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Unpacking policy developments in marine natural product research: a scientist's guide to DSI and BBNJ

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Covering: 2014 up to February 2025

Since the Nagoya Protocol came into force in 2014, scientists working with genetic resources have integrated compliance with Access and Benefit-Sharing (ABS) legislation at international and national levels into their research practices. However, two key gaps left by the Nagoya Protocol are being addressed, introducing new obligations for marine natural product scientists: under the auspices of the Convention on Biological Diversity (CBD), a compromise agreement was reached in November 2024 that regulates the use of Digital Sequence Information (DSI) on Genetic Resources. Within the next few years, the 2023 Biodiversity Beyond National Jurisdiction (BBNJ) Agreement is expected to take effect. This treaty covers the access to and use of marine biodiversity of areas beyond national jurisdiction for research and development. In a time when genetic research and marine biodiversity are key to scientific advancement, these evolving policies affect how genetic information is stored, shared, and used, raising emerging questions for the scientific community about their direct impact and the complexities of compliance. Despite continuous developments and scientific community involvement, there remains a notable gap in communication between policy changes and their accessible dissemination to researchers. Addressing this gap is crucial for the continuation of research and the effective use of relevant resources. The main goal of this viewpoint article is to provide a concise guide to recent policy developments relevant to natural product researchers that should be incorporated and harmonized into ongoing scientific activities.

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1 Introduction

The history of maritime exploration aligns significantly with the quest for understanding and utilizing the contents of the ocean, particularly its genetic resources.[1,2] This interest has led to a deepened knowledge of marine biodiversity, which has in turn fuelled growing interest in the economic and scientific potential of marine genetic resources (MGRs) (Fig. 1).[4]

"Marine genetic resources" are legally defined‡ as any material of marine plant, animal, microbial or other origin containing functional units of heredity of actual and potential

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‡ MGRs are only legally defined in the BBNJ agreement, which thus necessitates that MGRs within this context must be sourced from ABNJ. The legal definition given in the agreement aligns with the Convention on Biological Diversity (CBD) definition on a genetic resource. From a scientific viewpoint, MGR could equally occur within or outside of national jurisdiction.

value. The significance of these resources has been supplemented by a rapidly advancing biotechnological field in the past few decades, including but not limited to the sequencing and synthesis of DNA.[4,5]

While the importance of wet laboratory work persists, the continually evolving technological landscape has made it possible to develop products solely based on the digital information available on genetic resources.[6] This has generated another classification of relevant resources throughout the marine biodiscovery pipeline, termed 'Digital Sequence Information (DSI)'. This term encompasses genomic sequence data and possibly other data such as protein sequences and metabolites.[7] Currently, the marine biodiscovery pipeline comprises several stages requiring the exploration of key legal classifications (Fig. 1). From the exploration of marine biodiversity to the analysis and preservation of collections and the curation of marine genetic resources, this process culminates in the generation of scientific outputs, publications, products, decision support tools, and advances in technology, all falling under the category of genetic materials and derivatives.[8]

With the potential value and benefits of these advancements, a need has arisen to further expand the regulatory landscape. The Nagoya Protocol, which came into force in 2014, marked a pivotal moment by operationalising the Convention of Biological

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Thomas Vanagt

Thomas Vanagt holds a PhD in biology from Ghent University (Belgium) and is a co-founder of 3BIO, a company specializing in guiding users through the complex legal landscape of Access and Benefit Sharing (ABS). He has been working on ABS and the Nagoya Protocol since 2012 and has published several peer-reviewed papers on the topic. He was one of the leading authors of the Mare Geneticum paper that laid the foundations for the MGR section of the High Seas Treaty. In his capacity as independent expert, he has advised both Global North and Global South delegations at the BBNJ negotiations on the topic of MGR.

