finally, it is possible to make payments to trust funds which are financial tools that hold and administer assets for the benefit of others. The financial resources so collected could be used to support the conservation and sustainable use of biodiversity, but also to fund joint research undertakings. Both create benefits for all humankind. Furthermore, the generation of financial support for the conservation and sustainable use of biodiversity is a means to link a benefit-sharing regime with other policy instruments such as area-based management tools, including marine protected areas, environmental impact assessments, and general governance principles for biodiversity conservation and sustainable use.

However, some payment approaches may not be practical in the ABNJ context. Payments of access fees, up-front payments, or milestone payments might require a complex and potentially costly institutional and administrative structure to be implemented.[3] In addition,

[3] It needs to be recalled that no provider or representing institution with the mandate to receive such payments currently exists. Furthermore, monitoring access and enforcing payments would be difficult to implement.

access fees and up-front payments could discourage researchers from accessing MGR in ABNJ as it would increase research costs. Milestone payments could again lead to barriers to commercialization, if payable before revenues are forthcoming. A more practical way could be through the payment of royalties, e.g. by collecting a global levy on the profits generated by the commercialization of products developed from MGR from ABNJ, or by requiring a royalty payment based on net profits after a certain stage of production.

In addition to such monetary benefits, Paragraph 2 of the Nagoya Protocol provides a list of non-monetary benefits. Some of these non-monetary benefits are similar to what is set out in relation to marine scientific research under the United Nations Convention on the Law of the Sea (UNCLOS):

- Sharing of research and development results;
- Collaboration, cooperation and contribution in scientific research and development programs; or
- Transfer of knowledge and technology.

Furthermore, non-monetary benefits suggested by the Nagoya Protocol which could be interesting to consider in the ABNJ context include:

- Participation in product development;
- Strengthening of capacities for technology transfer;
- Institutional capacity-building;
- Training related to genetic resources;
- Collaboration, cooperation and contribution in education and training;
- Admittance to *ex-situ* facilities of genetic resources and databases; or
- Access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies.

In addition to those non-monetary benefits listed in the Annex of the Nagoya Protocol, an important non-monetary benefit is also highlighted under the ITPGRFA: facilitated access to plant genetic resources for food and agriculture itself is recognized as a major benefit.

It should be noted that non-monetary benefits are sometimes considered as the most practical and immediately valuable aspect of ABS. As the chances of “hitting the jackpot” through the development of a commercial product are relatively small, there is no guarantee of monetary benefits arising from the utilization of genetic resources (see also the Information Paper 3 on *Technological, Environmental, Social and Economic Aspects*). In contrast, non-monetary benefits (in particular, training of scientists, transfer of research results and scientific information, transfer of technology, or access to *ex-situ* collections) might create more direct, immediately available and more sustainable/long-term benefits, as they may contribute to building capacities, creating opportunities, and promoting research and development in all countries (not only developing ones) (Glowka and Normand, 2012).

4. Benefit-sharing in Practice

While monetary benefit-sharing is not practiced for MGR from ABNJ (due to the lack of an applicable regime), non-monetary benefits may already be shared to some extent. For example, different ways of exchanging materials and relevant information exist, such as through

- Gene banks which are biorepositories collecting, processing, storing, and distributing samples of genetic material;
- Digital databanks which catalogue biological and genetic material, as well as related meta-information;
- International scientific journals which publish research results in print or online;
- Patent pools which are consortia of entities agreeing to cross-license patents relating to a particular technology in order to save time and money, to mitigate patent-related risks, and to create collective benefits.

In the case of microbial materials, for instance, the scientific research community is already practicing an exchange of samples as well as data through biological resource centers which provide international access to biological materials and information for scientific research and development (Dijkshoorn *et al.*, 2010).[4] In order to harmonize and systematize the provided information, certain standards (e.g. common formats and common language) have even been developed.[5]

Moreover, non-monetary benefits are shared in practice through the creation of joint research programs. Global as well as regional efforts are being made to develop and better coordinate researchers, projects, programs and infrastructure, and various cases of trans-regional collaboration in research activities already exist (see also the Information Paper 8 on *Exchange of Information on Research Programs Regarding Marine Biodiversity in Areas beyond National Jurisdiction*).

It is also safe to say that a number of benefits are created already today through research and development on MGR in ABNJ. Creating inventories of which organisms currently live in the ocean, and undertaking research and development on them are prerequisites for a better understanding of the marine ecology, the oceanic system, the sustainable use of the oceans, as well as possible changes in ecosystem functioning. Such improved understanding represents a benefit for all humankind that goes beyond the availability of any products made from these resources. Some of these marine-derived natural products also present significant global benefits through their contributions to public health (such as discovery of novel antibiotics in response to multidrug resistant bacteria and fungi, development of antiviral drugs, or promising anticancer treatments), bioremediation (the use of biological agents, namely microorganisms, to remediate organic contaminants in the environment), or food security (such as microbial research has already contributed to improving aquaculture production systems) (Glöckner *et al.*, 2012).

However it is important to recognize that it is not always clear if the above described non-monetary benefits relate to MGR from ABNJ, to MGR from within national jurisdiction, or to both. This makes it difficult to clearly establish that benefit-sharing through these modalities is already taking place for MGR from ABNJ. Furthermore, even under the assumption that such non-monetary benefit-sharing also relates to MGR from ABNJ, it is still unclear to what extent these benefits are shared equitably or globally, to whom such benefits most directly accrue, and to what extent developing countries currently benefit.

[4] Furthermore, different initiatives – not only focusing on microorganisms – have been started to promote the exchange of relevant information and data at the global scale, such as the Genomes Online Database, the International Nucleotide Sequence Databases, GenBank, SeaDataNet, just to mention a few.

[5] See for example StrainInfo at www.straininfo.net.

5. Obstacles to Equitable Benefit-sharing

Current practices indicate a number of obstacles for equitable benefit-sharing at a global level. So far, non-monetary benefit-sharing practices largely depend on the particular stakeholders involved (research communities and/or private sector), the types of resources addressed (such as microorganisms or other types of genetic resources), as well as the levels of information made available. Furthermore, using scientific research on microbial resources as an example, the following can be observed (Dijkshoorn *et al.*, 2010):

- Exchange of samples and data takes place between biological resource centers. However, much greater numbers of strains are kept in non-public collections (e.g. at private universities and other research institutions, or private companies) which are not necessarily part of a global exchange network.
- Non-public collections are not required to report their existence at a given platform so that awareness about and accessibility to them may be incomplete.
- Long-term maintenance of non-public collections is not necessarily ensured as they may only be part of a temporary project which does not provide sustainable financial resources and appropriate conditions.
- Database management, storage conditions and quality control measures differ considerably and collectors are not necessarily trained to comply with standards which may limit the value of certain collections.
- Metadata in relation to deposited samples as well as data is often fragmented.
- Free exchange of information may not always happen, as requests can be ignored, logistics and required administration can make it difficult or impossible to comply with requests for exchange, and certain organisms with important value for future publications or known or likely commercial value might not be exchanged freely due to institutional policies or demands.

As similar bottlenecks are likely to apply to the exchange of other MGR, it must be determined that no structured, fully comprehensive, inclusive and equitable benefit-sharing practices exist so far. It is important to note in this context that it is not only developing countries that are at a disadvantage from the above described deficiencies but rather the entire global research community (Glowka, 2010, 22) that needs more efficient access to MGR samples as well as data. Only then the full potential of building strategic alliances between public sector scientific institutions, creating public-private partnerships, and establishing efficient and effective research chains beginning in universities and culminating in industry can be tapped by the global research community.

6. Existing Legal Frameworks

The Convention on Biological Diversity, the Bonn Guidelines on Access and Benefit-sharing, the Nagoya Protocol on Access and Benefit-sharing, and the International Treaty on Plant Genetic Resources for Food and Agriculture are part of an international ABS regime. However, the jurisdictional scope of these instruments does not apply to MGR in ABNJ.

UNCLOS sets out the legal frameworks within which activities in the oceans and seas, including ABNJ, must be carried out.[6] With regard to benefit-sharing, the common heritage of mankind concept and its benefit-sharing obligations under Part XI of the UNCLOS and the 1994 Part XI Agreement do not apply to MGR, as only mineral resources are covered by the

[6] UN doc A/RES/65/37, of 7 December 2010, Paragraph 4 of the Preamble.

Part XI regime (see Article 133(a)). The exercise of the freedom of the high seas (see Article 87) is accompanied by a number of conditions, which include some form of benefit-sharing, including the obligation to pay due regard to the interests of other States when exercising the freedom of the high seas (Article 87.2).

In addition, general provisions of UNCLOS related to marine scientific research and to the Area also embody some form of benefit-sharing. These include the obligations to:

- Promote international cooperation in marine scientific research (Articles 242 and 143.3(a));
- Make knowledge resulting from marine scientific research available by publication and dissemination (Articles 244.1 and 143.3(c)); and
- Promote data and information flow and the transfer of knowledge, in particular to developing States (Articles 244.2 and 144.2).

