

A tiered approach to the marine genetic resource governance framework under the proposed UNCLOS agreement for biodiversity beyond national jurisdiction (BBNJ)

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ABSTRACT

Developing a governance framework for Marine Genetic Resources (MGRs) is a crucial element of the proposed treaty on the conservation and sustainable use of marine biodiversity in areas beyond national jurisdiction (BBNJ). Negotiating countries' positions on MGRs, including questions on the sharing of benefits from their use, range from no regulation to elaborate infrastructure for access and benefit sharing (ABS) of all MGRs. This article proposes a Tiered Approach to MGR governance that finds a middle ground between negotiating countries' positions on ABS and aims to foster scientific research on samples and data, protect traditional and local knowledge, promote consistency with existing ABS frameworks within national jurisdiction and address conservation gaps including the absence of a biosafety framework. This practical activities approach to MGR governance provides an alternative to the 'one size fits all' approach to ABS currently under negotiation with range of governance options more suited to BBNJ's unique environmental and geo-political conditions. These include an BBNJ Activity Notification and Monitoring System, a Facilitated Information and Sample Sharing Hub, an BBNJ Benefit Sharing System and an End-user Due Diligence approach to monitoring and benefit sharing. This article concludes that MGR governance should implement the *United Nations Convention on the Law of the Sea's* vision for an 'equitable and efficient' utilisation of resources and protection of the marine environment, offering a range of tools and approaches that complement ABS, but that are more diverse and flexible than the ABS concept alone.

1. Introduction

The *United Nations Convention on the Law of the Sea* (UNCLOS) forms the 'Constitution of the Seas and Oceans' and, among other things,

provides a framework for environmental protection, scientific research and technology transfer in different maritime zones [1]. The zones include States' territorial waters, the continental shelf, the exclusive economic zone (all areas within national jurisdiction) and areas beyond

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national jurisdiction (ABNJ), which is comprised of the High Seas water column and the seabed, ocean floor and subsoil below the High Seas water column ('The Area'). Marine genetic resources (MGRs) are the biological building blocks for biodiversity in all of these areas. Governance of MGRs *within* national jurisdiction is affected by a range of international, national and local measures and tools. Conservation tools include those that protect the genetic diversity of wild species, such as biosecurity to manage the spread of disease, protected species regulations and biosafety measures that manage the risks of genetically engineered organisms. Tools for sustainable use of marine biodiversity include regulating the access to, and use of MGRs. Although technologies are making it easier to conduct activities in ABNJ, there are significant international governance gaps due to the fact that countries do not have sovereign rights to adopt effective measures for MGRs in these areas. In response, United Nations countries agreed to negotiate an international legally binding instrument (ILBI) under UNCLOS on the conservation and sustainable use of marine biological diversity of ABNJ [2]. This article: (1) explores the negotiators' approach to date; (2) argues that the focus on a narrow, 'one size fits all' approach does not take into account the unique characteristics of ABNJ environmental and geo-political conditions; and (3) offers a practical pathway, called the Tiered Approach, for a more sustainable, equitable and efficient MGR governance regime that could accommodate technological advances and increase conservation measures for ABNJ.

At the first negotiating session for the ILBI, delegations reaffirmed that it 'should operationalize and strengthen the provisions of UNCLOS for the conservation and sustainable use of marine biodiversity of areas beyond national jurisdiction (ABNJ) [3]. The program of work for the negotiations addresses four elements of governance: (1) MGRs, including benefit sharing; (2) Environmental Impact Assessments; (3) Area Based Management Tools, including marine protected areas; and (4) Capacity Building and Transfer of Marine Technology [2]. Unless the Member States agree on all of the elements, there will be no ILBI [2]. Negotiating the MGR element is challenging with few areas that countries agree upon [4]. This may derail the entire agreement unless new options are explored to overcome the impasse.

In November 2019, the President of the intergovernmental conference (IGC) released a revised Draft Text that consolidated governance options raised at previous negotiating sessions [5]. This states that the primary objective of the ILBI is 'to ensure the [long-term] conservation and sustainable use' of marine biodiversity in ABNJ (draft article 2). While the text is for discussion purposes only, the objectives and framework of the MGR element appear to focus only on the *Convention on Biological Diversity's* (CBD) [6] concept of access and benefit sharing (ABS), without consideration of broader concepts of equity, or other tools to achieve equity, conservation and sustainable use.

The 1992 CBD and its supplementary agreement the 2010 *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation to the Convention on Biological Diversity* (Nagoya Protocol) [7], provide the basis of the international framework for ABS within national jurisdiction. The CBD recognises sovereign rights over genetic resources and encourages countries to provide access to their genetic resources in return for a share in the monetary or non-monetary benefits from their use (article 15). Two core legal and institutional processes have evolved since the CBD entered into force to achieve this in practice:

- An administrative (government) process for regulating access to genetic resources and associated traditional knowledge for their utilisation, through prior informed consent and permitting; and
- A contractual process for determining how the benefits arising from the utilisation of genetic resources are 'fairly and equitably' shared between users and providers (on mutually agreed terms).

ABNJ present particular environmental, geo-political, legal and social contexts that vary considerably from the biodiversity and genetic

resources envisaged by the CBD. For example, most of the deep ocean is located in ABNJ, an environment presenting high pressures, stable low temperatures (-4°C) and low oxygen concentrations, meaning that organisms grow very slowly in this environment and that environmental damage can take decades or centuries to repair. Trenches, forming less than 1% of the ocean area, are isolated ecosystems where unique life-forms may have evolved over millions of years. Many other unique environments exist in ABNJs that have extraordinarily high diversity of marine macro- and micro-organisms. The marine biotechnology industry is interested in these unique organisms as biological diversity translates to chemical and genetic diversity, leading to the discovery of new products and processes. However, with no sovereign rights recognised in ABNJ (in contrast to the CBD) there is no legally recognised 'provider' entitled to prior informed consent and a share of the benefits from genetic resource use under bilateral arrangements. Instead the ILBI needs to conceive an ABS system that is not dependent on this transactional approach but still creates incentives for governments and stakeholders to be transparent about collection and use of MGRs of ABNJ and to share benefits from their use. With potentially billions of organisms not yet discovered in the most remote marine areas of the globe, the scope of a model based on the CBD, where enforcement for benefit sharing is dependent on proving a link with an entitlement for the original access, would be enormous. There are other ABS models that narrow the scope of their regimes such as the United Nations Food and Agriculture Organisation's *International Treaty for Plant Genetic Resources for Food and Agriculture* (ITPGRFA) [8] and the World Health Organisation's *Pandemic Influenza Preparedness (PIP) Framework* [9]. These multilateral systems tailor the ABS concept to the special circumstances for biological resource use within their scope to achieve a particular purpose - food and health security goals respectively.

This article explores the challenges and opportunities associated with MGRs of ABNJ, including access, benefit sharing and monitoring. We argue that attempting to retrofit the CBD's concept of access and 'fair and equitable' benefit sharing to the unique circumstances of ABNJ could lead to unintended consequences, such as an inequitable and inefficient utilisation of ocean resources.

While ideally countries would design an MGR policy from scratch that takes into account ABNJ's unique characteristics, to date they have more narrowly focused on the CBD's framing of ABS during negotiations. We propose a way forward, called the Tiered Approach, navigating between 'open' or 'restrictive' positions on ABS but in a way that supports biodiversity conservation and fosters scientific research, protects traditional and local knowledge, operationalises international collaboration and promotes consistency with existing MGR benefit sharing frameworks within national jurisdiction.

The article concludes that MGR governance should be considered in the broader context of equity, sustainable use and biodiversity conservation, offering a range of tools and approaches that complement, but are more diverse and flexible than the ABS concept alone. Strong engagement with key stakeholders, such as scientists, the private sector, local communities and traditional knowledge holders will likely increase the odds that any new framework will not only be practical and remain relevant in decades to come but also provide a platform that will foster research, collaboration and marine conservation.