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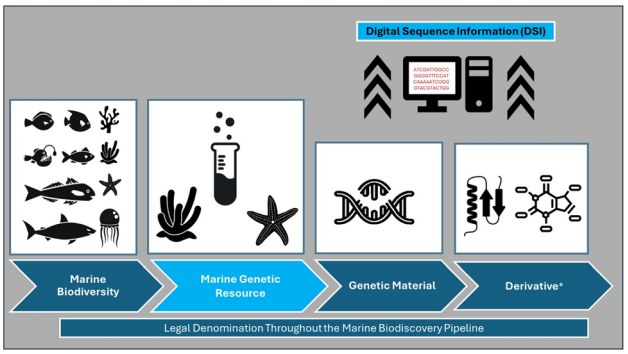

Fig. 1 Scheme showing the steps in the marine biodiscovery process explaining the relationship between Marine Genetic Resources (MGRs) and Digital Sequence Information (DSI). *"Naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources".[3]

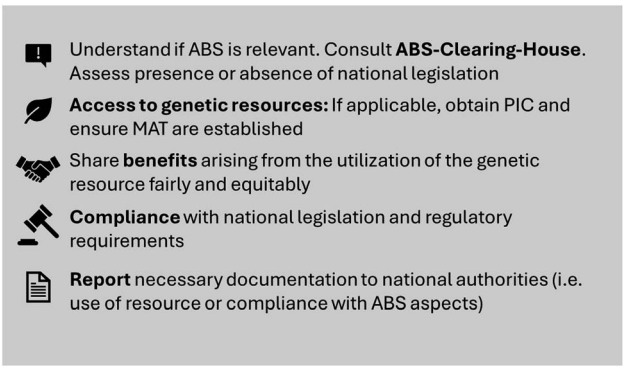

Fig. 2 Overview of Nagoya ABS obligations.

Diversity (CBD) framework for ABS of genetic resources.[3] Building on the CBD, subsequent developments, such as the collaborative agreements discussed in a review by Cragg *et al.*, underscore the necessity of continued collaboration between scientific innovation and regulatory frameworks.[9] However, this overarching framework, as well as the previously established UN Convention on the Law of the Sea (UNCLOS) for ocean governance, has left gaps in regulatory reach. These gaps were compounded by the combination of technological advancement and increased capabilities to explore relatively unexploited areas of the ocean. Thus, the Agreement on Biodiversity Beyond National Jurisdiction (BBNJ) and Decision on DSI under the CBD have been negotiated.

As researchers begin to navigate and incorporate these regulations alongside current practices, it is essential to understand the implications for their work and the broader scientific community. This viewpoint article aims to present tangible applications and impacts that natural product researchers must observe and prepare for in the current and immediate future. To outline these implications effectively, it is crucial to define the relevant frameworks and key classifications of genetic resources. Understanding the scope and overlap among them will be essential for anticipating the impact on research practice and compliance.

2 Existing obligations under ABS legislation

The scope of the Nagoya Protocol encompasses genetic resources obtained from within national jurisdictions. Under the principles of ABS, researchers working with genetic resources are required to comply with several key obligations (Fig. 2).[3,10] These obligations aim to promote transparency and legal certainty in the use of genetic resources while respecting the sovereign rights of countries as well as the rights of indigenous people and local communities over natural resources.

The actual decision to regulate access to and the use of genetic resources is determined by the individual state, allowing countries to develop their own ABS framework for access, utilization, and enforcement.[3,11]

In addition to further implementing the obligation under the Nagoya Protocol to conduct compliance checks in user countries, certain countries or regions have established compliance systems.[12] For instance, EU Regulation 511/2014 introduced a harmonized due diligence-based compliance system for all 27 EU member states.[13] The Nagoya Protocol has defined certain principles on ABS, but the spectrum of national ABS laws has resulted in a complex landscape for researchers to navigate, a challenge that has posed significant challenges for the scientific community.[14,15]

3 Identification of gaps

Access and benefit-sharing under the CBD and its Nagoya Protocol applies to physical genetic resources over which countries can exert sovereign rights. It is the prerogative of each country to establish an ABS framework aligned with these principles.

There are two major gaps related to genetic resources that are not covered by the Nagoya Protocol. The first pertains to its geographical scope. As mentioned above, the CBD framework only oversees resources within national jurisdiction. However, marine genetic resources of areas beyond the Exclusive Economic Zones (EEZs) of coastal states are not covered by the Nagoya Protocol and national ABS laws. EEZs extend up to 200 nautical miles off a country's coastline, in addition to which a state may claim an 'extended continental shelf' (UNCLOS Article 76).[16] This gap has been addressed by the development of a separate agreement under the United Nations Convention on the Law of the Sea (UNCLOS), titled 'Conservation and Sustainable Use of Marine Biological Diversity of Areas Beyond National Jurisdiction' (BBNJ).

