

*The High Seas Alliance has commissioned the following brief to assist delegates discuss traceability options. The views expressed are those of the authors.*



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## Traceability options for marine genetic resource from areas beyond national jurisdiction

The negotiations on a legally binding instrument for the conservation and sustainable use of biodiversity in areas beyond national jurisdiction (BBNJ) have included discussions over Part 2 on “Marine Genetic Resources, including questions on the sharing of benefits” (MGRs)<sup>1</sup>, one of the four items of the package deal. MGRs from areas beyond national jurisdiction (ABNJ) refer to genetic resources found in parts of the ocean outside the sovereignty of any country from a wide range of organisms. Key issues relating to MGRs revolve around how benefits arising from the use of MGRs should be shared and how scientific and commercial uses will be traced to inform benefit-sharing.

MGRs have attracted substantial interest from science and industry over the past decades (Blasiak et al. 2020; Martins et al. 2014). However, capacities to access and use MGRs are unequally distributed between countries, as very few possess the necessary technology and research facilities to access their benefits (Tolochko & Vadrot 2021). This imbalance, together with concerns that a) economic benefits arising from genetic knowledge may only benefit countries with highly developed industries in this sector, and b) regulation may introduce extensive burdens on research and scientific cooperation, has led to complicated discussions (Vadrot et al. 2021). Underlying these discussions is, in part, a lack of reliable data on the significance of ABNJ-specific MGRs to the overall marine biotechnology sector (Oldham et al. 2014), which is, not least, due to the current lack of a functional traceability system in place.

While there is general agreement that some form of benefit-sharing should be included in the BBNJ agreement, two major uncertainties remain regarding the extent to which this will include monetary benefit-sharing and the type of traceability system needed to implement such provisions. Various traceability options have been discussed during the negotiations, resulting in two options outlined in the President's draft text for IGC-5<sup>2</sup>. Option 1 is based on a voluntary transparency system that does not include monetary benefits, while Option 2 includes a comprehensive monitoring system that tracks MGRs from collection to commercialization to

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<sup>1</sup> Because this policy brief addresses MGRs under the BBNJ instrument, the authors always refer to MGRs from areas beyond national jurisdiction when using the term “MGRs”.

<sup>2</sup> [Further revised draft text](#) from June 1, 2022. This text is currently the last version with public distribution and will remain the reference throughout this brief.

support monetary benefit-sharing. During IGC-5, some developing countries signaled a willingness to soften the monitoring system outlined in Option 2, while some developed countries signaled acceptance of some form of monetary benefit-sharing. This has led to the emergence of two alternative approaches that explore less extensive traceability systems while still supporting the implementation of monetary benefit-sharing provisions (described as Options 3-4). However, these new proposals, which have implications for both benefit-sharing and traceability, have not yet been included in a draft treaty text.

This policy brief provides a structured overview of the different options that, as far as the authors are aware, are currently on the table and assesses their implications for traceability of MGRs and the overall implementation of the BBNJ treaty. We screened the relevant scientific literature and conducted a number of informal consultations with stakeholders and experts to assess options according to a set of criteria. Where appropriate, the brief also highlights linkages to the recent decision by CBD COP15 on DSI (see box below), while fully acknowledging that decisions made in other fora do not automatically translate to the BBNJ context.

Given uncertainty around which negotiation text will be used for the resumed session of IGC-5, and the dynamic status of different proposals, all options presented here should be considered as typologies for different ways to address traceability of MGRs in the BBNJ instrument, rather than specific proposals.

#### **CBD decision 15/9 (December 2022)**

In December 2022, the 15th CBD COP produced a long-awaited decision on digital sequence information (DSI).<sup>3</sup> This decision 15/9, *inter alia*,

- *agrees that the benefits from the use of digital sequence information on genetic resources should be shared fairly and equitably (Art. 2)*
- *recognizes that tracking and tracing of all digital sequence information on genetic resources is not practical (Art. 5)*
- *recognizes that the monetary and non-monetary benefits [...] should, in particular, be used to support conservation and sustainable use of biological diversity and, inter alia, benefit indigenous peoples and local communities (Art. 10)*
- *decides to establish [...] a multilateral mechanism for benefit-sharing from the use of digital sequence information on genetic resources, including a global fund (Art. 16)*

Although the CBD's mandate is separated from the future BBNJ mandate, States have repeatedly referred to the developments in the CBD and it appears reasonable to streamline both systems to some extent. Thus, the evaluations in this brief include a consideration of the consistency of each option with the CBD.