While these provisions establish a regime for the sharing of certain benefits, they can be considered as deficient in several ways:

- Firstly, they lack necessary implementing regulations that concretize the broad benefit-sharing obligations and support their operationalization in practice.
- Secondly, different interpretations exist as to whether they relate to commercial as well as non-commercial marine scientific research, or only to non-commercial research. However, in practice, it must be noted that the understanding is that the provisions of UNCLOS on marine scientific research apply to both pure and applied research.
- Thirdly, they are limited to non-monetary benefits.
- Fourthly, they do not provide legal certainty for intellectual property rights as under Article 241 of UNCLOS marine scientific research activities shall not constitute the legal basis for any claim to any part of the marine environment or its resources. The implications of this provision have raised questions (Querellou *et al.*, 2010, 64).

7. Conclusions

The previous sections described existing opportunities and challenges related to benefit-sharing. Benefit-sharing obligations are inherent in UNCLOS. However, the extent to which these obligations are applied with regard to MGR from ABNJ is currently not clear. Furthermore, their implementation in relation to MGR from ABNJ could benefit from a more elaborated/detailed policy and regulatory framework creating an enabling environment for pure, applied and commercial research on the one hand (e.g. by setting standards for the deposit and exchange of samples, data and related metadata), and ensuring equity in the sharing of benefits from such research on the other hand.

Issues that require closer consideration by policy-makers include how to overcome the general problems in accessing data and samples when they have not been made publicly accessible, and how to address the existing inefficiencies in finding data and samples – for example through standard-setting, systems for implementation and facilitation and the promotion of transparency (Glowka, personal communication, 2013). It could be considered how the capacities of developing countries to access and use materials and data can be developed in order to ensure the creation of sustainable/long-term benefits on their side (Glowka, 2010, 22). In this context, long- as well as short-term measures could be identified in order to expand joint (“North-South” as well as “South-South”) research and development initiatives. Possible monetary benefit-sharing approaches could be discussed based on a distinction between pure, applied and commercial research and development. Finally, the possible contribution of benefit-sharing from MGR in ABNJ for the conservation and sustainable use of marine biodiversity in ABNJ could be further explored.

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Intellectual Property Rights

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1. Introduction

In cases of privately funded research as well as university research and public-private partnerships, intellectual property (IP) protection and the appropriate management of IP assets can promote research, innovation and their wide dissemination. Patents can provide incentives to promote investments in research and development and – through licensing – potential pathways towards technology transfer, product development and commercialization. However, uncertainties about the legal status of materials, which may arise from the presence of patent claims over marine organisms – and their separate parts and components, – may potentially discourage research by others within the technological prospects covered by such patents (Kitch, 1977). The management of other types of intellectual property rights (IPRs), including copyright, trade secrets and proprietary databases, also plays a role for the generation and the dissemination of data, information, knowledge and technologies arising from the discovery and exploitation of marine genetic resources (MGR).

This paper considers key aspects of the law of patents, trade secrets, copyrights and databases by explaining why they are relevant to the utilization of MGR and their intangible informational contents in the context of the United Nations Convention on the Law of the Sea (UNCLOS) and its normative framework for marine scientific research (MSR).

2. Patentability of MGR-based Inventions

Biomolecules, DNA and marine microorganisms can be utilized in industrial processes, and they can be synthesised and replicated in a lab. When such human interventions result in a *new* biotechnological invention that involves an *inventive step* and is capable of *industrial application*, the invention may qualify for patent protection (Chiarolla, 2011). The World Trade Organization's (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs) requires all WTO Member States to provide minimum standards of protection for a wide range of IPRs. It provides that a patent shall confer on its owner the right to prevent others from making, using, offering for sale, selling or importing the patented product for a period of 20 years or more. In the case of a process patent, the same rights extend at least to the product obtained directly by the patented process. TRIPs further requires that *"[…] patents be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced."* Its purpose is to protect right-holders against arbitrary policies that may undermine their rights.

[1] The views expressed in the following information paper belong solely to the author and do not represent the views or policies of IUCN, BfN, BMU, or any organization(s) mentioned in this work.

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The question of whether a WTO Member State may be allowed to take measures that would exclude the granting of patents (or the enjoyment of patent rights) for inventions based on MGR that are taken from areas beyond national jurisdiction (ABNJ) has not yet arisen. However, such form of discrimination does not appear to be prohibited under TRIPs, since Article 27.1 does not refer to the origin of the resources used for the invention but rather the place of the invention itself.

The effects of biotechnology patents on research and innovation are controversial since their inception in the 1980s. Certain inventions have been purposely excluded from the scope of patentable subject matter as defined by national patent law. This may vary from one country to another. WTO Member States are allowed to not grant patents for plants, animals and essentially biological processes for their production. However, microorganisms and micro-biological or non-biological processes must be protected (Article 27.3(b) TRIPs). Some countries thus exclude from patentability, *inter alia*: plants and animals; discoveries of natural substances; and any invention where the prevention of its commercial exploitation is necessary to protect public order, morality or public health.[3]

Nonetheless patent offices in countries with advanced biotechnology capacity have routinely granted patents for gene-based inventions. For instance, in the European Union, *"biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature"* (see the 1998 EU Directive on the Legal Protection of Biotechnological Inventions). In the United States, three categories of inventions are not patentable: laws of nature, natural phenomena, and abstract ideas (based on the "product of nature doctrine"). The boundaries of such doctrine are routinely tested in disputes that concern the patentability of DNA and its alleged positive or stifling effects on biological innovation (see the test case *Association for Molecular Pathology v. Myriad Genetics, Inc*.). In addition to the United States, Australia, Canada, Indonesia, Japan, Singapore and the 18 Member States of the African Regional Intellectual Property Organization generally allow full patentability of animals, plants and biological processes without particular restrictions (Dutfield *et al*., 2006).

As regards the implementation of subject matter exclusions, a group of countries – including China, India, Malaysia, the Philippines, the Russian Federation, Tunisia, the 16 Member States of the Organisation Africaine de la Propriété Intellectuelle (OAPI) as well as the Member States of the European Patent Organisation (EPO) – provide for a limited subject matter exception that generally covers plant varieties and/or animal breeds, and essentially biological processes (Dutfield *et al.*, 2006). However, this entails that in the above jurisdictions patents over a gene-based invention (which do not name in the claims a particular variety or breed) may be still allowed. Finally, countries such as those from the Andean Community of Nations, Brazil and Thailand entirely exclude plants, animals (in whole or any part thereof) and essentially biological processes from patentability.

3. Patents on MGR-based Inventions in Practice[4]

Arrieta *et al.* (2010) have analysed a set of patent documents (available as of April 2008),[5] which discloses *"4,928 non-redundant marine gene sequences derived from **558** distinct*

[3] WIPO, Understanding Industrial Property, at p. 6, available at http://www.wipo.int/export/sites/www/freepublications/en/intproperty/895/wipo_pub_895.pdf accessed 29/03/2012.
[4] This section of the paper is based in part on Vierros *et al.* (2013, forthcoming).
[5] The authors report that the data was obtained from the Patent Division of GenBank release 165 (April 2008), which contains patent records obtained from patent authorities in various jurisdictions including

named marine species." It also shows an increase in the rate of species appearance in patent documents of 12% per year between 1999 and 2008. Arnaud-Haond *et al.* (2011) have analysed a dataset comprising patent applications filed through the Patent Cooperation Treaty (PCT) between 1991 and December 2009. The authors found that a total of 677 claims from the PCT dataset were associated to 8,648 sequences belonging to **520** distinct marine species.[6] More recently, Oldham *et al.* (2013, forthcoming) have *"identified 4,162 marine species in patent data of which **1,464** species appear in patent claims"*.[7] Any comparison of the above studies would be inappropriate due their different methodological assumptions in the selection and assessment of patent data. However, the figures in bold roughly show that there is a non-negligible number of marine species, whose appearance in patent claims suggests their utilization is subject to patent restrictions in various jurisdictions.

While the extent of patent activity that concerns MGR may be even larger than the above estimates suggest, it is important to recognize that the exact geographical origin of these resources (i.e. within or beyond national jurisdiction) is often unknown and therefore it is difficult to ascertain what the true extent of patenting activity may be in relation to MGR from ABNJ. This is because in most cases the naming of the species of origin of the genetic material used in a biotechnological invention, as well as its geographical origin, may not be required by patent law. Besides, metagenomics allows determining genes' functions by simply screening a mix of DNA from multiple organisms against a reference library without requiring knowledge of the source organism (see also the Information Paper 2 on *Extent and Types of Research, Uses and Applications*).

