

# Micro B3: Marine Microbial Biodiversity, Bioinformatics and Biotechnology

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## Workpackage 8: Intellectual Property Management for Marine Bioprospecting

**Task 8.1: Model agreements for pre-competitive access to microbial materials and exchange of materials and data within research networks**

**Deliverable 8.1. Part 1: Report on literature review for pre-competitive access to microbial materials**

**Deliverable 8.1. Part 2: Synthesis report on model contracts on pro-competitive access to marine microbial resources and exchange of data and materials**

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## List of Abbreviations

ABS	Access and Benefit Sharing
BS	Benefit Sharing
CBD	Convention on Biological Diversity
COP	Conference of the Parties
EEZ	Exclusive Economic Zone
EU	European Union
GR	Genetic Resource
GTLE	Group of Technical and Legal Experts
MAT	Mutually Agreed Terms
MSR	Marine Scientific Research
MTA	Material Transfer Agreement
nm	Nautical Miles
PIC	Prior Informed Consent
R&D	Research and Development
SBSTTA	Subsidiary Body on Scientific, Technical, and Technological Advice
TK	Traditional Knowledge
UN	United Nations
UNCLOS	United Nations Convention on the Law of the Sea
UNEP	United Nations Environment Programme
UNGA	United Nations General Assembly
WG-ABS	Ad Hoc Open-Ended Working Group on Access and Benefit-sharing

## Introduction

Workpackage 8 is aimed at elaborating the legal framework for intellectual property management concerning marine bioprospecting. Intellectual property management comprises three major sets of rules: rules of resource states determining access to their marine genetic resources and claiming a share of the benefits based on them, the rights and duties of researchers exchanging material and data outside or inside material collections and data banks, and the law on patent and copy right protection for users on results from R&D of marine genetic resources. The first deliverables of WP 8 are concentrated on the first two sets of rules: those concerning access and benefit sharing (8.1), and those concerning access to material and data (8.2). The tasks of deliverable 8.1. are specified in the research programme as research step 8.1.1 which shall comprise a “review of relevant legislation on pre-competitive access to marine microbial resources and exchange of material and data” as well as a “synthesis report on model contracts on pre-competitive access to marine microbial resources and exchange of material and data”. The following first text follows the structure in these two tasks. The first part (Part 1) is an analysis of the legal framework and literature on access to marine genetic resources and benefit sharing, as required. The second text (Part 2) includes a catalogue of collected model agreements on access to genetic resources and participation in material and data bases (these model agreements are on file with UCL) (I.) and a draft model agreement for access to marine genetic resources and the exchange of material and data (II.) that can be used by MicroB3 partners when acceding to genetic resources and using them for R&D. This somewhat deviates from the second deliverable as described in the programme, which was to be a synthesis report. We found it superfluous to produce a separate analysis of the many model agreements. Rather we proceeded immediately to drafting a model agreement for MicroB3 purposes taking bits and pieces of the collected existing model agreements into account.

One terminological clarification appears appropriate concerning the distinction between non-commercial and commercial R&D activities. This distinction which is suggested by the Nagoya Protocol (NP) is also important for the MicroB3 project because the two notions have different effects on access and benefit sharing rights and obligations. We suggest first of all to take “non-commercial/commercial” to be synonymous with “pre-competitive” and “competitive”, as used in the MicroB3 programme, as well as with “non-proprietary/proprietary” as used in the draft model agreement. In the following first report it

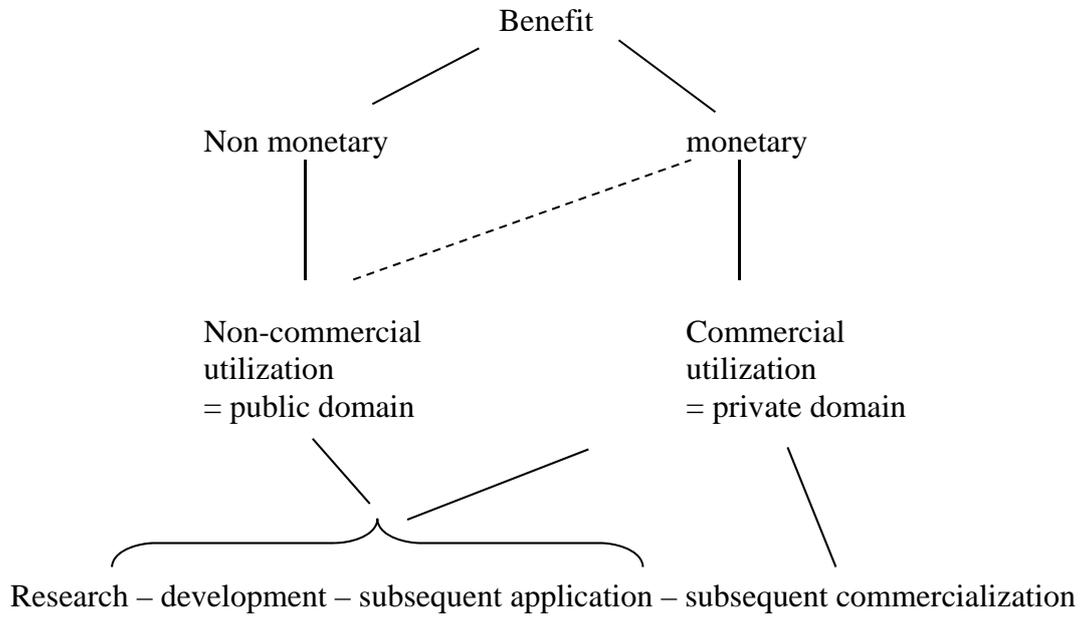
will become clear that the distinction also overlaps (but is not identical) with another one used in the UN Convention on the Law of the Sea (UNCLOS), i.e. “research/research for exploration or exploitation purposes”.

When defining “non-commercial/commercial” three variants are possible and all used in different fora: one looking at research institutions such as universities on the non-commercial side and private enterprises on the commercial side. The second variant looks at an ideal chain of valorization of “raw” organisms through basic and applied research to the development of products, equating non-commercial with basic research and commercial with applied research and development of products. The third takes a functional perspective and distinguishes between R&D for the public domain and R&D for the private domain (or market, or private property). For reasons which are explained in the first of the following texts we suggest the functional approach which means that R&D for the public domain is considered as non-commercial and R&D for the private domain (or proprietary R&D) is considered as commercial. The functional approach asks: are the results from R&D flowing into the public domain (access is free and open to everybody, providers are able to make use of them like anybody else) or into the private domain (the holder claims property on the material and information, access is limited)? In the first case the user may be granted simplified access modalities and only non-monetary benefits are to be shared; the provider may profit from privileged access to research results. In the latter case the user is in general bound to qualified access conditions and obliged to share monetary benefits; the provider shall thus economically profit from proprietary utilization. More details to this argumentation and reasons for rejecting alternative criteria are elaborated later in the following first report (3.2.1.).

Apart from different kinds of utilizations of genetic resources, and especially non-commercial and commercial R&D, the CBD and the Nagoya Protocol introduce the terms monetary and non-monetary benefits drawn from the utilization. This distinction is by and large linked to non-commercial and commercial R&D, but not completely because non-commercial research may sometimes yield monetary benefits such as income from the sales of publications.

The relationship between kinds of benefits and of utilizations are represented in the attached figure. The figure covers two of the approaches to define non-commercial/commercial R&D leaving out the institutional definition. For further elaboration see section 3.2.1. in the following first report.

Overview of terminology



## **Deliverable 8.1.**

### **Part 1: Report on literature review for pre-competitive access to microbial materials**

#### The international law framework of access to marine microorganisms and benefit sharing

A comparison between UNCLOS and the CBD/Nagoya Protocol

#### **Section 1. Introduction**

The primary objective of deliverable 8.1. is to review relevant legislation on “pre-competitive access to marine microbial resources”.

Besides the review of legislative texts we have studied relevant literature on the topic including books, articles and information documents from international organizations such as the UN and the CBD secretariat. In addition we took advantage of the discussions with the participants of Work Package 8 at several project related meetings, including the kick off meeting in Bremen in February 2012, WP8 skype meetings and a workshop in Bonn in November 2012.

Section 2 introduces to the relevant international agreements UNCLOS and the CBD including the Nagoya Protocol. After an overview of the provisions follows a deeper analysis of the definition of the terms “exploration/exploitation” and “marine scientific research” (UNCLOS) and “utilization” and “research for non-commercial purposes” (Nagoya Protocol). In the following, section 3 discusses the legal conditions for accessing genetic resources in the different maritime zones; the first part concerns the territorial sea (3.3.), the second part concerns the EEZ and the Continental Shelf (3.4.) and the third part concerns the Areas beyond national jurisdiction (ABNJ) (3.5.). Each part distinguishes between the requirements for commercial use and those for non-commercial use. Section 4 provides for a summary comparing the international agreements. Section 5 concludes the report with an explanation of the implications the study has for the recent and upcoming tasks within MicroB3.

#### **Section 2. Relevant legal framework under international law**

## **2.1. Historical background**

In a study on the regulation of access to microorganisms in the marine realm two international treaties have to be taken into focus: The United Nations Convention on the Law of the Sea (hereinafter UNCLOS) and the Convention on Biological Diversity (hereinafter CBD). The earlier adopted treaty was the UNCLOS in 1982. At that time it was a prevailing desire to establish a comprehensive regulatory system addressing the use of the ocean space within different maritime zones. While exploring the genetic potential of natural resources was of less importance due to biotechnologies being much less developed than today, mineral resources, oil and fish were the prime objects of potential conflicts between developed and developing countries (UN 1998). The long-needed legal order in this respect therefore addressed in detail the fishing situation and the question of mining while access to marine genetic resources was not as such the object of specific attention during the negotiations of UNCLOS. Nevertheless, as this study will show, the legal terms are broad enough to cover the specific activity (collection) as well as the collected object (marine genetic resources).

Yet, the interest in research on the genetic structure of marine microorganisms, for example for the development of pharmaceuticals to cure diseases or for the creation of cleaner and cost-effective industrial processes, had steadily increased during the following decades and, in parallel, the potential for interest clashing between users and providers of genetic resources had grown. This made it necessary to introduce a reliable international instrument to solve the related upcoming questions and provide a legal fundament for both providers and users when negotiating on access conditions. In this respect, the CBD, which entered into force in 1993, introduced an equitable approach balancing the interests of users and providers of terrestrial and marine genetic resources: the Access and Benefit-sharing mechanism. Within UNCLOS, issues of equity are only cautiously treated, although the preamble postulates an equitable utilization of marine resources (para 4) and the establishment of an equitable international economic order (para 5).

## **2.2 Overview of the provisions**

### **2.2.1 UNCLOS**

The UNCLOS establishes a comprehensive set of rules for all activities that may occur in the marine realm. The General Assembly of the UN states that 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 RES 65/37, preamble para 4). Its objective is not only to contribute to the maintenance of peace and justice in the ocean space, but also to promote an equitable utilization of the ocean resources and the protection and preservation of the environment (UNCLOS, preamble, para 1 and 4). It combines two principles: the principle of state sovereignty over natural resources and the principle that natural resources belong to the common heritage of mankind. According to the geographic location of genetic resources (areas within national jurisdiction or areas beyond national jurisdiction) the principles justify the establishment of different access instruments and conditions.

Within the substantive scope of application, the UNCLOS covers on the one hand exploration and exploitation of non-living and living natural resources which comprise also genetic resources (Dux 2011: 97 at 552) and other economic activities, such as the production of wind energy. On the other hand, the lawmakers sought to give marine scientific research (MSR) a special legal order because the UN has ever since its inception highlighted the importance of marine science “for eradicating poverty, contributing to food security, conserving the world’s marine environment and resources, helping to understand, predict and respond to natural events and promoting the sustainable development of the oceans and seas” (UN 2010: iii).

Every marine medium is addressed (vertical division): the seabed, the subsoil, the water column, and the air space above the waters.

The regulatory regime is divided into different maritime zones (horizontal division): the territorial sea and contiguous zone, the exclusive economic zone (EEZ), the continental shelf, the high seas and the Area.

The nearer a maritime zone is to the coast, the stronger are the rights of the coastal state to regulate access to marine genetic resources. While the coastal state has full national sovereignty over its territorial sea it has less regulatory power regarding its EEZ and even less regarding the part of the continental shelf which lays beyond the EEZ. Being out of the

boundaries of national jurisdiction, the high seas and the Area may be accessed under conditions set forth only by the UNCLOS. Although access to marine genetic resources in areas beyond national jurisdiction is not explicitly regulated by the UNCLOS, it can be argued that some of its provisions are nevertheless applicable.