<sup>3</sup> The CBD COP decisions can be found under: <https://www.cbd.int/doc/decisions/cop-15/cop-15-dec-09-en.pdf> and will from here on be referred to as CBD COP decision 15/9.

## Current proposals

### Option 1: Transparency system

Option 1, which corresponds to draft Art. 13, Option II 'Transparency system for benefit-sharing', is in essence a codification of current forms of transparency in scientific best practices. It foresees the sharing of non-monetary benefits such as access to samples and data. It was proposed by States concerned that regulation may place excessive burdens on scientific research, that implementation costs would outstrip benefits from the monetization of MGRs of BBNJ, and that open access to DSI could be impacted.

### Option 2: Monitoring system

Option 2 corresponds to draft Art. 13, Option I 'Monitoring and transparency'. Contrary to Option 1, it foresees monetary benefit-sharing, underpinned by an extensive traceability system monitored by the ABSM. Advocates of this option have argued that traceability of MGRs from initial collection of samples to patenting and product development is needed to implement monetary benefit-sharing in the form of royalties & milestone payments.

### Option 3: End-user PPP registration system

The PPP registration system (publications, patents, products) requires that States implement legislation which obliges the end-user to register publications, patents or products that contain MGRs. This system is inspired by [existing domestic legislation](#) to implement the CBD Nagoya Protocol and could be re-purposed for BBNJ to facilitate monetary benefit-sharing, e.g. as a percentage of the final product revenue.

### Option 4: Decoupled payment system

The [decoupled payment system](#) was developed as an alternative solution for monetary benefit-sharing, eliminating the requirement for a complex monitoring infrastructure. In its simplest form, this would consist of a regular fee paid by States that is decoupled from requirements to trace access to and use of MGRs. That said, a decoupled system could still include a review clause underpinned by a periodic study or a light traceability system (e.g. a hybrid between Option 3 & 4). Hence, Option 4 is flexible to include different levels of traceability.

**Note:** a separate non-paper summary of broad options for benefit sharing is available [here](#).



Option	Option 1: Transparency system	Option 2: Monitoring system	Option 3: End-user PPP registration system	Option 4: Decoupled payment system
<b>What is being traced?</b>	<ul style="list-style-type: none"> <li>Pre- and post-cruise report</li> <li>Research and development only to the extent that users self-report</li> </ul>	<ul style="list-style-type: none"> <li>Pre- and post-cruise report</li> <li>Access to and use of MGRs and DSI during research, development and commercialization</li> </ul>	<ul style="list-style-type: none"> <li>Pre- and post-cruise report</li> <li>End-user registration</li> </ul>	<ul style="list-style-type: none"> <li>Pre- and post-cruise report</li> <li>Optional forms of review:</li> </ul>
				<table border="1"> <tr> <td>No review of uses or products</td> <td>Registration of products to estimate market value</td> <td>Regular study by ABSM<sup>4</sup> or STB<sup>5</sup></td> </tr> </table>
No review of uses or products	Registration of products to estimate market value	Regular study by ABSM <sup>4</sup> or STB <sup>5</sup>		
<b>Which key obligations are introduced?</b>	<ul style="list-style-type: none"> <li>Voluntary forms of benefit-sharing</li> <li>Left to national institutions or the WIPO to introduce further regulation (e.g. patent offices)</li> </ul>	<ul style="list-style-type: none"> <li>Comprehensive reporting regulations including on the access, upload, download, and use of data from MGR databases</li> </ul>	<ul style="list-style-type: none"> <li>Register every product, publication or patent (PPP) which contains MGRs or DSI</li> <li>Certificate of registration needs to become mandatory under national legislation</li> </ul>	<ul style="list-style-type: none"> <li>States will have to pay a regular fee to global fund</li> </ul>
<b>How does it relate to existing research practices?</b>	<ul style="list-style-type: none"> <li>Compatible with existing scientific practices that can further be improved from within the scientific community</li> </ul>	<ul style="list-style-type: none"> <li>Novel unique identifier to trace MGRs across all stages</li> <li>May challenge open-access principles</li> </ul>	<ul style="list-style-type: none"> <li>Provides platform for the sharing of open-access scientific publications</li> <li>Relies on companies having to declare revenues each year</li> </ul>	<ul style="list-style-type: none"> <li>Compatible with existing scientific practices that can further be improved from within the scientific community</li> </ul>
<b>Which institutions monitor implementation?</b>	<ul style="list-style-type: none"> <li>After uploading of reports, no central institution monitors the implementation</li> </ul>	<ul style="list-style-type: none"> <li>Task the ABSM under BBNJ to monitor implementation, which requires wide competences and capacities</li> </ul>	<ul style="list-style-type: none"> <li>States control the registration by requiring the certificate</li> <li>One multilateral mechanism (potentially the same as CBD)</li> </ul>	<ul style="list-style-type: none"> <li>Purposed fund</li> <li>Possible periodic review by the ABSM or the STB to assess the fee</li> </ul>

