Trends in
Biotechnology

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Science & Society

# Improving awareness, understanding, and enforcement of responsibilities and regulations in Blue Biotechnology

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**Blue Biotechnology is developing rapidly worldwide. However, the Nagoya Protocol (NP), Responsible Research and Innovation (RRI) and other regulatory requirements in this field are falling behind. This article identifies the main RRI, NP, and regulatory gaps and provides key recommendations to mitigate these challenges.**

## Blue Biotechnology and EU regulations

Marine Biotechnology (MB) or **Blue Biotechnology (BB)** (see Glossary) is considered an essential innovation sector for the EU **Sustainable Blue Economy and the Green Deal (GD[i]) Goals** [1]. BB is a multidisciplinary, knowledge and capital-intensive technological area that contributes significantly to innovations in the industry, including pharmaceutical, aquaculture, agriculture, and energy [2]. The global BB market is estimated to reach 6.8 billion euros by 2026, growing at a compound annual growth rate (CAGR) of 8.7% from 2021 to 2026[ii]. In 2020, Europe had the highest share (37%) of the global BB market due to its growing research and innovation (R&I) activities.

With increasing opportunities in the EU and global BB sector, the needs and requirements for **Responsible Research and Innovation (RRI)** are rising faster than scientists and entrepreneurs can find solutions to ensure societal relevance, ethical, responsible, and sustainable financial returns [3]. Applying EU and international regulatory frameworks ensures sustainable BB development and minimizes pressures threatening marine environments. The most important global policy framework is the **Convention on Biological Diversity (CBD[iii])** with its derivatives: **Access and Benefit Sharing (ABS)** and the **Nagoya Protocol (NP[iv])**, recognizing that biodiversity provides value to humankind and provider countries (donors), which have sovereign rights over their genetic resources (GR) and traditional knowledge (TK).

As of April 2023, the NP has been ratified by 139 UN Member States and the EU[v]. The EU played a key role in the negotiations and maintains an essential contribution in the upcoming international negotiations on a new global framework to halt biodiversity loss, given its GD prospects and goals. The GD was launched in December 2019 as a coordinated set of policies with the overarching aim of making Europe climate neutral by 2050. At the core of the GD is the EU Biodiversity Strategy for 2030, a comprehensive action plan for protecting ecosystems, reversing their degradation, and fighting the illegal wildlife trade by committing to ecosystem restoration in law[vi], highlighting the sustainable management of marine areas and retracting biodiversity loss by further pushing the adoption of the CBD.

The EU complied with the NP through Regulation EU No 511/2014[vi]. When realizing possible noncompliance with the legislation, countries require applicants to disclose the origin and compliance of GR and TK during patent submission and examination. However, researchers perceive

## Glossary

**Access and Benefit Sharing (ABS):** emerging biodiversity jurisprudence mechanism for securing a fair and equitable share of the benefits arising out of the access and utilization of genetic resources for commercial purposes.

**Areas Beyond National Jurisdiction (ABNJ):** oceanic regions whose management is shared by several countries. Together, these account for 40% of the planet's surface, including 64% of the ocean's surface and nearly 95% of its volume.

**Biodiversity Beyond National Jurisdiction (BBNJ) Treaty:** (Also known as the Treaty of the High Seas) an international agreement on the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction. The process began in 2004, and the international community has been negotiating for almost 20 years to set a consensual agenda. Institutional agreements and intersecting disputes included: (i) marine genetic resources (MGRs); (ii) area-based management tools (ABMTs), including MPAs; (iii) environmental impact assessments (EIAs); and (iv) capacity building and transfer of marine technology (CBTMT).

**Blue Biotechnology (BB):** application of science and technology to living aquatic organisms to produce knowledge, goods, and services (OECD, 2016).

**Environmental Impact Assessments (EIAs):** requirement under the EU's Environmental Impact Assessment Directive to ensure that a private or a public project considers a wide range of environmental factors, including biodiversity. The EIA procedure guarantees environmental protection and transparency with regard to the decision-making process from the beginning of a project. It allows the public to actively engage in the EIA procedure. Moreover, the requirement of EIAs under customary international law has been made more evident by international jurisprudence, particularly regarding its legal standing, threshold norms, procedural requirements, and the problem of State responsibility, an essential tool for promoting environmental protection and sustainable development.

**Nagoya Protocol (NP):** international legal framework that legally binds Member States to ensure the conservation and sustainable use of their genetic resources and traditional knowledge and the fair and equitable benefit-sharing with the provider countries, including both results of R&I and the benefits from the commercialization.

