Reports

This part of the EJRR hosts reports in which our correspondents keep readers up to date on the most recent developments in different areas of risk regulation. Our aim is to fuel the debate and trigger future research on cutting-edge risk subjects. The Reports are organised under different policy sections. Further sections will be added at regular intervals. If you are interested in contributing to any of the existing sections, please contact the Reports Editor at enrico.bonadio.1@city.ac.uk

Biotechnology

This section aims to update readers on decisions related to marketing products of modern biotechnology (e.g., GMOs, animal clones) at EU level and on national measures concerning their production. Special attention is devoted to problems of competence between Member States and the EU in regulating biotechnology issues; the institutional dynamics of decision making regarding products derived from modern biotechnology; the relationship between the EFSA and the EU institutions on green biotech-related issues; the evolution of EU regulatory framework and of national attitudes towards the risks and benefits of biotechnology derived products and their production. This section will also delve into the interaction between the EU legislation and WTO law regarding advances in the application of biotechnology within the agri-food value chain.

Exploration and Exploitation of Marine Genetic Resources in Areas beyond national Jurisdiction and Environmental Impact Assessment

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Introduction

The oceans cover two-thirds of the Earth's surface, and approximately 70% of these bodies of water has an average depth of more than 4 kilometers. Solar light does not reach beyond one-kilometer deep, where the water temperature is around 1° C and the pressure reaches very high levels[1]. For these reasons, the deep seabed has long been treated as though it were empty of life. In the late 70s the scientific expedition of the submergible *Alvin*, by the *National Oceanic and Atmospheric Administration*, discovered some hotspots of biodiversity near the hydrothermal vents of the Galapagos Islands, along the black smokers, changing the perception of modern oceanography[2]. Up to now more than one hundred hydrothermal vents have been discovered, mainly near the mid-oceanic ridges, and "it is probably reasonable to speculate that many more, possibly thousands, of hydrothermal vents sites lie hidden below the deep sea, yet to be discovered.[3]" These areas contain some of the richest biodiversity on the planet[4]: approximately 500 species discovered around hydrothermal vents proved to be new to science[5], especially invertebrates and microbes. Only 10% of the deep seabed has been explored[6]: the potential value of its biodiversity, and

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1 Data released by the UNESCO International Oceanographic Commission: http://ioc-unesco.org/

2 This discovery has been identified as one of the most important pieces of progress of oceanography in the Twentieth Century, Paul Dando and S. Kim Jupiter, *Management and Conservation of Hydrothermal Vent Ecosystems,* Report from an InterRidge Workshop, Sidney (Victoria), B. C. Canada 28–20 September 2000.

3 David Kenneth Leary, *International Law and the Genetic Resources of the Deep Sea, (*Leiden: Martinus Nijhoff Publishers, 2007), at p. 12.

4 Maria C. Baker "An Environmental Perpective" in WWF/IUCN, *The Status of Natural Resources on the High Seas*, (2001), at p. 5; "The deep ocean floor is one of the richest, but at the same time one of the least known, ecosystems in the planet", 1999 *U.N. Secretary General Report on Oceans and the Law of the Sea,* U.N. GAOR, 54th Session, Agenda Item 40 (a), (c), 78, 509, U.N. Doc. A/54/429 (1999).

5 Maria C. Baker "An Environmental Perspective" in WWF/IUCN, *The Status of Natural Resources on the High Seas*, (2001), at p. 16.

6 *Ecosystem and Biodiversity in Deep Waters and High Seas,* UNEP Regional Seas Report and Studies No. 178 (2006).

the related marine genetic resources (MGRs), is unknown but promising: the number of marine species used by humans is growing at unprecedented rates. A recent study[7] showed that marine genetic resources are a promising source for biotechnology with 18.000 natural products and 4.900 patents associated with genes of marine organisms[8]. The number of these patents is growing at 12% per year. Ten countries, representing only 20% of the world's coastlines, own 90% of the patents on marine genes, with 70% belonging to the top three[9].