The details of the regulation of access within the different zones are elaborated in section 3.

### **2.2.2 CBD/Nagoya Protocol**

The CBD introduces a global regulatory mechanism for the conservation and sustainable use of biological diversity without addressing a special part of earth mass. As it covers the marine realm as well, its geographical scope of application overlaps with UNCLOS.

The CBD's objectives are threefold (Art. 1 CBD): the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of benefits arising out of the utilization of genetic resources, including by appropriate access, by appropriate transfer of technology and by appropriate funding. Principles and rules for the implementation of the third objective, for access and benefit sharing (ABS), are laid down in Art. 15, 16.2 and 19.2 CBD and, in greater detail, in the non-binding Bonn Guidelines as well as in the Nagoya Protocol (NP). As the NP is the most precise and consequential of these legal documents it will be referenced as the main legal guidance in the following analysis. It must however be considered that it is not yet in force. It is expected to enter into force in about one or two years. The EU is currently preparing its ratification together with a regulation on the implementation of the provisions regarding compliance obligations of user states.<sup>1</sup>

The concept of ABS is based on the philosophy that conservation and sustainable use of biological diversity is better served when states: (i) provide access to genetic resources situated within their national territory, amongst others for the purpose of meeting the growing food and health needs of a growing world population (CBD, preamble, para 20), and (ii) in return are therefore granted the benefits arising out of the utilization of the genetic potential of these resources. As a result, an incentive for the conservation of biological resources which include these genetic resources (see Art. 2 CBD) shall be created.

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<sup>1</sup> Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union, COM(2012) 576 final.

The cornerstones of the ABS legal framework within the CBD and its Nagoya Protocol are the following:

- Access to genetic resources for their utilization shall be subject to prior informed consent (PIC) of the providing party (Art. 6.1 NP);
- Access shall be granted upon the definition of mutually agreed terms (MAT) (Art. 6.3 NP);
- Access shall be simplified for non-commercial research (Art. 8 (a) NP);
- Benefits arising from the utilization of genetic resources as well as subsequent application and commercialization shall be shared with the providing party (Art. 5.1, 5.4 NP);
- Indigenous and local communities holding genetic resources or traditional knowledge on genetic resources shall equally be asked for their prior consent to access and shall participate in the benefit-sharing (Art. 5.2, 5.5 NP)<sup>2</sup>;
- The Parties are obliged to establish compliance measures (Art. 15, 16, 18 NP);
- Monitoring mechanisms such as the establishment of “checkpoints” are to be introduced (Art. 17 NP);
- The Parties shall cooperate in capacity-building and technology exchange (Art. 22, 23 NP);
- An indicative list of non-monetary and monetary benefits helps to define the benefits that are to be shared according to Art. 5 NP (Annex to the NP).

### **Section 3. Access to marine genetic resources in the different maritime zones**

The following chapter will first examine how access to and utilization of genetic resources can be captured by the provisions of the UNCLOS and the CBD/NP. Especially the question is crucial where to draw a delimitation line between two categories of R&D activities, one being concerned with commercialization and the other not. They bear different names in the UNCLOS and the Nagoya Protocol: exploration/exploitation and marine scientific research within the UNCLOS, and research for commercial and non-commercial purposes within the Nagoya Protocol. These categories shall first be defined, then the rules applicable to them shall be presented taking account of differences attached to the different maritime zones.

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<sup>2</sup> This issue will not be pursued further in this article because it is of minor relevance concerning marine microorganisms.

### 3.1. Categories of R&D on genetic resources

#### 3.1.1. Exploration/Exploitation and MSR under the UNCLOS

As mentioned, the UNCLOS distinguishes between exploration/exploitation and MSR, and attaches different access regimes to them. The two terms play a decisive role in relation to the acknowledgment of sovereign rights of coastal states. While exploration and exploitation according to Art. 56.1 (a) UNCLOS is part of the sovereign rights of coastal states in their EEZ, MSR shall according to Art. 246.3 UNCLOS in principle be free.

The Convention lacks an explicit definition of “exploration” and “exploitation”. Looking simply at the normal linguistic usage, exploration means “an examination of something in order to find out about it” (Oxford Advanced Learner’s Dictionary, online edition): The examination result is purely intellectual and a (non-monetary) benefit as such. On the contrary, exploitation means to “use or develop something (*p.ex. natural resources*) for your advantage” (Cambridge Dictionaries, online edition). The essence of the activity is the focus on the use of the examination result for (monetary) self-benefit. Thus, the character of the purpose behind the two activities is not congruent. However, if the terms are used together, which is mainly the case (preamble, para 6, Artt. 56.1 (a), 153, 246.5 (a), 249.2, 266.2, 269 (a) UNCLOS), the non-monetary exploratory activity cannot be interpreted independently. Because then, it is a preconditional step towards the profit-oriented exploitation activity. Hence, if the collector of marine genetic resources uses the samples for commercial research, he falls under the definitions of “exploration and exploitation”.

Exploration and exploitation provisions which are designed in expression of the coastal state’s territorial sovereignty are opposed to provisions on MSR which direct the regulatory power away from the state’s unlimited discretion. MSR is likewise not legally defined as such within UNCLOS. Yet meanwhile<sup>3</sup> MSR is commonly regarded as an “activity that involves collection and analysis of information, data or samples aimed at increasing mankind’s knowledge of the environment, and is not undertaken with the intent of economic gain” (UNEP/CBD/SBSTTA/8/INF/3/Rev.1, para 47). In general, it aims at openness and free circulation and dissemination of data and research results in the public domain. This is

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<sup>3</sup> –Representative overview on development of definitions for marine scientific research see Vitzthum (2006), margin number, 233-235

underlined by Art. 246.3 UNCLOS which obliges the coastal state to give its consent to MSR if, besides other conditions, it is carried out, “in order to increase scientific knowledge of the marine environment for the benefit of all mankind.” It is common ground that the benefit for all mankind can only be achieved if research results are put into the public domain. This is an “essential characteristic” (Vitzthum 2006: ch. 5 at 235) of MSR. This clearly differs from the profit-oriented and private domain character of exploration and exploitation activities where the product development process is carried out in the private realm for the purpose of establishing property rights in the R&D results. In other words: a researcher who aims at disseminating his research results through the public domain, unexceptionally falls under the regime of MSR (Fedder 2011: 70/71).

While the general provisions on exploration and exploitation do not frame the material and procedural access requirements in greater detail, the MSR regime elaborates on material conditions, on the form of application and on benefit-sharing duties of the involved parties. It is essential mentioning that, according to UNCLOS, MSR may take various forms and may imply different technical features. In that regard different legal consequences are attached depending on the nature and implications of the research project. We will come back to the details later in the study.

The distinction between exploration/ exploitation and MSR is somewhat further complicated by the introduction of a category of research that is “of direct significance for the exploration and exploitation of natural resources” (Art. 246.5 (a) UNCLOS). Systematically it is treated as an exception to the rule that MSR is normally carried out for the benefit of all mankind (see above). The rule attached to this category moves the related MSR into the neighbourhood of exploration/exploitation and thus further into the control of the coastal state.

But what means “of direct significance” in this context? In legal understanding, significance is the importance of something, especially when it has an effect on what happens in the future. This rather broad definition would grasp any production of research results that will be directly important for future commercial profit following also the above definition of what is marine exploration and exploitation. One may question if, in order to qualify for a “direct” significance, it is enough to have the intention to commercialize the results without knowing if the results will be useful, or useless and thus non-profitable. The United Nations Division for Ocean Affairs and the Law of the Sea suggests in a guidance paper that “direct” should be

understood to mean that a project “can reasonably be expected to produce results enabling resources to be located, assessed and monitored with respect to their status and availability for commercial exploitation” (UN 2010: 10). This means that the mere intention must be accompanied by a certain likelihood of commercializability.

We will come back to this question in section 3.1.2. where criteria are developed in order to distinguish non-commercial from commercial activities. This will be helpful to even further substantiate the meaning of “direct significance for the exploration and exploitation of natural resources”.

One more term which is often used in the context of access to and utilization of genetic resources is bioprospection. Although the term does not appear neither in the UNCLOS nor in the Nagoya Protocol we will discuss it because of its practical significance, and try to subsume it to the relevant legal terms.

In the 1990ies bioprospecting was often qualified as pure scientific research (with the consequence that the authorization by the coastal state within the EEZ under Art. 246.3 UNCLOS would have been mandatory). Rothwell/Stevens (2010: 329) are for example of the opinion that “in terms of process surrounding the actual collection of samples, bioprospecting does not differ from pure MSR” and thus should normally be allowed by coastal states. Today the definition has shifted to understanding bioprospection to have an economic orientation. In fact, the definition of the CBD Secretariat (2000) is now widely accepted: bioprospecting can be defined as “the process of gathering information from the biosphere on the molecular composition of genetic resources for the development of new commercial products” ((UNEP/CBD/COP/5/INF/7, para.6).

UNCLOS provisions do not explicitly regulate the case of bioprospecting. Especially, the Third Conference on the Law of the Sea<sup>4</sup> did not introduce regulations distinguishing between “applied scientific research” (which would have presumably been a widely accepted category for bioprospecting) and “pure scientific research”.

Some authors (Fedder 2011, Treves 2008) conclude that bioprospecting cannot be qualified as marine scientific research and therefore does not fall within the scope of Part XIII governing

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<sup>4</sup> The Conference was convened in New York in 1973. It ended nine years later with the adoption in 1982 of a constitution for the seas - the United Nations Convention on the Law of the Sea

MSR. If bioprospection entails an economic profit then it should be seen as an exploration activity which would need to be treated under the provisions on exploration and exploitation of natural resources (Fedder 2011: 71) which confer the coastal state full sovereignty on the activity.

Other authors (Wolfrum/Matz 2003: 27, Rothwell/Stevens 2010: 329, Scovazzi 2012: 312) argue that the case of Art. 246.5 (a) UNCLOS more precisely reflects the character of bioprospecting. If it is only in later steps in the bioprospecting research process that commercialization of a discovery is targeted then the activity is research but of direct significance for the exploration and exploitation of natural resources. As a consequence the coastal states would be vested with the right to withhold their consent.

This view is convincing and can be supported with other arguments. First, the provisions on exploration and exploitation (Art. 17 UNCLOS for the territorial sea, Art. 56.1 UNCLOS for the EEZ) introduce instruments for coastal states to regulate and manage the bulk use of fish and mineral resources to be able to, *inter alia*, protect and preserve the marine environment (see Art. 56.1 (b) (iii) UNCLOS). Exploitation in the classical sense means the commercial extraction of minerals or taking economically important amounts of fish out of the waters (traditional “exploitation”, Wolfrum/Matz 2003: 25). In addition, the production of energy from wind or water is also qualified an exploitation activity, see Art. 56.1 (a) UNCLOS. Thus, exploitation is, historically, an activity *in situ*.

Bioprospecting does not fit well to this language. On the one hand, bioprospection activities hardly affect the environmental balance because the quantity of samples taken from the ocean is generally quite small. On the other hand, the discovery of new genetic sequences relevant for the development of products takes place in laboratories on the territory of the researching state and it is, if at all, only at a later stage that the knowledge, information and useful materials extracted from such resources enter a commercial phase (also Hayes 2007: 692). Therefore exploitation of marine genetic resources differs from the traditional exploitation in terms of substance (amount of collected resources is small), place (*ex situ*) and time (not known at the stage of sampling).

It can therefore be concluded, that Art. 56.1 lit. (b) rather than lit (a) UNCLOS applies to bioprospection. This means that bioprospection is not to be regarded as an exclusive right of

coastal states in the sense of Art. 56.1 (a) but as an activity that falls under their jurisdiction and can thus (only) be regulated by them. According to Art. 246 UNCLOS, such regulation can require prior consent which to provide is subject to the discretion of the coastal state. Further explanations follow under paragraph 3.3.1.1.

### **3.1.2. Utilization and research for non-commercial purposes under the NP**

The Nagoya Protocol's vocabulary differs from the one used within the UNCLOS. This is due to the fact that its objective is much more specific, as stated by Art. 1 NP which reads as follows:

“The objective of this Protocol is the fair and equitable sharing of the benefits arising from the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components.”

While UNCLOS covers any use of the seas for any purpose the citation shows that the scope of utilizations of the sea envisaged by the NP is confined to genetic resources and their R&D for biodiversity conservation and sustainable use.

In Art. 2 NP (use of terms) “utilization of genetic resources” is defined as “conducting R&D on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology”. Biotechnology is defined by the same article as meaning “any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use”.

