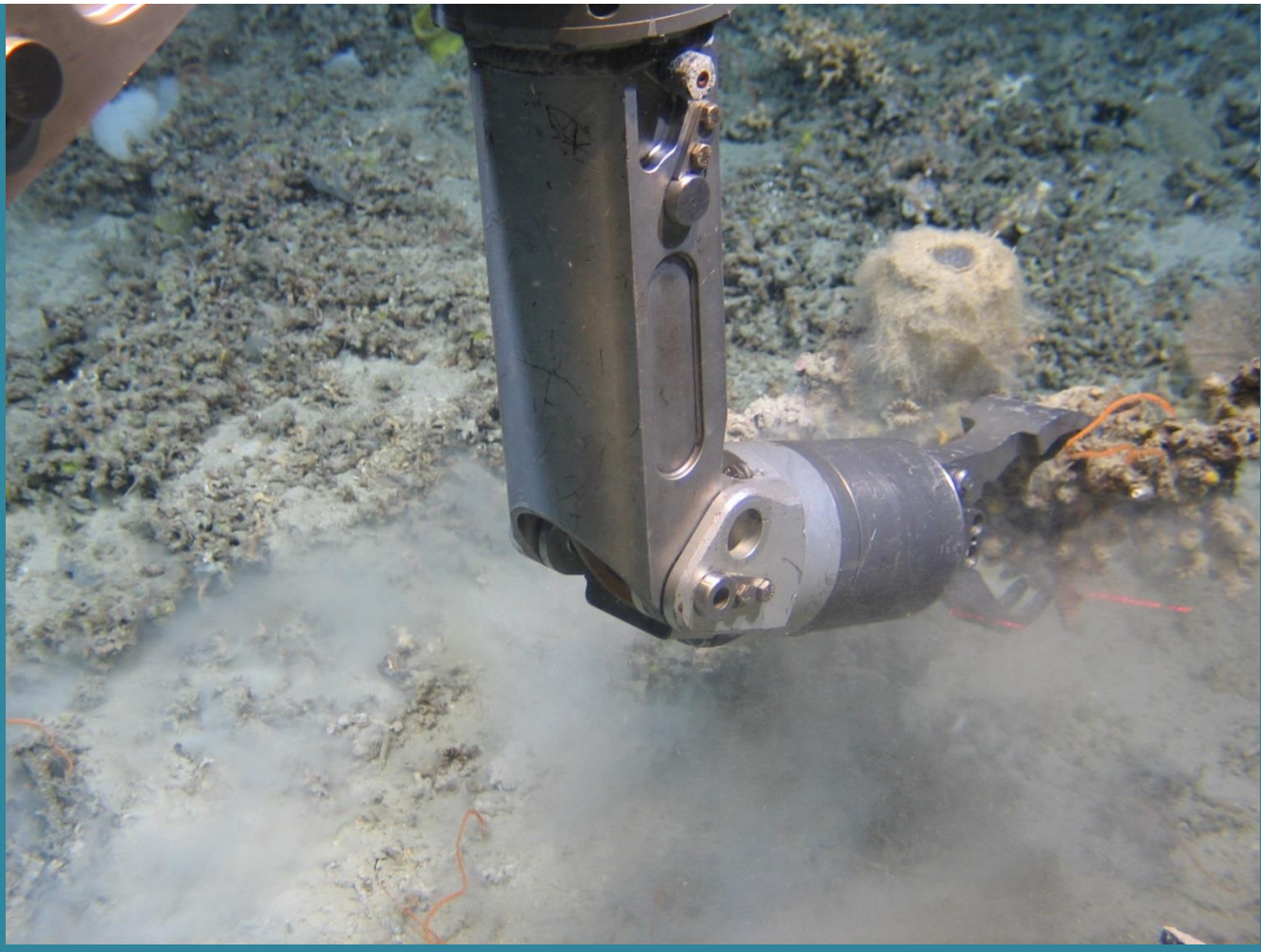
Report of the PharmaSea WP6 Stakeholder Workshop on

'Options for an Access and Benefit-Sharing Regime for Marine Genetic Resources from Areas Beyond National Jurisdiction'



June 2014

McMeel O., Greiber T., Vanagt T. and Jaspars M.

Report of the PharmaSea WP6 Stakeholder Workshop on 'Options for an Access and Benefit-Sharing Regime for Marine Genetic Resources from Areas Beyond National Jurisdiction'.

Pharmasea-eCOAST-6.8a. Ostend, Belgium

Cover photo: Robot arm from the remotely operated vehicle (ROV) Holland I on the Irish Research Vessel RV Celtic Explorer (courtesy, Irish Marine Institute)

Funded by	European Commission 7th Framework Programme
Status	Final Report
Project number	PharmaSea grant agreement no: 312184
Report number	Pharmasea-eCOAST-6.8a
Publication date	June 2014
Title	Report of the PharmaSea WP6 Stakeholder Workshop on 'Options for an Access and Benefit-Sharing Regime for Marine Genetic Resources from Areas Beyond National Jurisdiction'
Authors	Oonagh McMeel,[a] Thomas Greiber,[b] Thomas Vanagt[a] and Marcel Jaspars[c]
Contributors	Workshop Participants
To cite as	McMeel *et al.,* (2014) Report of the PharmaSea WP6 Stakeholder Workshop on 'Options for an Access and Benefit-Sharing Regime for Marine Genetic Resources from Areas Beyond National Jurisdiction' PharmaSea-eCOAST-6.8a Ostend, Belgium
Approved by:	Dr Thomas Vanagt (eCOAST)
Checked by	Professor Marcel Jaspars (University of Aberdeen)

The PharmaSea project has received funding from the European Union's Seventh Framework Programme for research, technological development and demonstration (FP7/2007-2013) under grant agreement no 312184 . The PharmaSea project is solely responsible for this report. The report does not represent the views of the EU and the EU is not responsible for any use that might be made of the information contained herein.

a eCOAST Marine Research, Oostende, Belgium
b IUCN Environmental Law Centre, Bonn, Germany
c Marine Biodiscovery Centre, University of Aberdeen, United Kingdom

TABLE OF CONTENTS

LIST OF ABBREVIATIONS

ABS	Access and Benefit-Sharing
ABNJ	Areas Beyond National Jurisdiction
APPLE	Advisory Panel of Policy and Legal Experts
BBNJ	Biodiversity Beyond National Jurisdictions
CBD	Convention on Biological Diversity
CH	Clearing-House
EC	European Commission
EC COM	European Commission Communication
EIA	Environmental Impact Assessment
EU	European Union
FP7	EU 7th Framework Programme
IPR	Intellectual Property Rights
MAT	Mutually Agreed Terms
MGR	Marine Genetic Resources
MSR	Marine Scientific Research
MTA	Material Transfer Agreement
NP	Nagoya Protocol
PIC	Prior Informed Consent
ROV	Remotely Operated Vehicle
UNCLOS	United Nations Convention on the Law of the Sea
WP6	Work Package 6

EXECUTIVE SUMMARY

The PharmaSea project, funded by the European Union Framework Programme 7, represents a model marine biodiscovery pipeline within which existing challenges hampering marine biodiscovery research and development (R&D) are addressed.

Within the PharmaSea project, one work package (WP6) aims to clarify the legal and policy obligations relevant to users of marine genetic resources (MGR) and provide guidance to ensure that MGR used in marine biodiscovery are sourced and utilized legally. PharmaSea WP6 also aims to contribute the experience of MGR practitioners to policy discussions concerning regulations which may impact on their R&D activities.

Issues related to MGR from Areas Beyond National Jurisdiction (ABNJ), including questions on the sharing of benefits, are one of a package of issues currently under discussion at the UN General Assembly in the context of its *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.

In this context a stakeholder workshop was held in Leuven on 7-8 May 2014 to consider 'Options for an Access and Benefit-Sharing (ABS) Regime for Marine Genetic Resources (MGR) from Areas Beyond National Jurisdiction (ABNJ).'

The workshop participants comprised an interdisciplinary group of experts and policy makers including marine biodiscovery practitioners, legal experts (in the fields of ABS, IPR and law of the sea), policy-makers and other relevant stakeholders.

A background document was developed and circulated by WP6 which aimed to provide a non-exhaustive list of preliminary ideas, questions, problems and potential solutions for a future ABS regime to provide a basis for discussions at the workshop. The primary objective of the workshop was to promote R&D on MGR from ABNJ whilst building on the existing UNCLOS framework (instead of amending UNCLOS provisions).

The workshop discussions were structured around three sessions to consider options for non-monetary benefit-sharing, options for monetary benefit-sharing, and issues related to compliance and monitoring. The discussions considered both current practices and future options, both from the perspective of the scientific community engaged in R&D on MGR and from legal experts and policy makers.

It was originally planned that the proposals presented and elaborated at the workshop would then be submitted to and presented at the UN *Ad Hoc* Open-ended Informal Working Group meeting in June 2014 in order to support the decision-making process within the UN General Assembly.

However, in considering the options proposed by WP6 for a potential future ABS regime for MGR from ABNJ, the participants agreed that it was too early in the process of the BBNJ working group for such a detailed regime to be presented at the UN Working

Group meeting in June 2014. The participants advised that a more acceptable approach would be the development and coordination of current practices in sampling and curation of MGR, data-sharing and integration which were identified during the workshop and which could form the basis of a future regime. Such an approach would limit the introduction of additional administrative burden for the marine scientific community.

The discussions also highlighted areas where a potential future regime could support and enable sustainable and environmentally responsible marine scientific research.

Whilst MGR sourced from ABNJ fall outside of the scope of the Nagoya Protocol, the entry into force of the Protocol will have implications for how researchers utilize all (M)GR in their R&D. Research institutions will have to adapt their procedures to deal with these new measures. This will, however, pave the way for any potential future ABS regime for MGR from ABNJ. It will be important to ensure that an imbalance is not created in regards to obligations on researchers between sampling within or beyond national jurisdiction.