<sup>4</sup> Access and benefit-sharing mechanism (ABSM)

<sup>5</sup> Scientific and Technical Body (STB)

<p><b>When and how would monetary benefits flow?</b></p>	<ul style="list-style-type: none"> <li>• Monetary benefits may flow voluntarily and ad-hoc</li> </ul>	<ul style="list-style-type: none"> <li>• Theoretically with every commercialization of an MGR</li> <li>• Relies on extensive track &amp; trace monitoring framework</li> </ul>	<ul style="list-style-type: none"> <li>• Likely delay in set up and beginning of flow of benefits</li> <li>• Benefit-sharing triggers when a product contains MGRS from ABNJ</li> <li>• Percentage of revenue of registered products would constitute benefit-sharing (same as envisioned in CBD)</li> </ul>	<ul style="list-style-type: none"> <li>• Early and predictable monetary flow</li> <li>• Possible review of fee based on different parameters, e.g. actual value of MGR commercialization per State</li> <li>• States may be encouraged to monitor use of MGRs under their jurisdiction to reclaim fee</li> </ul>
<p><b>How consistent is it with existing regimes?</b></p>	<ul style="list-style-type: none"> <li>• This system codifies the status quo to some extent</li> <li>• May be inconsistent with the CBD COP 15/9 decision on the sharing of monetary benefits from DSI (Art. 2)</li> </ul>	<ul style="list-style-type: none"> <li>• In line with CBD decision 15/9 on the sharing of benefits from the use of DSI</li> <li>• Needs to carefully consider the notion of practicality in CBD COP decision 15/9 (Art. 5)</li> </ul>	<ul style="list-style-type: none"> <li>• Very alike to the CBD and the Pandemic Influenza Preparedness (PIP) Framework under WHO</li> </ul>	<ul style="list-style-type: none"> <li>• Draws on experiences from the implementation of the Nagoya Protocol and ISA where little benefit-sharing has occurred thus far</li> <li>• Needs to carefully consider the relation between DSI use and benefit-sharing in CBD COP decision 15/9 (Art. 2)</li> </ul>
<p><b>Main open questions and challenges</b></p>	<ul style="list-style-type: none"> <li>• Uncertainty and unpredictability of voluntary monetary benefits</li> </ul>	<ul style="list-style-type: none"> <li>• Differences in national IPR regulations and possibly disrupted traceability across countries</li> <li>• Potentially high costs and significant burdens on research practices relative to benefits generated</li> </ul>	<ul style="list-style-type: none"> <li>• Differences in national IPR regulations and possibly disrupted traceability across countries</li> <li>• Companies may register their profits in non-signatory countries</li> </ul>	<ul style="list-style-type: none"> <li>• How should the amount of the fee be reviewed and based on which indicators?</li> <li>• If there is no monitoring or review, there is no possibility to adjust the regular fee</li> </ul>

## Option 1: Transparency system

This proposal foresees only voluntary benefit-sharing and relies on already established forms of 'open-access traceability' (Humphries et al. 2021; Rabone et al. 2019). Instead of building a coherent traceability system to report collection and scientific or commercial uses of marine genetic resources, it proposes to use already available open-access databases and unique identifiers to support transparency. The system of pre-cruise and post-cruise information will establish transparency on the collection of MGRs. Unless further regulated, uses beyond this point can only be identified if scientists report them to open-access databases, or in publications or patent applications. In this sense, it is a self-declaratory system that relies on trust and the good-will of users.