Geo-referencing of sample collection locations appears to be already standard good scientific practice. However, it is also true that the metadata containing such important information is often fragmented, making it difficult to establish whether a given MGR was collected within national jurisdiction or in ABNJ. More routine disclosure of the geographical coordinates of collection locations could help overcome this (see also the Information Paper 8 on *Exchange of Information on Research Programs Regarding Marine Biodiversity in Areas beyond National Jurisdiction*). Such information could follow all samples of the collected material and their sequence data throughout the chain of utilization, including for materials held by *ex-situ* collections, by using unique identifier numbers (see also the Information Paper on *Global and Regional Regimes, Experiences and Best Practices*). Such an approach could promote synergies and provide complementarities with the monitoring regime established under the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity.

The possibility to claim molecules and DNA constructs previously existing in nature to replicate the processes they perform in nature may impinge on the ability of others to undertake research on the claimed MGR (Correa, 2012). Thus, the patenting of results of basic research and, in particular, isolated DNA and biomolecules that are identical to their natural counterparts, could limit access to materials and research tools. In such cases, patents may impede further innovation. Therefore, unrestricted or facilitated access to basic information and discoveries as well as upstream research results relating to MGR may be critical for the advancement of science and by extension MSR (Kesselhein and Avorn, 2005).

Europe, Japan, the United States as well as from the World Intellectual Property Organization (PCT applications).

[6] Although this study provides no information about the status of relevant patent applications once they have entered the national phase, it provides an indication of the growing interest for marine biotechnological applications arising from the utilisation of MGR.

[7] Relevant Latin species names were identified by using the Ocean Biogeographic Information System (OBIS) Database. The analysis includes text mining of 11 million patent documents from the United States, the European Patent Convention and the PCT in the period 1976-2010.

Patent laws normally provide for research exemptions. A research exemption is an exception to the exclusive rights granted by a patent that allows researchers to undertake experiments on the patented invention with the view to discovering unknown effects or making improvements on the invention without the prior consent of the patent holder (WIPO, 2009). The TRIPs Agreement provides for a research exemption.[8] However, this is of a permissive nature and there is no international obligation to include such exemption in national patent law. Therefore, research exemptions provided in various countries can greatly diverge and they can be construed in narrow terms (Chiarolla, 2011).

Finally, a potential norm that aims at establishing or preserving a public domain status of selected MGR, if such were the policy objective, may also involve an obligation of the concerned states to regulate (and subject to limits) the entitlements that researchers may have to file patents on such resources. Instruments for implementing such obligations could be of a contractual nature. In particular, they could take the form of contract clauses associated with the granting of research funding and/or relevant research permits or – when the material is received from *ex-situ* sources – they could be inserted into material transfer agreements (MTA). At the international level, an example of such form of regulation, which entails the management of a global public good through a private law contract, is provided by the FAO International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) and its standard material transfer agreement (SMTA). The SMTA establishes that recipients of plant genetic resources for food and agriculture shall not claim *"any intellectual or other property rights that limit the facilitated access to the Material […] or its genetic parts or components, in the form received from the Multilateral System"* (Article 12.3(d) ITPGRFA, and Article 6.2 of the SMTA). The interpretation of this clause and of the limits it imposes on the appropriation of plant genetic resources (that are shared in the Multilateral System and in public domain) remains controversial (Chiarolla and Jungcurt, 2011).

4. Patents, Trade Secrets and Dissemination of Information and Knowledge

Under Article 244 of UNCLOS, *"States and competent international organizations shall [...] make available by publication and dissemination through appropriate channels information on proposed major programmes and their objectives as well as knowledge resulting from marine scientific research. For this purpose, States [...] shall actively promote the flow of scientific data and information and the transfer of knowledge resulting from marine scientific research, especially to developing States, as well as the strengthening of the autonomous marine scientific research capabilities of developing States through, inter alia, programmes to provide adequate education and training of their technical and scientific personnel."*

Against this backdrop, on the one hand, patent protection may generate tensions with the above Article, because confidentiality and non-disclosure of information is required prior to patenting in order to safeguard the novelty of the invention. On the other hand, patent protection promotes the dissemination of useful technical information (on how to perform the invention) once the patent application (and the disclosure therein) is published. However, nationals in most developing countries have difficulties in benefiting from knowledge on technologies and processes that is disclosed in the patent literature, if such knowledge is only

[8] Such exemption must meet three cumulative conditions, namely that it: (1) does not unreasonably conflict with the normal exploitation of the patent and (2) does not unreasonably prejudice the legitimate interests of the patent owner, (3) taking account the legitimate interests of third parties. See *Canada – Patent Protection of Pharmaceutical Products*, WT/DS114/R, WTO (17 March 2000).

available in the form of publications made by foreign IP offices in foreign languages (Matthews and Chiarolla, 2009). The digitization of documents concerning national IP filings and their dissemination through publicly-available databases could enhance access to knowledge, including in the field of marine biological innovation. Another common assumption is that in jurisdictions where patents are not available for gene-based inventions (e.g. because of subject matter exclusions), a more widespread recourse to secrecy and confidentially is relied upon by commercial developers for protecting their innovations compared to jurisdictions where patent protection is available.

It must be highlighted that in current commercial practices, patents and trade secrets are used as complementary means of protection that strengthen each other's exclusivity. Patents usually protect the core invention and their disclosure normally covers only embryonic or early stage research and development results, *"which are insufficient for commercializing the patented technology, absent access to collateral proprietary know-how"* (Jorda, 2007). Such proprietary know-how, which is often developed after the first filing of the patent application, is protectable as a trade secret (Article 39.2 TRIPs). It can also be contractually protected under a confidentiality agreement (Kowalski and Krattiger, 2007). However, the management of IP assets that arise from MSR under a regime of confidentiality or trade secrecy appears to be at odds with the spirit of UNCLOS. This is because its Article 244 expressly provides for the publication and dissemination of relevant information and knowledge with the view to promoting openness and transparency of marine science. For example, the Oceanographic Data Exchange Policy of the Intergovernmental Oceanographic Commission (IOC) implements the principles of Article 244 by stating that: *"Member States shall provide timely, free and unrestricted access to all data, associated metadata and products generated under the auspices of IOC programmes"* (Resolution IOC-XXII-6).

Finally, in the context of technology transfer, Article 267 of UNCLOS provides that: *"States, in promoting cooperation pursuant to article 266 [Promotion of the development and transfer of marine technology], shall have due regard for all legitimate interests including, inter alia, the rights and duties of holders, suppliers and recipients of marine technology."* However, the application of this provision seems to be primarily concerned with the transfer of hard (tangible) technologies, not with the dissemination of data, information and knowledge.

5. Copyright, Academic Publishing and Open Access to Scientific Publications and Data

The traditional model of returning value to creators and other right holders is rapidly changing in light of the convergence of digital technologies and the distributive power of the Internet. In the field of copyright, there is a need to raise awareness of the opportunities provided by the copyright system, including copyright limitations and exceptions, to support new models of distributing information and creative content and thereby helping to bridge the digital divide (Matthews and Chiarolla, 2009). In particular, open-access scientific publishing and free and open source software may contribute to the spread of marine biological innovations and the dissemination of MSR results. Open access to relevant scientific publications, data and software (to analyse this data) could be viewed as an important component of non-monetary benefit-sharing (see also the Information Paper 5 on *Types of Benefits and Benefit-sharing*). However, the moderate optimism, which arises from the new opportunities created by open-source business models in scientific publishing, cannot obscure the reality for developing countries, where many researchers and users may not have the same access to the Internet, bandwidth and alternate models for managing and distributing information and creative content, as their counterparts in developed countries.

The recent push towards open access to research in Europe and in the United States are a promising development, with positive spillover effects for all those involved in MSR. For instance, in the United Kingdom, most research funds are allocated under the condition that researchers make their results available in open-access environment, that is, unrestricted, online access to research papers free of charge. The UK-based Wellcome Trust's open-access policy *"requires electronic copies of any research papers that have been accepted in a peer-reviewed journal, and are supported in whole or part by the trust, to be made available […] within six months of the journal publishers' official date of final publication"*.[9] The United States' Fair Access to Science and Technology Research Act, which is now under discussion, proposes to make government agencies design and implement a plan to facilitate public access to federally funded research by requiring researchers *"to submit a copy of resulting journal articles to the funding agency, which will then make that research widely available within six months."*[10] Other countries such as Brazil, China and South Africa are leading the field in open access implementation in the developing world.[11]

The journals *BioMed Central* (BMC) and the *Public Library of Science* (PLOS – one of the most common cell biology cancer research journals) provide a good example of a business model, which was successfully adopted for open-access peer-reviewed scientific publishing. Publication fees – including those necessary to cover peer review, edition, journal production, and online hosting and archiving – are paid by the authors rather than by the readers. The *PLOS Global Participation Initiative* pricing program, which was launched with the aim of promoting the widest possible global participation in open-access publishing, offers to waive or reduce the payment required of authors from Low and Lower Middle Income Countries. Besides, open-access policies also concern digital data that are owned, or produced with the support of, public bodies. For instance, the European Commission's Open Data package – in particular, the Commission's updated directive on re-use of public sector information – proposes to make favorable re-use conditions applicable to data held by cultural heritage institutions such as libraries (including university libraries), museums and archives. However, bodies of industrial or commercial character, educational and research establishments, and performing cultural institutions will be exempted.