**Responsible Research and Innovation (RRI):** an approach to R&I that anticipates, reflects, and assesses its potential implications and societal expectations to make R&I actions responsible, ethical, inclusive, and sustainable.

**Second World Ocean Assessment (WOA II):** A major output of the second cycle of the UN Regular Process for Global Reporting and Assessment of the States of the marine environment, including socioeconomic aspects.

**Sustainable Blue Economy and the Green Deal (GD) Goals:** aim for the efficient use of resources by moving to a clean, circular economy and stopping climate change, reverting biodiversity loss, and withdrawing pollution.

such legislation as a hurdle instead of an enabler. The majority of the BB community ignores the fact that various countries demand compliance with regulations for achieving intellectual property protection, for example, in a patent. Poor compliance or noncompliance may withdraw the researcher's R&I results, uses, and implementation in industrial development [4]. Many scientists are unaware that when having a patent submitted and/or accepted, information will be openly disclosed and, thus, exposed to misconduct, misappropriation, or misuse of GR and TK [5].

To highlight the value of biodiversity in economic terms and oppose the common belief that marine protected areas (MPAs) are decreasing economic development, the EU emphasizes that for every euro invested in MPAs, benefits increase by giving a triple return on investment. The EU legally protects at least 11% of the EU seas, and the Member States are responsible for enforcing MPAs by 2023. Hence, the EU aims to protect and monitor 30% of its seas by 2030 and has declared zero-tolerance towards illegal practices and nonsustainable harvesting of marine resources[viii]. This reinforces the need for BB researchers and entrepreneurs to be acquainted with regulations and ethics and in line with the UN Sustainable Development Goal 14 (UNSDG14), 'Life below water' [ix]. In this context, RRI enables research and innovation to meet societal needs considering ethics and sustainability [4].

## Areas Beyond National Jurisdiction, Biodiversity Beyond National Jurisdiction, and Second World Ocean Assessment

The cumulative effects of human activity pose an increasingly serious threat to marine **Areas Beyond National Jurisdiction (ABNJ)**, causing biodiversity loss and environmental degradation. A formalized framework, such as **Biodiversity Beyond National Jurisdiction (BBNJ)**, related to ongoing intergovernmental negotiations on the conclusion and execution of an agreement implementing the UN Law of the Sea Convention (UNCLOS) on the conservation and sustainable use of biological diversity in ABNJ would effectively implement environmental protection and conservation [6].