User-driven forms of transparency are common practice in scientific publications and databases. Scientific journals effectively require scientists to publish openly accessible data, and databases have some agency in making reporting fields obligatory. For instance, the INSDC, which is an international collaboration between the largest genetic sequence databases worldwide, introduced a [new policy](#) in 2021 (expected to phase in in 2023), to make year of collection and country of origin information obligatory for the submission of DSI. A study commissioned by the CBD found that 16% of all nucleotide sequence data accessible via the INSDC have country of origin information available, but that this has steadily increased over the past years, and risen up to 50% for new submissions in 2019 (Rohden et al. 2020). At present, the INSDC does not seem to plan to implement a specific label for ABNJ origins in this tag, even when this could be technically feasible. Geographic coordinates may be reported alongside the country of origin tag, which would allow for identification of ABNJ or national origins. However, coverage is also far from complete in this case (Rohden et al. 2020). If available, such 'user-driven' forms of transparency can provide possibilities to re-construct use patterns of physical samples and DSI in science at a general level (e.g. Rohden et al. 2020; Scholz et al. 2021), but they do not constitute a centralized monitoring system that can ensure compliance. Proponents of this approach argue that building on existing systems creates high uptake compared to other more complex systems - the easier it is made to comply, the more people will do so.

When it comes to patenting, there are currently no enforced procedures for the reporting of MGR origins (a few exceptions include national regulations in Malaysia, Vietnam and India; Humphries et al. 2021). Some origins can be re-constructed when looking into patent texts, but a study found that this is rarely done in a standardized manner (Blasiak et al. 2019). [WIPO's new reporting standard for DSI in patents](#) will further improve transparency. In combination with the above-mentioned INSDC policy, this should improve abilities to reconstruct geographic origins of patent sequences by matching them with DSI available via INSDC (Rohden et al. 2020). Further discussions on the topic are scheduled in the WIPO. Importantly, linkages between patents and commercialization will remain difficult to trace despite these developments. Our limited knowledge on this link is based on a remarkably small number of case studies (Jaspars et al. 2021; Humphries et al. 2021) that rely on the willingness of individuals in companies and academia to share information.

This system would not require the creation of new institutions or infrastructure to monitor the implementation beyond the already agreed-upon clearing-house mechanism (CHM) for

sharing of basic information such as pre-collection and post-collection notifications. It would be up to the providers of benefits to decide which form of monetary or non-monetary benefit-sharing would be appropriate, and this decision would have no formalized relation to traceability. Because of the voluntary and user-driven character of this system, it is unlikely to generate reliable monetary benefit-sharing. With a lack of systematic information on uses of MGRs, it will also remain difficult to evaluate the balance between voluntarily shared benefits and the actual economic value of MGR-related commercial activities.

This system would follow the spirit of CBD COP 15/9 decision Art. 5, by establishing transparency via open-access databases instead of tracing access to DSI, but contrary to CBD does not include DSI as part of the access & benefit-sharing (see CBD COP 15/9 decision Art. 2). In the BBNJ negotiations, States have until now been hesitant to address DSI so as to not interfere with parallel CBD discussions. Now that a decision has been made, it is up to States to decide if and if yes, how they wish to consider CBD's decisions, noting that CBD & BBNJ access and benefit-sharing approaches will co-exist with different scopes. However, based on the fact that most researchers do not distinguish origins of DSI in their research practices, inconsistencies with the CBD decision may become problematic.

## **Option 2: Monitoring system**

This proposal foresees mandatory monetary benefit-sharing and proposes a comprehensive monitoring system to ensure this. It has similarities to the notion of 'track & trace' (see Humphries et al. 2021), which entails a coherent monitoring system from the moment of sampling to access, use and commercialization of MGRs and DSI. The system relies on unique identifiers to allow for tracking and tracing across the different stages of the MGR development process. Every time a researcher accesses samples or DSI on a database, a notification has to be made to the implementing body and the subsequent progress of related research needs to be documented and registered in every step until the possible final commercialization of a product. Whereas the transparency system (Option 1) or decoupled payment system (Option 4) leave downstream users largely unregulated, this proposal implies substantial reporting obligations at every step of the MGR research process.

Most significant changes to existing practices would probably lie with the users of MGRs and DSI and States who would need to implement the extensive monitoring infrastructures such as administrative identifiers, reporting requirements, checkpoints and other measures (Humphries et al. 2021). Researchers have indicated that extending the traceability system to the use of DSI may become very expensive and complex in practice, as many research processes entail comparisons of thousands of DSI (Scholz et al. 2022).