Additionally, the Nagoya Protocol and national ABS laws are based on a bilateral framework between a user and a provider. MGRs from Areas Beyond National Jurisdiction (ABNJ) cannot be managed bilaterally because of their geographical nature; the resources do not originate from a single 'provider'. This requires a multilateral framework to ensure the fair and equitable sharing of benefits derived from MGRs. The BBNJ Agreement aims to fill this gap by providing a comprehensive, multilateral approach to managing MGRs.

The second gap pertains to the material scope. Most countries' interpretation of the Nagoya Protocol only explicitly covers

genetic resources and genetic material but excludes the DNA sequences derived from these resources (*i.e.*, Digital Sequence Information, DSI).[16] However, this is not universally applied, as there are exceptions among countries that incorporate DSI within their national ABS laws. The issue of how to address benefit-sharing related to DSI has been the subject of discussions at the CBD for several years, as DSI was not prevalent when the CBD was originally negotiated. Due to the way DSI is generated, stored, and shared, it was agreed at COP15 in 2022 that managing DSI bilaterally is nearly impossible, leading to the establishment of a multilateral framework. At the recent COP16 of the CBD, further operational details of the DSI mechanism were developed.

4 Explaining frameworks

4.1 MGR part of BBNJ

The BBNJ Agreement addresses the regulatory gaps in the governance of biodiversity of marine areas beyond the national jurisdiction. These areas, which include the "High Seas" (*i.e.* the water column) and the "Area" (*i.e.* the seabed and subsoil), account for nearly two-thirds of the global ocean (Fig. 3A). This creates the potential for unregulated exploitation of marine living resources. The classification of ABNJ depends on the geographical scope and layers of jurisdictional claims, as shown in Fig. 3.

In order to address the concerns raised during extensive international discussion on protecting and promoting equitable access to biodiversity in ABNJ, the Agreement focuses on four key pillars: MGRs including the sharing of benefits, area-based management tools (ABMTs), environmental impact assessments (EIAs), and capacity building and the transfer of marine technology.[18] The most important aspect for the natural product research community is MGRs, which remain an ongoing debate in the face of ratification of the agreement – a formal approval process by which countries agree to be bound by the terms of the treaty.

The BBNJ agreement defines the utilization of MGRs (paragraph 1.14) and outlines other key terms therein such as "biotechnology" (paragraph 1.3).[18] The term MGR also includes the genetic material found in all marine organisms, including both physical genes and gene clusters (DNA and RNA). The information encoded within these sequences is referred to as 'DSI on MGR.' This, along with additional biological and technological resources, facilitates the production of diverse biochemicals with biodiscovery applications in pharmaceuticals, cosmetics, dietary supplements, research tools, and industrial processes, thereby benefiting humanity.[19]

One of the main challenges of the BBNJ agreement is developing a more collaborative and standardized approach to benefit sharing. Determining whether genetic resources originate solely from ABNJ or stem from multiple jurisdictions presents significant challenges.[20] This distinction is critical for determining which ABS framework is applicable to ensure the fair and equitable sharing of benefits derived from the use of MGR. The risk of overlapping obligations under multiple ABS frameworks, and any associated challenges, still needs to be addressed and mitigated.[21]

As a tool to navigate these challenges, the BBNJ Batch Identifier will be established to help researchers accurately manage utilized MGRs.

This system aims to standardize how samples, metadata (with a focus on the specific origin of the sample in question), and genetic data are managed within ABNJ, further facilitating compliance and transparency. The concept and development of the batch identifier needs to take this specific complexity under consideration. Fortunately, many of the terms in the BBNJ Agreement are concordant with the Nagoya Protocol, giving hope that the two UN instruments can work together to cover genetic resources within and beyond national jurisdiction.