MGR from ABNJ are often collected and deposited in *ex-situ* collections via basic marine scientific research activities. Any future regime on ABS of MGR from ABNJ would potentially impact most on the activities of the basic marine scientific research community. Since their work contributes to the protection and preservation of the marine environment but also directly or indirectly facilitates the entry of MGR into the value chain, their needs and concerns must be considered.

The scientific community engaged in basic and applied research on MGR must not remain silent in these discussions. Their input at an early stage in this process can help ensure a potential future Implementing Agreement enables rather than impedes marine scientific research.

Finally in considering ABS of MGR from ABNJ, future practices must be considered including the collection of MGR via means other than marine scientific research, for example via environmental impact assessments for deep sea mining.

1 INTRODUCTION

1.2 The PharmaSea Project

PharmaSea is a Framework Programme 7[1] (FP7) project that focuses on the obstacles which impede marine biodiscovery research, development and commercialization in Europe. PharmaSea brings together a multi-disciplinary team of academic and industry researchers and specialists to identify and characterize blockages in the marine biotechnology innovation chain and to develop solutions to overcome them. The partners are ideally placed to demonstrate how to widen the bottlenecks and increase the flow of ideas and products derived specifically from the marine microbiome towards a greater number of successes in a larger number of application areas.

PharmaSea will establish a robust pipeline to process microbial samples drawn from very different origins, including marine microbial strain collections held by partners and new strains taken from extreme environments (deep, cold and hot vent habitats). By screening such a broad genetic diversity, the project partners will concentrate their combined expertise and resources on the key objective of producing new products with desirable characteristics for development by the SME partners in three accessible market sectors: health, personal care and nutrition. Ultimately PharmaSea aims to ensure that all bottlenecks in the marine biodiscovery pipeline are widened sufficiently to make marine bioresources attractive to industry on an equal footing to terrestrial bioresources. For further information see www.pharma-sea.eu.

1.3 PharmaSea Work Package 6

Within the PharmaSea project, one work package (WP6) focuses on analysing bottlenecks in the legal and policy framework surrounding the sustainable exploitation of marine bioresources for European biotechnological research, development and commercialisation. Ultimately WP6 aims to clarify the legal and policy obligations which are relevant to the MGR practitioner and to provide guidance and tools to support the use of only lawfully acquired MGR in their research and development activities.

WP6 will consider the new and existing legal and governance frameworks which are relevant to the sustainable exploitation of MGR sourced from within or beyond national jurisdictions, either *in-situ* or from *ex-situ* collections. Through stakeholder consultations, two stakeholder workshops and case studies, WP6 will identify the most significant challenges which these frameworks present to marine biodiscovery R&D and propose pragmatic solutions to address these.

[1] Framework Programme 7 (FP7) is the EU programme for research and technology development for the period 2007 to 2014.

To oversee and advise on the progress of WP6 an advisory panel consisting of PharmaSea partner MGR practitioners and invited legal and policy experts from governmental and non-governmental bodies has been convened. In addition to its advisory role, this panel will act also as a *de facto* science-policy interface focusing on the policy and legal bottlenecks in the marine biodiscovery process. Via this panel, and other fora, WP6 also aims to contribute the voice of the MGR practitioner to policy discussions concerning regulations which may impact on their R&D activities.

1.4 PharmaSea Stakeholder Workshop 'Options for an Access and Benefit-Sharing Regime for Areas Beyond National Jurisdiction'

A decision was taken at the first meeting of the PharmaSea WP6 Advisory Panel of Policy and Legal Experts (APPLE) that the first PharmaSea WP6 stakeholder workshop would develop a model for how MGR from ABNJ, and related data, could be made more widely available to the global community. The model would consider also how the sharing of benefits arising from the utilization of these resources could be facilitated.

To this end, an interdisciplinary group of experts and policy makers was convened in Leuven on 7-8 May 2014 to consider 'Options for an Access and Benefit-Sharing (ABS) regime for Marine Genetic Resources (MGR) from Areas Beyond National Jurisdiction (ABNJ).' The workshop participants included; marine biodiscovery practitioners, legal experts (in the fields of ABS, IPR and law of the sea), policy-makers and other relevant stakeholders (Annex I). PharmaSea project leader, Professor Marcel Jaspars, chaired the workshop.

In advance of the workshop Thomas Greiber, IUCN-ELC - with support from eCOAST and University of Aberdeen - prepared and circulated a background document which aimed to provide a non-exhaustive list of preliminary ideas, questions, problems and potential solutions for a future ABS regime to provide a basis for discussions at the workshop (Annex II). The primary objectives of the workshop were to promote international R&D on MGR from ABNJ (instead of creating obstacles) whilst also building on the existing UNCLOS framework instead of amending UNCLOS provisions (in particular the freedom of marine scientific research (MSR) and the relevant UNCLOS requirements including international cooperation in MSR, the creation of favourable conditions for the conduct of MSR, the publication and dissemination of information and knowledge resulting from MSR, and the promotion of data and information flow and transfer of knowledge).

The background document noted that the issues addressed were to be envisaged as part of an overall international instrument for ABNJ rather than as a stand-alone ABS regime for ABNJ. As agreed in 2011 by the UN *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, the scope of such an international instrument for

ABNJ could include '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' together and as a whole in a single package (so called 'package deal').

Thomas Greiber introduced possible options for an ABS regime for MGR from ABNJ as outlined in the background document. As a starting point he noted that without scientific research, no benefit-sharing (whether monetary or non-monetary) can take place. He highlighted that the results from R&D can be considered as true global benefits and, therefore, the freedom of MSR as envisaged under the UNCLOS should be maintained. However, he also clarified that the freedom of MSR is not unlimited but subject to environmental considerations (e.g. the obligations of all States to protect and preserve the marine environment and rare or fragile ecosystems). He also indicated that existing MSR obligations under the UNCLOS already foresee different forms of non-monetary benefit-sharing. For example the obligations to promote international cooperation in MSR, to make knowledge resulting from MSR available by publication and dissemination, and to promote data and information flow and transfer of knowledge. Furthermore, he referred to the UNCLOS Preamble stating the vision of realizing a just and equitable international economic order taking into account the interests and needs of mankind as a whole and, in particular, the special interests and needs of developing countries. Based on these starting points, Thomas Greiber then presented different ideas for a possible ABS regime in more detail, and encouraged the scientific community to engage proactively in the UN Working Group discussions.

It was planned that proposals presented and elaborated at the workshop would then be submitted to and presented at the UN Working Group meeting in June 2014 in order to support the decision-making process within the UN General Assembly.

The workshop was structured around three sessions to consider options for non-monetary benefit-sharing, options for monetary benefit-sharing and issues related to compliance and monitoring. The discussions considered both current practices and future options, both from the perspective of the scientific community engaged in R&D on MGR and from legal experts and policy makers. It should be noted that while the focus of the workshop was on aspects relevant to MGR sourced from ABNJ, current marine scientific research practices (sampling, *ex-situ* collections, data sharing and integration and downstream R&D) do not necessarily distinguish between MGR based on the different maritime zones within which they were originally sourced. Furthermore, ABS instruments, such as the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, or the FAO International Treaty on Plant Genetic Resources for Food and Agriculture, already provide a number of ABS regulations and approaches which are interesting to consider in the discussions on a future ABS regime for MGR from ABNJ. For this reason this report includes aspects relevant to MGR sourced from both within and beyond the limits of national jurisdiction.

Figure 1 Participants at the PharmaSea WP6 stakeholder workshop

Top Row: John Brincat European Commission DG MARE, Jan-Bart Calewaert EMODnet Secretariat, Lyle Glowka Secretariat of the Convention of Migratory Species, Laura Giuliano CIESM, Geoff Burton UNU-IAS, Laura Lallier eCOAST, Camilla Esguerra KU Leuven, Kjersti Lie Gabrielsen Marbank
Middle Row: Isabelle Huys KU Leuven, Alex Crawford KU Leuven, Johanna Wesnigk EMPA (MicroB3), Arianna Broggiato Université Catholique Louvain (MicroB3), Kathryn Garforth CBD Secretariat.
Bottom Row: Charlotte Salpin UN Division for Ocean Affairs and the Law of the Sea, Meredith Lloyd-Evans BioBridge, Hugo-Maria Schally European Commission DG Environment, Thomas Greiber IUCN-Environmental Law Centre, Oonagh McMeel eCOAST and Marcel Jaspars University of Aberdeen (Chair)
Participants not pictured: Marie-Cécile Barras Novamen SeaBioTech, Alicja Kozlowska European Commission DG Environment, Kate Larkin European Marine Board and Thomas Vanagt eCOAST

2 SAMPLING AND UTILIZATION OF MARINE GENETIC RESOURCES: FROM CRUISE TO COMMERCIALIZATION

For reporting purposes, the workshop discussions are summarised below under sub-headings reflecting stages in the MGR 'sampling and utilization' process; from planning a cruise campaign to the point at which the sample(s) may be utilised for R&D and how benefits may be shared.

2.1 Sourcing MGR in-situ

Considering the first stage in the process, sourcing MGR *in-situ*, this section considers the planning and execution of a research cruise to sample MGR.

- It is important to recognise that cruises are not always planned solely to sample in an ABNJ. Generally cruises and marine scientific research (MSR) target particular ecosystems to address basic research questions. The jurisdiction will be considered only in so far as access requirements are necessary e.g. permits etc. A cruise path may include sampling points lying both within and beyond the limits of national jurisdiction.
- Considering options for a future regime, it was pointed out that an obligation on States to request authorization to sample in ABNJ via a permit or licence might not be acceptable to many States based on current discussions within the BBNJ working group. A 'notification of intent to sample' might be preferable.
- Sampling of MGR from ABNJ *in-situ*, is considered to be the preserve of developed nations with ocean going research vessels (RVs) and related infrastructures, e.g. remotely operated vehicles (ROVs), as well as sufficient financial resources. However, even within this international community there exists a continuum of capacity, reflected not only in the available infrastructure but also in the extent to which nationally coordinated programs exist to coordinate sampling and the curation and exchange of both samples and associated data.
- Sampling can be differentiated into targeted (e.g. with ROV) and non-targeted (trawling, coring etc.). Both types of sampling are carried out in ABNJ.
- Considering that the freedom to carry out MSR has to be balanced with the protection and preservation of the marine environment, the question was raised as to whether there are currently any guidelines, codes of conduct, procedures etc. for sampling including, e.g. restrictions on sample quantity? The InteRidge guidelines for responsible sampling at hydrothermal vents[2] and also the CIESM charter on ABS of MGR[3] were cited.
- It was further stated that marine scientific research does not exist in a vacuum, which means that other sets of rules could also apply, such as those related to

[2]. http://www.interridge.org/IRstatement
[3] http://www.ciesm.org/forums/index.php?post/2013/03/14/CIESM-Charter-on-ABS

fisheries. In the specific context of fisheries, this could lead to a situation where in some countries the collected samples will be deducted from fisheries quota if the amount sampled is of a substantial nature.