While “utilization” clearly includes R&D activities it is less clear whether it also comprises subsequent steps towards the production and bringing on the market of products. Art. 5.1 NP which lays down the benefit-sharing obligation speaks of “benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization”. While here the terms utilization, subsequent applications and commercialization stand in enumeration next to each other, in other articles on the implications of the utilization of genetic resources, “subsequent applications” and “commercialization” are not explicitly mentioned. For

example, Art. 6.1 NP lays down: “In the exercise of sovereign rights over natural resources, and subject to domestic access and benefit-sharing legislation or regulatory requirements, access to genetic resources for their utilization shall be subject to the prior informed consent of the Party providing such resources...”. From a systematic point of view “utilization” here *includes* subsequent applications and commercialization, because the ABS concept implies that the provider grants access through PIC and MAT (1<sup>st</sup> step, Art. 6 NP) to the genetic resource found within its territory in exchange for potential benefits the user draws from that resource no matter at what stage in the valorization chain the benefits accrue (2<sup>nd</sup> step, Art. 5.1 NP). Thus, “utilization” in Art. 6.1 NP needs to be read to include subsequent applications and commercialization. The narrow or broad understanding of “utilization” has an important effect on the compliance obligations of user states. According to Art. 16 NP the user state must ensure that genetic resources “utilized” within its jurisdiction was accessed in conformity with the provider state legislation. If utilization is R&D excluding applications and commercialization the checking does not extend to applications and commercialization; it does however, if these stages are included in the term utilization.<sup>5</sup>

In any case, the R&D comprized by the term utilization may be intended to be conducted for purposes of pure science or of bringing results on the market. Even if the term utilization does not cover actual applications and commercialization, it does include intentions to do this at the stage of R&D. Thus, utilization includes R&D activities for commercial as well as non-commercial purposes. The former are subject to the standard access conditions established by the NP, in particular PIC and MAT. For non-commercial research, however, a special provision was introduced requiring provider states to simplify access conditions (Art. 8 (a) NP). This means that for commercial and non-commercial research different rules apply. This necessitates to properly define what commercial/ non-commercial research means.

The NP is however silent on how the terms shall be defined. Nevertheless, the word “non-commercial” provides more guidance than the term “marine scientific research” under the UNCLOS. Relevant reports have been produced by CBD Working Groups which describe the non-commercial character with the following elements (p.ex. UNEP/CBD/ABS/GTLE/1/INF/2, 2008): a) public availability, b) purely non-commercial intentions, c) results benefit providers, conservation, ecosystem analysis, and characterization of organisms, and d) generation of near-term, non-monetary benefits. In contrast, commercial

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<sup>5</sup> For a narrow reading Buck/Hamilton (2001): 53

research a) often restricts access, b) generates market products, c) primarily benefits users, and d) generates long-term, monetary benefits.

However, helpful as such listing is in clarifying options for legal purposes the definition must be more concise. We submit that there are basically three ways how to define the terms commercial/non-commercial:

- One is related to the financial and institutional framework of activities; it may be called the institutional definition. The leading question is then: Does the money flow from public or private resources, is the study project located in a university or private company, are the project objectives and content at the discretion of the researcher or determined by the funder or institution?
- A second is related to the valorization chain; it may be called the substantial definition. The question here is: Is the activity concentrating on the taxonomy of the genetic resources, or does it elaborate it further towards a marketable product? The distinction between basic/fundamental/pure research on the one side and applied research on the other is relevant in this context.
- A third is related to the public or private realm into which the results from R&D are placed; this may be called the functional definition: Is the GR, the knowledge about it and/or the product elaborated from it flowing into the public domain or is the holder capitalising on it, in other words does he/she claim property on the material and information, and/or does he sell it for money?

The options shall be analyzed looking at the objectives of the NP. These are that providers shall have a share in the benefits drawn from genetic resources and traditional knowledge, and that they can use their sovereign rights of regulating access to genetic resources and traditional knowledge in order to ensure ex ante that benefit sharing takes place. On the other hand, users shall be allowed to easily accede to and work on genetic resources and traditional knowledge.

In view of these objectives the first option - the institutional definition - appears to be inappropriate. The private or public institutional setting and financial source may often indicate but does not per se determine whether benefits shall be shared or not.

The second option – the substantial definition - also proves to be flawed. It is based on the distinction between fundamental and applied research. It perceives the working on GR and TK as a sequence from basic research via the development of products to their patenting and marketing. This perception has well characterized R&D in the past. However, with the advent of genomics and the extension of the intellectual property concept to nature-forms the “old” taxonomy has lost its distance from business. Already at the stage of analyzing the genome some strain can be and is often searched to be patented and thus made a source of license payments from those who wish to make use of it. For this reason, the early phase of fundamental research should not anymore be equalized with non-commercial. Hence, the distinction between commercial and non-commercial should not be attached to the sequence of steps of R&D.

We are thus left with the third option – the functional definition. It appears indeed to be the most appropriate one. Arico/Salpin (2005: 33) also suggest the functionality criterion when they conclude that “the difference of regime lies in the treatment of research results”. The UN Secretary-General (2005) stresses that “the difference between MSR and bioprospecting therefore seems to lie in the use of knowledge and results of such activities, rather than in the practical nature of the activities themselves” (Secretary-General 2005: para. 202, also Treves 2008).

Distinguishing between opening the research results to the public domain on the one side and privatization of the results for capitalization on the other the functional definition best captures benefits whenever they emerge. If the benefits are in the public realm – most often these will be non-monetary benefits - access is free and open to the public, providers being able to make use of them like anybody else. If the benefits are in the private realm – they will normally be monetary benefits – the provider must secure a share bilaterally by way of setting conditions in the access permit and contract.

Equally alike to the UNCLOS, there may in praxi not always be a clear boundary between a commercial and a non-commercial activity. The intended activity may in substance be in both cases the same as we understand “utilization” in the NP as an umbrella term for the whole chain from the fundamental and applied research to development, patenting and marketing. Instead, the decisive element for granting facilitated access is if there is non-commercial intent of the user at the moment the permit for access is issued and the access contract is

concluded. Given the fact that “academic researchers play a key role at the forefront of biodiversity and biotechnology sciences” (Arico/Salpin 2005: 15) it is therefore their intent that counts. Unforeseen use (change of intent to commercial use) or disclosure or transfer to third (commercial) parties may nevertheless pose a problem. This can however be solved by concluding in the contract that the user must come back to the provider for renegotiation of the contractual conditions for use and of respective rules for eventual obligations of third parties.

**3.1.3. Comparison**

	Non-commercial use	Commercial use
UNCLOS:	Marine scientific research	Marine scientific research with direct significance for exploration/exploitation of natural resources
CBD/NP:	Non-commercial research, contribution to conservation and sustainable use of biological diversity	Utilization other than non-commercial research

From the above analysis of the terminology, which the two conventions use with regard to scientific research, the following conclusion can be drawn: The difficulties to decide if an activity falls under the one or the other category can in both cases be mastered with the functional definition – regardless of the differences in legal terminology. “Marine scientific research” (UNCLOS) and non-commercial research (NP) alike aim at increasing the knowledge of all mankind and the sharing of the benefits (i.e. the research results) with the global community. In contrast, “exploration/exploitation” (UNCLOS) and “commercial” “utilization” (NP) aim at increasing the proprietary knowledge of the user or third parties and reserving the benefits for their proprietary sphere. Concerning MSR with direct significance for exploration/exploitation we suggest to categorize this as commercial use assuming that the results will normally be held in the private domain.

Interestingly, there is a striking difference in the legal systematic between the relevant provisions of the two conventions: within UNCLOS the commercial research is the exception to the rule that in general marine scientific research is supposed to be for the public domain whereas in the Nagoya Protocol the non-commercial research is the exception to the rule that in general utilization of genetic resources shall be accessed and utilized under PIC and MAT.

(Art. 6 NP). We will come back to compare these and other aspects of legal requirements in the final conclusion.

### **3.2. Geographical scope of application**

As said before, the access provisions under UNCLOS are divided into chapters regulating the different maritime zones, i.e. the territorial sea, the EEZ, the continental shelf and areas beyond national jurisdiction (ABNJ) which includes the high seas and the Area.

The CBD with its ABS regime and the NP apply to all maritime zones within the limits of the states' national jurisdiction (Art. 4 CBD). These zones comprise the territorial sea, the EEZ, the continental shelf including its possible extension beyond the 200 nm-zone of the EEZ, but within the limits of 350 nm. Subject to the jurisdictional power of coastal states in the different zones are the components of biological diversity as well as processes and activities, regardless of where their effects occur, carried out under the state's jurisdiction or control even if this happens beyond the geographical limits of the state's national jurisdiction (as for instance from a vessel under the control of its flag state) (Art. 4 (a) and (b) CBD; Fedder 2011: 72). The CBD does not rule on the components of biodiversity in the ABNJ, unless these are affected by activities or processes under the jurisdiction or control of a coastal state (see 3.5.2.).

The territorial scopes of application of the CBD and NP are therefore overlapping, but not fully congruent.

The study will discuss the territorial sea, the EEZ and the extended continental shelf, and the ABNJ. It compares to what extent the coastal state has rights to regulate access to marine genetic resources under the UNCLOS and under the CBD.

### **3.3. The territorial sea**

According to Art. 8 UNCLOS, all waters lying landward of the baselines are the internal waters of the state (which include harbour waters and estuaries). Art. 2.1 UNCLOS lays down: "The sovereignty of a coastal state extends beyond its land territory and internal waters, ..., to an adjacent belt of sea, described as the territorial sea."

The breadth of the territorial sea extends to 12 nautical miles from the baseline (Art. 3 UNCLOS). The baseline is in general the low-water line along the coast as marked on large-scale charts officially recognized by the coastal State. Special methods for calculating the baseline exist for archipelagic states (Art. 46 et seq. UNCLOS), reefs, deeply indented coastlines, mouths of rivers, bays and low-tide elevations.

The sovereignty of the coastal state over the territorial sea extends to the air space above the waters, to the seabed and to the subsoil thereof (Art. 2.2 UNCLOS).

As has been described above, research on samples of marine microorganisms taken from the sea can be qualified as MSR in the sense of the UNCLOS. Such MSR can either be aimed at the public domain or be directly significant for exploration/exploitation. The first kind of research was suggested to be called non-commercial and the second commercial. In the following we shall explore what rules are attached to the two kinds of research, starting with the category of commercial research and then proceeding to non-commercial research.

### **3.3.1. Access regime for commercial users**

#### **3.3.1.1. UNCLOS**

Coastal states have almost exclusive sovereignty in the territorial sea. This includes that they have the exclusive right to conduct, regulate and authorize MSR (Art. 21.1 (g), 245 UNCLOS, Rothwell/Stevens 2010: 75, 327) and to determine the individual setting of material, procedural and benefit-sharing requirements. To further reinforce the right to fully control MSR, Art. 19(2) (j) UNCLOS stipulates that passage through the territorial sea becomes non-innocent if it involves any research or survey activities. Thus, research may be undertaken only with the express consent of the coastal state.

In addition, research activities “shall not constitute the legal basis for any claim of any part of the marine environment or its resources” (Art. 241 UNCLOS). This provision might be interpreted to be an obstacle for commercial research such as bioprospecting if it aims at keeping results confidential or have them protected by intellectual property rights. In fact, the clause must be understood to exclude exclusive rights at least on the collected genetic resources as such, if not also on products and procedures developed on its basis. Yet, the

clause implies that such claims can be subject to negotiation (Gorina-Ysern 2003: 2). It is, for instance, imaginable that the coastal state gives the user state its consent to the proprietary use of the genetic resources under condition of ownership sharing.

Yet, the coastal states' right to regulate MSR is not absolute since it stands in relation to the right of research of other states and international organizations (UN 2010: 7). According to Art. 238 UNCLOS states and international organizations have the right to conduct MSR, albeit subject to the rights and duties of the coastal state. According to Art. 239 UNCLOS the coastal state shall also "promote and facilitate the conduct of marine scientific research", an obligation which must be understood to also facilitate research by other states and international organizations. In addition, according to Art. 243 UNCLOS the coastal state shall also "cooperate, through the conclusion of bilateral and multilateral agreements, to create favorable conditions for the conduct of marine scientific research in the marine environment". The MSR thus supported is however subject to a number of general conduct principles and conditions set out in Art. 240 UNCLOS:

- The research shall be only for peaceful purposes;
- The research shall be conducted with appropriate means and methods compatible with the Convention;
- The research shall not interfere with other legitimate uses of the sea ("element of equity" (Vitzthum 2006, ch.5 at 245));
- The research shall comply with regulations for the protection and preservation of the environment.