The MGR-related provisions in the BBNJ Agreement mandate the sharing of both monetary and non-monetary benefits. The value of MGRs and DSI of MGR may include monetary worth associated with commercial products as well as the notion of 'tangible and intangible' value, which pertains to the preservation or improvement of the adaptability and resilience of marine species and ecosystems.[22]

Article 12 of the BBNJ Agreement outlines the process for notifying authorities about activities involving MGRs and DSI on MGR from ABNJ (Fig. 4).[18]

This component of the agreement is particularly relevant to the scientific community as it directly impacts research

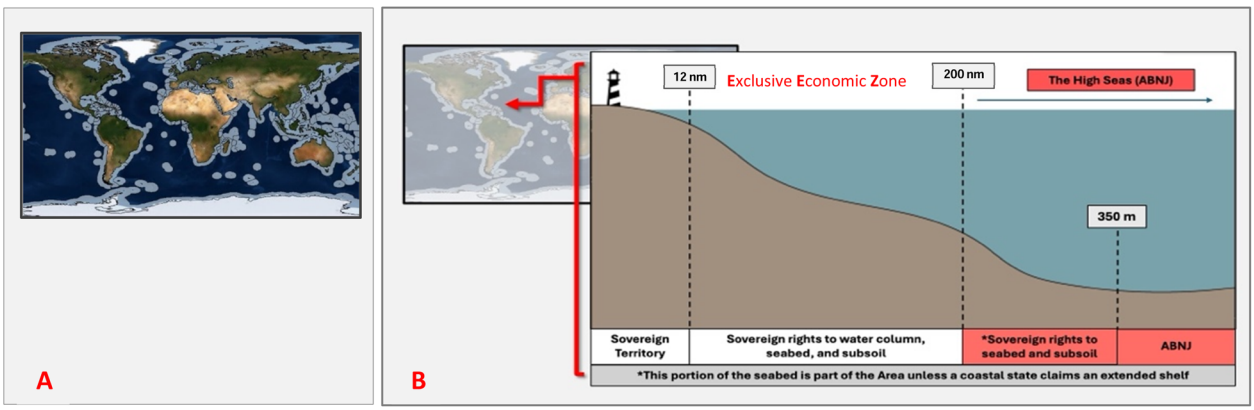

Fig. 3 Geographical scope of ABNJ; dark blue indicates ABNJ (A). Layers of ABNJ (B). *Figure adapted from Arctic Council, *Arctic Marine Shipping Assessment 2009 Report* (Tromsø, Norway: 2009), p. 52.[17]

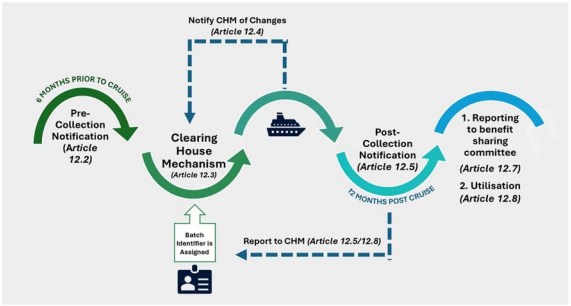

Fig. 4 Implications on marine research referencing Article 12 of the BBNJ Agreement.

activities. Proper integration of these requirements into research practices is necessary to ensure compliance and continued promotion of sustainable and fair use of MGR.

4.2 Digital sequence information under the CBD

"Digital Sequence Information" first appeared in CBD documentation in 2016, where it was introduced as a placeholder without a clear definition.[23] The importance of DSI lies in its role in modern life science research. DSI has facilitated substantial advancements in medicine, conservation, agriculture, and other sectors. Every country uses and contributes to DSI, which is employed in basic and applied research across public and private sectors.[24]

The utilization of DSI allows researchers to study MGRs without needing physical samples. This further advances the conservation and sustainable use of marine biodiversity from the perspective of collecting fewer physical samples as well as gaining understanding into the genetic makeup of marine organisms. Although tracing DSI origin is complex, sequences submitted to global databases are freely available online to the scientific community.[25]

However, expert knowledge is necessary to comprehend how to find, download, and use such resources for MGR research purposes.