- In considering where and how samples from ABNJ should be deposited and curated, and whose responsibility this was, it was explained that samples are usually taken and distributed on-board based on the requirements of the multi-disciplinary, and often international, researchers present. Each scientist taking samples will prepare an individual report. These individual reports will be collated into a cruise report by the principal scientist (see 2.2). Samples will then be transported back to the relevant institutions following docking.
- In relation to environmental impact assessments (EIAs), it was noted that basic scientific research, which would comprise the majority of sampling in ABNJ, is considered to be low impact. UNCLOS provisions state that "When States have reasonable grounds for believing that planned activities under their jurisdiction or control may cause substantial pollution of or significant and harmful changes to the marine environment, they shall, as far as practicable, assess the potential effects of such activities on the marine environment." This is open to interpretation. It was noted that in other instances where the extent/level of EIA was left to the discretion of the researchers the 'lighter' option will always be chosen. Developing standard EIAs for sampling in marine ecosystems in ABNJ is difficult because most research cruises are still 'discovery' and so no baseline exists.
- Monitoring of *in-situ* sampling is already well developed. All ships will carry transponders so that their GPS position can be tracked to a high degree of accuracy. This will record only the location of the ship and not the location of the sampling device. Automated Under-water Vehicles (AUVs) typically have their own automated information system (AIS). Research cruise paths are visible in real-time via various portals e.g. www.pogo-oceancruises.org
- Including an observer on-board was proposed as a means of further monitoring sampling sites in ABNJ which are close to external limits of the exclusive economic zones (EEZ) of coastal States. Many countries already request that foreign vessels carrying out marine scientific research (MSR) in their EEZ include a national observer on-board. This is an exercise of their right to regulate MSR under UNCLOS. It was pointed out that an on-board observer is not always effective where there was intent to evade e.g. fisheries quotas.
- Considering who would be responsible for carrying out the administrative work associated with sampling in ABNJ under a future regime, current practices with regard to research cruises were considered. Many scientists are unaware of obligations with regard to both MSR provisions of UNCLOS and also ABS obligations under the Nagoya Protocol. Larger marine institutes will have research vessel services who liaise with scientists for some of the administrative procedures e.g. applications through diplomatic channels.

2.2 *In-situ* Data Collection and Traceability

The following section summarises the information discussed in relation to the collection and traceability of sample data and associated environmental data which has been obtained during the cruise i.e. '*in-situ*'.

- Standard good practice in marine scientific research includes recording the GPS coordinates of all samples and their depth, the substrate from which the samples were taken i.e. water column, seabed, subsoil, together with associated environmental data including parameters such as temperature, pressure, salinity etc.
- A cruise report is compiled on board which registers every sample / specimen. Some countries will have strict guidelines on cruise report formats. https://www.bodc.ac.uk/data/information_and_inventories/cruise_inventory/ All samples are identified, as far as possible, on board and given unique identifiers for tracking purposes (particularly important when it is not possible to identify samples *in-situ*). Cruise reports are logged at institutional or national level depending on the capacity of the Flag State / country of the principal scientist. In some cases these cruise reports are stored in open access libraries. http://seadata.bsh.de/csr/retrieve/pogo_index.html
- In response to questions regarding the accuracy/reliability of data it was pointed out that the increasing automation of data-logging means the accuracy and quality of sampling data is excellent. For scientists on-board it is basic good scientific practice to ensure the reliability of their data. Moreover, the lack of such metadata would make the samples nearly useless for further scientific purposes.
- Sensors for collecting environmental datasets are always calibrated on-board and this calibration data accompanies the dataset when submitted to the database. Protocols and best practice are also in place for metadata, in particular for physical and biogeochemical datasets e.g. cruise metadata report for UK cruise: https://www.bodc.ac.uk/data/documents/cruise/3378/
- Storage of samples with unique geo-referenced identifiers will become increasingly important following the entry into force of the Nagoya Protocol in order to allow researchers to demonstrate that samples were sourced from ABNJ and thus have no associated ABS obligations under the CBD and its Nagoya Protocol.

2.3 Curation and Storage of MGR: Ex-situ Collections

Curation and storage of samples (MGR) in biorepositories, be they small institutional collections or nationally / internationally coordinated collections, provides a bridge between the basic research community engaged in sampling and the applied and commercial research community utilizing samples for R&D purposes. In a limited number of countries nationally coordinated collections of MGR are maintained for biodiscovery purposes. However, it would be more often the case that researchers on-board RVs store samples in their own laboratory collections under conditions appropriate to their own research area. It is important to note that in discussing biorepositories it is impossible to consider only samples sourced from ABNJ. Current standard procedures for sample storage will apply equally to samples sourced from within the limits of national jurisdiction. Therefore the summary points include reference to MGR within the scope of the Nagoya Protocol.

- Encouraging researchers to deliver duplicate samples to a biorepository could be seen as a form of insurance for researchers but would introduce additional effort for them. It would, however, provide legal certainty as to provenance and ownership in the case of downstream commercialisation. An example was provided in Australia's Great Barrier Reef Marine Protected Area, where sub-samples must be prepared on board and delivered, with barcodes, to a repository. However, not all samples can be duplicated and/or cultured. For some research uses, e.g. taxonomy, the entire sample may be required.
- A general issue related to biorepositories is how to prioritise access to finite samples. Currently researchers requesting samples are asked about the purpose of their research. Obtaining sufficient detail on this can be problematic if researchers wish to ensure confidentiality.
- Current considerations to prioritise access include, amongst others:
    - Priority to those carrying out new research as opposed to re-testing samples for the same purposes. This can be difficult to establish as the work may not yet have been published or it may be protected by patent and so parallel independent research on the same samples can and does occur.
    - Priority to researchers intending to scale-up.
    - Priority to those agreeing to report back in a timely manner on research results (again IP issues arise).
- In relation to finite samples it was noted that policies devised for repositories of human tissue representing rare diseases could be adapted.
- The question was raised as to how to consider samples from ABNJ housed in national collections. Who owns these samples? How should State collections deal with ABNJ samples. This is of particular relevance to States which have national capacity-building / wealth creation policies associated to their *ex-situ* collections (e.g. Norway, Ireland).

- Conversely, if ABNJ samples are in national collections and are not considered to be under the ownership of the State, who should support the associated maintenance and administrative costs?
- Considering non-finite samples i.e. those which can be cultured etc., monitoring 3rd party transfer of these samples can be a problem for biorepositories.
- It is policy in some repositories not to supply taxonomic information with samples. In other cases some taxonomic information is provided to allow researchers to make informed choices based on the chemistry which might be expected from the sample. Researchers are encouraged to obtain further samples via the repository allowing curators to identify samples of interest due to repeated requests for the same sample. This, in theory, reduces targeted *in-situ* sampling for these species by commercial companies.
- Taxonomic information is actually of limited use to researchers who wish to obtain more of a particular sample. It must be combined with the GPS position of the producing organism because the same species from different locations may have very different chemistries. GPS coordinates are sometimes provided only at publication stage.
- Biorepositories may have to consider a combination of different levels of access to facilitate the interests of industry (again particularly in countries wishing to add value to their national collections) e.g. restricted licences incorporating periods of exclusivity for industry.
- Again, following the entry into force of the Nagoya Protocol, the decision as to whether access to samples is open or restricted may not be for the biorepository to decide. If samples in national collections were sourced from other jurisdictions the repository must consider any associated ABS obligations based on where and when the samples were collected.
- In terms of considering all the potential downstream uses of a sample the question was raised as to whether samples should, as far as practicable, be stored with all uses in mind and if, where possible, some nucleic acid extraction should be carried out in the first instance, in particular from finite samples.
- The distinction between public and private repositories was discussed. Often an institutional repository may have been set up by public funding but the maintenance and administration is covered by the host institute. It was pointed out that this is still a public collection.
- It was noted that in relation to 'ownership' of samples sourced from an ABNJ and related IPR, as well as the granting of access to samples for R&D, Article 241 of UNCLOS needs to be considered which states that "Marine scientific research activities shall not constitute the legal basis for any claim to any part of the marine environment or its resources."

2.4 Data-Sharing, Integration and Traceability

In considering the integration of downstream genetic data with upstream environmental and sample data and data-sharing the following points were discussed:

- An obligation to make data publicly available is a requirement of most funding bodies. There are also provisions of UNCLOS relevant to the dissemination of knowledge resulting from MSR. Generally, these obligations are cloaked in vague language e.g. 'as soon as practicable' or 'when appropriate,' and contain no specific time limits. This can be translated by researchers into 'as little as possible as late as possible'.
- Data generation times will depend on the specific research area. Setting a fixed time after which data must be made available may not suit all sectors. One option would be to provide grace periods for different research interests to provide competitive advantage.
- Various examples were provided of platforms at national and global level which collate, integrate and share data collected from the marine environment. These included the British Oceanographic Data Centre (BODC),[4] the Ocean Biogeographic System (OBIS)[5] and the Partnership for Observation of the Global Oceans (POGO) which forges networks around the world to promote long-term cooperation in global ocean observations.[6]
- The European Marine Observation and Data Network (EMODnet)[7] was described as a consortium of organisations within Europe that assembles marine data, data products and metadata from diverse sources in a uniform way.
- An example was provided of a publicly funded project which was prevented from making data available because provider countries had not all given consent. (Tara Ocean Expedition[8])
- It was suggested that it did not matter when data was made available so long as it was eventually released. However, this could lead to a situation where there was duplication of efforts or unnecessary re-sampling owing to a delay in releasing information on work already carried out. Timely access to data is also very important for States that do not have capacity to sample in ABNJ.
- It was advised that it would not be wise to put limits in place regarding data obtained from research on MGR from ABNJ which did not also apply to MGR sourced from within national jurisdiction. Creating a dichotomy could act as a deterrent to carry out marine scientific research on MGR from ABNJ.
- It was noted that it can be difficult to link downstream genetic data to cruise data or sample location. Many gene sequences report the species but not necessarily the location of origin.