6. Legal Protection of Databases

When implementing institutional data sharing policies, an important IP management issue concerns the appropriate consideration of third parties' intellectual property restrictions that may be carried not only by the data *per se*, but also by the arrangement of such data (e.g. in a database). For instance, Dodds *et al.* (2007) explain that a compilation of data or information is copyrightable if the latter *"[…] have been selected, coordinated, or arranged in such a way that the resulting work, as a whole, constitutes an original work of authorship."* If more authors have contributed to the compilation, the database may be subject to joint copyright ownership. Although the data or information does not need to be new, the way in which it is selected and arranged must show some degree of originality and creativity for the compilation to be protectable under copyright law. In general, copyright protection does not extend to individual data in a database, and such data may be used once extracted from it.

[9] See the Open Access Policy, available at www.wellcome.ac.uk/About-us/Policy/Policy-and-position-statements/WTD002766.htm accessed 20/04/2013.
[10] See FASTR, available at https://action.eff.org/o/9042/p/dia/action/public/?action_KEY=9061 accessed 12/03/2013.
[11] See UNESCO Open Access Portal, available at www.unesco.org/new/en/communication-and-information/portals-and-platforms/goap/access-by-region/ accessed 09/04/2013.

This is why commercial database providers normally restrict the right to (re)use and further distribute contents extracted from the database by including restrictive clauses into the licensing agreements.

Besides copyright protection, the Member States of the European Union are the sole countries that also provide *sui generis* legal protection for databases. In accordance with the 1996 EU Database Directive, the makers of a database enjoy the right to prevent unauthorized acts of extraction and re-utilization of *"the whole or of a substantial part"* of a database content, if it is demonstrated *"that there has been qualitatively and/or quantitatively a substantial investment in either the obtaining, verification or presentation of [such] contents"* (Article 7). Thus, in the case of the *sui generis* right, there is no requirement for creativity or originality in the way data is selected and arranged, as it is the case for copyright. Database protection normally lasts for 15 years from the date of its creation, with an additional 15 years of protection if substantial changes are made to the content of the database (Dodds *et al*., 2007). Finally, the 1996 EU Database Directive only protects the rights of nationals of EU Member States, while nationals of other countries are protected solely under conditions of reciprocity.

7. Open Source Licensing in Marine Biological Innovation

Open source licensing is a form of management of IP assets, initially developed in the software context, whose objective is to disseminate innovation in a non-proprietary fashion. As such, it is alternative to "straightforward publication" strategies that would directly place the innovation in the public domain by foregoing IP protection altogether (Hope, 2007). In the field of bioinformatics, most enabling technologies are developed under open sources terms.[12] Besides, since 1999, various open-source initiatives have been launched in the life sciences to promote a more transparent, participative, open and inclusive research and development model than it would be in proprietary setting. Such initiatives include *"[…] a Canadian proposal for a General Public License for plant germplasm, a draft license (never adopted) for human genome project sequence data, the data access policy of the international haplotype mapping (HapMap) project, the Biobricks Foundation, Tropical Diseases Initiative, Science Commons, and Biological Innovation for Open Society (BIOS)"* (Hoppe, 2007). However, the application of open source licenses to non-software technologies is not something obvious since marine biotechnology, in comparison with software development, is far more technologically diverse and dependent on expensive, time-consuming and complex patents – instead of copyright, which is an automatic and inexpensive form of protection.

8. Conclusions

The appropriate management of IP assets that arise from MSR needs to be considered carefully in the context of promoting research, innovation and their widest possible dissemination for the benefit of society as a whole. Patents can provide incentives for private sector investments in research and development on MGR, and – through licensing – they can also promote the transfer and commercialization of relevant marine technologies. However, newly discovered MGR may also be *locked up* by patent monopolies which could eventually provide a research barrier, in particular for non-profit research on these resources. Besides, with the exception of basic molecular techniques, most of the technology necessary for

[12] See Open Bioinformatics Foundation (OBF), available at www.open-bio.org accessed 14/03/2013.

accessing the deep sea and studying and isolating marine organisms is owned and operated by research institutions in very few countries (Arnaud-Haond et al., 2011).

Furthermore, many countries could benefit from implementing patent subject matter exclusions and exceptions and limitations to patent rights that are allowed under the TRIPs Agreement (Correa, 2012). The various experiences described in this paper have shown, on the one hand, that the use of MGR and associated knowledge may be usefully widely promoted, including through legal flexibilities. On the other hand, countries may decide to provide patent protection to inventions that embody new human-made constructs that are different from their naturally occurring counterparts (Vierros et al., 2013, forthcoming).The management of IP assets arising from marine scientific research under a regime of confidentiality or trade secrecy could contradict the UNCLOS requirement to provide for the publication and dissemination of MSR-related information and knowledge. By contrast, researching the patent literature helps disclose knowledge on technologies and processes, which can be in the public domain in many jurisdictions (other than those where patent protection has been sought and granted). Thus, the digitization of documents concerning national patent applications, their translation in different languages and their dissemination through publicly-available databases could enhance access to knowledge that is potentially relevant for the utilization of MGR. The application of open access to research and data, and open source licensing of MGR-based inventions might therefore hold potential for promoting benefit sharing.

Finally, the routine disclosure, including in patent applications, of the geographic coordinates of sample collection locations could provide greater legal certainty for all those concerned with MSR. Geo-referencing as good practice for MSR holds a huge potential for creating synergies between UNCLOS and the implementation of the Nagoya Protocol on ABS.

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Global and Regional Regimes on Genetic Resources, Experiences and Best Practices

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1. Introduction

The UNCLOS *"sets out the legal frameworks within which all activities in the oceans and seas must be carried out and is of strategic importance as the basis for national, regional and global action and cooperation in the marine sector"* (UNGA Resolution 67/78). However, while a number of its provisions are relevant, UNCLOS does not specifically address marine genetic resources (MGR) in areas beyond national jurisdiction (ABNJ).

The following paper provides information on different global and regional regimes, as well as existing experiences and best practices related to genetic resources which may provide lessons learned to inform the discussions on MGR in ABNJ. In particular, the principles and main characteristics of these regimes, as well as various experiences and practices are explained. Furthermore, criteria are identified according to which such regimes, experiences and practices can be considered successful.

2. Global Regimes

The United Nations Convention on the Law of the Sea

As mentioned before, the UNCLOS does not specifically provide for a regime of access and benefit-sharing (ABS) with regard to MGR in ABNJ. However, it includes provisions on marine scientific research (MSR) that aim at balancing different interests: the interests of coastal states keen to protect their sovereignty over the resources within their national jurisdiction; the interests of researching states in unimpeded scientific research; and the interests of states that do not have research at sea capacity. Moreover, the Convention regulates MSR in ABNJ, the high seas and the Area (see the Information Paper 8 on *Exchange of Information on Research Programs Regarding Marine Biodiversity in Areas beyond National Jurisdiction*). In this context it provides for obligations that embody some form of non-monetary benefit-sharing in terms of promotion of scientific cooperation, dissemination of knowledge resulting from MSR and promotion of data and information flows and transfer of knowledge (see also the Information Paper 5 on *Types of Benefits and Benefit-sharing*).

[1] The views expressed in the following information paper belong solely to the author and do not represent the views or policies of IUCN, BfN, BMU, or any organization(s) mentioned in this work.
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The Convention on Biological Diversity and its Nagoya Protocol

The Convention on Biological Diversity (CBD) was the first international treaty that linked the objectives of conservation and sustainable use of biological diversity with the fair and equitable sharing of benefits arising out of the utilization of genetic resources. According to its Article 22.2, the CBD shall be implemented *"with respect to the marine environment consistently with the rights and obligations of States under the law of the sea"*. During its negotiations, the agreement on conservation obligations was made conditional on more directly use-oriented provisions, as well as on obligations and measures on three types of access: access to genetic resources subject to national authority; access to relevant technology, including biotechnology; and access for the providing states to benefits ultimately gained from the use of genetic material in the development of biotechnology (Glowka *et al.*, 1994). This link is now made more explicit by the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization through the obligation to direct ABS benefits towards conservation and sustainable use (Article 9).

The ABS regimes of the CBD and its Nagoya Protocol are based on the sovereignty of states over their genetic resources and on a bilateral approach (see also the Information Paper 4 on *Access-related Issues*). Given the absence of state sovereignty over ABNJ, this bilateral approach which is based on the prior informed consent of the provider country, unless otherwise determined, and on mutually agreed terms between the provider and the user is not applicable in respect of MGR from ABNJ. Therefore, both ABS regimes only cover genetic resources accessed within national jurisdiction. In other words, MGR from ABNJ are outside of their scope.