2. The proposed 'ABS one-size-fits all approach' to MGRs of ABNJ under the ILBI

This section argues that while negotiating parties recognise that ABNJ is a unique jurisdictional area, they continue to import objectives, values and tools based on the CBD's concept of ABS that suits genetic resource transactions (material and knowledge exchanges) within national jurisdictions. First, a narrow view of the CBD's approach to equity and technology transfer has been adopted as the basis of MGR governance, rather than conservation of MGRs, equity and efficiency as envisaged by UNCLOS. Second, the CBD's approach of regulating access

to MGRs based on the form and location of the tangible or intangible genetic resource, compounds the governance challenges already faced in national jurisdictions. Third, a ‘one size fits all approach’ to benefit sharing and monitoring, imports the CBD’s model of benefit sharing that is dependent on establishing a direct link with access (the transaction approach) – an approach that would consume enormous resources for monitoring and compliance.

2.1. Proposed MGR governance objectives

While UNCLOS does not directly provide a framework for MGR governance in ABNJ, its vision for a legal order for the seas and oceans includes the ‘equitable and efficient utilisation of [the ocean’s] resources’, *Recognizing* the desirability of establishing through this Convention, with due regard for the sovereignty of all States, a legal order for the seas and oceans which will facilitate international communication, and will promote the peaceful uses of the seas and oceans, the equitable and efficient utilisation of their resources, the conservation of their living resources, and the study, protection and preservation of the marine environment ... [preamble]

2.1.1. The missing link to conservation of MGRs

The overall objective of the ILBI in the Draft Text is to ‘ensure the long-term conservation and sustainable use of marine biological diversity of ABNJ through effective implementation of the relevant provisions of the [UNCLOS] and further international cooperation and coordination’ (preamble). However, the draft objectives of the specific MGR governance section of the ILBI at the time of writing are more narrowly focused:

1. Build the capacity of developing States Parties to access and utilize MGRs of ABNJ;
2. Promote the generation of knowledge and technological innovations;
3. Promote the fair and equitable sharing of benefits arising from the utilisation of MGRs of ABNJ;
4. Promote the development and transfer of marine technology;
5. Contribute to the realization of a just and equitable international economic order (draft article 7).

These objectives focus largely on access, benefit sharing and technology transfer as the means of achieving MGR governance in ABNJ. Conspicuously absent are goals for ensuring the long-term conservation of marine biological diversity. Although many would argue that the ABS concept inherently supports conservation as an economic incentive, conservation has largely fallen out of the spotlight within CBD ABS discussions; this is contrary to the early years of implementation when ABS measures, contracts and partnerships often required conservation measures [10]. Today, it is more common for governments to consider benefits for conservation to result indirectly from sharing of materials, scientific data, forms of capacity building and contractual agreements between parties. However, there is little or no published research providing evidence that the ABS transaction *per se* is an effective tool for conservation of genetic resources (as opposed to equitable use) [10]. Tier 5 of the Tiered Approach (section 3.5 below) identifies ways in which the missing link to conservation can be more directly incorporated into MGR governance under the ILBI.

2.1.2. The missing link to UNCLOS values for benefit sharing

The Draft Text imports the CBD’s values of ‘fair’ and ‘equitable’ into MGR benefit sharing, terms that are undefined but underlie the transaction between provider and user of a particular resource within national jurisdiction. The CBD leaves what is ‘fair and equitable’ to be negotiated between the parties. In the absence of an identified ‘provider’ of MGRs in ABNJ with whom to negotiate and share benefits or a contractual mechanism for achieving benefit sharing, it is unclear how these values alone can guide behaviour under the ILBI’s MGR

framework. The President of the negotiations has said that the ILBI’s provisions ‘should be fully consistent with the provisions of’ UNCLOS [5]. In the absence of express provisions on MGRs under UNCLOS, its preamble might serve as a guide to the values that underlie MGR exchanges between countries. The preamble recognises the desirability of ‘establishing a legal order for the seas and oceans’ that promotes the ‘*equitable and efficient* utilisation of resources’ (emphasis added). The UNCLOS values of equity and efficiency apply to both living and non-living resources [11]. Section three on the Tiered Approach below demonstrates how incorporating UNCLOS values of ‘equity and efficiency’ into designing an MGR governance framework can have a profoundly different effect on guiding the achievement of conservation and sustainable use goals.

2.2. Proposed MGR access framework

The Draft Text proposes to achieve its objectives by requiring parties to take legislative, administrative or policy measures to ensure compliance with the ILBI’s access arrangements, benefit sharing, monitoring and intellectual property restrictions [5].

Countries have not yet agreed whether the MGR provisions apply to *in situ*, *ex situ* and/or *in silico* MGRs and ‘derivatives’ of MGRs. However, the Draft Text proposes different access procedures depending on the form and location of the subject matter:

- *In situ* access options include prior notification or permit or prior informed consent systems;
- access to *ex situ* MGRs of ABNJ is proposed as ‘free and open’ (undefined);
- access to *in silico* information or data is proposed as ‘facilitated’ (undefined); and
- access to traditional knowledge associated with (or useful for unlocking the value of) MGRs of ABNJ would require the prior informed consent or approval and involvement of those holding this knowledge on mutually agreed terms.

The CBD’s distinction between *in situ* and *ex situ* genetic resources is relevant in situations where a country can exercise control over its resources but may cause confusion in ABNJ’s unique geo-political conditions. In the ABNJ context where there are no sovereign rights to *in situ* MGRs, as soon as they are landed on the research vessel and the flag state jurisdiction becomes the relevant regulatory framework, they become *ex situ* and could be regarded as ‘free and open’. This means that unless the ILBI clearly defines what it means by ‘*in situ*’, ‘*ex situ*’ and ‘*access*’, most MGRs of ABNJ will be ‘free and open’ and incapable of being subject to a form of benefit sharing that depends on maintaining the chain of custody of the resources from the point of access. It is therefore concerning that there is no explanation in the ILBI about the relationship with domestic ABS laws that already control *ex situ* genetic resources located in national jurisdiction.

By adding a separate (undefined) procedure for accessing *in silico* information or data about MGRs, the ILBI is further complicating one of the biggest challenges facing national ABS frameworks – the dematerialisation of genetic resources. There is ongoing debate in other ABS forums (CBD [12], ITPGRFA [13] and the PIP Framework [14]) about whether including intangible aspects of genetic resources such as digital sequence information (DSI) as the subject matter of ABS transactions is feasible in practice, and if so, how benefit sharing and monitoring can be practically effected [15,16]. Section 3.3 analyses this debate to propose an alternative approach to governance of information separate to the physical material.

2.3. Proposed benefit sharing and monitoring frameworks

The Draft Text takes a ‘one size fits all’ approach to benefit sharing and monitoring, which appear to apply equally to all forms of MGRs in

ABNJ, regardless of whether they are *in situ*, *ex situ* or *in silico*. It draws on the CBD concept of ABS where benefits are triggered only by the act of access or utilisation (negotiators have not yet agreed on the options). It is unclear how this link is to be proven in practice for *ex situ* MGRs if access is to be ‘free and open.’ This causal link may also disproportionately require the initial researcher (rather than downstream users) to provide benefits at the time of access, before any commercial value of the genetic resource is unlocked.

3. The Tiered Approach

Given the deficiencies described, we propose a Tiered Approach for accessing MGRs and sharing the benefits associated with their use. The current iteration of the ILBI Draft Text outlines an ABS system modelled from the CBD and Nagoya Protocol that were designed for accessing genetic resources within national jurisdictions. The Tiered Approach is a novel approach to ABS that better suits the unique nature of MGRs of ABNJ.