Although the obligations of the coastal state apparently are very broad and thus might not confer any concrete commitments for the conduct of MSR (Fedder 2011: 81) the broad message nevertheless is that MSR shall be supported as much as possible.

The special status of MSR being regularly an activity for the common heritage of mankind is further reinforced by the duty of states and international organizations to disseminate and publish widely the results and data from MSR (Art. 244 UNCLOS). The states shall also promote international cooperation in MSR. In other words, the states have various benefit-sharing obligations concerning MSR "on the basis of mutual benefit", as it is put in Art. 242.1 UNCLOS.

### 3.3.1.2. CBD/NP

Under Art. 15 CBD and the Nagoya Protocol which implements the respective CBD provisions, a state holding genetic resources may adopt a comprehensive access and benefit sharing legal regime.

In detail, the general access regime is regulated in Art. 6.1 NP:

“In the exercise of sovereign rights over natural resources, and subject to domestic access and benefit-sharing legislation or regulatory requirements, access to genetic resources for their utilization shall be subject to the prior informed consent of the Party providing such resources....., unless otherwise determined by that Party.”

The prior informed consent provides a title for the user to the taking of samples in the provider state’s marine realm. In order to have a clear-structured and transparent application procedure for obtaining the PIC, the provider states shall, according to Art. 6.3 NP, adopt a set of appropriate measures. They shall

- provide for legal certainty, clarity and transparency of their domestic ABS legislation
- provide for fair and non-arbitrary rules and procedures on accessing genetic resources
- provide information on how to apply for prior informed consent
- provide clear, cost-effective and timely decision-making, recognition of a permit or its equivalence as evidence of PIC
- provide criteria and procedures for the involvement of indigenous and local communities
- establish clear rules and procedures for requiring and establishing mutually agreed terms (MAT)

The MAT are the Protocol’s basic instrument to define all contractual obligations. The core of MAT shall be the obligation for the user to fairly and equitably share benefits arising from the utilization of genetic resources as well as subsequent application and commercialization with the providing party (Art. 5.1 NP). Benefits listed under the Protocol include monetary and non-monetary benefits and are almost a word-for-word repetition of benefits listed in the

Bonn Guidelines (Art. 5.4 and Annex to NP). The list is non-exhaustive. Here are some examples for monetary benefits:

- Access fees/fee per sample collected or otherwise acquired
- Up-front payments
- Licence fees in case of commercialization
- Research funding

Some examples of non-monetary benefits are:

- Sharing of R&D results
- Collaboration, cooperation and contribution in scientific R&D programmes
- Collaboration, cooperation and contribution in education and training
- Admittance to ex situ facilities of genetic resources and to databases

Additionally, the Protocol prescribes collaboration and cooperation in technical and scientific R&D programmes (Art. 23 NP), which preferably take place in and with participation of provider parties. In this regard, access to technology by and transfer of technology to developing country parties should be encouraged.

### **3.3.2. Access regime for non-commercial users**

#### **3.3.2.1. UNCLOS**

Non-commercial users of genetic resources in the territorial sea are subject to the coastal state's national access legislation (Art. 245 UNCLOS); in this maritime zone the UNCLOS does not privilege non-commercial over commercial research. Thus, all the conduct principles and non-monetary benefit-sharing obligations described above for commercial use of genetic resources (3.3.1.1.) also apply to the non-commercial use of genetic resources.

#### **3.3.2.2. CBD/NP**

The NP contains special provisions for non-commercial research. According to Art. 8(a) NP the parties to the Protocol shall

“create conditions to promote and encourage research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries, including through simplified measures on access for non-commercial research purposes, taking into account the need to address a change of intent for such research.”

As we have seen above, the most appropriate criterion to distinguish non-commercial from commercial is the functionality of the research: If the results of R&D are supposed to be placed in the public realm, then Art. 8 (a) NP applies with the following conditions and consequences.

As a precondition of facilitated access (apart from the non-commercial intention) the research must be capable to contribute to the conservation and sustainable use of biological diversity, particularly in developing countries. In consequence this kind of research shall be promoted and encouraged through, for example, simplified measures on access. Some scientific experts to the COP 10 meeting went further proposing an exemption from PIC or that MAT could automatically be considered as PIC (UNEP/CBD/COP/10/INF/43, 2010) but this did not win the support of provider states.

As a mutual obligation to the right to facilitated access the user has to share non-monetary benefits. There are case studies which have demonstrated that provider states of genetic material reap greater advantage from participation in research, technology transfer and professional exchanges than from monetary arrangements (Hayes 2007: 700). Besides the general access to public domain information, additional benefits may be adapted to the provider's interest on a case-by-case basis. This could be the privilege to have first access to research results or the participation in research operations.

### **3.4. EEZ and Continental Shelf**

The exclusive economic zone is an area beyond and adjacent to the territorial sea; it shall not extend 200 nm from the baselines from which the breadth of the territorial sea is measured (Art. 55, 57 UNCLOS). The continental shelf is the geographical sea-bed area beyond the territorial sea up to a distance of 200 nm (Art. 76.1 UNCLOS). Where the geological

continental shelf exceeds 200 nm a state may, by declaration, establish the outer limits up to 350 nautical miles and thus extend the legal realm of sovereign rights (Art. 76.4 and 5 UNCLOS). As will be further explained below, this declaration plays a crucial role for the admissibility of MSR in the extended continental shelf.

### **3.4.1. Access regime for commercial users**

#### **3.4.1.1. UNCLOS**

The EEZ is a “sui generis” zone which confers on the coastal state sovereign rights to legislate on the exploration and exploitation of genetic resources also in the water column of the EEZ (Art. 56.1(a) UNCLOS), as well as on the seabed and in the subsoil of the continental shelf (Art. 76.1, 77.1 UNCLOS). The water column of the extended continental shelf, by contrast, belongs to the high seas (Art. 78.1 UNCLOS). Over commercial research activities in the EEZ the States’ sovereignty is almost exclusive; Art. 56.2 UNCLOS only requires that the coastal state shall have due regard to the rights and duties of other States and shall act in a manner compatible with the provisions of this Convention.

As concluded above (section 3.1.1.) a researcher who has commercial purposes falls under the rubric of marine scientific research (Part XIII of the UNCLOS) but carries out a project with direct significance for the exploration or exploitation of natural resources. This qualification empowers the coastal state to freely grant or withhold consent (Art. 246.5 UNCLOS). This right results from the linkage to the sovereign rights the coastal state has over its resources within the EEZ (Vitzthum 2006, ch.5 at 256).

If the project falls under this category of Art. 246.5 (a) UNCLOS the coastal state may freely determine details of the duties listed in Art. 249.1 UNCLOS. It may especially oblige the user state to ask the coastal state for “prior agreement for making internationally available the research results of a project of direct significance for the exploration and exploitation of natural resources” (Art. 249.2 UNCLOS). The benefit-sharing commitments in this article can thus be seen as a kind of negotiation material (Gorina-Ysern 2003: 2).

However, the discretion to grant or withhold consent for MSR projects under Art. 246.5 UNCLOS does not extend to those parts of the continental shelf that lay beyond 200 nm – obligatory consent even if resource-related research – unless the state has therein designated

special areas as areas in which the state plans exploratory operations and exploitation (then again facultative consent), Art. 246.6 UNCLOS. This reservation for special areas finds its justification in Art. 76 and 77 UNCLOS where the right to explore and exploit natural resources on the continental shelf also extends to the zone beyond 200 nm from the baselines.

#### **3.4.1.2. CBD/NP**

As said above (3.2.), the CBD's territorial scope of application includes the 200 nm belt of the EEZ and the continental shelf. Neither the CBD nor the Nagoya Protocol contain provisions that confer the EEZ a special status regarding the ABS rules. To this, the valuable legislation pertaining to the EEZ and the continental shelf has been developed above with the territorial sea (Point 3.3.1.2. and 3.3.2.2.).

#### **3.4.2. Access regime for non-commercial users**

##### **3.4.2.1. UNCLOS**

The UNCLOS confers jurisdiction upon a coastal State to regulate, authorize and conduct MSR within its EEZ and the continental shelf (Art. 56.1 (b) (ii), 246.1 UNCLOS). All research activities require a prior consent of the coastal State. This right to grant prior consent is however less explicitly formulated than for research projects within the territorial sea ("consent" in art. 246.2 UNCLOS compared to "express consent" in Art. 245 UNCLOS).

Art. 246.3 UNCLOS requires that under "normal circumstances" the granting of the permit is obligatory (Fedder 2011: 84). This is the case if the project is carried out for peaceful purposes and is intended to increase scientific knowledge of the marine environment for the benefit of all mankind (Art. 246.3 UNCLOS). Art. 246.5 (b), (c) UNCLOS mandates that the authorization may not be unreasonably denied or delayed (Art. 246.3 2<sup>nd</sup> sentence UNCLOS). This proves that a scientific researcher conducting a project in the public interest profits from privileged material and procedural requirements (Gutiérrez 2011: 168). If the research project is carried out for peaceful purposes and is intended to increase scientific knowledge of the marine environment for the benefit of all mankind, the consent is compulsory.

If circumstances are not “normal”, the coastal state may withhold its consent (facultative consent). This is the case (see (Art. 246.5 (a)-(d) UNCLOS) if

- the project is of direct significance for the exploration or exploitation of natural resources (in that case it would be commercial use, see above 3.4.1.1.);
- the project involves drilling into the continental shelf, the use of explosives, the introduction of harmful substances into the marine environment;
- the project involves the construction, operation or use of artificial islands and structures; or
- information on the research project is inaccurate.

As a corollary duty to the privileged access the researching state must in advance provide full information on the details of the intended project to the coastal state (Art. 248 UNCLOS) and must respect its right to participate or be represented in the project and to have (first) access to reports and conclusions arising from the research (Art. 249.1 (a), (b) UNCLOS). In addition, the researching state must make research results internationally available (Art. 249.1 (e) UNCLOS). If the non-commercial researcher fulfills these benefit-sharing obligations no further conditions shall be required from the coastal state (Rothwell/Stevens 2010: 329).

#### **3.4.2.2. CBD/NP**

Art. 8 NP is equally applicable to facilitated access in the territorial sea as well as in the EEZ and the continental shelf. Therefore we can here refer what has been developed above (see 3.3.2.2.).

### **3.5. Areas beyond national jurisdiction (ABNJ)**

As depicted above, ABNJ include both the high seas and the Area. The term high seas means the water column beyond national jurisdiction, i.e. all waters of the sea that are not included in the EEZ, in the territorial sea, or in the internal waters of a state, or in the archipelagic waters of an archipelagic state<sup>6</sup>. In other words, the high seas are the water column beyond 200 nm from the baseline. However, if a coastal state does not declare an EEZ the high seas starts

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<sup>6</sup> Art. 86 UNCLOS

already 12 nm from the baseline.<sup>7</sup> In addition, ABNJ include the Area which is the seabed and subsoil thereof, including non-living resources located beyond the continental shelf. In other words the Area is the vertical column of land outside sovereign national rights.

Access to marine genetic resources in ABNJ is not explicitly regulated under a specific legal instrument. As marine areas outside national jurisdiction, ABNJ fall outside the scope of the CBD and its NP (as will be further explained below). Hence, any rules relevant for access to marine genetic resources in ABNJ arise from the UNCLOS. However, it should be noted from the outset that with regard to ABNJ the division between an access regime for commercial users and an access regime for non-commercial users (as seen with MSR under UNCLOS or non-commercial purpose under CBD/NP) is not established in the UNCLOS provisions governing ABNJ.

### **3.5.1. UNCLOS**

Within the relevant UNCLOS provisions, access to marine genetic resources from ABNJ is not specifically addressed. In fact, the term “marine genetic resources” is neither utilized nor described within the treaty text. Nevertheless, the broad language of the UNCLOS establishing general freedoms and minimal obligations in the relevant marine realms can be interpreted to regulate access to microorganisms in ABNJ. Provisions that might be applicable in this regard include those in Part VII High Seas, Part XI The Area, and Part XIII Marine Scientific Research.

#### **3.5.1.1. The high seas**

Part VII governing the high seas affirms this marine realm as open to all States, whether coastal or land-locked; this general freedom is deemed the “freedom of the high seas.” According to Art. 86 UNCLOS, it includes, *inter alia*, the freedoms of

- 1) navigation
- 2) overflight
- 3) laying submarine cables and pipelines

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<sup>7</sup> Of the states relevant in the MicroB3 project the UK for instance has not declared an EEZ. Access to genetic resources is therefore possible without prior consent in the seas surrounding the UK beyond 12 nm from the baseline.