Experiences from ABS implementation at the national level indicate that a bilateral approach can become very complicated, time-consuming, costly, and impractical.[3] Other risks of a bilateral ABS approach are that bilateral negotiations of ABS terms and conditions can be impaired by eventual inequity of negotiation capacity or by political influence. Finally, it should be considered that the same genetic resource might be found under the jurisdiction of two or more countries, or in areas within and beyond national jurisdiction. These situations add further complexity to a bilateral ABS approach.

The International Treaty on Plant Genetic Resources for Food and Agriculture

The FAO International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) is based on the sovereignty of states over their plant genetic resources for food and agriculture. It establishes a Multilateral System (MLS) which is designed to facilitate access to genetic resources listed in its Annex I, and to ensure the fair and equitable sharing of the benefits arising from the utilization of these resources (see also the Information Papers 4-6 on *Access-related Issues, Types of Benefits and Benefit-sharing, and Intellectual Property Rights Issues*).

Under the MLS, the recipient who receives a resource from the MLS and commercializes a product that incorporates material accessed from the MLS shall pay to the mechanism an equitable share of the benefits arising from the commercialization of that product, except

[3] To assist Parties, Governments and other stakeholders in establishing legislative, administrative or policy measures on ABS and/or in negotiating contractual ABS arrangements, the CBD Conference of the Parties adopted in 2002 the voluntary Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of the Benefits Arising from their Utilization which now should be read together with the obligations of the CBD and its Nagoya Protocol.

when such a product is available without restriction to others for further research and breeding. In the latter case, the recipient who commercializes the resource is only encouraged to make such payment. Therefore, commercialization of a product alone does not trigger a compulsory payment of monetary benefits. Instead, commercialization needs to go along with further restriction on the use of the materials accessed from the MLS. The triggering point is the enclosure of research results on the genetic materials through the apposition of intellectual property rights.

The MLS can be considered as a common pool of resources. Common pools have been characterized as an alternative resource management approach to privatization and governmental regulation. The main objective of a common pool is resource management for the benefit of all, leading to sustainability, efficiency and equity. Common-pool resource systems are traditionally used for ecosystem management such as rivers and pastoral land (Ostrom, 1990). Nowadays, pool systems are also increasingly used in the area of knowledge and in the area of public health. A similar common-pool approach could provide an opportunity to preserve the public domain status of MGR from ABNJ, if this was the policy objective. A multilateral approach may also offer the advantage of lowering transaction costs and avoiding delay in the transfer of resources.

However, the MLS presents some shortcomings in terms of insufficient incentives that have been given to the private sector to join the system, and in terms of efficiency. First, the common pool of resources within the MLS is very limited, and excludes some crops of fundamental importance for food and agriculture, leaving the door open for bilateral case-by-case negotiation of benefit-sharing. Second, any Contracting Party can decide at any moment to opt out of the system (and to seek private rents by doing so), either by introducing restrictions on the use of materials held in a collection within their national boundaries, or by imposing restrictions on the use of materials originally collected in their country, but held in a collection in another country (Halewood, 2012). Third, it usually takes a decade or more to reach the commercialization stage of a new product developed from materials accessed from the MLS and so to trigger eventual benefit-sharing. Finally, the material scope of the MLS is restricted to plant genetic resources for food and agriculture with a strong focus on ensuring food security. A similar selection seems to be impossible for the management of MGR from ABNJ.

The Pandemic Influenca Preparedness Framework

The World Health Organization’s (WHO) Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits (PIPF) is a new multilateral mechanism for exchanging viral samples, relevant epidemiological information, as well as resulting benefits and vaccines (see also the Information Paper 5 on *Types of Benefits and Benefit-sharing*). Its novelty is the benefit-sharing obligation for institutions which are not part of the Global Influenza Surveillance and Response System (GISRS). These institutions are now requested to share the actual benefits of commercial research (in the form of vaccines, medical treatment, relevant production licenses or similar means) on the basis of a material transfer agreement concluded among the WHO and the relevant non-GISRS institution. The benefits are not shared with countries on a bilateral basis but with the WHO membership as a whole (i.e. in a multilateral framework).

The Framework offers to the users two different binding standard material transfer agreements (SMTA) which apply automatically when an actor participates in the GISRS. SMTA1 is to be used for exchanges within the system and SMTA2 with outsiders (which can also be commercial companies). Both SMTAs state that the recipient shall only further transfer the PIP biological material if the prospective recipient has concluded an SMTA with the WHO (and not with the National Influenza Centers providing the samples). Any further transfer shall be reported to the WHO. For GISRS laboratories, any breach of a relevant SMTA may be sanctioned with the suspension or revocation of the laboratory's WHO designation.

The PIPF system functions more as a common pool of resources, rather than a bilateral exchange system (Wilke, 2013), as stakeholders submit and share different resources (biological samples, epidemiological information, vaccines and medical treatment) for the free access and use of others, including outsiders that are bound by some terms of reference of the framework once they accept to adhere to it.

While it is too early to evaluate the efficiency of the Framework, a few shortcomings and innovations are already evident. A shortcoming is that the PIPF is limited to H5N1 and other influenza viruses with human pathogenic potential only. A strength, however, is represented by the benefit-sharing obligation which requires outsiders to choose at least four out of a list of 10 possible benefits.

3. Regional Regimes

Apart from these global regimes related to genetic resources, a number of regional ABS regimes already exist.

Andean Pact Decision 391 on the Common Regime on Access to Genetic Resources was the first regional instrument in response to the CBD's ABS regime. It provides a legally binding common framework with minimum legal requirements for accessing genetic resources *in-situ* and *ex-situ* in order to create conditions for the sharing of benefits. The scope of the Decision covers genetic resources, their derivatives and intangible components (knowledge, innovations and practices) provided by the Member Countries from which they originate. It also applies to genetic resources of migratory species, the natural ranges of which include the territories of Member Countries.

The draft Framework Agreement on Access to Biological and Genetic Resources developed by the Association of South East Asian Nations (ASEAN) has the objectives, amongst others, to ensure cooperation among ASEAN Member States in the utilization of biological and genetic resources and the provision of acccess to these resources; to ensure that ABS regulations within the ASEAN region are uniform and consistent with minimum requirements; to promote technology transfer and capacity-building at the regional, national and community levels and involving local communities in the negotiation of benefits. The scope covers biological and genetic resoruces, including derivatives and, where applicable, intangible components. The Agreement explicitly states that Member States shall not allow the patenting of plants, animals, microorganisms or any parts thereof. It is interesting to note that a Common Fund for Biodiversity Conservation is created sourced from shares in the revenues derived from any commercialization of the use of shared resources, shares of a portion of the national fees to access resources, and shares of a portion of whatever benefit-sharing is negotiated by each Member States.

The African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources was developed by the African Union as a framework for developing national ABS instruments reflecting the needs and priorities of each individual African country. It provides conditions for access to biological resources (both *in-situ* and *ex-situ*) – including genetic resources – and their derivatives. It also extablishes the Community Gene Fund, an autonomous trust to support monetary and non-monetary benefit-sharing.

The Central American Agreement on Access to Genetic Resources and Bio-chemicals and related Traditional Knowledge was developed by the Member States of the Central American Commission on Environment and Development. The draft agreement is meant to regulate access to genetic resources and related traditional knowledge, innovations and practices of Member States in order to ensure the fair and equitable sharing of benefits arising out of their utilization. The agreement also covers the protection of traditional knowledge, innovations and practices, regional cooperation and institutional mechanisms.

Finally, a draft Charter on ABS is currently being developed by the Mediterranean Science Commission (CIESM). CIESM promotes communication and active cooperation among marine scientists of various disciplines engaged in research on the Mediterranean and the Black Seas. It aims at the development of scientific standards across the Basin. The ABS Charter is built upon nine clear fundamental principles or core values to favor marine research and development, while preventing abuses of the ocean global commons. It is designed to facilitate the dialogue among the different parties engaged in negotiation for the access and use of MGR; it provides ethical guidelines to providers, enquirers and end-users regarding these issues; and it emphasizes essential core values as transparency, reciprocal relations, traceability, certainty of property rights, public domain conditions in case of non-commercial use, as well as fair and equitable sharing of benefits (monetary and non-monetary) arising from the use of genetic resources. This novel instrument has vocation to be applied in future sampling campaigns within and beyond national jurisdiction.

Such regional ABS instruments allow provider countries with similar biological and genetic resources to establish the same (or comparable) ABS conditions and procedures. They may introduce common ABS measures automatically applicable in all neighboring countries (as is the case for the Andean Decision 391), they may provide a framework/guidance for the development of individual but harmonized ABS laws and regulations in each country, or the may promote voluntary standards and best practices (as in the case of CIESM). Regardless of the concrete approach taken, regional harmonization and standards may provide a means to promote legal clarity and certainty. Furthermore, joint trust funds and benefit-sharing strategies may be developed which can be linked to regional conservation activities.