The scope of this paper covers one single portion of marine genetic resources: the ones that are found in areas beyond national jurisdiction (ABNJ), that is to say the high seas, defined in Article 86 of the United Nations Convention on the Law of the Sea (UNCLOS) as "all parts of the sea that are not included in the exclusive economic zone, in the territorial sea or in the archipelagic waters of an archipelagic State", and the Area, defined in Article 1 (1) (1) of UNCLOS as "the seabed and ocean floor and subsoil thereof, beyond the limits of national jurisdiction". Marine genetic resources in areas under national jurisdiction are regulated by national laws and by the international treaties ratified by the relevant States, while marine genetic resources beyond national jurisdiction (BNJ) are not comprehensively regulated by any specific regime. For some years now the International Community has been discussing the conservation and sustainable use of marine biodiversity in ABNJ, under the auspices of the United Nations General Assembly (UNGA) and 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 (BBNJ Working Group)[10]. Within this framework, States must decide by the end of the 69th session of the UNGA (2014) if they agree to launch the negotiations of an Implementing Agreement to the United Nations Convention on the Law of the Sea (UNCLOS).[11] In this context the management of marine genetic resources occupies an important place.

The present paper will look at this issue through the perspective of the assessment of the risks related to the exploration and exploitation of marine genetic resources in areas beyond national jurisdiction. Obligations and procedures for environmental impact assessment[12] for activities likely to cause significant adverse impacts on the environment are well-established at the national level and in transboundary contexts, but this is not the case in ABNJ.

The first part of the report will introduce practical issues related to research and applications of marine genetic resources, together with technological and environmental aspects, since before debating how to regulate environmental impact assessment for MGRs in ABNJ, it is necessary to see if such a regime is warranted in the first place. The second part will look at the legal frameworks of both the Convention on the Law of the Sea (UNCLOS) and the Convention on Biological Diversity (CBD) to see which are the legislative gaps that the political process is called to fill in.

I. Research and applications of marine genetic resources

Genetic resources are defined as "genetic material of actual or potential value", where genetic material is intended as "any material of plant, animal, microbial or other origin containing functional units of heredity[13]". What gives to the genetic material the title of genetic resources is a potential value, which obviously could be of an economic nature, but not exclusively. Value could also be scientific value *per se.*

The exploitation[14] of marine genetic resources is already a common activity for the biotechnology industry: in 2005 the total global sales of marine biotechnology products has been estimated to be

7 Sophies Arnaud-Haond, Jesus M. Arrieta, Carlos M. Duarte, "Marine Biodiversity and Gene Patents", 331 *Science*, 25 March 2011.

8 The study refers to marine genes in general without being able to make the distinction between marine genes coming from areas beyond national jurisdiction and the ones coming from areas within national jurisdiction.

9 USA, Germany and Japan.

10 Arianna Broggiato, "Marine Biological Diversity Beyond Areas of National Jurisdiction", 38(4) *Environmental Policy and Law* (2008), at p. 182.

11 UNGA Resolution 66/288 of 27 July 2012, "The future we want", § 162.

12 Environmental Impact Assessment is defined as "a process of evaluating the likely environmental impacts of a proposed *project or development taking into account inter-related socio-economic, cultural and human health impacts, both beneficial and adverse",* Voluntary Guidelines on biodiversity-inclusive impact assessment, §5, Annex to CBD COP 8 Decision VIII/28 on Impact Assessment.

13 Convention on Biological Diversity, article 2.

14 This paper will not touch upon the distinction between marine scientific research and bioprospecting ("generally understood, among researchers as the search for biological compounds of actual or potential value to various applications, in particular commercial applications" General Assembly Resolution A/62/66 *Oceans and the Law of the Sea* – Report of the Secretary General (March 2007), para. 150") because it does not concern the scope of environmental impact assessment.

100 billion American dollars[15], and even though the portion of that market attributable to marine genetic resources collected in areas beyond national jurisdiction is quite marginal[16] for now, it is likely to increase[17].

Firstly, to assess the risks related to marine scientific research activities in relation to MGRs, it is important to analyze the sampling techniques and their impacts on the oceans' environment. Secondly the applications techniques needs to be analyzed.

Advance sampling techniques make environmental impacts of MSR expeditions rather negligible, especially in the water column. This is less the case in the seabed where sampling can disturb the physical habitat. At sea most sampling is undertaken by lowering or towing sampling devices from the vessels, including water sampling bottles, nets and coring devices. Two disturbance effects to the marine habitats have been reported: the use of acoustic devices (sonars and seismic soundings) that can disturb marine mammals and the introduction of artificial light by submersibles to which some fish and crustaceans might be sensitive[18]. For example, the Project Neptune Canada[19], which studied the role of disturbance in deep-sea benthic ecosystems, reported concerns about possible impacts of the lights used by the submersible. Therefore, submersibles within this project use lights only 60–100 minutes a day and 5–10 minutes each hour. Environmental concerns for the impact on ecological dynamics are more relevant in certain very small and popular hydrothermal vents[20]. Disturbance due to the exploration of MGRs is considered minor compared to bottom fisheries activities, but it is important to underline that the seabed hosts several and sometimes conflicting activities (bioprospecting, bottom fishing, marine scientific research, seabed mining, sea-based tourism, military activities, etc.) and that their cumulative impacts are not assessed.