- 4) constructing artificial islands and other installations
- 5) fishing
- 6) scientific research

Access to marine genetic resources is not specifically listed as a freedom enjoyed by all states. Access to and utilization of marine genetic resources may though pertain to “scientific research” if there is non-commercial intent. But also the sampling by commercial users is covered. As the term “inter alia” is used prior to the listing of different freedoms, it is clear that the given list is not an exhaustive, but only an indicative list. As a consequence, it can be argued that access to and subsequent utilization of marine genetic resources are covered by the freedoms of the high seas even if they are not explicitly mentioned.

The listed freedoms 3-6 are subject to additional provisions established within the UNCLOS (Art. 87.1), especially the freedom of scientific research is subject to Parts VI (Continental Shelf) and XIII (Marine Scientific Research).

Furthermore, these freedoms of the high seas are not absolute but subject to broad restrictions: Art. 88 UNCLOS requires that the high seas are reserved for peaceful purposes and Art. 87.2 UNCLOS requires states to pay due regard to the interests of other states when exercising these freedoms.

Art. 87.1 UNCLOS again determines that the freedom of the high seas is exercised under the conditions laid down by the UNCLOS. This provides a link to the obligations under Part VII section 2 which imposes on all states the duty to cooperate with other states in the conservation of the living resources of the high seas and to take the relevant necessary measures (Art. 118 UNCLOS). In reference to these conservation efforts, harvested species, species associated with or dependent upon harvested species and marine mammals in the high seas are specifically addressed in Art. 119 UNCLOS. Whether this is an exclusive list is controversial but should be answered in light of the general obligations established under Part XII section 1. Accordingly, states are obliged “to protect and preserve the marine environment” (Art. 192 UNCLOS) as a whole, and to take the necessary measures “to protect and preserve rare or fragile ecosystems as well as the habitat of depleted, threatened or endangered species and other forms of marine life” (Art. 195.5 UNCLOS).

### 3.5.1.2. The Area

Under Part XI, the Area and its resources are considered the common heritage of mankind<sup>8</sup>. As such, the resources accessed in this area must be in compliance with other rules of international law and those specified under the UNCLOS. Specifically,

- States cannot claim or exercise sovereignty over any part of the Area or its resources, nor appropriate any part of the Area<sup>9</sup>;
- Activities in the Area must be carried out for the benefit of mankind as a whole (irrespective of the geographic location of states and taking into particular consideration the interests and needs of developing states, etc.)<sup>10</sup>; and
- Similarly to the high seas, the open use in the Area is limited by the broad requirement that use be exclusively for peaceful purposes<sup>11</sup>.

Furthermore, Part XI requires that the International Seabed Authority and State Parties cooperate in promoting the transfer of technology and scientific knowledge relating to activities in the Area so that all may benefit therefrom (Art. 144.2 UNCLOS). In the instance that activities within the Area relate to resource deposits which lie across limits of national jurisdiction, coastal states retain rights and a legitimate interest in the Area<sup>12</sup>. Access in this instance may be restricted accordingly.

However, it is important to note that Art. 133 (a) UNCLOS defines the term “resources” to mean “all solid, liquid or gaseous mineral resources in situ in the Area at or beneath the seabed.” So that when resources are recovered from the Area, it is referred to as minerals. Consequently, the regime of Part XI does not apply to living resources which include marine genetic resources (Leary 2007: chap.2, 50). This means that no specific regime on genetic resources is established for the Area.

### 3.5.1.3. Marine scientific research

Regarding MSR, Part XIII specifically addresses both the Area and the high seas.

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<sup>8</sup> Art. 136 UNCLOS

<sup>9</sup> Art. 137 UNCLOS

<sup>10</sup> Art. 140 UNCLOS

<sup>11</sup> Art. 141 UNCLOS

<sup>12</sup> Art. 142 UNCLOS

Art. 256 UNCLOS addressing the Area stipulates that all states and competent international organizations have the right to conduct MSR as long as it is done in accordance with Part XI and its Art. 143 UNCLOS. According to this provision which refers vice-versa to Part XIII, MSR in the Area must be carried out exclusively for peaceful purposes and done for the benefit of mankind as a whole<sup>13</sup>. These general limitations are parallel to those applicable to the high seas and the Area. Furthermore, MSR in the Area may be carried out by either the International Seabed Authority (the Authority) or State Parties. In the latter case, State Parties must promote international cooperation by<sup>14</sup>:

- Participating in international programmes and encouraging cooperation in MSR by personnel of different countries and of the Authority;
- Ensuring that programmes are developed through the Authority or other international organizations as appropriate for the benefit of developing states and technologically less developed states; and
- Disseminating the results of such research and analysis when available<sup>15</sup>.

Likewise, MSR in the high seas is regulated under Part XIII. Similarly to what applies in the Area, here all States and competent international organizations have the right to conduct MSR.<sup>16</sup> However, according to Art. 257 of the UNCLOS, states and international organizations conducting research need to be in conformity with the general provisions of the Convention, including those calling for cooperation between States, such as Art. 244 UNCLOS. According to Art. 244, states 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;”
- 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

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<sup>13</sup> Art. 143.1 UNCLOS

<sup>14</sup> Art. 143.3 UNCLOS

<sup>15</sup> Art. 143.2 and 143.3 (c) UNCLOS

<sup>16</sup> Art. 257 UNCLOS

of developing States through, inter alia, programmes to provide adequate education and training of their technical and scientific personnel.”

### 3.5.2. CBD/NP

Art. 4 of the CBD establishes the jurisdictional scope of the CBD and is broken into two prongs. As previously mentioned, Art. 4(a) of the CBD applies to “*components of biological diversity*” found “*within the limits of national jurisdiction*” (emphasis added). Therefore, the territorial scope regarding marine genetic resources applies to those found within the internal waters, the territorial sea, the 200 nm EEZ and the continental shelf beyond the EEZ (see the above relevant access restrictions). For these areas and their resources, a state can develop access regulations applicable to nationals and/or foreigners.

The ABNJ is however addressed under the second prong of the CBD’s scope. Art. 4(b) CBD applies “in the case of *processes and activities*, regardless of where their effects occur, carried out under its jurisdiction or control, within the area of its national jurisdiction or *beyond the limits of national jurisdiction*” (emphasis added). Although this treaty language extends the scope of the CBD to the ABNJ, Art. 4(b) CBD is distinctively limited to processes and activities under a state’s jurisdiction or control. By express distinction to Art. 4(a), Art. 4(b) defines the scope of the CBD by referring to types of activities rather than the place of activity. This is due to the fact that states by definition have no territorial jurisdiction over ABNJ, and thus may only regulate the activities of their nationals within these areas (Glowka 1994: 27). Thus, jurisdiction is extended only to the method(s) of achieving access (i.e. the sampling of marine genetic resources and its potential impacts on biological diversity), but not to the actual components of biodiversity or in this case, the marine microorganisms in the ABNJ.

This limited jurisdiction regarding access to marine genetic resources to those found only within national jurisdiction is further solidified by the NP. From the aforementioned explanations of marine access (Points 3.3 and 3.4), it is the language of the NP that gives structure to the implementation of the ABS provisions of the CBD. And this language is specifically confined to Art. 15 CBD, not the more general scope of the CBD established under its Art. 4<sup>17</sup>. Art. 15 CBD, recognizing the sovereign rights states have over their natural

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<sup>17</sup> Art. 3 NP

resources and the national government's authority to determine access to genetic resources, subsequently confirms the dependency on state sovereignty and its application to only those genetic resources found within national jurisdiction.

This treaty interpretation is also supported by the language found in Art. 4 CBD. While Art. 4 CBD in principle applies to the whole of the CBD, including its Art.15, the chapeau of Art. 4 reads "except as otherwise expressly provided in this Convention". This exception to the general rule supports the argument that Art. 15 CBD stands alone as a special rule. Indeed, every paragraph of Art. 15 addresses States exercising their sovereign rights to grant access which makes it a unique article within the CBD with a primary purpose of establishing the CBD's bilateral ABS regime. Therefore, components of biological diversity, including the marine microorganisms in question, are subject to the CBD and the NP only when found within national jurisdiction (Leary 2007: chap.2, at 52).

### **3.5.3. Conclusion**

Ultimately it is unclear which, if any, is the appropriate mechanism governing ABS for marine genetic resources from the ABNJ. However, the United Nations General Assembly (UNGA) is currently working to address this issue. Several resolutions to the UNCLOS call upon states to further consider the relevant legal regime applicable to ABNJ<sup>18</sup>. Additionally, an Ad hoc Open-ended Informal Working Group (AHWG) was established by UNGA in 2004 to study issues relating to the conservation and sustainable use of marine biological diversity beyond areas of national jurisdiction<sup>19</sup>. At the fourth Meeting of the AHWG, which took place 31 May to 3 June 2011, it was recommended that

“1. A process be 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;

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<sup>18</sup> For example, UNGA Resolution 65/37, UN doc. A/RES/65/37, of 7 December 2010, available at [http://www.un.org/Depts/los/general\\_assembly/general\\_assembly\\_resolutions.htm#2010](http://www.un.org/Depts/los/general_assembly/general_assembly_resolutions.htm#2010)

<sup>19</sup> UNGA Resolution 59/24 para 73, UN doc. A/RES/59/24, of 17 November 2004

2. This process would address the conservation and sustainable use of marine biodiversity in areas beyond national jurisdiction, in particular, together and as a whole, marine genetic resources, including questions on the sharing of benefits, measures such as area-based management tools, including marine protected areas, and environmental impact assessments, capacity-building and the transfer of marine technology;<sup>20</sup>

These on-going processes may lead to the development of an ABS regime for marine genetic resources in ABNJ - specific coverage - or conclude that UNCLOS provides a sufficient legal framework for regulating activities in marine ABNJ, which has repeatedly been recognized by the CBD COP<sup>21</sup>.

Concerning the protection of deep seabed genetic resources beyond national jurisdiction, the CBD COP has recognized a preliminary range of options which Parties and other states may utilize, including<sup>22</sup>:

- The use of codes of conduct, guidelines and principles; and
- Reduction and management of threats including through: permits and environmental impact assessments; establishment of marine protected areas; prohibition of detrimental and destructive practices in vulnerable areas.

Depending on the intended activity following access, these recognized options for protection may place additional restrictions on access.

## **Section 4. Summary /remarks**

### **4.1. Relationship between CBD – UNCLOS**

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<sup>20</sup> Recommendations by 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 to the General Assembly, adopted on 3 June 2011

<sup>21</sup> CBD COP 7 Decision VII/5.31 *Marine and coastal biological diversity*. CBD COP 8 Decision VIII/21.6 *Marine and coastal biological diversity: conservation and sustainable use of deep seabed genetic resources beyond the limits of national jurisdiction*. CBD COP 9 Decision IX/20 *Marine and coastal biological diversity*.

<sup>22</sup> CBD COP 8 Decisions VIII/21.5 *Marine and coastal biological diversity: conservation and sustainable use of deep seabed genetic resources beyond the limits of national jurisdiction*

Before drawing a final comparison between the access regimes of the UNCLOS and the CBD/NP, the relationship between these legal instruments needs to be clarified. For this a closer look has to be taken at Art. 22 CBD, Art. 4 NP and Art. 311 UNCLOS.

Art. 22.1 CBD states that the CBD shall not affect the rights and obligations of any Contracting Party deriving from any existing international agreement, which includes the UNCLOS, “except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity”. The clause at the end of the paragraph means that when there is a conflict between a CBD provision and the provision of another international agreement that would lead to serious damage or threat to biological diversity, the CBD provision generally prevails.

However, in relation to the marine environment, Art. 22.2 CBD provides for an exception. Here it is stated that the CBD Parties shall implement the CBD “consistently with the rights and obligations of States under the law of the sea”. This second paragraph therefore determines that Parties must implement the CBD provisions consistently with state’s rights and obligations derived from UNCLOS or customary law of the sea. Deviating from the general rule under Art. 22.1, Art. 22.2 therefore affirms that the UNCLOS provisions prevail where the CBD implementation conflicts with them (Glowka 1994: 109).

Such interpretation of the UNCLOS-CBD relationship is further supported by Art. 311.2 UNCLOS. Accordingly, the UNCLOS shall not alter the rights and obligations of State Parties which arise from other agreements, but only if these rights and obligations are compatible with the UNCLOS and do not affect the enjoyment by other States Parties of their rights or the performance of their obligations under the UNCLOS. In other words, in case of contradicting rules the UNCLOS prevails over the CBD.