The purpose of the Tiered Approach is to identify the building blocks for a sustainable, equitable and efficient framework that negotiators can tailor to meet the agreed purposes of MGR governance and to satisfy individual country interests. It integrates MGR governance with other ILBI elements (Environmental Impact Assessment, Area Based Management Tools and Capacity Building/Technology Transfer) as well as arrangements for MGR governance within national jurisdiction to promote a coherent global system for the conservation and sustainable use of MGRs. It also builds on lessons learned from challenges facing other ABS systems, including managing traceability across jurisdictions and addressing challenges posed by DSI which does not involve the exchange of physical materials. Also incorporated is the intent of Draft Text options and some of the ideas from innovative governance proposals such as the OPEN system [17]. Finally, the Tiered Approach attempts to find a balance between creating a flexible regime that: (1) uses obligations and incentives for regulating MGRs of ABNJ so that their benefits can be equitably shared; and (2) minimises the cost of governance infrastructure and the regulatory burden on low income countries and researchers. Table 1 highlights the key differences between the current Draft Text approach and the Tiered Approach.

The Tiered Approach has five tiers that suggests governance elements around the following activities:

1. Collection of MGRs in ABNJ (Tier 1);
2. ILBI scope activities concerning physical materials of ABNJ (including contextual information) (Tier 2);
3. ILBI scope activities using DSI separately from the physical sample (Tier 3);
4. Access and use of traditional knowledge (Tier 4); and
5. Conservation of MGRs in ABNJ (Tier 5).

Fig. 1 provides an overview of the Tiered Approach’s key infrastructure outlined in this section.

Table 1
Key differences between Draft Text and Tiered Approach.

Draft Text approach (November 2019)	Tiered Approach
Heavy reliance on the CBD access and benefit sharing (ABS) concept as a governance tool	Broader conservation and sustainable use tools and integration with other ILBI elements
Importing CBD values (fairness & equity)	UNCLOS values driven approach (equity & efficiency)
Subject matter approach to ABS and monitoring (<i>in situ</i> , <i>ex situ</i> , <i>in silico</i> , traditional knowledge)	Activities approach to ABS and monitoring (collection, research/development and market engagement)
One size fits all model for benefit sharing	Benefit sharing tiers based on proportionality, equity and efficiency

3.1. Tier 1 collection and storage of MGRs in ABNJ

3.1.1. ABNJ Activity Notification and Monitoring System (ANeMONE)

For now, marine scientific research in ABNJ is challenging due to the expense and difficulties of travelling to and operating in the High Seas. Most expeditions involve cruises by international partnerships of a range of research institutions and activities, one of which may be to collect samples that might be relevant to MGR research [18]. This means that a system of prior notification must be broad enough to feed into each of the ILBI elements but not burden the researchers with reporting requirements on collection for potential finds (discoveries) that are unknown at the prior notification stage.

An ABNJ Activity Notification and Monitoring System (ANeMONE), which could be part of the Clearing House Mechanism proposed in the Draft Text, could offer researchers a one-stop-shop for assessing whether their activities trigger MGR, Environmental Impact Assessment, Area Based Management Tools and/or Capacity Building/Technology Transfer obligations and opportunities. In return for cruise ‘prior notification’ and/or cruise registration, a designated ILBI body could allocate a ‘cruise identifier’ with information about ILBI requirements and matches from a Capacity Building database. This database could be managed as part of the Clearing House Mechanism to ‘match’ providers and users of capacity building initiatives (e.g. low income country researchers seeking on board experience). Real time vessel tracking databases are already available²; however, developers of the notification or registration system would need to take into account some countries’ national security requirements. A notification system with publicly available cruise registration information could offer significant benefits to the deep-sea research community, for example, enhanced cooperation, efficiency for cruise planning and capacity building opportunities [18].

3.1.2. Monitoring under the Facilitated Information and Sample Sharing Hub (FISSH): traceability v track and trace

The Tiered Approach makes a distinction between a monitoring system that serves a ‘track and trace’ function and one that serves a traceability function. The former is akin to a parcel tracking system, which records the location of the parcel at every point along the delivery chain. The latter is like an automobile recall system, where it is not necessary for manufacturers to track where the car is at every moment, or record whose custody it passes through, until there is a problem. Then the system will trace the product number and ownership (e.g. through a car registration system) to pinpoint the relevant car and issue a notice to the current owner. Track and trace (the former) is a common monitoring approach under national ABS laws that need to ‘prove’ the chain of custody of a genetic resource from the point of access - through to the hands of subsequent users in order to have a legal right to the share of benefits. However, using prior notification, identifiers and status reports as the foundation of a ‘track and trace’ system where benefits are tied directly to access (as proposed in the Draft Text) for potentially trillions of organisms from ABNJ covering 40% of the surface of the planet, is an inefficient use of infrastructure and funding. ABS laws within national jurisdiction have the advantage of a close contractual relationship between a user and provider where monitoring and compliance is built into the contract obligations, which is not possible in the ABNJ context. One option for ABNJ is to have any ‘track and trace’ system associated with a more targeted multilateral ABS system (see section 3.2 below).

Another option is to develop a user-driven and transparent web-based traceability platform similar to the PIP Framework’s Influenza Virus Traceability Mechanism that records the movements of influenza viruses between laboratories.³ Fig. 2 indicates where a proposed

² E.g. <https://www.marinetraffic.com/en/ais/home/centerx:84.9/centery:-18.3/zoom:2>.

³ See <https://extranet.who.int/ivtm/>.

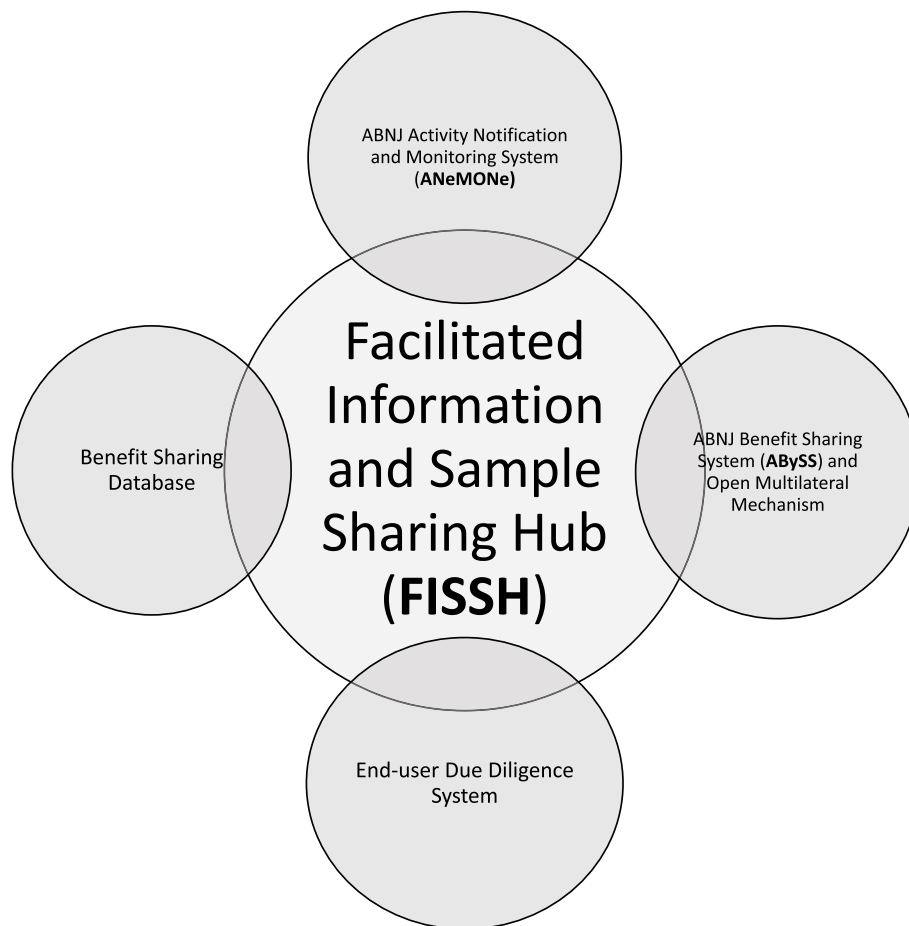


Fig. 1. Key infrastructure of the Tiered Approach.