The rapid development of (marine) biodiscovery technologies (*e.g.* genome mining) underscores the importance of integrating DSI within the BBNJ agreement with respect to MGRs. Incorporating DSI into the BBNJ agreement allows researchers to continue accessing these resources while ensuring the sustainable use of MGRs and the fair sharing of benefits arising from DSI research and development.

Fig. 5 provides an overview of key decisions under the CBD that impact the utilization of DSI in practice (for further details, see Rohden *et al.*[25]). These decisions have shaped the current landscape of DSI usage, and understanding these milestones is crucial for navigating this regulatory framework as a natural product researcher. These decisions underscore the progressing nature of DSI policy. By staying informed of these developments, researchers can ensure they remain compliant with current regulations.

5 Implications for researchers

Up until now, scientific researchers have had to comply with various obligations under the Nagoya Protocol and national ABS legislations, as described in Fig. 1. However, gaps in communication regarding policy changes have left researchers with limited resources to navigate compliance requirements. Furthermore, as neither the BBNJ Treaty nor the new DSI regulations are fully enforced yet, there is a need for indication of potential future impact on scientific operations. Tangible application of these policies is best presented in following a mind map across decisions to be made when conducting research which utilizes an MGR (Fig. 6).

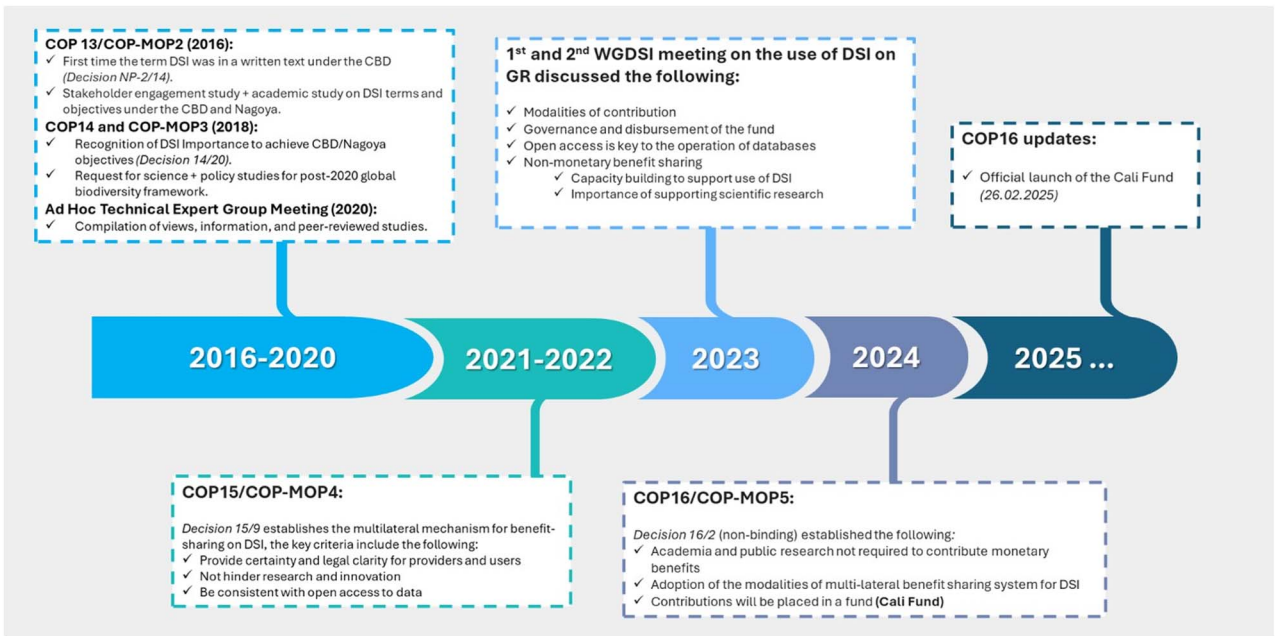

Fig. 5 Overview of decisions impacting scientists working with DSI under the CBD.