[4] http://www.bodc.ac.uk/about/what_is_bodc/
[5] http://www.iobis.org/home
[6] http://www.ocean-partners.org/ocean-observations
[7] http://www.emodnet.eu/
[8] http://oceans.taraexpeditions.org/en/expeditions/tara-oceans/the-expedition.php?id_page=24

- The data-integration work of the MicroB3 project[9] was provided as an excellent example of linking upstream environmental data archived in the PANGAEA[10] information system with downstream genetic data submitted to the European Nucleotide Archive (ENA)[11] of the European Bioinformatics Institute (EBI). This could provide a starting point for future data-integration platforms.
- With regards to traceability of downstream data, again the work of the MicroB3 project in regards to their Ocean Sampling Day was cited. This involves bioarchiving of samples by the Smithsonian Institute and submitting data sets to ENA/MG-Portal which will facilitate sample and information tracking by the provider countries.
- Other examples of data integration initiatives in medical research were provided.

2.5 Product Development

In considering the development of products for commercialisation and the generation of monetary-benefits which could then be shared under any future ABS regime, the following points were raised.

- It was considered unlikely that commercially sponsored cruises were targeting MGR from ABNJ for biodiscovery purposes. Commercial partners may 'piggy-back' on a publicly funded cruise, or obtain samples or extracts through public-private partnerships.
- However, obligations to sample as part of the environmental permit for deep seabed mining in the Area, will result in an increase in commercial cruises undertaking biological research in ABNJ.
- Comments indicated that parties with commercial intent considered potential future benefit-sharing obligations in the first instance and targeted samples from either their own jurisdiction or other jurisdictions where no such obligations existed.

[9] The EU FP project Micro B3 develops innovative bioinformatic approaches and a legal framework to make large-scale marine microbial genomic and metagenomic data accessible for marine ecosystems biology and for biotechnological applications. Public deliverables relevant to this work can be found at www.microb3.eu/work-packages/public-deliverable

[10] The information system PANGAEA is operated as an Open Access library aimed at archiving, publishing and distributing georeferenced data from earth system research. The system guarantees long-term availability of its content through a commitment of the operating institutions. Most of the data are freely available and can be used under the terms of the license mentioned on the data set description. A few password protected data sets are under moratorium from ongoing projects. The description of each data set is always visible and includes the principle investigator (PI) who may be asked for access. http://www.pangaea.de/about/

[11] The European Nucleotide Archive (ENA) provides a comprehensive record of the world's nucleotide sequencing information. Provision of nucleotide sequence data to ENA or its INSDC partners has become a central and mandatory step in the dissemination of research findings to the scientific community. ENA works with publishers of scientific literature and funding bodies to ensure compliance with these principles and to provide optimal submission systems and data access tools that work seamlessly with the published literature. http://www.ebi.ac.uk/ena/home

- Small biotech companies might take a risk on developing a product where there is ambiguity of ownership but 'big pharma' will not.
- The question was raised whether there is a point in the development of a product from an (M)GR at which benefit-sharing would no longer apply and if so how could this point could be distinguished.
- Considering the Nagoya Protocol and the forthcoming regulation to implement it in the EU, if researchers cannot show, with documentation, that the MGR they are utilizing was sourced from an ABNJ then it cannot be considered exempt from ABS obligations and all work on it must cease[12].

2.6 Monetary and Non-Monetary Benefit-Sharing

Fair and equitable benefit-sharing could be achieved through a multilateral system which sets up a framework for the generation and sharing of both non-monetary benefits and monetary benefits arising from the utilization of MGR from ABNJ. The discussions relevant to these aspects are summarised below.

- It was pointed out that even non-monetary benefits have a cost. For example capacity building, data-sharing etc. all cost money which raises the question whether a clear distinction between monetary and non-monetary benefits can really be made.
- The possibility of using monetary benefits purely to support conservation of biodiversity would not be acceptable to all States. In some cases something more 'tangible' is necessary based on the individual needs of the country.
- In considering capacity building it was proposed that research itself costs money and may not be of interest to all developing countries although it was noted that some developing countries are interested in, and capable of, exploiting research.
- The work of the Ferrero group in developing contracts with provider countries was provided as an example of best practice with regard to benefit-sharing.
- Benefit-sharing in relation to MGR from ABNJ has to be considered in a global context and not just as a North versus South, developing versus non-developing country context. There is a continuum of capacity globally as there is within the EU.
- It was noted that basic marine scientific research in ABNJ is a benefit to the conservation of biodiversity.
- Considering that most research vessels are publicly funded then any upfront payment would target the basic scientific research community and could be considered as hampering MSR. However, it was argued that if this payment was

[12] Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union

used to support and enable MSR and protect biodiversity in ABNJ then it could be justifiable to the publicly funded research community.

- If a tax or upfront payment was targeted solely towards industrial partners then it could be considered as a disincentive to R&D on MGR from ABNJ. If the intention of the tax was to generate monetary benefits then it might be more useful to incentivise R&D on MGR from ABNJ.
- Alternatively a one-off upfront payment may be preferable to industry than paying royalties in the future. Such upfront payments could become part of, and be calculated in as, regular business costs. However if a product with a high market value was derived from an ABNJ derived MGR then it would not be possible to capitalize on this.
- Considering whether upfront payments should depend on whether the intent of the research is commercial, or not, is not helpful. Research can change from basic research to commercial at any point. The 'commercial versus non-commercial intent' discussions were considered at length during negotiations for the Nagoya Protocol and proved to be frustrating and fruitless.
- Payment at the point of commercialisation would be considered fair. The challenge was to identify the point at which the intent of the research changed from basic to commercial. Protecting research results, in particular filing of patents was proposed as the most useful trigger point. It was noted, however, that filing of a patent does not always mean a commercial intent. Also some industries e.g. cosmetic sector do not patent despite their clear commercial intent.
- Considering patent pools these could be seen as an attractive option where it is difficult to put a patent into production.
- Considering royalties, examples of maximum percentages considered to be acceptable to industry were quoted from 3% (GlaxoSmithKline) to less than 1%.
- Considering again Article 241 of the UNCLOS, then any payment should only be charged once a product has been identified and monetary benefits have been derived.
- Attention was drawn to the financial terms set out in the provisions Part XI of UNCLOS and the Part XI Agreement as these provided examples of how the commercial and financial interests of the mining sector had been taken into account in the development of a financial sharing scheme related to mining in the Area.
- It was noted again that sampling in ABNJ is primarily carried out by the basic scientific research community e.g. marine biologists, taxonomists, population geneticists, fisheries biologists etc. This community has an interest in the ecosystems and biodiversity which may be found within an ABNJ but may have no interest or intention to develop products from the collected MGR. They may, however, deposit samples in biorepositories which are subsequently used for commercial purposes.
- Even though deep seabed mining is a commercial activity, the exploration and prospection phase may or may not lead to exploitation and it was proposed that

the conceptual ideas and principles developed in the negotiations for deep seabed mining in the Area could be useful in these discussions.

- In relation to how utilization of genetic resources from ABNJ could be monitored the example of the Access and Benefit-Sharing Clearing-House (ABSCH) was provided. The ABSCH will provide a platform for exchanging information on ABS and will be instrumental in facilitating the implementation of the Nagoya Protocol.

3 RECOMMENDATIONS

In considering the options proposed for a potential future ABS regime for MGR from ABNJ presented by WP6, the participants agreed that it was too early in the process for such a detailed regime to be presented at the UN Working Group meeting in June 2014. Based on the discussions the participants advised that a more acceptable approach would be the development and coordination of current practices in sampling and curation of MGR, data-sharing and integration which were identified during the workshop and which could form the basis of a future regime. Such an approach would also limit the introduction of additional administrative burden for the marine scientific community (Figure 2).

The discussions highlighted areas where a potential future regime could further support and enable sustainable and environmentally responsible marine scientific research. These included the following:

- Development of a voluntary code of conduct for sampling MGR in ABNJ.
- Training of marine biologists in sampling and onboard curation of samples to consider all the potential downstream uses of the MGR in the first instance. Such consideration at the point of sampling and curation would maximise the potential of samples for R&D and mitigate the costs of research cruises and the environmental impact of sampling.
- Development of guidelines and standard formats for sample logging and data recording.
- Support for global integration of data on MGR, (*in-situ* sample and environmental data and metadata together with downstream genetic data) could prevent repeated sampling of important ecosystems and facilitate access to data to those countries that do not have infrastructure to sample in ABNJ.
- Standardised policies/guidelines for curators of marine biobanks to deal with aspects of curation such as prioritising access to finite samples and balancing free access with restricted access to consider commercial interests.
- Guidelines for researchers sampling and utilizing MGR on the relevant MSR provisions of UNCLOS to ensure R&D results are put in the public domain.

4 CONCLUSIONS

Whilst MGR sourced from ABNJ fall outside of the scope of the Nagoya Protocol, the entry into force of the Protocol will have implications for how researchers utilize all (M)GR in their R&D. Within the EU, a new regulation to implement the Nagoya Protocol is expected to enter into force in late 2014 and will require scientists to demonstrate, with appropriate documentation, the provenance in time and place of any (M)GR being utilized in their R&D. Therefore, even samples from ABNJ must be documented as such for monitoring purposes. Research institutions will need to adapt their procedures to deal with these new measures.