While experience with respect to the implementation of these regional regimes is limited, major shortcomings are: the high transaction costs, the strong focus on controlling access to the detriment of facilitating access, and the fact that regional cooperation mechanisms for sharing benefits accruing from common resources have not yet been implemented.

4. Experiences and Best Practices

One of the most promising sources of marine genetic diversity is microbes (see also Information Paper 2 on *Extent and Types of Research, Uses and Applications*). Experiences from the microbial research community will be presented in the following as they might be considered as providing elements of so called best practices.

The World Federation of Culture Collections

The microbial research community is organized around the World Federation of Culture Collections (WFCC) which is concerned with the collection, authentication, maintenance and distribution of cultures of microorganisms and cultured cells. WFCC's aim is to promote and support the establishment of culture collections and related services, to provide liaison and set up an information network between the collections and their users.

The situation of the culture collections is characterized by a high level of interdependency[4] leading to intense collaboration and exchange amongst culture collections. More than 80% of the collections belong to public sector entities: 8% are semi-governmental, 4% private non-profit, and 1% industry. The latter two are more likely to impose restrictive license conditions.[5] However, most of the collections are publicly funded, with a strong commitment to the public availability of biomaterials.

The exchange of microorganisms between culture collections follows an informal pattern – i.e. between scientists, based on trust, and without a material transfer agreement (MTA) – and a formal one under the framework of quality management standards that guarantee integrity of the materials exchanged (Stromberg *et al*., 2006; Dedeurwaerdere, 2009). ABS awareness is generally very low in the field of microbial genetic resources (Dedeurwaerdere, 2009). However the culture collections have undertaken steps towards the practical implementation of ABS, such as the development of the Microorganisms Sustainable Use and Access Regulation International Code of Conduct (MOSAICC) and the World Data Centre for Microorganisms (see also the Information Paper 8 on *Exchange of Information on Research Programs Regarding Marine Biodiversity in Areas beyond National Jurisdiction*).

The microbial research community provides interesting experiences for several reasons:

- It applies a global framework for the exchange of microbial genetic resources, in line with the CBD framework, but also covering MGR from ABNJ.
- At least in the case of culture collections established with public funds and embracing the open access policy, this framework implements the concept of common pools of resources (Dedeurwaerdere *et al.*, 2012).
- Most (if not all) scientists, but also the private sector rely on it.
- The geographical origin of the resources (more and more often their GPS coordinates) is usually specified at the time of the deposit of the strains.
- While there is no general benefit-sharing policy for the use of marine microbes from ABNJ, culture collections handle this loophole on a case-by-case basis.
- Finally, this framework is based on a consolidated scientific sharing ethos.

On the other hand the WFCC framework also presents some shortcomings: the group of users is rather small; its substantive scope is limited comprising only culturable microorganisms, which is a very limited part of all microorganisms; there is a considerable risk of free-riding; individuals providing the materials can impose restrictions on their use through a verbal agreement including restriction of use to the host laboratory only; the

[4] The largest culture collection, with approximately 25.000 strains, holds less than 2% of the total number of strain holdings of the WFCC members and only an estimated 1.5% of the total biodiversity of unique strains holdings in the WFCC collections.
[5] An example is the American Type Culture Collection that affirms its ownership over the collection and allows only transfer for research purposes within the purchaser's laboratory, but still attracts interest both from developing and developed countries.

informal network can be possibly threatened by restrictive access policies (e.g. American Type Culture Collection). Therefore, the framework of the microbial culture collections needs to be further institutionalized and harmonized.

The European Culture Collection Organization

The European Culture Collection Organization (ECCO) comprises 61 culture collections from 22 European countries. The ECCO has adopted a core MTA[6] with the objective to make biological material from ECCO collections available under the same core conditions, which are to be implemented by ECCO members as such. The MTA is based on the following core clauses:

- The material exchanged within this MTA shall be used only for non-commercial purposes.
- Recipients are allowed to transfer the material to third parties involved in legitimate exchanges (i.e. scientists working in the same lab or partners in different institutions collaborating on the same project), if they use the same licensing conditions (viral license clause).
- In case of commercial utilization, recipients will have to negotiate in advance and in good faith the terms of benefit-sharing with the country of origin.

EU Micro B3 ABS Agreement

The European Union funded research project Micro B3 (Biodiversity, Bioinformatics, Biotechnology) aims at developing innovative bioinformatic approaches and a legal framework to make large-scale data on marine viral, bacterial, archaeal and protists genomes and metagenomes accessible for marine ecosystems biology, and to define new targets for biotechnological applications. The consortium is made up of 32 partners from 14 countries, 25 from the academic field and 7 small and medium enterprises. The research target are marine metagenomes, within and beyond national jurisdiction.

Under Micro B3 an open bio-informatics system of research integrated data will be developed representing a common pool of data extracted from MGR that will be collected through the Ocean Sampling Day (OSD) (see also the Information Paper 8 on *Exchange of Information on Research Programs Regarding Marine Biodiversity in Areas beyond National Jurisdiction*).The project consortium is currently developing an innovative standard ABS agreement to be used within OSD, whose main features are:

- Distinction between research and development for the public domain and proprietary research and development;
- A viral license clause according to which transfer to third parties is allowed only through an MTA which includes the same conditions for use and transfer of the genetic resources and dissemination of the knowledge as the standard agreement;
- Focus on non-monetary benefit-sharing with the provider countries, including access to integrated data, capacity-building, involvement in the research pipeline and scientific assitance;
- Come-back clause for re-negotiation of monetary benefit-sharing in case of commercialization of products developed with the acceeded genetic resources;

[6] Available at www.eccosite.org/MTA_core.html accessed 10/03/2013.

- Tracking of the geographical origin of the acceeded genetic resources, including in ABNJ; and
- References to best practices of the scientific community.

5. Conclusions

A regime for the management of genetic resources in general may be considered successful if it is able to balance the following interests: to guarantee sustainable multiple uses of biodiversity, to guarantee the widest access possible to the resources to different operators in order to foster scientific research, and to guarantee an equitable share of the benefits (monetary and non-monetary) with the country of origin and the operators that contributed to the development of new products and technologies.

Multilateral approaches aiming to ensure equitable access to and use of genetic resources have been undertaken in different sectors. These may provide interesting experiences to address critical issues in the management of MGR in ABNJ. Global regimes on genetic resources indicate some innovative instruments dealing with intellectual property rights and the public domain approach; benfit-sharing obligations; and the building of common pools of resources. Regional frameworks provide interesting steps toward harmonizing policies and fostering cooperation among the member countries, but some of them are lacking in terms of implementation or in terms of effectiveness.

The best practices adopted by the scientific community (such as the georeferencing of the Genomic Standards Consortium, the Globally Unique Identifier of the WFCC and the CIESM ABS Charter) are important efforts towards awareness-raising and voluntary standard setting (e.g. concerning the origin of genetic resources, including from ABNJ).

Finally, the policy option of establishing common pools of resources may offer the advantages of preserving the public domain condition of common or shared resources and of providing, without impairing commercial applications, the main benefit-sharing that is usually sought: access to resources or to data and research results for the benefit of mankind.

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Exchange of Information on Research Programs Regarding Marine Biodiversity in Areas beyond National Jurisdiction

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1. Introduction

Access to research results and data is a potential non-monetary benefit that, to a large extent, is already shared in practice in the context of marine genetic resources (MGR) from areas beyond national jurisdiction (ABNJ). This will be shown in the following paper by giving an overview of: the relevant legal framework under the United Nations Convention on the Law of the Sea (UNCLOS); existing codes of conduct providing voluntary frameworks and guidelines for exchange of information; ongoing or planned research activities, programs and expeditions; and important criteria for access and dissemination policies for databases.

2. Legal Framework under UNCLOS

The UNCLOS includes provisions on marine scientific research (MSR)[3] both within and beyond areas of national jurisdiction. These are directly relevant for the exchange of information on research programs regarding marine biodiversity in ABNJ, as well as their results. In particular, states and competent international organizations are required to:

- Promote international cooperation in MSR for peaceful purposes (Article 242.1);
- Cooperate to create favorable conditions for the conduct of MSR (Article 243);
- Make available by publication and dissemination through appropriate channels a) information on proposed major programs and their objectives, and b) knowledge resulting from MSR (Article 244.1); and
- Actively promote the flow of scientific data and information and the transfer of knowledge resulting from MSR, especially to developing States (Article 244.2).