In order to trace the use of DSI users need to register with the responsible monitoring body (Humphries et al. 2021). This body would need to be able to administer different checkpoints along the MGR process in order to control unauthorized access to MGRs and movements of samples and data. This would require the constant and very close cooperation with national authorities in State parties to enforce and control the reporting requirements. The system can theoretically rely on existing infrastructure stemming from the national implementation of the CBD and the Nagoya Protocol. But, as all countries have varying reporting obligations, it may be very challenging to ensure full traceability in cases where resources (e.g. samples) move across jurisdictions (Humphries et al. 2021). There is concern that users may falsely declare

the origin of an MGR of ABNJ to avoid the administrative burden and it remains unclear how DSI would be traced once it is downloaded from a database (Rohden et al. 2020).

Monetary benefit-sharing would be informed by and tightly linked to traceability measures. The amount of monetary benefit-sharing, depending on the development of the market, may potentially become high if regulation is implemented well and consistently. But the complexity of the system may make it difficult or burdensome for users to comply, regardless of intentionality. If this system was implemented without additional measures, benefit-sharing would not commence immediately, as it would require some years to be put in place.

This system follows the spirit of CBD decision COP 15/9 Art. 2, as it foresees benefit-sharing from DSI. However, as it envisions the tracking of access to (some) DSI, it is currently unclear whether it is consistent with CBD decision COP 15/9 Art. 5. If implemented, this system may lead to the situation in which DSI from national waters does not get tracked whereas DSI from international waters should be tracked. This may inadvertently disincentivize research on ecosystems located in ABNJ. Many MGRs from ABNJ can also be found in national waters (Oldham et al. 2014).

### **Option 3: End-user PPP registration system**

Option 3 also foresees the mandatory sharing of monetary benefits, but in contrast to the monitoring system under Option 2, would not require tracing every movement and access to MGRs or DSI during the whole R&D process. Instead, it only addresses the end user. This system aims to inform monetary benefit-sharing by registering the output from MGR-related research: publications, patents, products (PPP). It picks up the trace at the moment of the end-user registration, which triggers monetary or non-monetary benefit-sharing. A similar system is already implemented in the [reformed Brazilian system for access- and benefit-sharing under the Nagoya protocol](#).

This approach aims to avoid burdens on research practices as it leaves access and use of MGRs as free as possible while building on already existing intellectual property systems at the national level to share information (Humphries et al. 2021). It requires that every product, publication or patent which contains MGRs or DSI from ABNJ is registered ex-post under the multilateral mechanism. The ex-post registration is designed with specific consideration of patents - the registration indicating MGR use can only occur once the patent claim is already filed to avoid that innovations may still be unprotected at the moment of registration. For simplicity, this ex-post registration system will not only apply to patents, but also be streamlined to publications and products.

Drawing on end-user registrations generally makes traceability of MGRs administratively lighter than full track & trace monitoring systems (Jaspars et al. 2021). It also limits traceability from a large number of initially collected MGRs to a much smaller subset that is actually used in end products. Importantly, an end-user registration comes with different benefit-sharing obligations if it contains MGRs from ABNJ. If it is a scientific paper, it needs to be made publicly available (which is already an obligation under UNCLOS Art. 244); if it is an IPR claim, its registered information would be considered as non-monetary benefit-sharing; and if it is a commercial product, it will trigger monetary benefit-sharing obligations of a certain to-be-determined percentage of the revenue.

This means that while the registration could take place under a newly established multilateral benefit-sharing mechanism (which could also be used for other fora such as CBD), the implementation needs to be monitored at the national level. Every State party would create national-level regulation that requires nationals to go through a global mechanism if MGRs are used to receive the certificate of registration. As such, it will be crucial that all, or at least the most active MGR user countries establish such a system to not undermine traceability, particularly for cases where MGRs traverse multiple jurisdictions from sampling to later stages (Humphries et al. 2021). Another important point of consideration is the extent to which MGRs from ABNJ were used for an innovation in order to trigger the ex-post registration. For instance, a patented genetic trait may be merely present in an innovation, without functional role (Humphries 2015). Related questions may arise for DSI - if a scientist compares 10000 genetic sequences, and one of the 10000 is sourced from ABNJ, does this warrant ex-post registration? The same questions may be asked for Option 2, and to some extent also for Option 4.