This will, however, pave the way for any potential future ABS regime for MGR from ABNJ because many of the issues identified above in relation to traceability and benefit-sharing will have to be addressed by the research community. Considering this, much can be learned from the Nagoya Protocol process including with respect to the Access and Benefit-Sharing Clearing-House which will be central to the successful implementation of the Protocol.

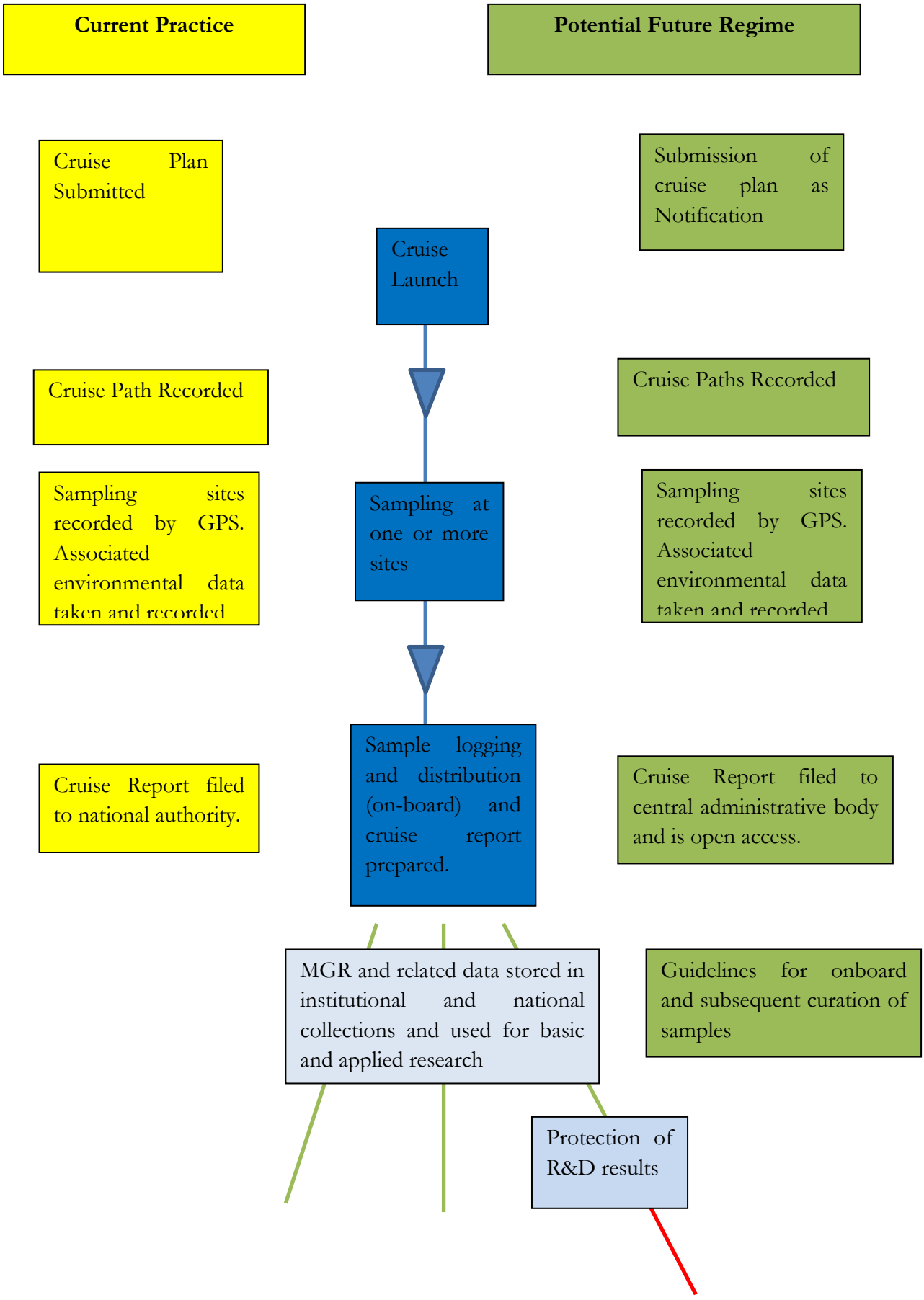
It will be important to ensure that an imbalance is not created, with respect to obligations on researchers, between sampling within or beyond national jurisdiction. The workshop discussions indicated that researchers with commercial intent already consider benefit-sharing obligations in choosing the source of their sample. When the sampling is for non-commercial activities, excessive administrative burdens can dictate the choice of sampling site.

It is important to recognise that MGR are often collected and deposited in *ex-situ* collections via basic marine scientific research activities. This is particularly so for MGR from ABNJ. Basic marine scientific research is necessary for the further discovery, understanding and conservation of marine ecosystems and the biodiversity therein. From a biodiscovery perspective, basic marine scientific research also identifies the environments from which organisms with potential bioactivity may be sourced. Any future regime on ABS of MGR from ABNJ would potentially impact most on the activities of the basic marine scientific research community. Since their work contributes to the protection and preservation of the marine environment but also directly or indirectly facilitates the entry of MGR into the 'value' chain, their needs and concerns must be considered.

For these reasons the scientific community engaged in basic and applied research on MGR must not remain silent in these discussions. Their input at an early stage in this process can help to ensure that a potential future Implementing Agreement enables, rather than impedes, marine scientific research.

Finally, in considering ABS of MGR from ABNJ, the collection of MGR by means other than marine scientific research, for example via environmental impact assessments for deep sea mining, must be considered.

Figure 2 Schematic representation for how current practices in R&D on MGR could be modified and coordinated to form the basis of a future ABS regime for MGR from ABNJ.



ANNEX 1: LIST OF PARTICIPANTS

PharmaSea Project Partners	Affiliation
Marcel Jaspars	University of Aberdeen, Scotland (Pharmasea Project Leader)
Camilla Esguerra	KU Leuven, Belgium (PharmaSea Coordinator)
Alex Crawford	KU Leuven, Belgium
Thomas Greiber	IUCN Environmental Law Centre, Germany
Isabelle Huys	KU Leuven, Belgium
Kjersti Lie Gabrielsen	MarBank, Norway
Meredith Lloyd-Evans	BioBridge Ltd, UK
Laura Lallier	eCOAST Belgium
Oonagh McMeel	eCOAST Belgium
Thomas Vanagt	eCOAST, Belgium
External Participants	**Affiliation**
Alicja Kozlowska	European Commission DG Environment, Belgium
Arianna Broggiato	MicroB3 Project (Catholique University Louvain), Belgium
Charlotte Salpin	United Nations Division for Ocean Affairs and Law of the Sea, USA
Geoff Burton	United Nations University Institute of Advanced Studies, Australia
Hugo Schally	European Commission DG Environment, Belgium
Jan-Bart Calewaert	EMODNET Secretariat, Belgium
Johanna Wesnigk	MicroB3 Project (EMPA), Germany
John Brincat	European Commission, DG MARE, Belgium
Kate Larkin	European Marine Board, Belgium
Kathryn Garforth	Secretariat of the Convention on Biological Diversity, Canada
Laura Giuliano	Mediterranean Science Commission (CIESM), Monaco
Lyle Glowka	Secretariat of the Convention on Migratory Species, United Arab Emirates
Marie-Cécile Barras	SeaBioTech Project (Novamen), France

ANNEX II: BACKGROUND DOCUMENT

'Options for an Access and Benefit-Sharing Regime for Areas Beyond National Jurisdiction'

Possible Ideas on How to Address ABS for MGR in ABNJ

Background

Before the end of the 69th session of the UN General Assembly in 2015, States shall take a decision whether to start the negotiation of an international instrument on the conservation and sustainable use of biodiversity in areas beyond national jurisdiction (ABNJ).[13] As agreed in 2011by the UN *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, the scope of such an international instrument for ABNJ would include '*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'* together and as a whole in a single package (so called 'package deal').[14]

In order to avoid a new international legal framework hampering future research and development (R&D) on marine genetic resources (MGR) from ABNJ, the scientific community has to inform policy-makers about the feasibility and modalities of scientific activities undertaken, and the already advanced practices in place within the scientific community, especially regarding sharing of non-monetary benefits. **Furthermore, the scientific community should use the opportunity to become proactive, influence the UN debate at an early stage, and propose concrete ideas, concepts and options with regard to a potential access and benefit-sharing (ABS) regime for MGR from ABNJ.**

The objective of the workshop is to further developed ideas and concepts with regard to a potential ABS regime for MGR from ABNJ by bringing together marine biodiscovery practitioners with legal experts (in the fields of ABS, IPR and law of the sea), policy-makers and other relevant stakeholders. The proposals shall then be submitted to and presented at the UN Working Group meeting in June 2014 in order support the decision-making process within the UN General Assembly.

[13] UNGA resolution 66/288. *'The future we want.'* UN doc. A/RES/66/288, of 11 September 2012. Para 162.
UNGA resolution 67/78. *'Oceans and the law of the sea.'* UN doc. A/RES/67/78, of 11 December 2012. Para 181.
UNGA resolution 68/70. *'Oceans and the law of the sea.'* UN doc. A/RES/68/70, of 9 December 2013. Para 197.
[14] UNGA resolution 66/231. *'Oceans and the law of the sea.'* UN doc. A/RES/66/231, of 24 December 2011. Paragraph 167.

The following text is intended as a basis for discussion. It aims at providing a non-exhaustive list of preliminary ideas, questions, problems and potential solutions for a future ABS regime with the objective to:

- Promote international R&D on MGR from ABNJ instead of creating obstacles; and
- Build on the existing UNCLOS framework instead of amending UNCLOS provisions (in particular the freedom of marine scientific research (MSR) and the relevant UNCLOS requirements including international cooperation in MSR, the creation of favorable conditions for the conduct of MSR, the publication and dissemination of information and knowledge resulting from MSR, and the promotion of data and information flow and transfer of knowledge).

Furthermore, it is important to note that the issues addressed below are envisaged as and as part of an overall international instrument for ABNJ rather than a stand-alone ABS regime for ABNJ.