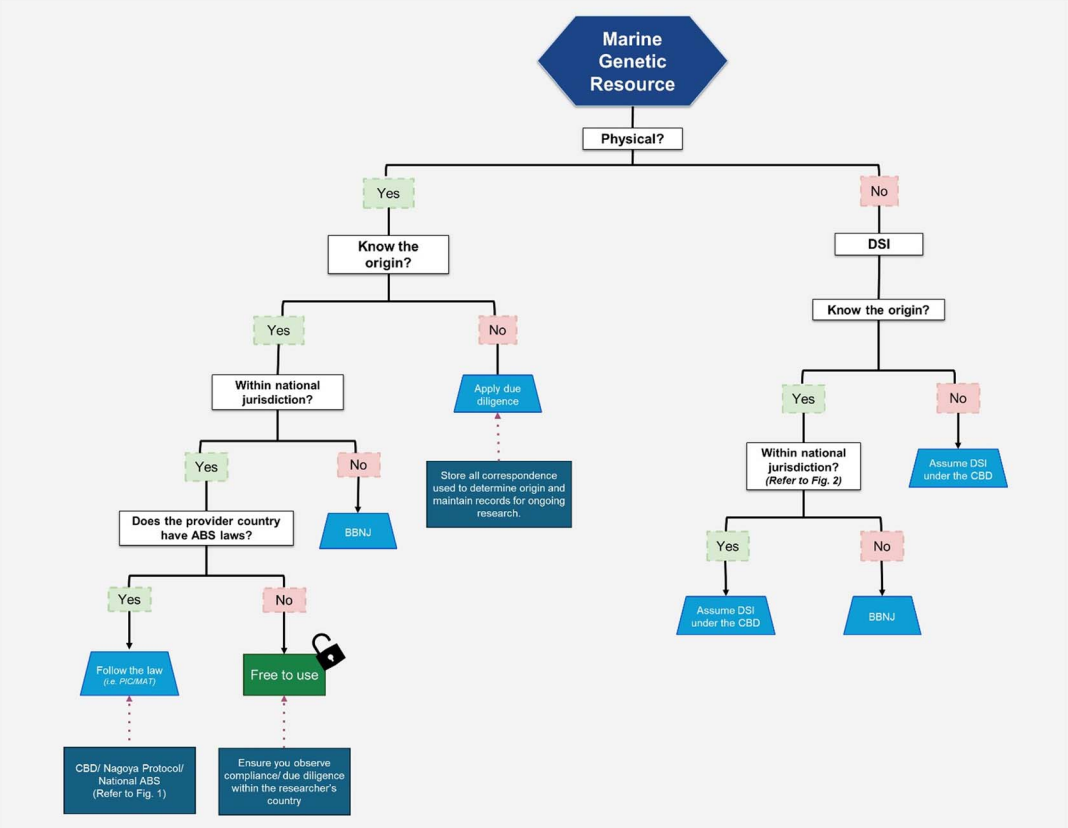

Fig. 6 Decision Tree for Compliant Utilization of MGR. This tool helps determine which framework applies and when, based on the various potential classifications of the resource. By utilizing this simplified decision tree as a practical guide, researchers can, on a surface level, navigate the complex regulatory landscape with greater ease and clarity. This will help researchers to streamline processes and hopefully reduce administrative burdens in the form of translating policy-based jargon into an implementable concept.

Scientists may be concerned about the additional burdens that will potentially accompany the implementation of these two policies. The extent of these challenges will depend on the degree of harmonization of these policies and the countries involved, as well as on interdisciplinary and inter-sector exchange of experiences and even resources. A lack of policy alignment could lead to fragmented governance, making both collaborative and independent research more difficult.[21] To mitigate this, clear communication, transparency, and ideally harmonization across disciplines and sectors are essential to address the impact of both bilateral and multilateral frameworks on the scientific community.[21] Researchers need to understand the shift from bilateral agreements under the Nagoya Protocol to the multilateral frameworks required for DSI and MGRs to navigate the evolving regulatory landscape effectively. The implementation of these policies will transform research conduct and benefit sharing amongst stakeholders. As outlined in the explanation of Article 12 above, the BBNJ Agreement will require increased transparency and collaboration among international bodies. Furthermore, the establishment of this international framework has the potential to bring global collaboration to the forefront of marine biodiscovery research, *i.e.* through multi-state research cruises (see requirement for LMIC-located scientists to be notified of available cruise berths).[8] The convergence of these global conversations and their success will rely on the practical mechanisms and enforcement that are still in development.