Facilitated Information and Sample Sharing Hub (FISSH) could offer a traceability system but not necessarily a ‘track and trace’ function for compliance, but still deliver information that supports benefit sharing. This is an information hub rather than a database for collection and storage of information, more akin to a transparency mechanism showing movement of the materials from user to user through the use of identifiers. It would be up to the ILBI to determine how ABNJ identifiers used to trace the materials would be assigned – most likely through the Draft Text’s Clearing House Mechanism (see below). The FISSH information hub could show linked identifiers assigned by databases such as accession numbers from the International Nucleotide Sequence Data Collaboration and digital object identifiers (DOI) from literary and other databases.

As researchers do not know what MGRs they may find from ABNJ until sample validation in the laboratory weeks (or even years) after collection [18] and each water sample may contain millions of organisms, the ILBI could take a bulk identifier approach instead of mandating a unique identifier for individual organisms and data as currently proposed in the Draft Text. The ‘bulk collection identifier’ could stay with the MGR as part of the metadata, which includes the relevant information described in the study and provenance information necessary to comply with the best scientific practices for publication and national ABS regimes [19]. This bulk identifier could be traced in the FISSH and be updated with unique identifiers, linked to the bulk identifier, for specific samples and sequences as database technologies improve.⁴ The FISSH could be tied with an End-user Due Diligence approach to monitoring and benefit sharing outlined in section 3.3 below. The ILBI

could require or encourage States Parties (and provide incentives for non-state parties) to integrate the ILBI collection identification system into their own monitoring systems for MGRs of ABNJ used within their national jurisdictions.

3.1.3. Conservation and sharing of collected samples and data

A fundamental tenet of the Tiered Approach is to find practical ways of achieving the conservation and sharing of collected samples of MGRs of ABNJ and their associated data, from which further discoveries and knowledge generation can be made. Upon collection, the Draft Text proposes mandatory deposit of samples and data in ‘open source’ platforms. MGR conservation and scientific advances will benefit from free access to samples and associated data, but the legal and scientific meaning and extent of ‘open’ access will vary with the individual facility/database protocols and any relevant national laws [20]. It is important to make the distinction between mandatory requirements to *deposit* samples in an *ex situ* facility separate to the collector’s facility for sharing with others and requirements to *share* samples and data *per se*. A deposit scheme would require enormous infrastructure and conservation risks associated with single large collections compared to distributed collections. From a scientist’s point of view, it may not be possible to take identical or multiple samples and complications may arise from potential of overlap of work on multiple sample sets. From a curator’s point of view, there are significant costs for the maintenance and storage of physical specimens, so any mandatory deposit scheme would need to include capacity building and associated resources (e.g. human, cost, infrastructure, etc.) for *ex situ* facilities [18]. Transferring samples to *ex situ* facilities in other countries may subject the materials and data to another set of national ABS laws and reporting obligations, increasing benefit sharing and reporting burdens on the initial collector.

⁴ See e.g. <https://www.ncbi.nlm.nih.gov/biosample/>.

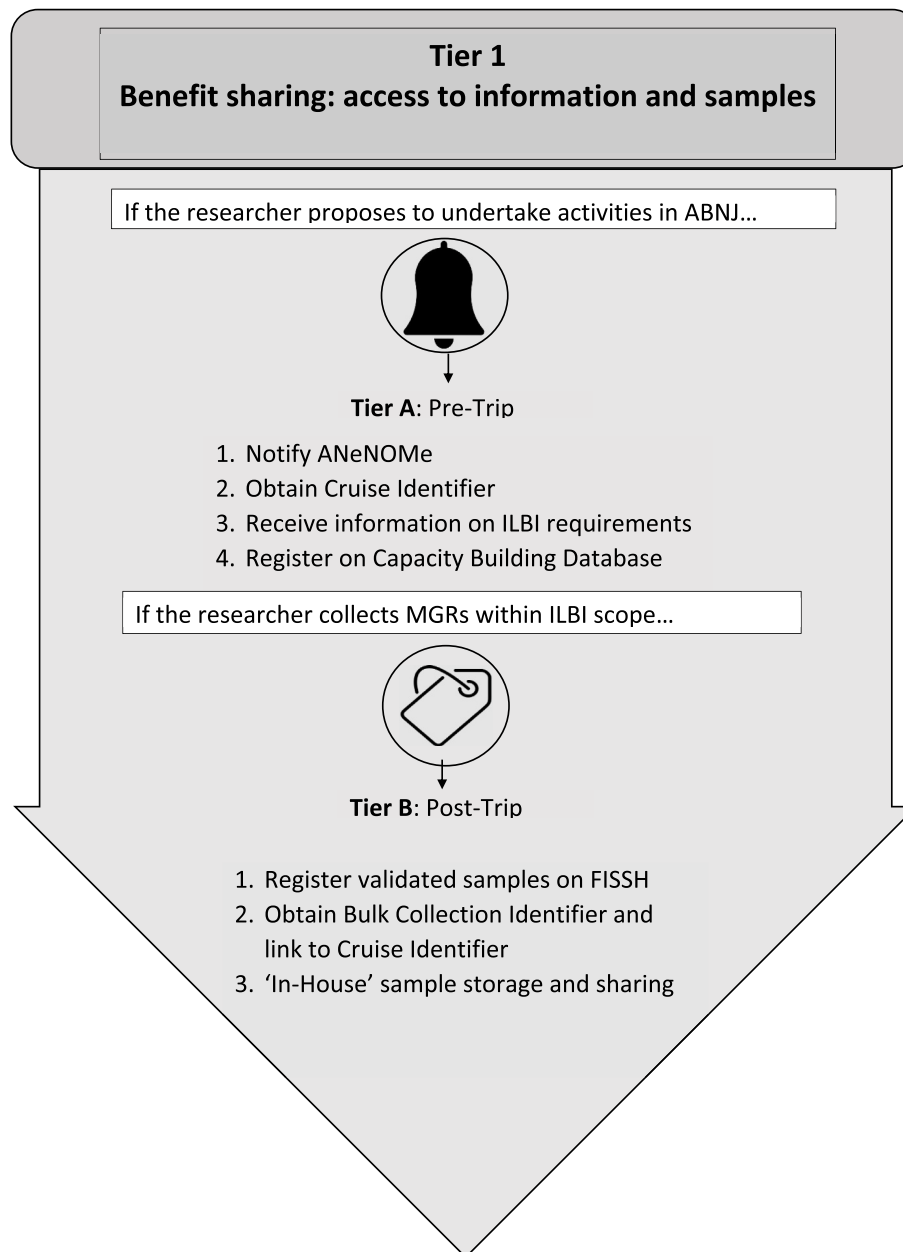


Fig. 2. Approach to benefit sharing under Tier 2 – collection and storage of MGRs.

However, requirements to share samples and data can still be achieved without mandatory deposit schemes and infrastructure. There are initiatives within the scientific community for open access to genetic resources and data upon publication⁵ [21]. The FISSH proposed under the Tiered Approach facilitates other researchers' access to materials and data while not requiring the original researcher to deposit duplicates or sub-samples in external *ex situ* facilities. As with the PIP Framework Influenza Virus Traceability System on which it is based, researchers can approach the institution holding the original or transferred collections to ask for a sub-sample or data for their own research. This online system provides information on 'In-House' storage (e.g. in the holder's laboratory or a biorepository) and sharing of samples and data, together with a real-time reporting of the movement and uses of samples and data. FISSH can be linked to the ILBI's proposed Clearing

House Mechanism and biobanks,⁶ which could also offer a forum for improving research institutions' social licence to operate if they share the materials and data. Similar to the Norwegian Marine Biobank Mar-Bank,⁷ multiple non-competing uses on the same sample are permitted depending on sample quantity and suitability for intended use. This would mean data is acquired on the same sample in parallel rather than sequentially, increasing the knowledge base on MGRs exponentially.

3.2. Tier 2 ILBI scope activities concerning physical materials of ABNJ (including contextual information)

3.2.1. Scope

All MGRs collected from ABNJ will be eventually located within

⁵ See e.g. https://www.nature.com/authors/editorial_policies/availability.html.

⁶ See e.g. CABI: <https://www.cabi.org/> and also WFCC: <http://www.wfcc.info/guidelines/> and <https://www.iode.org/>.