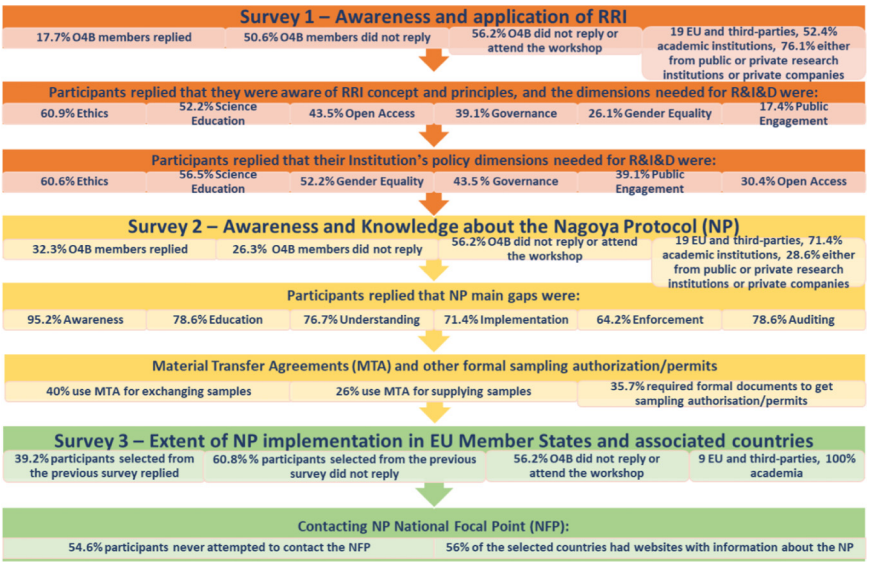


Figure 1. Results of three surveys: (1) Awareness and Application of RRI (orange); (2) Awareness and Knowledge about the NP (yellow); and (3) NP Implementation in EU Member States and Associated Countries (green). For this survey 66.7% of the participants were selected out of the participants from the previous survey. The surveys were distributed to the members of the COST ACTION CA18238 European Transdisciplinary Networking Platform for Marine Biotechnology (Ocean4Biotech; O4B), which comprises 130 experts in BB from 36 EU and third-party countries. Our surveys indicated that the NP and RRI topics are not appealing to the BB community. From 130 members of CA18238, O4B, 59.6% of the 57 O4B members that attended the dedicated RRI online workshop did not reply to the survey, and 56.2% did not reply nor attended the workshop. The RRI concept and principles of the dimensions needed for R&I&D are perceived differently by the participants when compared to their Institutions. Nevertheless, Ethics and Science Education are coincident. From the 17.7% of members that replied, it was clear from their answers that explanation, training, and application of RRI are needed in BB's R&I processes. Lack of awareness, education, understanding, implementation, enforcement, and auditing were the major gaps about NP and other BB-related regulations. Most survey respondents stated that their NFPs were either nonresponsive or not knowledgeable enough. This feedback was recorded for both research-intensive countries and inclusiveness target countries. Nevertheless, few survey respondents replied that their university facilitators were knowledgeable and provided them with information and application forms. Additionally, 12% of the 25 investigated NP-signee countries have ABS procedures and application forms available online, and 56% have national websites with information about the NP, due diligence, a checklist for BB researchers, innovators, and other stakeholders, and legal information. However, there is no available information regarding the NP implementation protocols for several countries, which was aligned with the participants' statements from these respective countries. Administrative processes should become transparent and easily accessible, with a fast turnaround, that is, national websites must provide readily available information and application forms. Knowledgeable, efficient, and quick-response NFPs would assist researchers in public and private organizations to correctly interpret and follow BB EU policies and regulations by offering support, awareness, and training initiatives. The promotion of briefings, training, communication at national and regional levels should be organized, targeting personnel both from the research center, and BB companies. Hence, the NFPs training needs must be fulfilled. They should be evaluated for their responsiveness, a maximum response delay, and/or support towards researchers and innovators. With EC support, a pan-European regulatory knowledge hub may provide researchers and innovators with a one-stop-shop information platform (i.e., EU, NP, and national regulations, guidelines, tools, facilities, funding information, projects results, innovations, databases, and biobanks) enhancing the BB innovation ecosystem's growth. Potentially generating profit through innovative products and increasing NP and RRI compliance. In the long term, these mitigation measures will create a new generation of BB actors fully aware and compliant with all BB regulations. Abbreviations: ABS, Access and Benefit Sharing; BB, Blue Biotechnology; NFP, national focal point; NP, Nagoya Protocol; R&I, research and innovation; RRI, Responsible Research and Innovation.

The **Second World Ocean Assessment (WOA II)** is a comprehensive study of the oceans worldwide, including marine environment and socioeconomic aspects to support decisions and actions for achieving the UNSDG14, as well as the implementation of the UN Decade of Ocean Science for Sustainable Development, providing scientific information in a comprehensive and integrated manner[x].

The BBNJ Treaty is an international agreement on the conservation and sustainable use of marine biological diversity in ABNJ. In 2023, the BBNJ negotiations are finally nearing their conclusion, and reaching an agreement is paramount. Concerning the relation of the BBNJ with other instruments, Article 4 states that the instrument should not 'undermine existing legal instruments and frameworks and appropriate global, regional, subregional and sectoral entities' [7]. Yet, there are still no provisions for culpability or compensation, which will affect the compliance outcomes with UNCLOS and the implementation efficiency [8].

## RRI and NP main gaps and recommendations by CA18238

The RRI framework enables scientists to anticipate and reflect, be open and transparent, include diverse stakeholders in their work and be responsive and adaptive to new knowledge. In 2021, three surveys: (1) Awareness and Application of RRI; (2) Awareness and Knowledge about the NP; and (3) Extent of NP Implementation in EU Member States and Associated Countries [4] (Figure 1) were distributed to the members of the European Cooperation in Science and Technology (COST) Action CA18238 European Transdisciplinary Networking Platform for Marine Biotechnology (Ocean4Biotech; O4B)[xi], which comprises 130 experts in BB from 36 COST Member countries [9,10]. Additionally, an online workshop dedicated to RRI and NP topics was held.