I. Objectives of an ABS Regime for ABNJ

- Creation of a multilateral system that facilitates greater access to MGR from ABNJ and ensures equitable and fair sharing of benefits from their utilization
    - Recognizing that facilitated access is a critical non-monetary benefit for ALL stakeholders involved in R&D related to MGR, i.e. a global benefit for MGR stakeholders in developing as well as developed countries (including land-locked states)
    - Aware that the results of successful R&D will be a benefit for all humankind
    - Acknowledging Para 5 of the UNCLOS Preamble referring to the *'[…] realization of a just and equitable international economic order which takes into account the interests and needs of mankind as a whole and, in particular, the special interests and needs of developing countries […]'*
- Striking an appropriate balance between on the one hand efficient dissemination of materials (i.e. collected samples), associated knowledge (i.e. data and research results) and capacities (i.e. technologies and biotech know-how) to global science communities and other users, and on the other hand appropriate intellectual property rights (IPR) protection and management (including the right to apply for patents and copyrights)
    - Acknowledging the UNCLOS obligations regarding MSR
    - Acknowledging also an uneven distribution of technologies and expertise amongst international researchers
    - At the same time recognizing high investment costs of R&D on MGR from ABNJ, as well as the interests and practices of researchers in publishing and protecting their research results and inventions
- Enhancing and complementing existing international ABS regimes
    - Recognizing the existing regulatory ABS gap in ABNJ under UNCLOS, and the need to close the ABS gap left by the CBD and its Nagoya Protocol without expanding their geographical scope

- Conservation and sustainable use of MGR from ABNJ for the benefit of present and future generations
    - Recognizing existing UNCLOS obligations to protect and preserve the marine environment (Art. 192) and *'[…] rare or fragile ecosystems as well as the habitat of depleted, threatened or endangered species and other forms of marine life'* (Art. 194.5)
    - Reflecting that ABS is one part of the 'package deal' comprising amongst others also area-based management tools (including marine protected areas) and Environmental Impact Assessment (EIA)

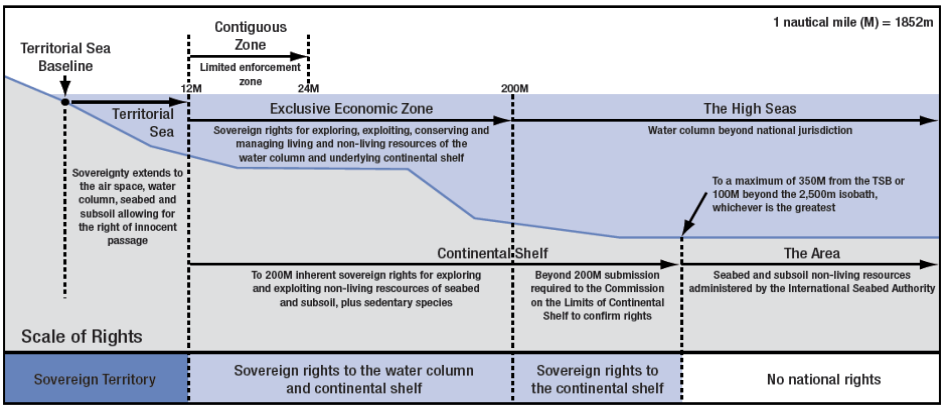
II. Definition of Terms

- Building on terms used/defined in the CBD and its Nagoya Protocol[15]
    - Leading to more clarity, consistency and compatibility of existing and new ABS regimes
    - Important to have a common ABS understanding under different regimes in order to ensure efficient and effective implementation and avoid potential loopholes
- Need to consider the development of a new definition for associated knowledge (i.e. data and research results related to R&D on MGR from ABNJ)
    - CBD and its Nagoya Protocol only address traditional knowledge of indigenous and local communities associated with genetic resources
    - Knowledge related to R&D on MGR from ABNJ lies mostly with researchers
    - Knowledge-sharing under a new ABS regime as a potential key benefit for the scientific community
- No need to distinguish between commercial and non-commercial R&D, as definition of utilization under Nagoya Protocol covers both
    - In practice distinction is difficult (if not impossible), as samples taken and utilized for basic research may subsequently be used for commercial purposes
    - However some distinction (IPR protection vs. open access) could kick in leading to differentiated benefit-sharing obligations depending on whether materials and associated knowledge are protected or made publicly available (see example of ITPGRFA[16])

[15] Genetic material: *'any material of plant, animal, microbial or other origin containing functional units of heredity'*
Genetic resources: *'genetic material of actual or potential value'*
Utilization of genetic resources: *'to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology'*
Biotechnology: *'any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use'*
Derivatives: *'a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity'*
[16] Art. 13.1 (d)(ii) of the ITPGRFA regulates that *'[…] a recipient who commercializes a product […] that incorporates material accessed from the Multilateral System, shall pay to the mechanism […], an equitable share of the benefits arising from the*

III. Scope of an ABS Regime for ABNJ

1. Geographical scope (i.e. maritime zones covered by the regime): ABNJ regime should cover both maritime zones, the Area as well as the water column beyond national jurisdiction



Source: Arctic Council, *Arctic Marine Shipping Assessment 2009 Report* (Tromsø, Norway: 2009), p. 52, available at www.pame.is/images/stories/PDF_Files/AMSA_2009_Report_2nd_print.pdf .

- Sampling of MGR takes place in both (see also different sampling techniques)
- Would solve the problem of samples moving between/found in both ecosystems

2. Substantive scope (i.e. actual resources and activities regulated by the regime):
   - ABNJ regime should cover materials (samples of MGR from ABNJ), associated knowledge (data and research results) and capacities (technologies and biotech know-how)
   - ABNJ regime should address access as well as benefit-sharing
     - Access to *in situ* MGR from ABNJ should continue to fall under the freedom of MSR (see below)
     - Access to *ex situ* MGR from ABNJ and access to associated knowledge as well as capacities should be addressed as part of benefit-sharing under a multilateral system (see below)
3. Temporal scope:
   - No retroactivity
   - **Potential problem:** How to deal with existing collections containing MGR, i.e. distinguishing between 'old' and 'new' resources
     - MGR from ABNJ collected in the future as well as associated knowledge could be marked to identify their origin
     - Biorepositories and databanks could also be invited to include ALL MGR samples and associated knowledge within the multilateral system (i.e. pre- as well as post-regime, and those from ABNJ and within national jurisdiction) on a voluntary basis, which in fact could be easier to manage

commercialization of that product, except whenever such a product is available without restriction to others for further research and breeding, in which case the recipient who commercializes shall be encouraged to make such payment.'

- **Potential problem:** Assuming a biorepository/databank decides to include all MGR/associated knowledge (i.e. from ABNJ as well as within national jurisdiction) in the multilateral system, what if a country of origin has given its PIC and granted MAT to do R&D on its resources and store the samples and knowledge, but third party transfer has not been approved

IV. Relationship with Other International Agreements and Instruments

- Part of an Implementing Agreement under UNCLOS
  - Nothing in the Implementing Agreement should prejudice the rights, jurisdiction and duties of states under UNCLOS; Implementing Agreement to be interpreted and applied in the context of and in a manner consistent with UNCLOS (see Art. 4 of the UN Fish Stocks Agreement)
    - Important to secure freedom of MSR, but also related obligations
- Implementing Agreement should not affect rights and obligations of any Party deriving from any existing international agreement
- Implementing Agreement should be implemented in mutually supportive manner with other relevant international instruments
  - Referring to the need to avoid conflicts with and rather complement the implementation of the CBD and its Nagoya Protocol (i.e. closing the existing gap and taking advantage of institutional structures created, such as ABS checkpoints)

V. Access

1. Access to (sampling of) *in situ* MGR should be subject to the principle of the freedom of MSR
   - Important aspect to get global support for an ABNJ ABS regime
   - Does not mean unlimited freedom, but freedom subject to
     - Environmental considerations (sustainability), and
     - MSR obligations[17]
   - Sustainability considerations could be addressed through EIA processes
     - EIA is another issue covered by the 'package deal'
     - EIAs conducted by flag states (in line with international standards) could mean less bureaucracy, more efficient processes and therefore limited burden for R&D
     - **Q: To what extent are EIAs already carried out? What is feasible keeping in mind that EIAs need a baseline while most of the *in situ* access/sampling is discovery (so there is no baseline)?**

[17] Promoting international cooperation in MSR (Art. 242 & 143.3(a)); making knowledge resulting from MSR available by publication and dissemination (Art. 244.1 & 143.3(c)); promoting data & information flow & transfer of knowledge (Art. 244.2 & 144.2).