⁷ <https://www.imr.no/marbank/en>.

national jurisdiction, which may cause confusion if there are different access or use regimes for *in situ*, *ex situ* and *in silico* MGRs applying to the one research activity (see section 2 above). The Draft Text's artificial distinction between the form and location of the genetic resource does not recognise that unlocking value of the physical material often requires information about the genetic resource. To avoid the monitoring challenges and disproportionate benefit sharing and reporting responsibility on the initial researcher arising from the Draft Text's three distinct access regimes outlined in section 2 above, Tier 2 targets the activities of MGR users, regardless of whether or not they relate to the form of *in situ* or *ex situ* resources and associated information. Tier 3 recognises that there are special additional governance challenges for managing the use of information separately from the physical resource, which is explored in section 3.3 below.

For activities that fall within scope of benefit sharing under the Tiered Approach, it is important to make a distinction between: (1) benefit sharing that is dependent on access (i.e. the 'ABS' transaction of the CBD and Nagoya Protocol), such as mandatory benefits under a multilateral system and benefits from MGRs of ABNJ managed under national bilateral ABS laws; and (2) benefit sharing that is *not* tied to access such as conservation of voluntary duplicate samples and a capacity-building database. A combination of the two may also be feasible.

3.2.2. Approaches to benefit sharing that are dependent on access or utilisation of MGRs – a 'tied' benefit sharing system

Currently the Draft Text includes all MGRs of ABNJ in its system of benefits that arise from the access to or utilisation of MGRs of ABNJ. At the time of writing, countries have not yet decided if the trigger will be access and/or utilisation but if benefit sharing is expected from *ex situ* materials, subsequent users would also need to be captured by ABS obligations. As discussed in Tier 1, this is a more 'closed ABS system' that would require extensive infrastructure to track and trace the MGR as it passes through the possession of subsequent users in order to require benefit sharing from the access or use of the resources.

A more targeted ABS framework using an 'open but facilitated' access multilateral system may be one option for an efficient means of achieving both equity and scientific advancement. Fig. 3 illustrates an example approach under an ABNJ Benefit Sharing System (ABySS) and Open Multilateral Mechanism that targets ABS to those MGRs in a defined geographical area (such as hydrothermal vents that only cover 50 km² of the sea floor). This example of defining scope was chosen because the high concentration of biodiversity in these areas has significant potential for commercial applications and/or economic returns, and for conservation and scientific advancement [22]. This targeted 'tied system' of ABS could include a registration process for collection of MGRs in ABNJ hydrothermal vents that integrates ABS with MGR conservation objectives.⁸

Exceptions could be made for certain ABySS materials to remain outside of the registration and multilateral system and fall under national bilateral ABS laws, if there were practical or strategic considerations, as agreed by the ILBI decision making body.⁹ All other ABNJ materials not within the ABySS system would also fall under national bilateral ABS laws. The ILBI could encourage State Parties to incorporate collection identifiers within their monitoring systems and encourage MGR users to share some benefits in accordance with the ILBI from MGRs of ABNJ used within their jurisdictions (if origin can be established, such as through the FISSH in Tier 1). Complementary incentive mechanisms identified in 3.2.4 below could have a strong role in encouraging stakeholders to participate in the ILBI benefit sharing

⁸ See the UN General Assembly's call for States to take urgent action to protect biodiversity in hydrothermal vents from harmful activities [23].

⁹ See the similar proposed 'opt-out' approach under the Plant Treaty discussed below.

regimes.

Any targeted benefit sharing system that is tied to access would need to ensure that there is not a disproportionate responsibility for benefit sharing on the initial researcher collecting the materials rather than downstream users, as may be the case in the Draft Text's current approach (see section 2.3). This could involve a tiered approach to triggering obligations depending on whether it is a depositing activity or a subsequent use activity. For example:

- The depositor of ABySS materials could choose;
 - (a) immediate access without restrictions to genetic materials, sequence data, research data and other information for other researchers with no further benefit sharing obligations; or
 - (b) defined short exclusivity period (e.g. for publication or patent application) subject to upfront payment to a fund (e.g. an ILBI benefit sharing fund) and periodic reporting requirements to the ILBI [17]¹⁰;
- A recipient of ABySS materials could choose from a range of benefit sharing and reporting options that become more onerous if they restrict access to the result of their research or products 'derived from' or 'based on' ABySS materials.

The wording of these options would need careful legal and scientific consideration to avoid loopholes for benefit sharing.

While the ABySS example is raised in this paper as one way of finding a compromise between those countries seeking a share of monetary benefits from MGRs of ABNJ and those seeking unrestricted access to the same resources, there are clear challenges for multilateral benefit-sharing models tied to access. First, existing multilateral funds such as under the ITPGRFA and PIP Frameworks have poor records of effectiveness, equity and transparency. Second, there are significant challenges for defining the scope of resources to be included in a targeted multilateral system. For example, after years of governance challenges with a defined list of genetic resources within scope, the ITPGRFA's Governing Body continues to debate a proposed amendment to the treaty's scope to move from an 'opt in' system based on the list to an 'opt out' system where all plant genetic resources for food and agriculture are within scope, subject to Party declarations for exclusions [24]. Third, some of the challenges with a mandatory deposit of duplicate samples identified in Tier 1 remain. For example, even if the ABySS only includes samples collected under the Tier 1 registration system from hydrothermal vents (less than $1 \times 10^{-5}\%$ instead of 40% of the surface area of the planet), one water sample may still contain millions of target or non-target living entities that may require tracing and inclusion in the multilateral system. Finally, having both multilateral and national ABS systems that potentially apply to the same MGRs found within and beyond national jurisdiction could create loopholes unless the purpose and scope of the multilateral system is clearly defined and adopted by user countries. Ideally, the globe could start again with a 'Whole Global Ecosystem Multilateral Benefit Sharing Mechanism' instead of separate CBD/Nagoya Protocol and BBNJ treaties that artificially carve up subject matter scope based on jurisdictional areas. Such a system is beyond the scope of this article.

3.2.3. Approaches to benefit sharing that is not dependent on access or utilisation of MGRs – an 'untied' benefit sharing system

One of the most valuable outcomes of any biodiversity research is greater knowledge of biodiversity [25]. This outcome is not dependent on tying a benefit sharing mechanism to access through a track and trace system. Instead, the proposed simple FISSH system in Tier 1 could provide information about the location and uses of MGRs of ABNJ as a valuable transparency tool for decreasing overlap between research

¹⁰ Note the scientific community's movement against any embargo on sequence data [21].