Marine scientific research activities with respect to deep sea genetic resources focuses mainly on the microbial communities associated with deep sea hydrothermal vents: these communities are highly diverse metabolically, physiologically and taxonomically and live in extreme conditions. As a consequence, they have been subject to considerable investigation with respect to their potential value for biotechnology. The objectives of research focusing on marine genetic resources consider their role within the biological diversity, their functions within the ecosystem and their biotechnology applications. These applications vary among the pharmaceutical industry[21], the cosmetic industry and the food, aquaculture, agriculture and nutritional supplement industries[22] and for purposes of the bioremediation and biofuel applications. Marine genetic materials are used for the genetic information they contain and not for traditional harvesting purposes. Therefore, it usually does not imply the gathering of huge quantities of resources[23]. Once harvested as samples, they can be cultivated in laboratories and analyzed through metagenomic techniques. It is important, however, to underline that only a very small percentage of genetic resources can be cultivated in laboratories, especially in the microbial sector[24].

15 Marjo Vierros, Gwenaëlle Hamon, David Leary, Salvatore Arico and Catherine Monagle, "An Update on Marine Genetic Resources: Scientific Research, Commercial Uses and Database on Marine Bio-prospecting", paper presented at the United Nations Informal Consultative Process on Oceans and the Law of the Sea Eight Meeting, United Nations, New York, 25–29 June 2007.

16 Beyond being marginal, the exact amount of MGRs taken beyond national jurisdiction that have been exploited and commercialized cannot be estimated. In fact, when resources (or a process derived from a resource) are patented, there is no legal obligation to declare where the resources have been taken from. Therefore, it is quite difficult to determine the market of MGRs beyond national jurisdiction.

17 For example, the English biotechnology company *Aquapharm* declared that in the year 2007, 10% of the genetic material used for research was collected in marine areas beyond national jurisdiction, and it estimated that this percentage will increase in the next years. Postnote of the Parliamentary Office of Science and Technology, UK *New Industries in the Deep Sea* 288 (London, July 2007).

18 Kim Juniper, "Technological, Environmental, Social and Economic Aspects of Marine Genetic Resources", IUCN Information Paper to be presented at the Intersessional Workshop on Marine Genetic Resources beyond National Jurisdiction, United Nations, New York 2/3 May 2013.

19 The world's first regional-scale underwater ocean observatory network, available at <http://www.neptunecanada.com/about-neptune-canada/> (last accessed on 14 May 2013).

20 Kim Juniper, "Technological, Environmental, Social and Economic Aspects of Marine Genetic Re-sources", IUCN Information Paper to be presented at the Intersessional Worskhop on Marine Genetic Resources beyond National Jurisdiction, United Nations, New York 2/3 May 2013.

21 Fernando de la Calle, "Marine Genetic Resources. A Source of New Drugs The Experience of the Biotechnology Sector", 24(2) *The International Journal of Marine and Coastal Law* (2009), pp. 209–220.

22 Marjo Vierros, Gwenaëlle Hamon, David Leary, Salvatore Arico and Catherine Monagle, "An Update on Marine Genetic Resources: Scientific Research, Commercial Uses and Database on Marine bioprospecting" paper presented at the United Nations Informal Consultative Process on Oceans and the Law of the Sea Eight Meeting, United Nations, New York, 25–29 June 2007.

23 Kim Juniper, "Technological, Environmental, Social and Economic Aspects of Marine Genetic Re-sources", IUCN Information Paper to be presented at the Intersessional Workshop on Marine Genetic Resources beyond National Jurisdiction, United Nations, New York 2/3 May 2013.

24 For example, only less than 2% of the world's ocean microorganisms can be cultivated with the available laboratory techniques.

While the first oceanographic cruises, sampling marine genetic resources worldwide, focused on the study of taxonomic diversity, with the development of new technologies, and especially metagenomics[25] , the trends for expeditions nowadays is to study the genetic diversity through metagenomics. New technologies include metagenomic libraries, and whole-genome shotgun sequencing makes it possible to search for genetic resources directly in 'environmental samples' rather than in individual organisms. Initially the costs of metagenomic sequencing was very high, but with the recent development of new, less expensive, ultra-high throughput sequencing technologies[26], the number and scope of metagenomic sequencing projects has risen and the costs of genetic sequencing have fallen to a level that is within the reach of researchers worldwide[27].