- MSR obligations would be reflected under fair and equitable benefit-sharing
- Sampling could be registered in Global Clearing House

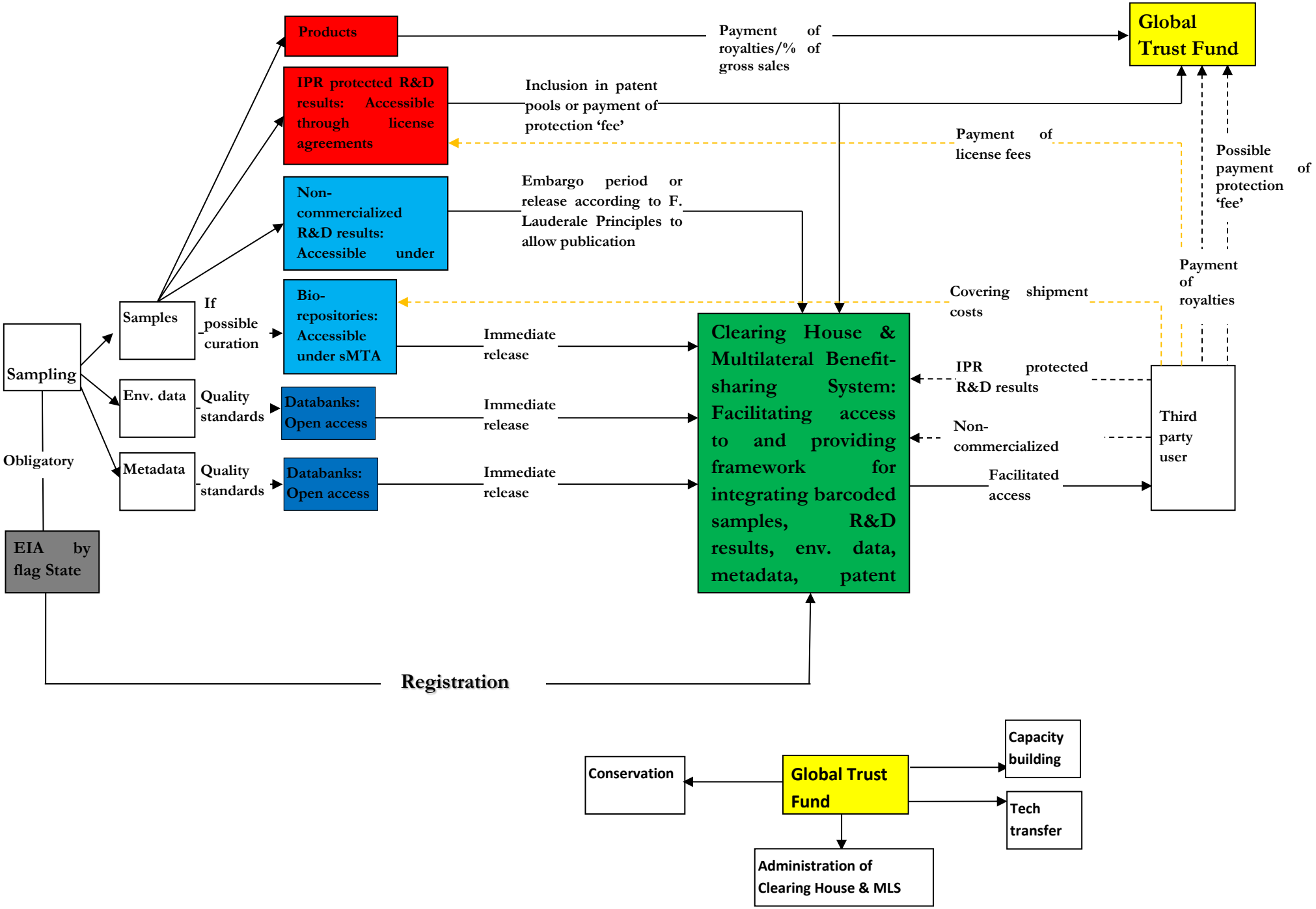
2. Access to *ex situ* MGR, associated knowledge (data and research results) and capacities (technologies and biotech know-how) would be addressed as part of the multilateral benefit-sharing system

VI. Fair and Equitable Benefit-sharing

1. Fair and equitable benefit-sharing could be achieved through a multilateral system which sets up a framework for the sharing of both
    - Non-monetary benefits arising from the utilization of MGR from ABNJ: Through the development of rules for efficient, effective, transparent and coherent implementation of the already existing MSR provisions under UNCLOS with regard to MGR from ABNJ
    - Monetary benefits arising from the utilization of MGR from ABNJ: Thereby promoting the *'realization of a just and equitable international economic order which takes into account the interests and needs of mankind as a whole and, in particular, the special interests and needs of developing countries'* (Para 5 of the UNCLOS Preamble) and building a compromise to get global support for an ABNJ ABS regime

Visualization of a possible ABS regime for ABNJ (see next page)[18]

[18] Inspired by Marcel Jaspars *et al*, *'The Marine Biodiscover Pipeline'*. advanced draft; and Caroline von Kries, Graphs visualizing the MICROB3 Ocean Sampling Day Research Pipeline.


Products
Payment of royalties/% of gross sales
Global Trust Fund
IPR protected R&D results: Accessible through license agreements
Inclusion in patent pools or payment of protection 'fee'
Payment of license fees
Possible payment of protection 'fee'
Non-commercialized R&D results: Accessible under
Embargo period or release according to F. Lauderale Principles to allow publication
Payment of royalties
Covering shipment costs
Bio-repositories: Accessible under sMTA
Samples
If possible curation
Sampling
Immediate release
Clearing House & Multilateral Benefit-sharing System: Facilitating access to and providing framework for integrating barcoded samples, R&D results, env. data, metadata, patent
IPR protected R&D results
Env. data
Quality standards
Databanks: Open access
Immediate release
Third party user
Non-commercialized
Metadata
Quality standards
Databanks: Open access
Immediate release
Facilitated access
Obligatory
EIA by flag State
Registration
Conservation
Global Trust Fund
Capacity building
Tech transfer
Administration of Clearing House & MLS

2. Non-monetary benefits would include: Facilitated access to collected samples (*ex situ* MGR), associated knowledge (data and research results for *in silico* analysis) and related capacities (research infrastructure, including technologies and biotech know-how)
    - Objective: create global benefits, i.e. benefits for both developing and developed countries
    - Facilitation of different types of access could lead to more R&D opportunities; increased access by multiple actors to an initial resource, data or research infrastructure could increase the number of potential leads developed

    2.1 Access to/exchange of samples (*ex situ* MGR)
    - Examples of current practices:
        - Sample materials collected during drilling operations under the International Ocean Discovery Program
        - European Marine Biological Resource Centre
        - World Federation of Culture Collections
    - **Potential problems:**
        - Sampling activities and storage vary depending on end usage/planned research
        - Correct curation, transport, etc. necessary to maintain samples
        - Integration/linkage of samples with associated environmental and metadata required
        - Samples of macroorganisms are finite (biomass might be exhausted/not sufficient for future research)
        - 90% of microbial strains cannot currently be cultured; interesting metabolic processes often linked to *in situ* environmental stimuli (which are difficult/impossible to replicate)
        - **Q: If synthesized genes (based on data) can be placed in easy to grow microorganisms for expression of useful products, does this at least partly solve the problem(s)? I.e. can such practical limitations of physical access to MGR be mitigated through appropriate access to/exchange of associated knowledge?**
    - Potential structure:
        - Multilateral system would not consist of one single biorepository, but a network of biorepositories and/or virtual repository **(Q: What would be needed to establish such a network? Could a Global Clearing**

House plus a framework of standards and data integration be feasible and sufficient?)

- Collections under management and control of a state (e.g. funded with public resources) and/or in the public domain could be obliged to join the multilateral system
- Other (purely private) collections could be invited and encouraged to join the multilateral system

- No change of ownership in transactions, but only temporary transfer/loan
- If material was finite:
  - **Q: Could there be a requirement to ensure a quantity of finite samples are stored in such a way to ensure nucleic-acids can be extracted in the future (i.e. a form of conservation)**
  - **Q: Would it make sense and be feasible to give preferential physical access to researchers from or consortia including developing countries lacking capacities? If so, how could these countries and researchers be identified?**
  - **Q: Otherwise could samples become part of a virtual repository: e.g. chemical databank in Strathclyde's drug discovery portal[19]**
- Global standards for curation, storage and transport to ensure sufficient quality
  - **Q: Is it possible to curate and store samples in a way that they can be used for all types of research work in the future?**
  - **Q: Could this be considered to be a form of conservation bearing in mind that many samples cannot be cultured or viable tissue maintained *ex situ***
- Global standards for necessary associated environmental and metadata to ensure sufficient quality
- Standard Material Transfer Agreement(s) (sMTA) regulating utilization of samples and sharing of associated knowledge resulting from R&D on the

[19] Strathclyde's drug discovery portal is an example of a matchmaking service which runs virtual screens at users 'request. Users will be asked to sign an online user agreement as part of the registration process which will protect IPR. If hits are identified users are informed a match has occurred so that they have the opportunity to initiate a new collaborative project.

samples, potential third Party transfer and protection of IPR, costs of shipping and handling, etc.

- To facilitate access/exchange click-wrap and shrink-warp approaches could be considered[20]

2.2 Access to/exchange of data

- Examples of current practices:
  - International Nucleotide Sequence Databases (INSD)[21]
  - InterRidge
  - Ocean Biogeographic Information System (OBIS)
  - Bermuda and Ft Lauderdale Principles[22]
  - Ocean Sampling Day (OSD)
  - GSC's MixS standard
  - Strathclyde's drug discovery portal
- **Potential problems:**
  - Integration/compatibility of different data-sets
    - **Q: Would it be possible to broaden INSD to include other genetic sequence databases? Would it be possible to transfer the INSD approach to other databanks, if any? Would INSD already provide the infrastructure needed, or to build on?**
    - **Q: Would it be possible to build on data integration work undertaken by projects like MICROB3 or others?[23]**
  - Potential embargo before release of data to the public
    - **Q: Would immediate release as soon as sequenced be acceptable?[24]**
    - **Q: Would application of Bermuda or Fort Lauderdale Principles be acceptable?**

[20] Software manufacturers generally attach license agreements inside the packaging of their products, which bind the consumer to the terms of the agreement upon removal of the shrink-wrap (cellophane wrapping that seals boxes of mass marketed software). Click-wrap licenses are another form of creating an electronic agreement, except that the license is included on the computer screen before installation rather than on the box. By clicking on a button that says 'I agree' or 'I accept,' the licensee agrees to the terms of use of the contract. An important difference between click-wrap agreements and shrink-wrap agreements is the fact that the user actually has an opportunity to read the contract before using or installing the program.

[21] Developed and maintained collaboratively between DNA Data Bank of Japan (DDBJ), European Nucleotide Archive (ENA), and GenBank for over 18 years.

[22] Bermuda Principles from 1996 ensured that the human genetic sequence was made available immediately in public databases with no terms or conditions on its use. Fort Lauderdale Principles entitle the data producers to make the first presentation and publish the first genome-wide analysis of the data. The data can be used freely for studies of individual genes or other individual features of these sequences.

[23] Under MICROB3 work is undertaken to provide an integrated view of microbial diversity and function in the marine environment; to develop innovative software approaches allowing users from biotechnology as well as ecosystems research to exploit information on microbial communities; and to support users in effectively managing, analyzing, and sharing genomic and metagenomic data.