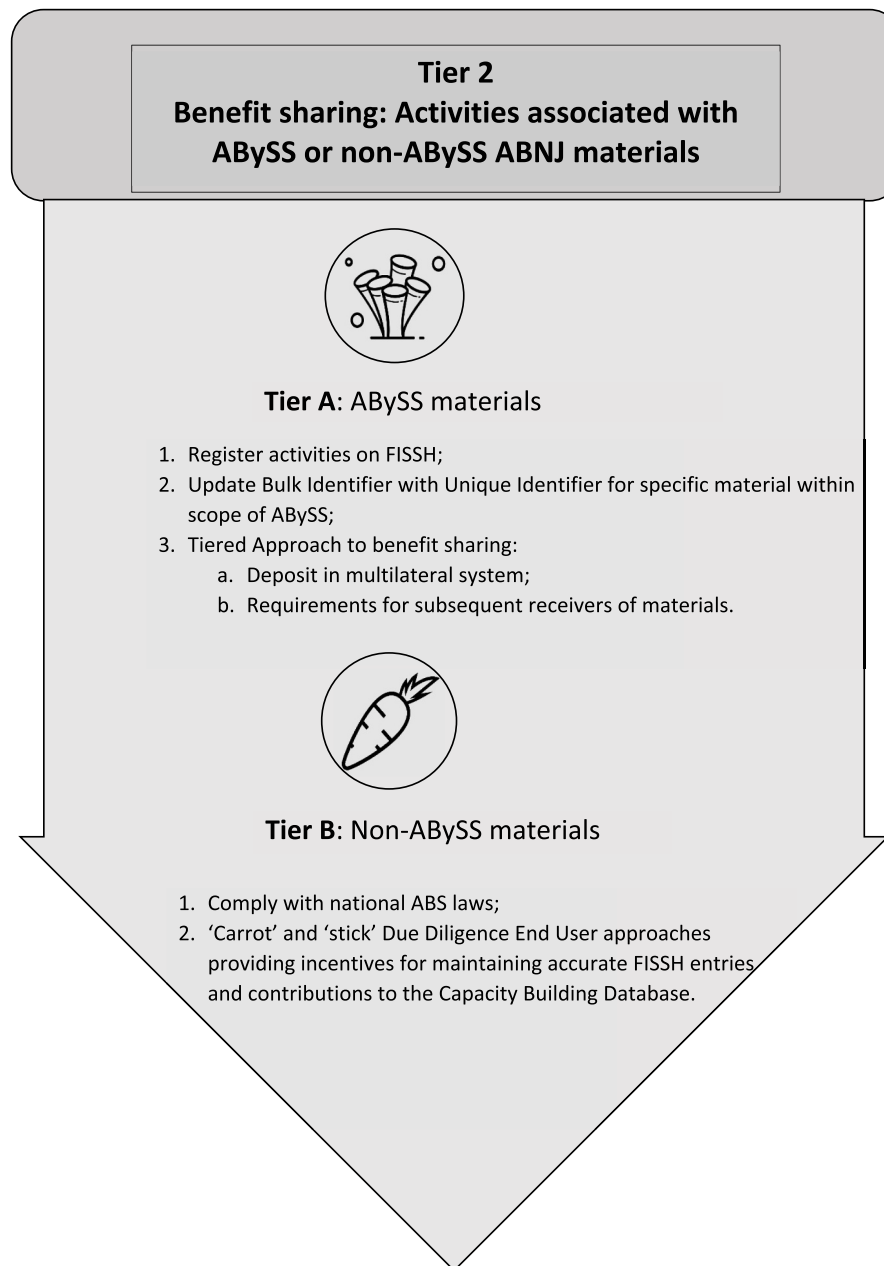


Fig. 3. Approach to benefit sharing under Tier 2 - use and transfer activities of the physical sample and associated information.

efforts and improving coordination and cooperation. Once MGRs and data are accessible through this system, people throughout the globe could use them to address environmental, economic and societal needs, providing local solutions to local problems with local benefits. The FISSH could be combined with the Capacity Building database to match users of samples and data with researchers seeking to bring new research capacities back to their national contexts (see 3.1 above).

Figs. 2–6 indicate the range of benefit sharing outcomes that are not tied to the activity of accessing physical materials including: country incentives to contribute to the benefit sharing database (section 3.1) or ILBI conservation objectives (section 2.1); market based, scientific prestige and private sector incentives to share the benefits of MGR research and commercial applications (section 3.3); and private or public direct contributions to a possible benefit sharing fund.

3.2.4. Innovative approaches to promoting benefit sharing – end user Due Diligence approach

An alternative to a 'track and trace' system from access to final use/product is an End-user Due Diligence approach to monitoring and benefit sharing. This requires motivation for the end user of a product to share benefits and report uses of MGRs of ABNJ and associated information or traditional and local knowledge either through 'stick' or 'carrot' measures. One option for 'stick' measures could be for the ILBI to require a CBD checkpoint¹¹ alert for products containing a unique identifier that is associated with species linked to ABNJ bulk collection identifier under the FISSH system for traceability (see section 3.1). To clear the checkpoint, the onus would be on the user to demonstrate benefit sharing or disprove that their product relates to those in a collection identifier.

¹¹ E.g. patent, export or research offices.

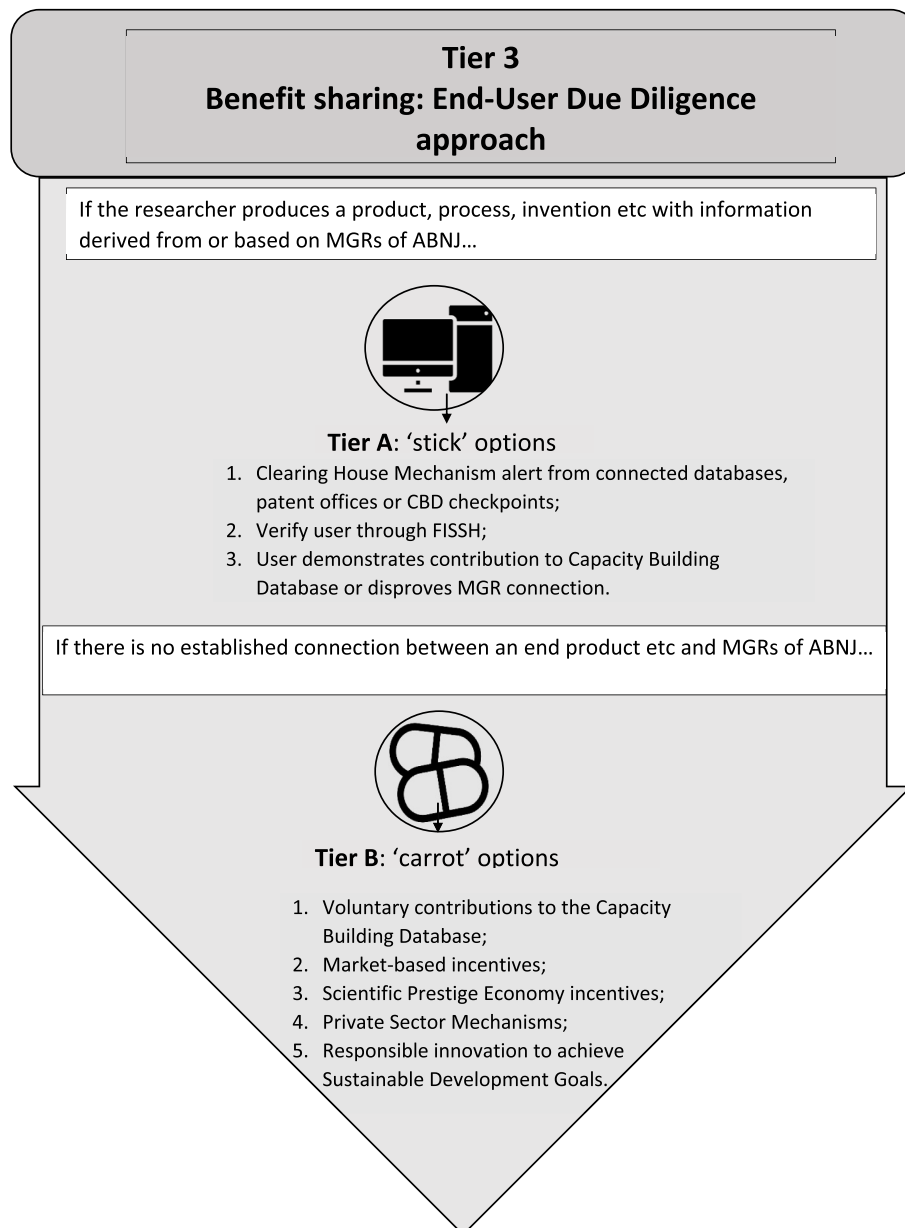


Fig. 4. Approach to benefit sharing under Tier 3 – use of information separate from the physical sample.

'Carrot' measures could include a range of options. Market-based incentives could harness consumer demand for more transparency and sustainability along value chains. Initiatives like the Union for Ethical BioTrade's verification and certification programs for biodiversity-based ingredients promote compliance with legal requirements on ABS, establish broader voluntary measures for benefit sharing along supply chains, and allow companies to communicate on their commitments, efforts and achievements.¹² Scientific 'Prestige Economy' incentives could include an ILBI system of 'trusted ABNJ researchers' if they proactively engage with ILBI benefit sharing (e.g. the Tier 1 Capacity Building database) or include ABS metadata (e.g. country of origin) in databases to assist with traceability. Such engagement could be in return for certain privileges (e.g. more streamlined procedures for docking in foreign ports) or a condition of a research grant process. Private sector mechanisms include options similar to the Global

Biosafety Compact, which is a private contract between its members (private companies, public research facilities and governments) regulating for example their stewardship obligations in relation to biodiversity [27]. Engaging these companies directly in benefit sharing through a similar compact that improves their social licence to operate could be a valuable benefit sharing option. Finally, ILBI benefit sharing could be tied to specific Sustainable Development Goals (SDGs) to achieve Agenda 2030,¹³ giving countries an opportunity to showcase their commitment to SDG's through their Voluntary National Reviews.