MSR in the Area is to be conducted exclusively for peaceful purposes and for the benefit of mankind as a whole (Article 143.1). The provisions dealing with MSR in the Area impose on states and/or the International Seabed Authority (ISA) the following obligations of particular relevance to exchange of information on research programs:

- Promoting international cooperation through participation in international programs

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[3] Part XIII of UNCLOS is dedicated to marine scientific research.

and encouraging cooperation in MSR by personnel of different countries and of the ISA (Article 143.3(a) – obligation for states);

- Effectively disseminating the results of research and analysis through the ISA or other international channels when appropriate (Article 143.3(c) – obligation for states);
- Coordinating and disseminating the results of research and analysis when available (Article 143.2 – obligation for the ISA); and
- Engaging in capacity-building by ensuring that international programs are developed through the ISA or other international organizations for the benefit of developing and technologically less developed states with a view to, amongst others, strengthening their research capabilities, and fostering the employment of their qualified personnel in research in the Area (Article 143.2(b) – obligation on states).

It is important to note in this context that the Intergovernmental Oceanographic Commission (IOC) of UNESCO is the United Nations body for ocean science, ocean observatories, ocean data and information exchange, and ocean services. Its mission is to promote international cooperation and to coordinate programs in research, services and capacity-building to learn more about the nature and resources of the oceans and coastal areas, and to apply this knowledge to improved management, sustainable development and protection of the marine environment and the decision-making processes of states.

Furthermore, the following sections will indicate that the scientific community is already implementing to some extent the above mentioned UNCLOS obligations, also as far as MGR in ABNJ are concerned.

3. Global and Regional Codes of Conduct

A number of voluntary frameworks have been developed which provide guidance on different research related aspects, including the exchange of information.

InterRidge Code of Conduct

The InterRidge[4] Code of Conduct for Responsible Research Practices at Deep-sea Hydrothermal Vents provides guidelines for scientists, most of them related to environmental protection, conservation and sustainable use. Guidelines related to information exchange encourage scientists to:

- Familiarize themselves with current and planned research in an area, and assure that own research activities and plans are known to the rest of the international research community through InterRidge and other public domain databases (Paragraph 5); and
- Facilitate the fullest possible use of biological, chemical and geological samples collected through collaboration and cooperation amongst the global community of scientists, and commit to open international sharing of data, ideas and samples in order to avoid unnecessary re-sampling and impact on hydrothermal vents, and to further global understanding of these habitats (Paragraph 6).

[4] InterRidge is a non-profit international organization, comprised of 30 Member States and 2,500 Member Researchers, concerned with promoting all aspects of mid-ocean ridge research. It promotes interdisciplinary, international studies of oceanic spreading centers by creating a global research community, planning and coordinating new science programs, exchanging scientific information, sharing new technologies and facilities, encouraging the protection and management of the oceanic ridge environment and promoting communication between non-scientists, scientists, educators and policy-makers.

InterRidge is committed to open international information exchange as a result of which open databases were developed. InterRidge continues to provide detailed information on all available vent biological samples preserved in laboratories and museums around the globe. In addition, many national ridge programs are hosting open-access databases of geological, chemical, and biological hydrothermal vent data. However, the level of effectiveness of, and interest among scientists in, the InterRidge Code of Conduct is not yet clear. Godet *et al.* (2011) indicate the difficulty to measure the extent to which scientists are aware of or comply with the Code. Nevertheless, codes of conducts are considered important and useful best practice but probably not a sufficient measure to ensure sustainability in research activities.

MOSAICC Code of Conduct

The World Federation of Culture Collections (WFCC) has adopted the Micro-organisms Sustainable use and Access regulation International Code of Conduct (MOSAICC) to facilitate access to microbial genetic resources and help partners in the development of appropriate material transfer agreements (MTA) in line with the obligations of the Convention on Biological Diversity and other applicable international and national law. MOSAICC combines the need for easy transfer of microbial genetic resources and the need to monitor such transfer. The MOSAICC MTA contains terms on training, technical and scientific cooperation, technology transfer, capacity-building, exchange of information and publication policy. Furthermore, the MOSAICC database registers the culture collections through a unique acronym and numerical identifier in its official list.

OSPAR Code of Conduct

The geographical scope of the Convention for the Protection of the Marine Environment of the Northeast Atlantic (OSPAR Convention) includes large areas of deep and high seas. Parties to the OSPAR Convention have agreed on a Code of Conduct for Responsible Marine Research in the Deep Seas and High Seas of the OSPAR Maritime Area. OSPAR adhere to the code of conduct when planning and carrying out their research. Moreover it calls on Contracting Parties, when assessing research plans, to ensure that the granting of research funds and ship time should be contingent on the application of the code of conduct.

Most of its provisions are related to environmental protection, conservation and sustainable use. With regard to marine research, including research on MGR, the OSPAR Code of Conduct provides guidelines on:

- International cooperation – Scientists should ensure the fullest possible use of all biological, chemical and geological samples through collaborations and cooperation within the global community of scientists. Samples that can be archived should be placed in accessible repositories for future use.
- Information exchange – Scientists should a) make themselves familiar with current and planned research in an area; and b) ensure that their own research activities and plans are known to the rest of the international research community via appropriate public domain databases and websites.
- Sharing of data, results and samples – Scientists should practice international sharing of data, samples and results in order to minimize the amount of unnecessary sampling.

CIESM Charter on ABS

The Mediterranean Science Commission (CIESM) is now in the process of adopting a Charter on ABS (see also the Information Paper 7 on *Global and Regional Regimes on Genetic Resources, Experiences and Best Practices*). This Charter is designed to facilitate the dialogue among the different parties engaged in negotiation for the access and use of MGR. It provides ethical guidelines to providers, enquirers as well as end-users, and emphasizes essential core values, such as transparency, reciprocal relations, fair and equitable sharing of benefits arising from the use of genetic resources. With regard to exchange of information, Core Value 7 on Concerted Handling of Commons calls, in cases of non-commercial use, for

- Simultaneous sharing of the data with all the active partners in the project and provider country; and
- The deposit of the data in the public domain, open access to the materials, related information and results (*in-situ* and *ex-situ* collections) as soon as possible.

Core Value 6 on Reciprocal Relations calls for cooperation of scientific communities (including from the provider country) in all aspects from design of campaigns to data analysis; and for capacity-building with the scientific community of the provider country on technical and legal aspects.

4. Research Programs and Initiatives

Much global and regional research on the world oceans is organized within research programs and initiatives, although research is also conducted independent of these. Such programs and initiatives often develop data-sharing principles and promote full and open exchange of data. The following table provides a non-exhaustive list of interesting research programs and initiatives targeting marine biodiversity.

Table 1: Selected Global and Regional Research Programs and Initiatives

Name	Scale	Interesting Aspects
Global Ocean Observing System (GOOS)	Global	- Coordinated approach to deployment of observation technologies, rapid and universal dissemination of data flows and delivery of marine information - Permanent global system for observations, modeling and analysis of marine and ocean variables to support operational ocean services worldwide - Provides accurate descriptions of present state of oceans, including living resources
International Oceanographic Data and Information Exchange (IODE)	Global	- Enhances IOC marine research and management programs - Facilitates exploitation, development and exchange of oceanographic data and information between participating Member States
Ocean Biogeographic Information System (OBIS)	Global	- World's largest open access, online repository of spatially referenced marine life data (migrated in 2010 under the auspices of IODE)
Census of Marine	Global	- Assessment of diversity, distribution, and abundance of ➡

Life		marine life - Allowed synergetic increase and globalization of knowledge through production of new research outputs, promotion of international cooperation among 80 countries, interoperability of existing databases, open access publication, capacity-building, standardizing sampling protocols - Partnerships with Encyclopedia of Life, World Register of Marine Species, Marine Barcode of Life, and Catalogue of Life projects
United Nations Global Earth Observation (UN GEO)	Global	- Partnership of governments and international organizations to develop new projects and coordinate strategies and investments - Global Earth Observation System of Systems (GEOSS): links existing and planned observing systems worldwide, supports development of new systems where gaps exist - GEOPortal: contains data, imagery, and analytical software packages relevant to all parts of the globe - GEONETCast: uses telecommunication satellites to provide similar information for users with limited access to Internet
Genomes Online Database (GOLD)	Global	- Online database providing access to information regarding genome and metagenome sequencing projects and associated metadata - No access to sequence data but only to information about sequencing projects - Accurate and efficient genome project tracking is vital criterion for launching new genome sequencing projects
Partnership for Observation of the Global Oceans (POGO)	Global	- Partnership of major institutions involved in oceanographic observations, scientific research, operational services, education and training - Focus more on information relating to topics than on specific MGR - POGO database accessible to the - public
International Network for Scientific investigation of deep-sea ecosystems (INDEEP)	Global	- Program to develop and synthesize understanding of deep-sea global biodiversity and functioning that was started under Census of Marine Life - Framework to bridge gap between scientific results and society to aid in formation of sustainable management strategies - Currently around 350 members representing 35 different countries
Integrated Ocean Drilling Program (IODP)	Global	- Program exploring Earth's history and structure recorded in seafloor sediments and rocks, and monitoring sub-seafloor environments - Builds upon earlier successes of Deep Sea Drilling Project (DSDP) and Ocean Drilling Program (ODP) - New program ("International Ocean Discovery Program - Exploring the Earth Under the Sea) planned by 26 nations
Genomic Observatories	Global	- Collaboration between Genomic Standards Consortium (GSC) and Group on Earth Observations Biodiversity