Companies would be required to register under the foreseen mechanism to be able to market their product at the national level. The idea is that the simplicity of the system creates further incentives for compliance. After successful commercialization, a percentage of revenue will flow to the multilateral benefit-sharing mechanism in exchange for the legal certainty to rightfully market the product that contains MGRs. This could be a valuable deal for users, and thus one can expect compliance. It may be important to ensure that the percentage of revenue remains consistent regardless of whether the MGR stems from ABNJ or national waters. This is to prevent any potential incentives for falsely claiming the origin of the MGR in order to pay a lower percentage.

This approach explicitly considers relevant CBD regulation (particularly Art. 2 and 5 of COP decision 15/9) and aims to mainstream both systems for registering and making products subject to benefit-sharing. Thus, if implemented well, this could be fully complementary to the CBD system. Theoretically, it could also complement the fund established under CBD COP Decision 15/9 Art. 16. This vision however depends to a large extent on the inclusion of DSI in the BBNJ benefit-sharing framework. If DSI were to be excluded, it would become very limited and complicated as a differentiation between products using only MGR samples and products using DSI needs to be made.

#### **Option 4: Decoupled payment system**

Option 4 developed in informal conversations prior to and during IGC-5 as a compromise between the two main interests of Options 1 and 2, namely, maintaining the freedom of scientific research and guaranteed monetary benefit-sharing (see Scholz et al. 2022 for a related proposal in the CBD context; [MARIPOLDATA 2022](#) for the BBNJ proposal; and Lawson et al. 2020 for a discussion of similar mechanisms in the Plant Treaty and PIP Framework).

States will have to pay a regular fee to the global fund that is established under the BBNJ instrument (or perhaps contribute to the fund to be established under the CBD). Importantly, this fee is decoupled from questions of traceability and access to MGRs. States will be obliged to pay the fee, and non-compliance would be handled as any other non-compliance under an international treaty without effect on access to databases. Thus, access to databases remains

unregulated (and thus open) under this option. There would be no trigger for the payments (such as product registrations or access to MGRs), but fees will be paid regularly from the moment of treaty ratification. This option assumes that regulation needs to target the States, and not the individual users, because a) it may be legally and practically difficult for an international treaty to oblige individual users to adhere, and b) any such regulation may disrupt open-access to scientific databases. It leaves the possible tracing to the State party, which should be encouraged (but not obliged) to implement national legislation to recover benefits from the commercialization of MGRs. As such, it does not establish a comprehensive international monitoring system and could rely on a proposed fund to be established in Art. 52 or under CBD COP decision 30/9. The aim is to ensure a reliable source of funding for capacity building and conservation projects from the onset of the benefit-sharing fund under the BBNJ system.

Because its main idea is to decouple the payment of monetary benefits from the access and use of MGRs, it is flexible about the extent to which MGRs would be traced beyond the pre- and post-cruise report uploaded in the CHM. In theory, after the pre- and post-cruise reports are uploaded and DSI is made publicly available, it is not required to specifically trace the access and use of relevant data. There is also no necessary tracing of the end products (publications, patents, products) of MGR research. In its simplest form, it is left to State parties to determine if and in how far they want to trace, keeping in mind obligations under other fora such as the CBD. In this case, the fee could be set according to existing scales such as the UN assessment scale.

However, this system could also incorporate different review provisions to determine the fee for each State party. To ensure that the fee reflects the value and potential future changes in the industry per State, it may incorporate measures such as a review of registered MGR products, an independent study, or a combination of both. Incorporating procedures for product registration, similarly to the PPP proposal, may help establish an empirical baseline for estimating the fee. This option would require the registration of every MGR-related product but would not incur the same transaction costs as Option 3, where each registration may trigger benefit-sharing obligations. An independent periodic study, possibly by the ABSM or STB, could also be used to estimate the amount of fee per State. This study could use the registry of products to inform the estimation of the benefit-sharing fee for the next period.

This option considers the challenges and limitations of the CBD Nagoya framework in relation to impediments to scientific research and benefit-sharing (Prathapan et al. 2018). Additionally, by introducing decoupled payments, it introduces an alternative to the benefit-sharing mechanism under ISA, where little monetary benefit-sharing has occurred to date, due to its reliance on actual benefit generation. This approach is aligned with key decisions made at the CBD COP 15, acknowledging that it is unfeasible to trace access and use of all DSI, but that monetary benefits from DSI should be shared. However, it should carefully consider the possible interpretation of CBD COP decision 15/9, Art. 2 that benefit-sharing shall be connected to the use of DSI (Oldham et al. 2023). In this regard, it may be useful to consider differences in consistency with the CBD decision for each of the optional forms of review. Devising a periodic study to inform the fees could be understood as a review of aggregate use, while solutions such as end-product registration may involve tracing individual uses. Finally, this option can contribute to the establishment of a special fund for benefit-sharing

(Art. 16) while acknowledging that the generated benefits should be directed towards specific purposes, such as conservation or capacity-building (Art. 10).