3.3. Tier 3 ILBI scope activities using DSI separately from the physical sample

ABS forums continue to debate whether it is possible or practical to regulate genetic information used separately from the physical sample

¹² <https://www.ethicalbiotrade.org>.

¹³ <https://www.un.org/sustainabledevelopment/development-agenda/>.



Fig. 5. Approach to benefit sharing under Tier 4 – access and use of Traditional of Local Knowledge within ILBI scope.

such as DSI [15]. Negotiators have not yet agreed whether to include ‘*in silico*’ (undefined) MGRs in the ILBI but the Draft Text proposes their access to be ‘facilitated’ (also undefined). The Tiered Approach avoids the intractable debate over categorising the meaning and scope of ‘*in silico*’ (the subject matter approach to ABS) and instead focuses on the activity of using MGR information (including DSI) separately from the physical sample. The Laird and Wynberg 2018 fact-finding study for the CBD [12] observed that the terminology and meaning of DSI varies across international and national policy processes as well as across the scientific community and databases. They found that DSI ‘permeates nearly every branch of the life sciences and modern biology today’ (at 9). In practice, commercial research strategies are relying less on collection of physical samples and more on DSI. On the other hand, academic groups continue to have an interest in physical sample collections because they provide information that the DSI alone cannot, including epigenetic modifications, transcription patterns and

interactions between organisms and their environment. The study suggests that interests in unique organisms from extreme environments, for example, may increase alongside digital technologies. For these reasons, the Tiered Approach recognises that DSI will also fall under Tier 2, but this section argues that using the information *separately* to the physical resource requires a different approach to meeting ABS objectives.

There are significant challenges for monitoring information (e.g. DSI) that is separate to the physical material for the purpose of benefit sharing. For example, a researcher’s computer program (e.g. a Basic Local Alignment Search Tool) may access (scan) millions of sequences for patterns or information they are looking for in order to create a research outcome. Tracing the origin of each of these sequences is impractical (even if a unique identifier could be attached to the metadata), as is knowing which parts have contributed to the outcome so that the ILBI could enforce benefit sharing. The FISSH system (Tier 1) could go so far as recording when a MGR user enters DSI into a database in

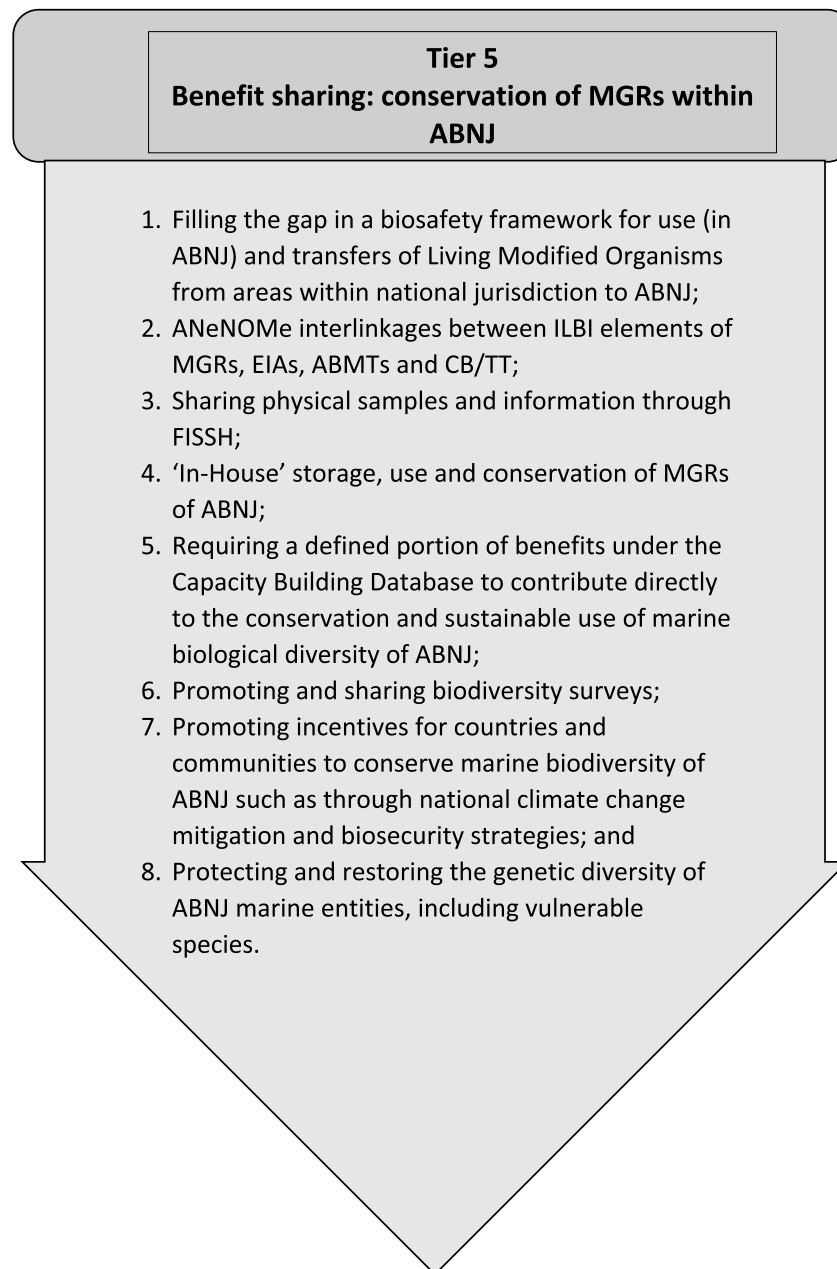


Fig. 6. Approach to benefit sharing under Tier 5 – conservation of MGRs within ABNJ.

return for an accession number (e.g. from the International Nucleotide Sequence Data Collaboration) but not record each movement after leaving open access databases. There are initiatives for connecting the multitude of databases¹⁴ into a decentralised network of databases, which could improve the efficiency of this system, but there may be difficult technical, management and legal questions around interoperability and copyright infringement [26]. The End User Due Diligence approach to promoting benefit sharing explained in Tier 2 could apply to DSI used separately from the physical material, without requiring each movement to be tracked. The 'stick' options such as checkpoints and 'carrot' options that improve companies or research institution's social licence to operate could provide motivation for users to share benefits and report uses of DSI concerning MGRs of ABNJ in a final product.

3.4. Tier 4 access and use of traditional and local knowledge

The Tiered Approach moves away from treating traditional knowledge as a static body of knowledge that is characterised as belonging in the past, and towards recognition that it is a dynamic system of knowledge, culture and ways of life that are constantly changing. It recognises that there is a growing and diverse body of national and local laws and protocols that build frameworks around how people can access and use traditional and local knowledge associated with genetic resources and share the benefits from its use, primarily through prior informed consent and mutually agreed terms. The Tiered Approach recognises that there can be no 'one size fits all approach' to these activities under the ILBI because the knowledge is not an abstract thing that can be traded, but rather is embedded in diverse cultural systems and contexts.