6 What is next?

Both policies are in different stages of development, ranging from conception to implementation (entry into force). The most recently adopted text for DSI under the CBD marks a step in the direction of implementation. However, the CBD will continue conducting studies before finalizing these decisions at the COP17 in late April of 2025.

The BBNJ agreement will take effect 120 days after its 60th ratification. As of November 29, 2024, fifteen states have ratified the treaty.[26] The pace of ratification varies by country, but the treaty could be enforced as early as 2026. Once in effect, a COP will be convened to make further decisions on essential aspects such as benefit-sharing modalities and the establishment and implementation of the BBNJ Batch Identifier, which will be crucial for researchers.

Both of these policies continue to evolve. As such, researchers should do their best to stay informed of these developments, and, when possible, communicate the impact on their work to the appropriate stakeholders. Furthermore, they should begin

aligning research practices with the potential requirements of these frameworks, as is described in the figures above.

The integration of these two policies will determine the advancement of biodiversity research in the context of sustainable and ethical practices. They also have the potential to facilitate broader scientific communication and collaboration, if implemented correctly. These policies promote the access and global sharing of DSI, directly tied into applied sciences such as new medical developments and sustainable biofuels. BBNJ policies align with these goals by emphasizing capacity building, increasing the potential for equitable participation and benefit-sharing among the international community, regardless of technological or financial capabilities.

Together, these policies can create a balanced approach between supporting scientific progress and protecting biodiversity while ensuring equitable access and benefit-sharing schemes. The dual focus on innovation and conservation, if preserved through implementation, has the potential to create a more harmonized global initiative in the context of biodiversity.

7 Conclusion

It is important to note that among other global frameworks on ABS such as COP15's DSI decision, BBNJ is the first to actively involve scientific voices in negotiations, demonstrating a commitment to aligning this policy with scientific progress.[27] If the DSI and BBNJ policies are effectively harmonized, there is potential for increased global collaborations and sustainable frameworks for marine genetic research. This would support innovations and shape the future landscape of marine biodiversity research. While there are potential challenges, continued scientific engagement will be key to addressing them effectively to benefit science.

The ongoing integration of the resource classifications of DSI and MGRs into global frameworks marks a pivotal moment for the marine biodiscovery field. While the policies present challenges, including jurisdictional complexities and potential additional burdens, proper implementation could streamline international collaboration and equitable access. However, the complexity of these frameworks is further compounded by current geopolitical tensions, which may increase pressure on governing marine territories and resources. These factors could undermine the implementation of the BBNJ Agreement's objectives, regardless of their suitability. Now more than ever, it is crucial for the global scientific community to engage in discussions as the final implementation stages approach over the coming years. Calls to action have been issued across the community, encouraging more scientists to attend upcoming negotiation points, join advisory panels, working groups and committees, offer targeted insights into the CHM, and participate in public forums and webinars to convey their dialogue to diplomats and the general society. As this is an update on the developments up to November 29, 2024, and based upon projected discussions to come over the next year, it should be noted that developments in these matters are fast-paced and will further rely upon crucial moments at the 2025 UN Ocean Conference.

8 Abbreviations

ABNJ	Areas Beyond National Jurisdiction
ABS	Access and Benefit-Sharing
BBNJ	Biodiversity Beyond National Jurisdiction
CBD	Convention on Biological Diversity
COP	Conference of parties
COP-MOP	Conference of the parties – meeting of the parties
DSI	Digital sequence information
EEZ	Exclusive economic zone
IWG	Informal working group
MGR	Marine Genetic Resources
OEWG	Open-ended working group
UNCLOS	United Nations Convention on the Law of the Sea
UNEP	United Nations Environment Program
UNGA	United Nations General Assembly

9 Data availability

No primary research results, software or code have been included and no new data were generated or analysed as part of this review.

10 Author contributions

FC: conceptualization and original draft preparation. AW: conceptualization and original draft preparation. TV: conceptualization and reviewing & editing. MJ: conceptualization and reviewing & editing.

11 Conflicts of interest

There are no conflicts to declare.

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