The relationship between the Nagoya Protocol and other international instruments, such as the UNCLOS, is specifically regulated in Art. 4 NP. Here, paragraph 1, sentence 1 repeats the general rule of prevalence as established by Art. 22.1 CBD. While there is no such exception clause for the marine environment as in Art. 22.2 CBD, Art. 4.1 NP nevertheless states in its second sentence that it is not intended to create a hierarchy between the Nagoya Protocol and other international instruments (neither in favour of the Protocol nor in favour of another agreement like the UNCLOS). Through the introduction of this so called saving clause, the

states negotiating the Nagoya Protocol indicated that the terms of the Protocol should not conflict with or override existing obligations unless clearly intended. Instead, according to Art. 4.3 NP, the Protocol shall be implemented in a mutually supportive manner with other international instruments relevant to the Nagoya Protocol. This requires a conciliatory reading of potentially conflicting rules in those agreements.

**4.2. Comparison of access regimes of CBD – UNCLOS**

**4.2.1. Access regime for commercial users**

Territorial sea:

	Relevant activity	Access requirements	BS
UNCLOS:	Marine Scientific Research with direct significance for exploration/exploitation	Prior informed consent (full sovereignty)  Conduct principles  Favorable conditions	Dissemination/publication of research results and data  International MSR cooperation, education and training of research capacities of developing states
CBD/NP:	Utilization	PIC and MAT	Monetary Benefits and/or non-monetary benefits - Annex

EEZ/Continental shelf:

	Relevant activity	Access requirements	BS
UNCLOS:	Marine scientific research with direct significance for exploration/exploitation of natural resources	Facultative prior informed consent  Conduct principles  Favorable conditions	Facultative duties (state sovereignty):  - Participation/representation of coastal state in the research project - coastal state shall receive preliminary report - coastal state shall receive assistance in assessment of the results and data - research results shall be made internationally available through appropriate channels
CBD/NP	Utilization	PIC and MAT	Monetary benefits and/or non-monetary benefits - Annex

As presented in the tables above, the following analysis holds for the CBD/NP: the legal access regimes for commercial research of marine microorganisms are the same whether the collection takes place in the territorial sea or in the EEZ; same material condition (utilization), same PIC and MAT requirement and same obligation to share monetary and/or non-monetary benefits.

Within UNCLOS a more differentiated picture becomes apparent: while the relevant activity (marine scientific research with direct significance for exploration and exploitation of natural resources) is the same whether it takes place in the territorial sea or in the EEZ, the access requirements differ between the two maritime zones, and likewise do the BS requirements.

In the territorial sea, the coastal state disposes of full sovereignty to regulate MSR; behavioral conditions (Art. 240, 241 UNCLOS) determine the character of the user states' activity but do not, if they are fulfilled, limit the coastal states' discretion to withhold or grant consent. In the EEZ, the consent is likewise facultative if commercial exploitation of the genetic resource is intended. Yet, there are three differences: first, the coastal state must have indications (such as from information to be submitted by the applicant according to Art. 248 UNCLOS) that commercialization is actually intended; if it fails the consent is obligatory according to Art. 246.3 UNCLOS. Second, the facultative consent does not extend to the continental shelf beyond 200 nautical miles from the baselines, outside specific areas which coastal states may designate as areas in which exploitation or exploration are occurring or will occur (Art. 246.6 UNCLOS). And third, the consent is implied according to Art. 252 UNCLOS: a user may start the research expedition six months after having furnished the application to the coastal state if that state has not meanwhile responded to the application within a period of four months.

Research operations in the territorial sea trigger benefit-sharing obligations of a general nature (dissemination of knowledge, international cooperation in research) and others only within the coastal states' discretion. For research operations in the EEZ and on the continental shelf, the UNCLOS provides for a list of benefit-sharing requirements which, according to Art. 249 UNCLOS, include inter alia:

- Participation/representation of coastal state in the research project;
- A preliminary report to the coastal state;
- Assistance to the coastal state in the assessment of the results and data;
- International dissemination of research results through appropriate channels.

Yet, it should be noted that according to Art. 249.2 UNCLOS, which is a corrolal provision to Art. 246.5 UNCLOS, these duties are facultative. Especially the publication of research

results may be dependant on the prior consent of the coastal state. With regard to knowledge which may possibly enhance the commercialization process, the prior consent obligation then protects the interests of the coastal state to safeguard upcoming monetary benefits.

That the coastal state has a discretionary power over MSR with direct significance for exploration and exploitation may be explained with the basic objective of a “just and equitable international economic order” (UNCLOS, preamble, para 5). To improve the economic stability of especially developing countries and ascertain potential economic benefits coastal states shall be vested with sovereign rights over the commercial exploitation of natural resources also within the EEZ. They shall thus at the same time be able to control operations which are potentially harmful to the marine environment due to extraction of soil which may lead to the destruction of marine habitats.

We will elaborate in the following what are the differences between the provisions of the CBD/NP on the one hand and the UNCLOS on the other.

Regarding the material requirements the activity of the user must be qualified “marine scientific research with direct significance for exploration and exploitation” within UNCLOS and “utilization” within the NP. While research activities aiming at exploration and exploitation have, as developed above, a profit-oriented character, “utilization” includes activities with a commercial intent as well as those with a non-commercial intent. This broader scope of application within the NP provision is though of no importance as long as the user intends to keep research results in the private realm; the researcher will in that case fall under both definitions.

The UNCLOS, unlike the NP, requires, for applications for access to the EEZ and to the continental shelf, a number of formal conditions. The state that will carry out the MSR project must deliver a full description of the following:

- Objectives and nature of the project;
- Methods and means to be used;
- Geographical areas in which the project is to be conducted;
- Expected date of appearance and departure of the vessel and removal of equipment;
- Name of the institution sponsoring the project; and

- Extent to which it is considered that the coastal State should be able to participate or to be represented in the project

These provisions are so specific that they may word by word be implemented into national law if not national law even prescribes the direct applicability of international law. On the contrary, art. 6 NP only requires that the Party to the protocol requiring prior informed consent shall provide for legal fair and non-arbitrary procedures and shall provide information on how to apply for prior informed consent; the NP is silent about any details concerning the application. A different picture emerges regarding the BS requirements: benefit-sharing obligations are listed in the UNCLOS (p.ex. Art. 249) as well as in the NP (Annex).

PIC, MAT and the sharing of financial benefits are in fact the formal and material conditions for access to and the utilization of genetic resources. By contrast, UNCLOS leaves unrestricted discretionary power to the coastal state to regulate access to its territorial sea and EEZ for commercial users. This means in practice that under the UNCLOS a state could forbid any access to its marine resources while under the CBD/NP a provider state must grant access if the user state accepts the prescribed conduct duties and the BS requirements. Hence, the NP provisions are more favorable to the commercial user state than the UNCLOS provisions.

#### 4.2.2. Access regime for non-commercial users

##### Territorial sea:

	Relevant activity	Access requirements	BS
UNCLOS:	Marine scientific research	Prior informed consent, conduct principles art. 240, 241  Promotion, facilitation, favorable conditions	Dissemination and publication of research results and data  Promotion of international MSR cooperation, education and training of research capacities of developing states
CBD/NP:	Non-commercial research, contribution to conservation and sustainable use of biological diversity	Conditions for promoting and encouraging, simplified measures on access PIC and MAT	Non-monetary benefits - Annex

EEZ/Continental shelf:

	Relevant activity	Access requirements	BS
UNCLOS:	Marine scientific research  Normal circumstances: peaceful and increases scientific knowledge for the benefit of all mankind	obligatory prior informed consent under normal circumstances, may not be unreasonably denied/delayed  Implied consent after 6 months of non-reaction  State may suspend activities in case of non-conformity with PIC	Duties of coastal state: Dissemination and publication of research results and data Promotion of international MSR cooperation, education and training of research capabilities of developing states  Duties of user: - Participation/representation of coastal state in the research project - coastal state shall receive preliminary report - coastal state shall receive assistance in assessment of the results and data - research results shall be made internationally available through appropriate channels
CBD/NP:	Non-commercial research. contribution to conservation and sustainable use of biological diversity	Conditions for promoting and encouraging, simplified measures on access PIC and MAT	Non-monetary benefits - Annex

The legal situation for non-commercial activities needs unequally more attention for analysis. First we will have a look at the provisions regulating non-commercial research within the territorial sea.

On the side of the relevant activity, “marine scientific research” in UNCLOS is opposed to “research with non-commercial purpose” in the NP. In section 3.1. we have developed criteria to define these terms. In summary of the legal analysis it can be noted, that a user falls under both scopes of application if the research activities he/she intends to undertake result in openly accessible genomic data and information about the collected microorganism, its properties and other research results. The decisive criterium in both conventions for distinguishing research from commercial activities is thus functionality.

In short, it can be resumed that both terms mean in substance the same research activity.

Contrary to what is regulated for exploration/exploitation, two fundamental rights determine the structure of the MSR provisions and create a potentially conflictuous situation: on the one hand the right of all states and international organizations to conduct MSR (Art. 238 UNCLOS) and on the other hand the exclusive right of the coastal state to regulate MSR (Art. 245, 246 UNCLOS).

In addition, conduct principles for the researcher shall guarantee a peaceful expedition for the benefit of all mankind. The prior informed consent required within UNCLOS is equivalent to the PIC under Art. 6 NP. Yet, unlike the NP provision, UNCLOS installs for the EEZ a detailed system of obligatory consent situations (“normal circumstances”), facultative consent situations (if the project is “of direct significance for the exploration or exploitation of non-living or living natural resources” or in the case of inaccurate information) and implied consent situations (Art. 252 UNCLOS). By contrast, the law-maker of the NP leaves it open for discretion what is meant by “simplified measures on access” in Art. 8 NP. In fact, this could be interpreted as that no formal PIC might be required but rather a simple notification of the intended research project could be sufficient, if a provider state so implements the provision into national law.

Yet, both conventions contain an overall valuable mandate: scientific research shall be “promoted” (Art. 8 NP, Art. 239 UNCLOS), “facilitated” (id.) , “encouraged” (Art. 8 NP), “favorable conditions” shall be created (Art. 243 UNCLOS) and “simplified measures” be introduced (Art. 8 NP).

Thus, it is clear that scientific non-commercial research shall be enhanced, this is shown by the formulations in the UNCLOS as well as in the Nagoya Protocol. This is understandable from the teleological point of view: the lawmakers of both conventions see scientific research as a means to broaden human knowledge about the marine environment and its processes to the profit of the whole mankind. Safeguarding the interest of science while sustaining the consent principle is the preponderant objective within Part XIII of the UNCLOS.

Whereas the Nagoya Protocol is silent about procedural details for achieving simplification, the UNCLOS provides for a comprehensive MSR regime adapted to different maritime zones or as Gorina-Ysern (2003) describes it: “The extent of international law regulation over MSR activities can be described as cumbersome but successful”.

## **Section 5. Outlook**

The analysis of relevant provisions within UNCLOS and the CBD/NP served as a basis for developing a comprehensive Model ABS Agreement between providers and users of genetic resources as required in WP8. The latest draft can be found below in Deliverable 8.1. Part 2.

As recalled in the preamble, access to and utilization of genetic resources shall be consistent with the provisions of UNCLOS, the CBD and the NP. A considerable number of definitions of terms and ABS requirements laid down in the legal texts were taken up in the Model ABS Agreement. In addition, the classification of R&D activities into public/private domain categories now allows an easier attribution of contractual obligations for users and providers when concluding an agreement.

The Model ABS agreement is currently under discussion and will be presented by WP8 to MicroB3 partners and multinational stakeholders in a workshop on 27<sup>th</sup>/28<sup>th</sup> February 2013 in Brussels (Workshop programme also in Deliverable 8.1. Part 2).

## **Deliverable 8.1.**

### **Part 2: Synthesis report on model contracts on pre-competitive access to marine microbial resources and exchange of material and data**

As already mentioned in the foreword Part 2 of Deliverable 8.1. consists of two texts: first a catalogue of collected model agreements on access to genetic resources and participation in material and data bases (I.) and a draft model agreement for access to marine genetic resources and the exchange of material and data (II.). We decided not to provide a report on the ABS agreement as required in the project description but we rather proceeded immediately to drafting a model agreement for MicroB3 purposes taking bits and pieces and the collected existing model agreements into account.

In addition we attach the programme of the Workshop (III.) which will be held end of February in Brussels to present the Model ABS agreement to a wider range of experts and partners.