Potential users of MGRs within national jurisdiction may have challenges for identifying the knowledge holders with whom to

¹⁴ E.g. <http://www.pimrisportal.org/global-marine>.

negotiate for the access and use of their knowledge. The Tiered Approach suggests extending the mandate of the proposed ILBI Scientific and Technical Body to include other knowledge systems including traditional and local knowledge. Indigenous Peoples and Local Communities could provide their expertise to find solutions for respectfully and efficiently incorporating traditional and local knowledge into the ILBI framework and infrastructure. For example, they could consider a system of traditional knowledge identifiers (similar to the collection identifiers in Tier 1) that links with the traceability mechanism (FISSH). They could develop a system for resolving how potential users would address situations where several Indigenous Peoples or Local Communities, possibly in different countries, hold the same or similar traditional knowledge associated to MGR. They could also explore how traditional and local knowledge could be incorporated into the End-User Due Diligence system under the Tiered Approach, including exploring motivations for engaging with benefit sharing ('carrot options') such as market-based incentives for researchers and the private sector.

3.5. Tier 5 conservation of MGRs in ABNJ

Part II of the Draft Text focuses on extractive activities (and sustainable use) relating to MGRs of ABNJ but overlooks other conservation considerations of MGR use in ABNJ (see section 2.1 above). These considerations include the unexplored effects on the genome of MGRs in ABNJ from the use of genetically engineered organisms and aquaculture selective breeding in the High Seas [28], or even alien biological contamination from the dumping of returning space equipment in ABNJ [29].

The ILBI's Draft Text relies on ABS to promote technology/knowledge transfer and capacity building through soft obligations that only 'encourage' benefits to be used to 'contribute to the conservation and sustainable use of marine biological diversity of ABNJ' (draft article 11 (4)). The ILBI could make this obligation mandatory and formally recognise that conservation and sustainable use of MGRs, (particularly access, use and transfer) are inextricably linked to the Environmental Impact Assessment, Area Based Management Tools and Capacity Building/Technology Transfer elements of the ILBI package and create more direct links between the elements to support conservation. Other MGR conservation objectives could include: promoting and sharing biodiversity surveys; promoting incentives for countries and communities to conserve marine biodiversity of ABNJ such as through national climate change mitigation, biosecurity and biosafety strategies; and protecting and restoring the genetic diversity of ABNJ marine entities, including vulnerable species.

One example of a conservation aspect that is missing from the ILBI negotiations concerns the regulating the risks of harm caused by the effect of living modified organisms (LMOs) on their wild-type counterparts. The CBD's *Cartagena Protocol on Biosafety to the Convention on Biological Diversity 2000* (Protocol) [30] is an international framework for the safe movement and handling of movements of LMOs between countries. This biosafety framework includes a consent procedure between governments prior to LMO movements and detailed risk assessment, precautionary decision making, risk management and emergency management frameworks.¹⁵ Significantly, it excludes from scope any movement of LMOs from the territory of a Party to ABNJ [31] and is silent about the use of LMOs in ABNJ. While the ILBI's Draft Text has drawn on the CBD and Nagoya Protocol provisions that promote the sharing of technologies and MGRs, it is silent on biosafety issues in ABNJ. The Environmental Impact Assessment provisions of the Draft Text do not cover the consent, decision making and emergency

¹⁵ It also has a supplementary agreement, the *Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety* 2010 that addresses response measures, liability and redress that might arise from the *trans*-border movement of LMOs.

management measures necessary to fill the gap in global biosafety in accordance with the Protocol. During the preparatory work leading up to the IGC, there was no mention of implementation gaps for managing the negative effects of genetic technology transfer.¹⁶ The International Council of Environmental Law was the first to raise biosafety as an issue for consideration during the second negotiating session for the ILBI¹⁷ but the issue remains neglected to date.

Any future agreement 'regarding intentional transboundary movements of LMOs' must be consistent with and 'not result in a lower level of protection than that provided for by the Protocol' (article 14(1)). This means that if the ILBI was to strengthen the conservation objectives of MGR governance by protecting the genetic diversity of MGRs in ABNJ, it would need to fill the global gap in biosafety governance with a consent mechanism for intentional movements and notification mechanism for unintentional movements of LMOs from ABNJ to national jurisdiction (and vice versa). It would also require the establishment of a body capable of giving and receiving consent or notification, and duties for information sharing, environmental impact assessment, precautionary decision-making, emergency management measures, monitoring and review and liability and redress measures.

4. Conclusion

The paradox of current approaches to ABS for genetic resources within national jurisdiction is that by seeking to promote benefit sharing from the utilisation of genetic resources, the regulatory and monitoring tools establish access requirements and restrictions which are so complex that they discourage research and projects seeking to generate information and other benefits. Yet seeking benefit sharing in a mandatory 'open access' approach also creates a paradox: it breaks the chain of custody that is necessary for tracing access to benefit sharing and would require enclosing users in an extensive monitoring system that contradicts the freedom of open access.

The Draft Text's separate access regimes based on whether MGRs are *in situ* ('notification'), *ex situ* ('free and open') or *in silico* ('facilitated') are likely to lead to unnecessary complexity and confusion for users and those implementing the monitoring systems, particularly as the same research activity is likely to use all three forms of MGRs. The Tiered Approach proposes a different approach to access: triggering obligations based on activities of collection, research and development and market engagement, rather than the form and location of MGRs. It also embeds best scientific practices and protects traditional and local knowledge, while ensuring coherence with national ABS laws and promoting benefit sharing to foster conservation and sustainable use of marine biodiversity.

The Draft text's one-size-fits-all benefit sharing and monitoring system creates a disproportionate responsibility on upstream users of MGRs, especially on those conducting basic research, without direct gains for conservation and equitable use of marine biodiversity. Attempting to include all MGRs of ABNJ in this kind of closed ABS system (with benefit sharing tied to access) will require enormous financial resources and monitoring infrastructure in the hope of distributing benefits from commercial applications. These commercial outcomes are likely to be overestimated [32] but even if they come to fruition, there are significant technical and legal challenges in monitoring and proving the origin of MGRs or data on which they are based, particularly if information is used separately from the physical resource.

The Tiered Approach promotes benefit sharing and conservation initiatives that are not necessarily dependent on the ABS *transaction*, in other words, tied directly to accessing the MGRs. A range of benefits and conservation outcomes can be achieved at each stage of the 'use'

¹⁶ <https://www.un.org/depts/los/biodiversity/prepcom.htm>.

¹⁷ <https://enb.iisd.org/oceans/bbnj/igc2/1apr.html#collapse4> (see the Daily Report for 1 April 2019).

continuum whether or not benefit sharing is directly tied to access: from exploration and collection (Tier 1); to use and subsequent access of physical materials (Tier 2); to access and use of information separate from the physical materials (Tier 3); to access and use of traditional and local knowledge (Tier 4); to conservation of MGRs in ABNJ (Tier 5). Where countries would like to include an ABS element into its broader governance framework that *does* tie benefit sharing to access, a more targeted multilateral system could simultaneously achieve some benefit sharing and facilitate open access and conservation outcomes depending on its agreed scope and purpose, but it will still have governance and monitoring challenges faced by other ABS frameworks.

The ILBI is under negotiation in a world far removed from the one that created the original ABS concept as a solution to conserve and sustainably use genetic resources. Developments in technologies for discovering, collecting, using, storing and sharing genetic resources and associated information are continuing to push the boundaries of the current models of ABS. Instead of focusing on ABS as the sole approach to MGR governance in ABNJ, negotiators have a rare opportunity to implement the UNCLOS vision for an 'equitable and efficient' utilisation of MGRs and protection of the marine environment through a range of MGR governance options, including ABS, that are more suited to ABNJ's unique environmental and geo-political conditions.

Credit for icons

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Declaration of competing interest

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CRediT authorship contribution statement

Fran Humphries: Conceptualization, Writing - original draft, Writing - review & editing. **Hiroko Muraki Gottlieb:** Conceptualization, Writing - review & editing. **Sarah Laird:** Conceptualization, Writing - review & editing. **Rachel Wynberg:** Conceptualization, Writing - review & editing. **Charles Lawson:** Conceptualization, Writing - review & editing. **Michelle Rourke:** Conceptualization, Writing - review & editing. **Morten Walløe Tvedt:** Writing - review & editing. **Maria Julia Oliva:** Writing - review & editing. **Marcel Jaspars:** Conceptualization, Writing - review & editing.

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