Network (GOs Network)		Observation Network (GEOBON) - Application of cutting-edge genomic technologies to observe flux of genetic variation across human and natural ecosystems - Genetic data linked to other biophysical and socioeconomic data; resulting information integrated in predictive models mapping quality and distribution of biodiversity and ecosystem services under various scenarios of human activity
EUROFLEETS	Regional	- Alliance of marine research centers across Europe to collaborate and share resources in order to improve quality of marine research - Provides transnational access to data and results, and access to ocean research vessels and equipment (knowledge and technologies across fields and between academia and industry) - Database available to the public working in conjunction with SeaDataNet, EurOcean, ISOM (International Research Ship Operators' Meeting), ERVO (European Research Vessel Operators), and POGO - Submissions from non-EUROFLEETS members encouraged - Development of innovative software for acquisition and analysis of data on board, and interoperable devices for use on European research submarines
International Council for the Exploration of the Sea (ICES)	Regional	- Network of more than 1,600 scientists from 200 institutes in 20 Member Countries linked by ICES Convention - Coordinates and promotes marine research on oceanography, marine environment, marine ecosystem, and on living marine resources in North Atlantic - Fills knowledge gaps; provides unbiased, non-political advice to support management of North Atlantic Ocean and adjacent seas

5. Databases

There are a large number of databases that provide information on research activities and/or their results, which also relate to marine biodiversity and MGR in ABNJ. However, it needs to be considered that the utility of such databases in practice depends on different criteria, such as the level of interoperability, the access criteria applied, and the target user. In the following, these criteria will be briefly explained and illustrated by selected database examples.

- **Interoperability**

Interoperability refers to the functionality of a database to operate in conjunction with other databases and thus the flexibility and ease of data retrieval. The utility of a database thus depends to some extent on how integrated the database can be with others. With an appropriate level of interoperability information of the same "kind" can be accessed in different databases with a single query, information can be shared between databases, and a complex query can draw on several databases simultaneously to build an answer. Requirements for interoperability include use of terminology that can be either harmonized or easily mapped to a single exchange standard, and use of exchange standards to allow communication between query systems and databases. These standards are developed through such bodies as

Biodiversity Information Standards (see www.tdwg.org). Another prerequisite for interoperability of a database is its accessibility through the Internet. Consequently, databases are non-interoperable if they are completely stand-alone, use idiosyncratic data modeling, architecture, software and terminology, and cannot be accessed from outside.

Table 2: Elements of Interoperability

Database	Elements of Interoperability
International Nucleotide Sequence Databases (INSD)	- Joint effort to collect and disseminate databases containing DNA and RNA sequences - Developed and maintained collaboratively by 3 main public databases: DNA Data Bank of Japan (DDBJ), European Nucleotide Archive (ENA) and GenBank - Allowed sharing of most sequence data produced through public, and sometimes private, funds since late 90's - Submission of primary data to these databases now mandatory as prerequisite for publication of genetic studies in most scientific journals, in particular peer-reviewed literature
SeaDataNet	- Standardized system for managing large and diverse data sets collected by oceanographic fleets and automatic observation systems - Established a network of national oceanographic data centers of 35 countries through unique virtual data management system that shall provide integrated data sets of standardized quality online - Acknowledges importance of access to data for marine research, and difficulty of accessing such collected data in currently highly fragmented infrastructure
Data Portal of the Global Biodiversity Information Facility (GBIF)	- Makes available point source and observational data shared by hundreds of data publishers worldwide, all using standards that can be mapped to one another - Taxonomic names provided by: Catalogue of Life initiative (www.catalogueoflife.org/), consortium of providers using an interoperable system - Data shared according to GBIF Data Use Agreement (http://data.gbif.org/tutorial/datauseagreement): users of data accessed through GBIF Portal will always give credit to original data publishers
ASSEMBLE	- EU FP7 research infrastructure initiative, comprising network of marine research stations in Europe - Aims at establishing three-tier system with (1) local databases hosted by ASSEMBLE partners (specific to the biological resource(s) maintained and representing day-to-day point of data input and management) (2) centralized data-base which will harvest data from distributed sites (3) ASSEMBLE website where database will be presented in standardized format
EU-OPENSCREEN (European Infrastructure of	- Builds on existing national networks of 14 countriesAims at integrating high-throughput screening platforms, chemical libraries,

Open Screening Platforms for Chemical Biology)	chemical resources for hit discovery and optimization, bio- and cheminformatics support, and a database containing screening results, assay protocols, and chemical information

- **Access**

Access criteria determine who may access the data and under what conditions. Databases usually develop their own distinct data policies which may apply (or not) different restrictions and/or licensing requirements for access, distribution and use of data. Furthermore, frameworks for intellectual property issues may be established in order to allow for the early protection of knowledge before it is published in a database, and to find the necessary balance between rapid knowledge sharing and exploitation activities. For example, patents or other intellectual property rights may be claimed with regard to all or a portion of the submitted data, and/or the release of information may be withheld for a specified period of time prior to publication. Finally, it is important to note that many of the databases illustrated above have adopted an open access policy.

Table 3: Elements of Database Policies

Database	Elements of Database Policies
International Nucleotide Sequence Databases (INSD)	- Free and unrestricted access to all data records contained in databases - No use restrictions or licensing requirements for any sequence data records - No restrictions or licensing fees placed on redistribution or use of database - Database records submitted become permanently accessible as part of scientific record - Submitting parties must ensure right to submit data - Copyrights: appropriate credit given by citing original submission, following practices of scientists utilizing published scientific literature
SeaDataNet	- Aim to strike balance between rights of investigators and need for widespread access through free and unrestricted sharing and exchange of SeaDataNet data, meta-data and data products - SeaDataNet User License: licensor grants to licensee non-exclusive and non-transferable license to retrieve and use data sets and products from SeaDataNet service in accordance with license - Retrieval, by electronic download, and use of data sets free of charge, unless otherwise stipulated - Data users should not give to third parties any SeaDataNet data or product without prior consent from data source - Data Users must respect any restrictions on use or reproduction of data - Use or reproduction of data for commercial purpose might require prior written permission from data source - Copyrights: users must acknowledge data sources, i.e. any person making substantial use of data must communicate with data source prior to publication, and should possibly consider data source(s)

	for co-authorship of published results
International Council for the Exploration of the Sea (ICES)	- Encourages public availability of data, but allows providers to place restrictions on use - Data users can obtain data but must respect all restrictions on use of data such as for commercial purposes - Data users must acknowledge data source - Data should be submitted as early as possible after collection - All data submitted to ICES considered to be in public domain unless otherwise explicitly specified and agreed
European Bioinformatics Institute (EBI)	- EBI (part of European Molecular Biology Laboratory (EMBL)) manages databases of biological data including nucleic acid, protein sequences, and macromolecular structures - Mission: provide freely available data and bioinformatics services to all facets of scientific community in ways that promote scientific progress; coordinate biological data provision throughout Europe - Public databases of EMBL-EBI freely available by any individual and for any purpose - No restrictions on use or redistribution of data available

- **Target user**

Finally, the utility of databases also depends on their target users, i.e. the question who are the databases for. The answer to this question depends on the type of data held, how such data can be accessed, and for what purposes it can be used. Generally scientific databases mainly target scientists from different disciplines. However, many of them also have the intent to render their data understandable by the general public. It should be also noted that there may be issues of fitness for use of data, in particular if the data was collected for a purpose which is different from the one a user intends. The rationale of data collection, the processes which they have been taken through, and the sampling strategy leading to what is presented, may all have to be considered and understood before use.

6. Conclusions

The above analysis shows that binding and non-binding rules, guidelines and practices already exist at global and regional levels with regard to international cooperation in, and promotion of, scientific research, as well as the exchange of information on research programs regarding marine biodiversity in ABNJ. While these rules and guidelines may not necessarily apply only to the collection of, and research on, MGR from ABNJ, they still provide an interesting source of information for policy-makers to consider.

Although the current rules and practices facilitate the exchange of information to a certain extent, a comprehensive and authoritative system/regime for exchanging information is still lacking, in particular for MGR from ABNJ. Current cooperation and information exchange systems tend to be linked to geographical locations or types of research involved. Many of these efforts do not distinguish between MGR originating within or beyond areas of national jurisdiction. Furthermore, differences exist with regard to rules of confidentiality as well as protection of intellectual property rights. As a consequence, information is scattered and cooperation is lacking efficiency.

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