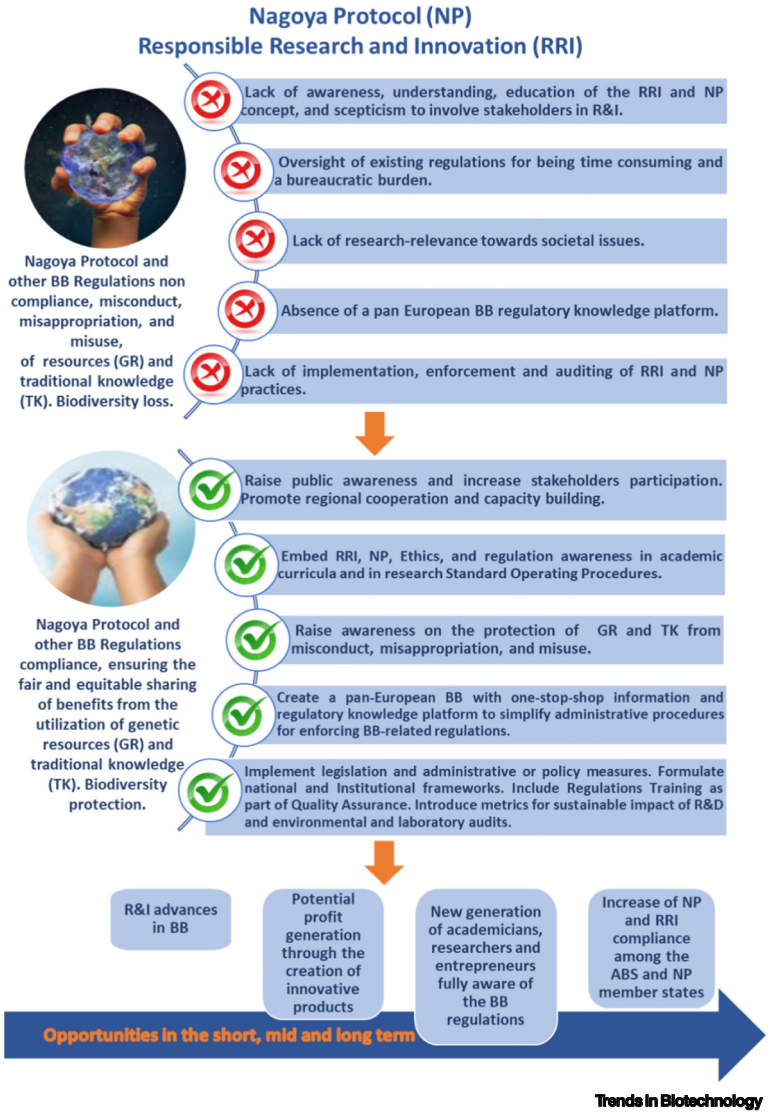


Figure 2. Main gaps and recommended mitigation actions for the NP, EU BB-related regulations, and RRI, for managing GR and TK and protecting biodiversity in marine ABNJ. Researchers and innovators overlook the NP, and its national implementation is falling behind. The implementation of the NP is a multilevel process. The government of each contracting party of the NP is the responsible authority for Implementing measures, raising awareness of the importance of the GR and TK (Article 21). Monitoring and Reporting (Article 29). These NP Articles are the hardest to follow since not all Parties have the same resources, trained personnel, and capacity to apply them at the regional or research-institutional levels. Links between EU policies, guidance, and directives to the NP and its sister protocols and conventions should be considered to become evident and known. Academia and public institutions need incentives to comply with the best practices as well as to introduce training and internal audits. Academia needs to introduce the NP and RRI frameworks and tools in its curricula and R&I activities. The introduction of metrics for evaluating their impact on sustainable R&I activities, followed by periodical environmental and laboratory audits, should be considered. Research centers and academia accessing GR and TK are responsible for applying the NP through the ABS Clearing House website and/or contacting the country's appointed ABS national focal point. Funding enabling genuine registration and maintenance of – biobanks – and tuning of crucial steps and procedures within applied biotechnological methods must be envisioned. Financial incentives in the form of vouchers, tax incentives, and RRI recognition prizes or seals of ethics for research organizations, provided by EC or Competent National or Regional Authorities are also suggested. Abbreviations: ABNJ, Areas Beyond National Jurisdiction; ABS, Access and Benefit Sharing; BB, Blue Biotechnology; GR, genetic resources; NFP, national focal point; NP, Nagoya Protocol; R&I, research and innovation; RRI, Responsible Research and Innovation; TK, traditional knowledge.