#### **I. MICROB3- List of ABS agreements that have been analysed**

##### **In situ Access contracts - ABS**

- Agreement on Access and Benefit Sharing for non-commercial research, Model agreement of the Swiss Academy of Science, 2010
- Australian Deed of Agreement – Access to biological resources in Commonwealth Areas and Benefit Sharing
- Memorandum of understanding between French Polynesia and the Moorea Biocode Consortium
- German Research Foundation – Model Agreement on Access to Genetic Resources and Benefit Sharing,
- Brazilian model MTA to be used when shipping genetic heritage samples for non-commercial research purposes, 2006
- Brazilian model MTA for transfer of genetic materials for bioprospecting purposes, 2005
- Argentinian model ABS agreement

##### **Ex situ distribution contracts - MTAs**

- European Culture Collection MTA, 2009
- General Agreement between the National Park Service and Smithsonian Institution for custodianship of National Park Service Natural History collections, December 2012
- Argentinian model project research collaboration agreement, 2010
- Memorandum of Agreement between the Department of Agriculture of the Republic of the Philippines and the Museum National D'Histoire Naturelle (France), January 2008

#### **Tara Oceans Expedition – Verbal Notes and contracts**

- Verbal note of the Ministry of Foreign Affairs of Portugal, dated 11/08/2009
- Verbal note of the Ministry of Foreign Affairs of Morocco, dated 8/6/2009
- Verbal note of the Ministry of Foreign Affairs and Cooperation of Spain, dated 2/9/2009
- Verbal note of the Ministry of Foreign Affairs of Italy, dated 8/8/2009
- Verbal note of the Ministry of the Sea, Transport and Infrastructure of the Republic of Croatia, dated 20/5/2009
- Verbal note of the Ministry of Foreign Affairs of the Hellenic Republic, dated 12 /8/2009
- Permit issued by the Ministry of Fisheries and Agriculture of the Maldives, dated February 2010
- Permit to enter South African Waters to conduct Marine Scientific research issued by the Ministry of Agriculture, Forestry and fisheries, dated 15/6/2010
- Memorandum of Understanding between Tara Oceans and the Instituto Oceanografico Universidade de Sao Paolo, Brazil, dated 22/9/2010
- Verbal note of the Ministry of International Relations and International Trade of Argentina, dated November 2010
- Convention relatif a la campagne de prelevements et de mesures de Tara Oceans en Polynesie Francaise, dated 16/6/2011
- Scientific Research Letter of Acknowledgement by the Bureau of Oceans and International Environmental and Scientific Affairs of the United States Department of State, dated 30/9/2011

#### **WIPO Existing contracts:**

- Access and Benefit-Sharing Agreement between the Lebanese Agricultural Research Institute, Tal Amara, Rayak, Lebanon and The Board of Trustees of the Royal Botanic Gardens, Kew, Richmond, Surrey, TW9 3AE United Kingdom
- Access Regulation to Plant Genetic Resources of the Pathumthani Rice Research Centre of Thailand
- Agreement 1 between Montreal Botanical Garden and Private Companies
- Agreement 2 between Montreal Botanical Garden and Private Companies
- Agreement for the Testing of Plant Extracts between the Company and the University (Sri Lanka), dated January 1st, 2000
- Contract for the Production of Hybrid Sorghum Seeds between INSORMIL, WINROCK and INRAN, represented by the Ministry of Rural Development, National Institute of Agronomic Research, Niger and Mr Abdou Garba, Producer, 2000

- Experimental Licensing Contract between the All-Russian Scientific Research Institute for Selections of Fruits Cultures (Licensor) and the Foreign Fruit Selection Organization, France (Licensee)
- Germplasm License Agreement for "Line Ten" between Her Majesty the Queen in Right of Canada (Licensor) and Company Canada Inc. (Licensee)
- International Rice Genome Sequencing Project. Member Institution Registration Agreement between Genoscope ("Principal Investigator") and Pharmacia Corporation (Extract of contract provided)
- Know How Licencing Agreement between The Tropical Botanic Garden and Research Institute, Kerala, India (TBGRI) and The Arya Vaidya Pharmacy (Coimbatore) Ltd, Coimbatore, India (the PARTY), dated November 10th, 1995
- Material Transfer Agreement (MTA) Germplasm and Unregistered Lines between the Department of Agriculture and Agri-Foods, Canada (AAFC) and several public breeding institutions
- Model Project on "Genetic Modification of hyaluronidase inhibitor glycoprotein (WSG) in the roots of
- Withania Somnifera (Hania plant) for Anti Venom Treatment" between Astra Zeneca, National Institute of Health and Local Government, Karimabad, Pakistan
- Research Agreement between Syngenta Crop Protection AG, Basel, Switzerland and HUBEL Academy of Agricultural Science, Wuhan, China, dated November 1997
- Scientific and Technical Cooperation Agreement between the Horticultural Science Research Institute (Russia) and the All-Russian Plant Science Research Institute

## **II. MicroB3 Model Agreement on Access to Marine Microorganisms and Benefit-Sharing**

### **DRAFT of MICROB3 WP8 (version of 17.12.2012)<sup>23</sup>**

THIS AGREEMENT is made on \_\_\_\_\_ [insert date]  
BETWEEN:

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[Insert the name of the provider state institution and its representative and the full contact details]

(“the Provider State”)

AND:

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<sup>23</sup> Thanks to Laura Onofri, Michele Barbier, Thomas Greiber, Frank Oliver Gloeckner, Dawn Field, Chris Lyal, Katherine Barker, Neil Davis, Johanna Wesnigk, Carol Butler, for their comments, suggestions and for the fruitful discussions.

[Insert the name of the Recipient institution and its representative and the full contact details]

(“the Recipient”)

hereinafter referred to as “the Parties”.

## **PREAMBLE**

Considering that the European Union funded research project MicroB3 (hereinafter the “MicroB3 Project”) is a scientific research program with the following objectives:

- to cooperatively sample marine microbial biodiversity at various sites, including through a global coordinated action called “Ocean Sampling Day”
- to generate large-scale data on marine microbial genomes in an environmental context and on biotechnological applications
- to develop innovative bioinformatic approaches to make the data accessible for the research and development community and for the public at large

Considering that the MicroB3 Project presents a unique opportunity to improve global scientific knowledge and to generate benefits to coastal states providing genetic resources by further understanding the biodiversity and ecological processes within their sovereign realm, including scientific cooperation, training and public outreach activities with and in the Provider State;

Recalling that access to and utilization of genetic resources taken from the territorial sea, exclusive economic zone or continental shelf of coastal states should be consistent with the provisions of the Convention on Biological Diversity (CBD) taking into account their specifications by the Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization, and, where appropriate, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization (NP, not yet in force), as well as of the United Nations Convention on the Law of the Sea (UNCLOS);

Recalling that according to these provisions access to the above described maritime zones is subject to prior informed consent of the coastal state and mutually agreed terms if the coastal state so legally requires;

Recalling that according to these provisions coastal states have the right to regulate, authorize and conduct marine scientific research in their territorial sea, exclusive economic zone and on their continental shelf; and that in the case of research undertaken by other states or international organizations the coastal state has the right, if it so desires and if practicable, to participate or be represented in the marine scientific research project and to access data and samples and receive preliminary reports, and final results;

Recalling that according to these provisions non-monetary and/or monetary benefits from the utilization of the genetic resources shall be shared with the Provider State if the same so legally requires and as it is set out in mutually agreed terms;

Recalling that according to these provisions the transfer of genetic material shall be set out in a material transfer agreement, and suggesting that this shall be included in the present agreement;

Recalling that according to these provisions access for non-commercial research purposes shall be simplified, if [environmentally sound][contributing to the conservation and sustainable use of biodiversity];

Suggesting that research and development can be for the public domain or proprietary;

The Parties to this agreement hereby agree as follows:

## **Article 1 AGREEMENT**

1.1 This agreement is between the authority designated by the Provider State and the Recipient. The agreement sets out the terms for access to genetic resources found in/on the Provider State's territorial sea, exclusive economic zone or continental shelf, for the utilization of the genetic resources, the transfer of the genetic material to third parties and the sharing of benefits drawn from its use.

1.2 The agreement is part of the MicroB3 Consortium Agreement so that its obligations extend to all MicroB3 partners.

## **Article 2 DEFINITIONS OF TERMS**

As used in this agreement, the following terms shall have the meaning provided below:

- a) **Access** means collecting genetic resources and removing them from the location/place where they are found.
- b) **Accessed genetic resources** means the genetic resources collected in the Provider State.
- c) **Genetic material** means any material of plant, animal, microbial or other origin containing functional units of heredity.
- d) **Genetic resources** means genetic material of actual or potential value.
- e) **Local Research Institution** is the research institution that undertakes the expedition and the sampling of the genetic resources in the Provider State's sovereign realm.
- f) **MicroB3 partner** means an institution or an individual who is partner of the MicroB3 Consortium Agreement.
- g) **MicroB3 accredited partner** means an institution and individual who is bound by subcontracts of MicroB3 partners for the purpose of providing research and development assistance.
- h) **Ocean Sampling Day** is a simultaneous sampling campaign in the world's oceans, as part of the European Union funded MicroB3 project, aimed to provide insights about the microbial diversity and the identification of novel ocean-derived biotechnologies.
- i) **Provider State** means the coastal state from whose territorial sea, exclusive economic zone or continental shelf genetic resources are collected *in situ*.

- j) **Research and Development for the Public Domain** means research and development that aims at making results publicly available at not more than incremental costs for dissemination, and without being protected by patent rights or restricted by other intellectual property rights.
- k) **Proprietary Research and Development** means research and development the results of which, including products developed, are protected by patent rights or restricted by other intellectual property rights, or the results of which are obtained made accessible at more than incremental costs for dissemination.
- l) **Specific data items directly linked to the accessed genetic resources** means any experimental or observational data item obtained directly from the accessed genetic resource, including, but not limited to, genetic sequence information, metabolic information, geographical location and environmental information.
- m) **Third party** means any entity, person or institution other than the Provider State, the Recipient and any other MicroB3 partner.
- n) **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, biotechnology meaning any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.

**Article 3 ACCESS TO GENETIC RESOURCES**

3.1 The Provider State hereby grants the Recipient access to the following genetic resources, subject to the terms and conditions set out in the provisions of this access agreement:

Kinds of genetic resources \_\_\_\_\_

Geographical areas of collection \_\_\_\_\_

Time period for collection \_\_\_\_\_

3.2. In accessing the genetic resources the Recipient will use the following sampling techniques:

\_\_\_\_\_.

3.3 The Recipient shall be entitled to move the accessed genetic resources to its premises and, subject to article 1.2 of this agreement, to the premises of other MicroB3 partners.

3.4 The Recipient shall send a sample of the genetic resources for deposit to a local collaborating institution in the Provider State.

The local collaborating institution is the following:

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The sample shall be sent in the following form:

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(This clause or part of it is to be crossed out if not applicable)

- 3.5 The Recipient shall bear all the costs incurred in accessing and sending the genetic resources.

#### **Article 4 UTILIZATION OF THE GENETIC RESOURCES**

- 4.1. The Recipient shall be entitled to utilize the accessed genetic resources for the public domain.

Specifications, if deemed necessary: \_\_\_\_\_

- 4.2 The Recipient shall be entitled to utilize the accessed genetic resources and/or to use knowledge resulting from the research and development for proprietary purposes.

Specifications, if deemed necessary: \_\_\_\_\_

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(This clause is to be crossed out if not applicable)

- 4.3 Should the Recipient, after the conclusion of this agreement, intend to utilize the accessed genetic resources and/or use the knowledge resulting from research and development for proprietary rather than only public domain purposes it must seek the consent of the Provider State.

Specifications, if deemed necessary: \_\_\_\_\_

#### **Article 5 TRANSFER OF GENETIC RESOURCES AND DATA TO THIRD PARTIES**

- 5.1 The Recipient may transfer to a third party (among which MicroB3 accredited partners) the collected genetic material, provided that the third party agrees, through a Material Transfer Agreement (MTA) with the Recipient, to apply to the transferred genetic material articles 4, 6 to 15 of this agreement.

- 5.2 The Recipient may transfer to a third party (among which MicroB3 accredited partners) specific data items directly linked to the accessed genetic resources provided that the third party agrees, through a Data Transfer Agreement (DTA) with the Recipient, to apply to the transferred data articles 4, 6, 7, 8.2, 8.3, 9 to 15 of this agreement.