## Summary

### Traceability approaches: Level of regulation & Benefit-sharing potential

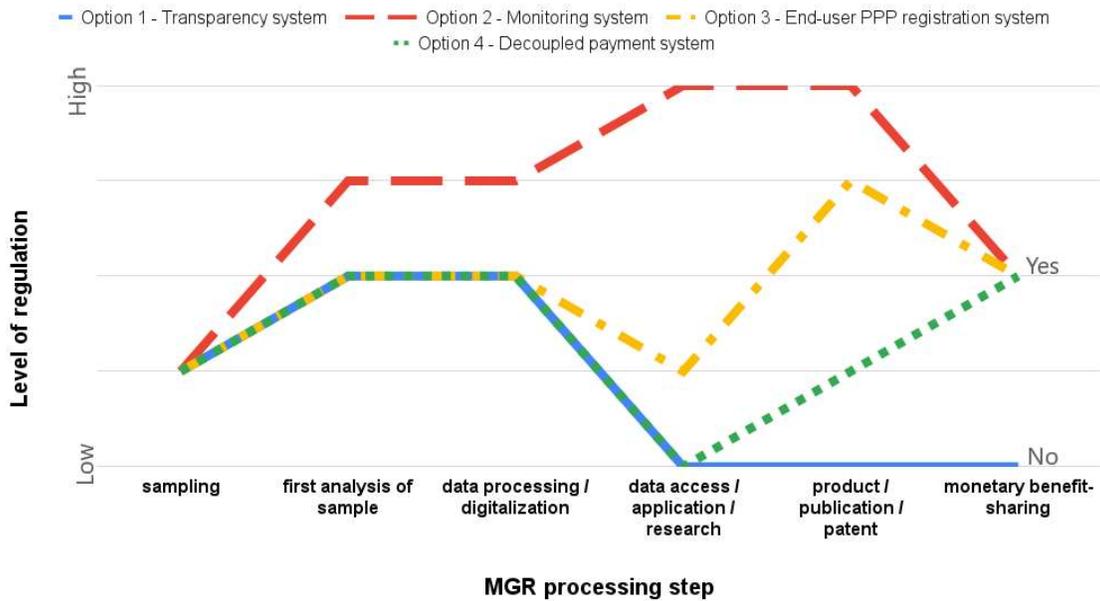


Figure 1 - Level of regulation includes regulatory obligations on users and the level of required traceability infrastructure

Different options for benefit-sharing would place different requirements on traceability systems, ranging from extensive track & trace monitoring, over more selective traceability systems for only parts of the chain of custody, to trust-based systems where open-access formats or periodic reviews are sufficient. Figure 1 summarizes and visualizes the level of regulation that the different options would imply for each stage of an ideal-type linear MGR process - from initial sampling to the commercialization of a product, and whether they would lead to monetary benefit-sharing.

Each system starts at a relatively low level of regulation during the sampling phase in which the notification of sampling activity (mostly in the form of a pre-cruise report) is demanded. However, the different options diverge in the level of regulation they foresee for the subsequent steps of the process. Whereas all options foresee the publication of a post-cruise report in which the storage and accessibility of the original sample and relevant (meta)data is indicated, Option 2 additionally requires the establishment of a unique identifier which must be assigned and registered with the monitoring body. In the next step, all options foresee that DSI be made publicly available so that the global research community can equally benefit from MGRs. However, the monitoring system implies that the upload of data must be registered through the unique identifier that needs to remain consistent or traceable throughout the subsequent stages.

At step 4 (access to data, application, research), the options begin to diverge significantly: Option 1 and 4 leave this step unregulated. Option 3 implies a higher regulation as the user of MGRs must remain aware of the origin of their MGR data in order to later correctly register their product or publication. However, the required user due diligence is expected to become standard practice in bioprospecting in any case. At this stage, the regulation level of Option 2 is relatively high as every access and subsequent use of MGR data must be registered and controlled, which implies a lot of work for users and the monitoring body.