Considering the nature of the new technologies, such as metagenomics and bioinformatics, and the sampling techniques, it is evident that the threat to marine genetic resources posed by MSR activities in relation to MGRs does not deal with the direct depletion and harvest of a large quantity of resources. It deals more with environmental disturbance produced by the activities themselves, and with the cumulative impacts of different activities undertaken in the deep sea. Since knowledge of the biodiversity of deep-sea genetic resources is still very limited, and since their biotechnological potential is unquantifiable and promising, there are strong ecological and economic arguments in favor of the application of the precautionary principle[28] for preserving hydrothermal sites and the genetic potential through conservation measures[29]. The first measure could be the adoption of a mechanism to undertake EIA for activities related to the exploration and exploitation of MGRs, as it is under discussion within the political context of the United Nations Working Group on marine biodiversity beyond national jurisdiction.

II. Legal Framework for Environmental Impact Assessment in ABNJ

The two international regimes that are relevant for marine genetic resources are the United Nations Convention on the Law of the Sea (UNCLOS) and the Convention on Biological Diversity (CBD). The present legal analysis starts from the premise that there is no comprehensive legal regime applicable to MGRs in ABNJ[30], and will concentrate only on the fragmented framework for environmental impact assessment in ABNJ.

Within the United Nations Convention on the Law of the Sea, article 206 contains a general weak obligation ("as far as practicable") to undertake EIA "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". First, no clear threshold is given about the meaning of "substantial pollution" or "significant and harmful changes". Second, this obligation does not provide minimum standards and requirements to apply uniformly to the conduct of EIAs. Finally, it is, however, poorly implemented. Part XIII of the UNCLOS, which deals with marine scientific research, does not prescribe any obligation to undertake EIA, but article 240 (d) indicates that MSR has to be conducted in compliance with all regulations adopted in conformity with the Convention, including those aimed at the protection and preservation of the marine environment.

Scientific requirements for EIA have been adopted by States and regional or sectoral organizations[31], but with no consistency[32].

EIA obligations and procedures have been adopted for some sectoral activities, such as deep-sea bottom fisheries, seabed mining in the Area, dumping of

25 Metagenomics is "the application of modern genomics techniques to the study of communities of microbial organisms directly in their natural environments, bypassing the need for isolation and lab cultivation of individual species". Kevin Chen and Lior Pachter, "Bioinformatics for Whole-Genome Shotgun Sequencing of Microbial Communities", 1(2) *PLoS Computational Biology* (2005), e24. doi:10.1371/journal.pcbi.0010024.

26 That can produce huge numbers of DNA reads at an affordable cost.

27 Graham Shimmield, "Extent and Types of Research, Uses and Application", IUCN Information Paper to be presented at the Intersessional Workshop on Marine Genetic Resources beyond National Jurisdiction, United Nations, New York 2/3 May 2013.

28 The precautionary principle has been defined as follows in Principle 15 of the Rio Declaration on Environment and Development: "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." UN Doc. A/CONF.151/26/Rev.1, *Report of the UNCED,* vol. 1 (New York).

29 Kim Juniper, "Deep-Sea Hydrothermal Vent Ecosystems – Arguments for Conservation". Paper presented at the Third Global Conference on Oceans, Coasts and Small Islands. Available at <http://www.globaloceans.org/globalconferences/2006/materials.html> (last accessed on 14 May 2013).

30 The complexity of this issue goes beyond the scope of this paper.

31 Within a small number of regional frameworks such as the Antarctic Treaty System, the OSPAR Convention, the Secretariat of the Pacific Regional Environmental Programme and the Barcelona Regional Seas Conventions.

32 Elisabeth Druel, "Environmental Impact Assessments in areas beyond national jurisdiction", 1 *IDDRI* (2013), p. 42 et sqq.

waste and ocean fertilisation. However, such requirements do not exist for some other activities[33] that take place in the deep sea, MSR included.

Under the CBD, the Member States recently adopted Voluntary Guidelines for the consideration of biodiversity in EIAs and strategic environmental assessments (SEAs) in marine and coastal areas[34]. However, their applicability in ABNJ has been contested, given the difference between these areas and coastal and terrestrial ecosystems[35]. Issues related to the costs of conducting EIAs and the necessary follow-up management, control, surveillance and monitoring were raised together with concerns about the governance of marine areas BNJ. This possibly presents the biggest issue since better governance structures would surely be needed to implement EIA in marine areas beyond national jurisdiction, including clarifying what qualifies a group as a "stakeholder", how all stakeholders can participate in decision-making on an equal basis, how entitlement to compensation is established, whose standards are to be applied in an EIA[36], together with solving the issue of which authority would have the competence to monitor the implementation.