#### **Article 6 DISSEMINATION OF KNOWLEDGE**

- 6.1 The Recipient shall make the knowledge resulting from research and development on the accessed genetic resources publicly available at no more than incremental costs of dissemination. The dissemination can be through online media, print media or delivery upon request. The possible forums for online dissemination include the MicroB3 Portal ([www.microb3.eu](http://www.microb3.eu)) and existing data bases and information networks such as the Global Biodiversity Information Facility (GBIF), the Consortium for the Barcode of Life (CBOL), SeaDateNet, Pangaea and the International Nucleotide Sequence Databases (INSDC).

- 6.2 Such knowledge shall be made available as soon as possible after its generation and, if an embargo period is required for publication purposes, no later than 12 months after that date.

- 6.3 The release of data resulting from research and development on the accessed genetic resources through online media, print media or delivery upon request will be

organized such that users are bound not to use the specific data items directly linked to the accessed genetic resources and taken from the portals for proprietary purposes unless they have obtained prior informed consent of the Provider State. This condition does not apply to the INSDC insofar as its practice is to release the raw genetic sequence information without any use restrictions.

6.4 Paragraphs 1-3 of this article do not apply to knowledge generated from proprietary research and development under articles 4.2 and 4.3.

6.5 The Recipient may make data available also through the MicroB3 Information System. The users of such data shall be required to provide to the MicroB3 Information System a copy of the results of their research using the data accessed from the MicroB3 Information System, in such form and format as MicroB3 Information System will reasonably require in order to promote the objectives of research and development for the public domain.

#### **Article 7 TRACING THE CONTRIBUTION OF THE PROVIDER STATE**

7.1 When making the knowledge resulting from research and development on the accessed genetic resources publicly available the Recipient shall indicate the origin of the utilized genetic resource.

7.2 When making the knowledge resulting from research and development on the accessed genetic resources publicly available the Recipient shall acknowledge the role of scientists from the Provider State, and, where any significant advice or recommendations have been provided by such scientists, their (co-)authorship.

#### **Article 8 RECORDING AND REPORTING**

8.1 The Recipient shall maintain records concerning the storage and transfer of the genetic material and allow access to such records to the Provider State or the authority designated by the same.

\_\_\_\_\_ (insert name and address of authority if applicable)  
8.2 The Recipient shall report in writing to the Provider State or the authority designated by the same every \_\_\_\_\_ [insert duration] months, beginning \_\_\_\_\_ and ending \_\_\_\_\_ providing details of the progress of research and development.

\_\_\_\_\_ (insert name and address of authority if applicable)  
8.3 Concerning knowledge determined by articles 4.2 and 4.3 of this agreement the Recipient shall when reporting according to paragraph 2 of this article also report on any steps taken towards obtaining or implementing intellectual property protection and the selling of products or services based on this knowledge.

#### **Article 9 SHARING OF INFORMATION**

9.1 The Recipient shall provide the Provider State or the authority designated by the same with the knowledge resulting from research and development on the accessed genetic resources and provide assistance in their assessment or interpretation as reasonably requested.

\_\_\_\_\_ (insert name and address of authority if applicable)  
9.2 The knowledge according to paragraph 1 of this article shall be provided at the latest 3 months after it was generated. It shall be provided at least 3 months prior to making it publicly available. The Provider State shall keep it confidential during this period.

- 9.3 The obligation under paragraph 1 of this article is also applicable to knowledge obtained by the Recipient under articles 4.2 and 4.3. When using the knowledge the Provider State shall not prejudice any proprietary use of the same by the Recipient. Specifications, if deemed necessary: \_\_\_\_\_
- 9.4 The Recipient shall furnish the Provider State or the authority designated by the same with \_\_\_\_\_ (insert number of copies) copies of any publication based on the accessed genetic resources.  
 \_\_\_\_\_ (insert name and address of authority if applicable)

**ARTICLE 10 FURTHER COOPERATION WITH PROVIDER STATE**

As part of the MicroB3 project the Recipient shall strive to involve scientists from the Provider State in the research and development activities based on this agreement. Such involvement shall take the following forms:

\_\_\_\_\_  
 \_\_\_\_\_  
 (to be specified by negotiations)

**Article 11 BENEFIT SHARING IN CASE OF PROPRIETARY RESEARCH AND DEVELOPMENT**

- 11.1 If the Recipient utilizes knowledge generated according to articles 4.2 and 4.3, it must share with the Provider State any monetary benefit obtained from the knowledge.
- 11.2 The share shall be determined by further negotiations between the parties to this agreement.
- 11.3. (alternatively to 11.2) The share shall be \_\_\_\_\_ percent of the revenue from sales of the product or service based on the accessed genetic resources. It shall be paid on the basis of a financial report to be sent to the Provider State or an authority designated by the same at the end of any year of any revenue generation to the account designated by the same.

\_\_\_\_\_  
 \_\_\_\_\_  
 (insert authority and account details)

- 11.4 If the Recipient utilizes the knowledge generated according to article 4.1 for proprietary purposes and in breach of the conditions of this agreement it must share with the Provider State any monetary benefit obtained. The share shall be \_\_\_\_\_ percent of the revenue from sales of the product or service based on the accessed genetic resources. It shall be paid on the basis of a financial report to be sent to the Provider State or an authority designated by the same in due time upon request by the same.

\_\_\_\_\_  
 \_\_\_\_\_  
 (insert authority and account details)  
 (This article or single paragraphs of it to be crossed out if not applicable)

**Article 12 OTHER LAWS TO BE RESPECTED**

The Recipient shall ensure that the collection, storage, moving, utilization and exportation of the genetic material complies with all applicable laws of the Provider State on the protection of human health and the environment, on taxes, on customs and any other concern.

**Article 13 TERMINATION OF THE AGREEMENT**

13.1 The agreement may be terminated at any time by mutual agreement in writing.

13.2 The agreement may be terminated by default if the Recipient fails to satisfy any of the following obligations under this agreement: articles 4.3, 5.1, 6.1, 6.3, 8, 9.1 and 9.3, 11.1, 11.4.

13.3 In the case of default the Provider State may immediately terminate this agreement by giving written notice to the Recipient of the termination, provided that:

(a) the Provider State has given prior notice to the Recipient of the alleged default; and

(b) the Recipient fails to respond to the Provider State within the period specified by the notice (being not less than 20 business days and not more than 60 business days) to rectify or explain to the satisfaction of the Provider State the reasons for the default.

13.4 If this agreement is terminated under paragraph 2 of this article the Recipient will not thereafter use, or allow to use any genetic resources or associated data accessed under this agreement; and it will transfer back to the Provider State or destroy, at the Provider State’s discretion, all genetic resources or associated data accessed under this agreement. The operation of this clause survives the termination of this agreement.

**Article 14 APPLICABLE LAW**

14.1 The applicable law on any matters relating to the interpretation and the application of the present agreement shall be

\_\_\_\_\_

14.2 The competent court for dispute settlement shall be

**Article 15 DISPUTE SETTLEMENT**

15.1 No party shall, in the event of a dispute arising from this agreement, commence court proceedings (except proceedings for urgent interlocutory relief) before searching for an amicable solution according to paragraphs 2 and 3 of this article.

15.2 A party to this agreement claiming that a dispute has arisen under or in relation to this agreement must serve the other party with a written notice specifying the nature of the dispute on receipt of which the dispute resolution shall forthwith begin.

15.3 Any dispute arising from this agreement shall be resolved expeditiously foremost by negotiation in good faith failure to which the parties shall engage informal dispute resolution techniques, such as mediation and arbitration or similar techniques agreed to by them.

[Location, Date, Signatures]

### III. Programme of the WP8 Workshop 27<sup>th</sup>/28<sup>th</sup> February in Brussels

#### MICROB3 – STAKEHOLDER WORKSHOP

#### **“Towards a Model Agreement on Access and Benefit Sharing for Marine Genetic Resources (with a focus on marine micro-organisms)**

*Proposed best practices to access MGRs and support metagenomic science for utilization in data-driven global research collaborations based on the Convention on Biological Diversity, taking into account the Nagoya Protocol”*

Date: 27-28 February 2013  
Venue: Bruxelles, University Foundation  
Rue d'Egmont 11 - 1000 Bruxelles  
Room: Emile Francqui

#### BACKGROUND

Micro B3 project is an EU FP7 Project that aims at reinforcing research on marine microbial biodiversity, bioinformatics and biotechnology in Europe and beyond. It builds on the experiences of a number of world leading research institutions and private industrial companies.

In this context, work package 8 of the project dealing with Intellectual Property Rights management for marine research and bioprospecting) is developing a model agreement on Access to and Benefit Sharing of Marine Genetic Resources within the framework of the Convention on Biological Diversity. The model aims to deliver a set of contractual tools that can be used by major European initiatives in this field.

The proposed workshop will present WP 8 results that are directly relevant for the draft model agreement, and discuss the agreement and its core clauses with the main stakeholders involved in research and bioprospecting of MGR from:

- provider and user countries' authorities (issuing permits)
- the scientific community on the provider and user side
- databases
- collections
- industry actors
- legal experts

#### PROVISIONAL AGENDA:

#### WEDNESDAY 27<sup>TH</sup> FEBRUARY

##### INTRODUCTION

- 10:00 – 10:15 Welcoming Remarks  
**Frank Oliver Glöckner, Max Planck Institute for Marine Microbiology Jacobs University Bremen (Coordinator of MICROB3)**
- 10:15 – 10:30 Introduction of the background of the workshop and panelists  
**Tom Dedeurwaerdere, Université catholique de Louvain (WP8 leader)**

##### THE LEGAL BACKGROUND FOR MICROB3 MODEL ABS AGREEMENT

- 10:30 – 10:50 The legal framework for ABS in comparison of the Convention on Biological Diversity (and the Nagoya Protocol) and United Nations Convention on the Law of the Sea (UNCLOS)  
**Gerd Winter, University of Bremen**

<u>10:50 – 11:10</u>	<u>COFFEE BREAK</u>
11:10 – 11:30	Provider state ABS legislation applicable to access to marine microorganisms: the example of Kenya <b>Evanson Chege Kamau, University of Bremen</b>
11:30 – 11:50	User state legislation: the example of the EU proposal for an ABS Regulation <b>Thomas Greiber, IUCN</b>
11:50 – 12:10	A new instrument, the CIESM Code of Conduct <b>Michele Barbier, CIESM</b>
12:10 – 12:30	Questions
<u>12:30 – 13:30</u>	<u>LUNCH BREAK</u>

### **THE SCIENTIFIC AND BIOINFORMATICS BACKGROUND FOR MICROB3 MODEL ABS AGREEMENT**

13:30 – 13:50	How can provider state researchers be involved in research and development on marine microorganisms? <b>Chris Bowler, scientific coordinator of Tara Oceans expedition</b>
13:50 – 14:00	How do taxonomic and genomics data bases work and adapt to ABS? <b>Chris Lyal, Dpt of Entomology, Natural History Museum, London</b>
14:00 – 14:20	How do material collections of micro-organisms work and adapt to ABS requirements? <b>Tom Dedeurwaerdere, Université catholique de Louvain</b>
14:20 – 14:40	Which research and development results might be candidates for what kind of intellectual property protection? <b>Fernando de la Calle, Head of Microbiology R&amp;D Department, PharmaMar SAU Madrid (Spain)</b>
14:40 – 15:10	Experiences with access to genetic resources for commercial research and development - Representatives from: <b>Matis ltd, Iceland or Bio Ilberis R&amp;D, Spain or PharmaMar, SA, Spain</b>
15:10 – 16:00	Questions

16:00 -16:30 COFFEE BREAK

### **INTRODUCTION OF THE ANALYSIS AND DISCUSSION OF MICROB3 MODEL ABS AGREEMENT**

16:30 – 17:00	Overview and structure of the MICROB3 ABS model agreement <b>Arianna Broggiato, Université catholique de Louvain</b>
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- 17:00 – 17:30      Crucial points of the MICROB3 ABS model agreement  
**Caroline v. Kries, University of Bremen**
- 17:30 – 18:00      Questions and voluntary division of the participants into the two panels
- 19:30                      Dinner

**Thursday 28<sup>th</sup> February**

**ANALYSIS AND DISCUSSION OF MICROB3 MODEL ABS AGREEMENT WITHIN  
TWO PARALLEL PANELS**

- 9:00 – 13:00      **PANEL A. Access to and utilization of genetic resources**  
**PANEL B. Transfer of genetic resources and data management**

13:00 – 14:00      Lunch break

14:00 – 15:00      Summary of the outcomes of the panels by the facilitators

15:00 – 16:00      Concluding remarks

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