When it comes to the output of biotechnological research and development (step 5), the regulation levels differ significantly. Option 1 and 4 do not foresee to centrally register and regulate the publication or marketing of the outcome of MGR research. Option 3 foresees that every product, publication or patent be registered with the global ABSM. This would require new norms and standards, including for patent offices, to be implemented in order to establish a functional traceability system across countries. At the last step, Option 2, 3 and 4 aim to ensure the sharing of monetary benefits whereas Option 1 does not necessarily lead to any form of monetary benefit-sharing.

The magnitude of obligations for MGR users varies significantly across the various stages. In all scenarios, new requirements for the sampling stage will be limited to the pre-cruise report, which will be part of the extensive planning and execution process for research cruises. Upon the completion of the cruise, the post-cruise report and potential data sharing will be necessary. However, later stages, such as access to data, research, and development of a product or publication may involve additional obligations which multiply each time MGRs or DSI are utilized, accessed, or uploaded. This should be considered when discussing the various options.

## Discussion

Based on the review of different options in this policy brief, this section discusses some general lessons that BBNJ negotiators may want to consider when designing the regulation for MGRs:

1. **Find a balance between regulation and benefit-sharing:** Consulted experts tend to agree that traceability is a scale and that costs of a traceability system become higher the more regulation it implies. Particularly the tracing of MGRs throughout all stages, including the access and use of DSI, can become highly complex. However, the amount of monetary benefits to be shared does not need to correspond to the extensiveness of traceability. It is conceivable that monetary benefit-sharing takes place under varying traceability levels. A new system should take this into account in order to facilitate the efficient sharing of benefits.
2. **Think across individual options:** Given the advantages and disadvantages of all approaches, and the fact that they are not mutually exclusive, it is also conceivable that delegations may want to consider hybrid approaches. For instance, a decoupled payment system, does not track access, and is supplemented by an end-user PPP registration system may make sense. Such a hybrid system would not infer the transaction costs related to the triggering of benefit-sharing obligations for each registration but would only use the registration to gather data on the value and development of MGR related markets per State. This could also be combined with an independent study to estimate the amount of the fee and the distribution per State. A

hybrid version could also be a system that starts off as a decoupled payment system and is later replaced by an end-user PPP registration system.

3. **Build on existing scientific practices and infrastructures:** Open-access databases and existing identifiers are useful building blocks to enhance transparency on MGRs (Oldham et al. 2023) and to make ocean economies more inclusive (Blasiak et al. 2023). These existing practices may be complemented by additional measures to further improve traceability and to support benefit-sharing under the BBNJ agreement. It may be useful and not particularly complicated to consider adding a special BBNJ label to the already available country of origin tag under INSDC to support these efforts. This would allow scientists to self-declare collection of MGRs from ABNJ and support retrospective traceability. Importantly, this depends on the willingness of the database providers to introduce such measures and needs to be bolstered financially as databases already suffer from high costs and fragile funding (Rabone et al. 2022).
4. **Consistency with other fora such as the CBD:** Negotiators of the BBNJ agreement have the opportunity to create regulation for an emerging field of marine science and industry. While acknowledging the different mandates and scope of BBNJ, delegates may still wish to carefully consider the decision of the CBD COP to avoid regulatory inconsistencies. A reference to the decision may solve questions on the extent to which DSI should be part of access- and benefit-sharing regulation under the BBNJ instrument (Oldham et al. 2023). The CBD COP decision 15/9 establishes a multilateral mechanism for benefit-sharing for DSI and a global fund. It may be worthwhile to explore how far these institutions can be used for both MGRs under the CBD regulation as well as BBNJ.

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## List of terms

ABNJ	Areas Beyond National Jurisdiction
ABSM	Access and Benefit-Sharing Mechanism
BBNJ	Biodiversity Beyond National Jurisdiction
CBD	Convention of Biological Diversity
CHM	Clearing House Mechanism
COP	Conference of Parties
DSI	Digital Sequence Information
INSDC	International Nucleotide Sequence Database Collaboration
IPR	Intellectual Property Rights
ISA	International Seabed Authority
MGRs	Marine Genetic Resources
PIP	Pandemic Influenza Preparedness
PPP	Publications, Patents, Products
STB	Scientific and Technical Body
WHO	World Health Organization
WIPO	World Intellectual Property Organization