[24] See Ocean Sampling Day data policy.

    - Differentiation between precompetitive and competitive data
    - Cost implications of open source
        - **Q: Will putting data in the public domain have considerable cost implications? Putting publications in open source might be costly.**
        - **Q: Is there a need to distinguish between data and literature publication (example of Tara Ocean)**
- Potential structure:
    - Funders could make it a requirement that associated knowledge is submitted to virtual repositories in order to make publicly available and share
        - However, a researcher could still decide to protect research results (file a patent) which then trigger payment of a 'protection fee' (see monetary benefit-sharing below)
    - Access could be granted to all researchers (also from non-Parties), but exchange of data could take place according to standard Data Transfer Agreements (sDTA) regulating: use and reuse of data under viral license clause, IPR and benefit-sharing, quality standards
        - **Q: Could sDTAs follow the creative commons license approach?**
    - Associated knowledge developed through accessed data would need to be put in the public domain again (see approach taken under ITPGRFA); IPR protection would again trigger a payment of a 'protection fee'
    - Implementing Agreement could lead to the development/updating and adoption of standards for metadata and environmental data (contextual information) to make information as comprehensive and uniform as possible to aid different analysis pipelines
        - **Q: Would standards for other data be needed, e.g. sequence data?**
    - Custom-made software and other knowledge discovery tools to be developed to integrate different data sets and facilitate data-mining

2.3 Access to/exchange of technology: expensive infrastructure (e.g. ocean vessels and ROVs) requiring sharing of ship time

- Examples of current practices:
    - Experiences from transnational initiatives (e.g. EUROFLEETS, Ocean Facilities Exchange Group, European Marine Biological Resource Centre)
    - Experiences from bids to national agencies
    - Experiences from public-private partnerships (e.g. SERPENT project)
- **Q: Do we know about any specific problems of these existing practices? And if so, what are they?**
- **Q: Could such national and regional initiatives be up-scaled to the global level?**

2.4 Capacity-building

- Examples of current practices:
    - International Seabed Authority
    - Global Environment Facility
    - Regional projects, such as MICROB3 and others
- **Q: Do we know about any specific problems of these existing practices? And if so, what are they?**
- **Q: What would be needed to scale up such national and regional capacity-building initiatives?**
- Potential structure:
    - Parties could be required to encourage their funding agencies to promote international collaboration in relevant R&D projects
    - Framework for developing international capacity-building programs (including infrastructure, tech and know-how transfer) could be set up with a special focus on researchers from developing countries
    - Framework for establishing data analysis working groups
        - Type of transparent collaboration where interested parties declare how they would like to contribute to the data analysis, which might help maximize the efforts of the scientific community and build the strongest possible interpretation of the data
    - Establishment of a Scientific Coordination Council

3. Monetary

3.1 Payments at outset of R&D (before access to *in situ* resources)

- Usually only applied where clear commercial intent
- **Problem:** Objective of sampling cruises mostly hybrid

3.2 Payments at milestones

- When accessing *ex situ* resources, associated knowledge and technology
    - **Q: Could a small amount be charged to those accessing the networks? Funds could be used by databanks to maintain/administer the system, or even to reward the ones who shared (creating an incentive to join).**
- When protecting research results (file for IPR)
    - 'General rule' could be that research results are put in the public domain
        - Reflecting Art. 241 UNCLOS *'Marine scientific research activities shall not constitute the legal basis for any claim to any part of the marine environment or its resources.'*
    - But if IPR is filed to protect research results, which is normal practice in current R&D, the IPR holder could be required to choose between
        - Either paying a 'Protection fee' (to be collected by a Global Trust Fund),
        - Or joining a patent pool (which could bring financial returns through license fees)
- Same obligations would apply to third party that accesses data through the multilateral system and protects R&D results incorporating resources/associated knowledge accessed through the networks

3.3 Payments after commercialization

- Royalties (share of income from gross sales of products)
    - Standard percentage (see ITPGRFA as an example)
        - **Q: Would it make sense to establish different percentage rates for different sector products (to reflect the need for hire upfront investments in different sectors)?**
    - To avoid unnecessary administrative burden, a global tax could be introduced
    - Funds to be collected and managed by a Global Trust Fund

3.4 Access to patent pools

- Reflecting Art. 241 UNCLOS
- IPR protected R&D results could be shared through different sector patent pools
    - Multiple patent holders agree to license their protected research results as a package to anyone willing to pay license fees, which are distributed among the patent owners
    - Pool members license all patents in one package and avoid spending time to research the relevant patents and separately negotiate all licenses
    - Sectoral approach as patent pools usually share IP with some commonalities in terms of innovation
- Objective of patent pools would be to support further innovation
    - In situations where a manufacturer has to license a number of patents from multiple patent holders, the price of the product shoots up; negotiating such patent thickets pose serious challenges (in particular for developing countries); licenses may be available but the transaction costs in dealing with the patent thickets are prohibitive
- Development of non-exclusive licenses[25]
    - Inclusion of so-called virus effect provision/viral clause: When the protected work is being redistributed, the new distributor has to redistribute the work under the same or an equivalent license, even if the work has been modified
    - **Q: Could we also argue that joining a patent pool also potentially increases the chances of financial returns (holding a patent does not necessarily lead to placing a product on the market; however, through licenses patent holders have an effective way to share their innovations and may be compensated by a fair royalty)**

[25] Under a non-exclusive license the licensor grants a right to use the intellectual property (or product) to more than one licensee simultaneously. That is to say, unlike exclusive licenses, non-exclusive licenses can be granted to several users at the same time. It is important to note that the sale of non-exclusive licenses provides the opportunity to increase the earnings of a product, while the owner also maintains a certain level of control.

VII. Monitoring and Compliance

1. Monitoring
    - Potential problem: MGR found in horizontal transboundary situation (water columns within vs. beyond national jurisdiction)
        - Issue to be solved through proper recording: records are normally kept what kind of sample is taken and from where
        - Codes of conduct for researchers could advise not to sample within a certain distance from the boundary in order to avoid confusion/lack of clarity
    - Potential problem: MGR found in vertical transboundary situation (water column beyond national jurisdiction which is in ABNJ vs. extended continental shelf of coastal states which is within the scope of the CBD and its Nagoya Protocol)
        - Issue to be solved through proper recording: records are usually kept what kind of sample is taken and from where
        - MGR from water column beyond national jurisdiction and from non-sedentary species from the extended continental shelf (not covered by Art. 77 UNCLOS) would fall under ABNJ ABS regime
        - MGR from sedentary species would not be covered by ABNJ ABS regime, i.e. only *'organisms which, at the harvestable stage, either are immobile on or under the seabed or are unable to move except in constant physical contact with the seabed or the subsoil'* (Art. 77.4 UNCLOS)
    - Potential problem: Could forum shopping become a problem? (i.e. Would researchers find themselves in the position that they chose cruise paths to avoid what they consider to be burdensome administrative procedures?)
        - Cruise paths are recorded and sampling is logged carefully (by national agencies and international organizations)
    - Potential problem: Distinction between samples and associated knowledge from ABNJ (covered by the regime) and those from within national jurisdiction (covered by the CBD and its Nagoya Protocol) stored in the same biorepository/databank
        - Unique identifiers could be used to help distinguish (see for example practices under the MOSAICC Code of Conduct[26])
    - Potential problem: Distinction between MGR in public and private biorepositories/databanks

[26] The Micro-organisms Sustainable Use and Access Regulation International Code of Conduct (MOSAICC) developed by the World Federation of Culture Collections foresees that members register their culture collections through a unique acronym and numerical identifier, and catalogue their microbiological resources. The culture collection acronym and its unique number facilitate access to data for multiple purposes: scientific, technical, administrative, etc.

    - Biorepositories/databanks under management and control of a state (e.g. funded with public resources) and/or in the public domain could be obliged to join the multilateral system
    - **Q: Is the assumption correct that in practice most R&D is at least partly funded by the public? This would put the problem into perspective**
    - Other (purely private) biorepositories/databanks could be invited and encouraged to join the multilateral system (see example of ITPGRFA[27])
- **Q: How could utilization of samples and data be monitored?**
    - Unique identifiers for collected samples and data?
    - Reporting to Global Clearing House
    - Checkpoints at national level

2. Compliance
    - **Q: What incentives could promote non-monetary benefit-sharing?**
        - Access to networks could generally be restricted to Parties
        - Parties to follow or expand the EU approach of "trusted collections" to "trusted research institutions": Those willing to share receive a special status which will allow access to the networks
    - **Q: How to deal with non-Parties?**
        - Researchers from non-Parties could be invited to join on a voluntary basis (see also example from ITPGRFA), but need to fulfill certain compliance criteria
        - Benefit would be that they get access to the networks
    - **Q: Would free-riding be a potential problem?**
        - Or could this be avoided through registration processes
    - **Q: What sanctions could be envisaged?** Being an international legal instrument, an Implementing Agreement can only set obligations for States, not for non-State actors (such as individuals, institutions)! At the same time, sanctions should not be addressed to the State as a whole, but only individuals and institutions in non-compliance should be held liable in the end. States could be obliged to take measures against individuals/institutions in non-compliance, such as
        - Fines
        - Restriction of access to future public research funding

[27] Under the ITPGRFA, if a collection is managed without direct Government control, it is not prima facie covered. Instead, the collection is only included in the Multilateral System with the consent of the institution concerned. However, Parties agree to take appropriate measures to encourage natural and legal persons within their jurisdiction who hold GR listed in Annex I of the ITPGRFA to include such resources in the Multilateral System.

- Following or expanding the EU approach of "trusted collections" to "trusted research institutions": Those in non-compliance could lose their status and face restriction of access to the networks

VIII. Other Issues to Consider

- Financial resources to administer the multilateral system
  - Perhaps at least partly through Global Trust fund
- Contribution to conservation, sustainable use and promotion of future R&D
  - Perhaps at least partly through Global Trust Fund
- Transboundary cooperation
- Codes of conduct/guidelines/standards
  - Awareness-raising