Considering that scientists are privileged stakeholders in the context of conservation and the sustainable development of the deep sea, EIA could also be boosted as a consequence of the practice of adopting codes of conducts in the framework of research, such as the InterRidge[37] Code of Conduct for Responsible Research at hydrothermal vents. This code focuses on environmental protection and collaboration among scientists and aims to reduce the impacts of expeditions at hydrothermal vents, avoiding unnecessary double samples of the same vents, for example. However, the level of awareness concerning this code and the corresponding level of compliance with the code seem quite low, according to a survey[38] conducted in 2010 among professional communities that engaged in deep-sea research. The survey showed it is still very difficult to measure the extent to which scientists comply with the statement. Moreover, codes of conducts are voluntarily, and they obviously struggle to overcome the loopholes created by the sectoral approach. As a result, a global instrument assessing impacts of activities in ABNJ is needed.

III. Conclusion

The main issues to consider in relation to the need of EIA for activities related to MGRs in areas beyond national jurisdiction are, on the one hand, the still very low level of available knowledge of deep-sea biodiversity and, on the other hand, the legislative gaps that the political process is called to fill in.

Due to the sectoral approach undertaken so far in EIA in the deep sea, there is a need for both a mechanism to assess impacts of emerging activities, such as the ones related to MGRs, and for a mechanism to assess the cumulative impacts of human activities in ABNJ. Very interesting inputs could be drawn from the Madrid Protocol to the Antarctic Treaty regulating the environmental impact of scientific research in areas beyond national jurisdiction including the deep sea[39], and the work undertaken so far by the International Seabed Authority to develop EIA regulations for the exploration and exploitation of non-living marine resources in the deep seabed[40].

33 Seabed activities other than mining, (e.g. cable and pipelines, seabed installations, marine scientific research, bioprospecting, sea-based tourism); high seas activities other than dumping and some fishing (e.g. shipping, marine scientific research, floating installations (e.g. wave, nuclear, CO_2 mixers)); impacts of high seas fishing activities on outer continental shelves of coastal nations (e.g. deep-sea fishing impacts on sedentary species and resources, vulnerable benthic ecosystems); impacts of outer continental shelf activities on high seas (e.g. seismic testing noise); military activities; new or emerging uses of the seas. Kristina Gjerde *et al.*, "Regulatory and Governance Gaps in the International Regime for the Conservation and Sustainable Use of Marine Biodiversity in Areas beyond National Jurisdiction", *IUCN*, (Gland, Switzerland, 2008) p. 8.

34 CBD COP 11, Decision XI/18 on Marine and Coastal Biodiversity.

35 UNEP/CBD/SBSTTA/16/INF/16, 11 April 2012. Background on the Development of *Voluntary Guidelines* for the *Consideration* of *Biodiversity* in *Environmental* Impact *Assessments* (*EIAs*) and *Strategic* environmental assessments (SEAs) in marine and coastal areas.

36 *Ibid.*

37 InterRidge is a non-profit international organization, comprised of 30 member nations and 2500 member researchers, concerned with promoting all aspects of mid-ocean ridge research.

38 L. Godet, K.A. Zelnio and C.L. Van Dover, "Scientists as stakeholders in conservation of hydrothermal vents", 2 *Conserv Biol.* (2011), pp. 14–22. 164 individuals from 26 different countries answered to the survey (out of more or less 3000 people reached by the survey query): 82% of them were aware of the InterRidge statement; the rate of compliance according to a self evaluation was higher for certain countries (Spain 100% and Portugal 96%) than in others (29% unsure in New Zealand and 14% unsure in Japan); less than 50% were confident in their colleagues' attitudes and compliance with the statement. Few respondents changed their behavior after reading the statement.

39 Marjo Vierros, Gwenaëlle Hamon, David Leary, Salvatore Arico and Catherine Monagle, "An Update on Marine Genetic Resources: Scientific Research, Commercial Uses and Database on Marine bioprospecting" paper presented at the United Nations Informal Consultative Process on Oceans and the Law of the Sea Eight Meeting, United Nations, New York, 25–29 June 2007.

40 Gwénaëlle Le Gurun, "Environmental Impact Assessment and the International Seabed Authority", in C.J. Bastmeijer and Timo Koivurova (eds.), *Theory and Practice of Transboundary Environmental Impact Assessment* (Leiden: Martinus Nijhoff, 2007), at p. 221.