Our study of BB R&I compliance with NP and EU BB regulations detected the following gaps (Figure 2). (i) Low awareness, education, and understanding of the RRI and NP concepts, and skepticism to involve stakeholders in R&I. Raising public awareness, increasing stakeholders' participation and promoting regional cooperation and capacity building is recommended to mitigate this issue. (ii) Oversight of existing regulations is time-consuming and a bureaucratic burden. The inclusion of RRI, NP, ethics, ABNJ, WOA II, BBNJ, and GD concepts and regulations awareness in academic curricula and research standard operating procedures, in the long term, will originate a new generation of academics, researchers and entrepreneurs compliant and fully aware of all BB regulations. (iii) Lack of research relevance towards societal issues, which may be overcome by raising awareness on the protection of GR and TK from misconduct, misappropriation and misuse, preventing biopiracy, and in turn advancing R&I in BB, and potential profit generation through the creation of marine-derived innovative products. (iv) Absence of a pan-European BB regulatory knowledge platform. Such a regulatory knowledge hub would provide researchers and innovators with a one-stop-shop information platform, enhancing the BB innovation ecosystem's growth and simplicity of administrative procedures for enforcing the BB Regulations. (v) Lack of implementation, enforcement, and auditing of RRI and NP practices and other BB Regulations. These could be overcome by implementing legislation, administrative or policy measures, formulating national and institutional frameworks, including BB Regulations training as part of Quality Assurance, introducing metrics for the sustainable impact of R&D, and environmental and laboratory audits.

## USA and China case studies

In 2011, one survey [11] concluded the following about US researchers: (i) most were actively involved in the exchange of GR; (ii) few exchanged large quantities of material; (iii) few reported paying for GR; (iv) used informal conduits were based on expected reciprocity; (v) low use of Material Transfer Agreements (MTAs); and (vi) expected exchange and intellectual property outcomes on projects. Overall, researchers expressed apprehension that the NP might hinder academic research by constraining the exchange and use of GR and TK [11]. Despite the USA not being an NP Party, its researchers and their international collaborators are required to follow the regulations of other countries when working with GR and TK obtained outside of the USA, as well as the local regulations imposed by the NP that differ from the country of origin, as the NP states that each Party shall, at its own discretion, establish a domestic legislative system [12].

China is an NP Party, so if a conflict arises, Article 30 of the NP provides for procedures and mechanisms to promote the compliance of the Parties and to control noncompliance. In case of a dispute, the settlement procedures under Article 7 of the Convention will be applicable [13].

## Concluding remarks

BB R&I compliance with NP and EU regulations is time-consuming. Mitigation of the perceived gaps by generating awareness, understanding, education, implementation, enforcement, and auditing, in academia, private and public research centers, and industry, including small and medium-sized enterprises (SMEs), would enforce compliance with regulations and the benefits of following the RRI approach and NP as part of their institutional governance and societal responsibility. Moreover, global knowledge of the NP, RRI, ABNJ, BBNJ, and GD and compliance would result in the worldwide fair and equitable sharing of benefits from the utilization of GR and TK, including biodiversity protection at the national level and in ABNJ.

## Acknowledgments

This publication is based upon work from COST Action CA18238 (Ocean4Biotech), funded by the European Cooperation in Science and Technology (COST) Program in the period 2019–2023. The work of Kalamujić Stroil B. and Tourapi C. was co-funded by the COST Action CA18238 through Virtual Mobility grants. This work is financed by national funds from FCT – Fundação para a Ciência e a Tecnologia, IP, in the scope of the project UIDP/04378/2020 of the Research Unit on Applied Molecular Biosciences – UCIBIO and the project LA/P/0140/2020 of the Associate Laboratory Institute for Health and Bioeconomy –i4HB. This work is also financed by the Research Council of Norway (319577SAFERIMTA, 326803SUSKELPFOOD, 294946SBP-N) and Møreforsking AS.

## Declaration of interests

No interests are declared.

## Resources

[i]https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/european-green-deal_en

[ii]www.industryarc.com/Report/16110/marine-biotechnology-market.html

[iii]www.cbd.int/convention/text/

[iv]www.cbd.int/abs/

[v]https://absch.cbd.int/en/

[vi]https://stl.pku.edu.cn/info/1004/3755.htm

[vii]https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R0511

[viii]https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020DC0380

[ix]https://sdgs.un.org/goals/goal14

[x]www.un.org/regularprocess/woa2launch

[xi]www.ocean4biotech.eu/

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https://doi.org/10.1016/j.tibtech.2023.05.011

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