



A technical and legal analysis of triggers for monetary benefit-sharing from digital sequence information on genetic resources

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2024

The European Commission's
Knowledge Centre for
Biodiversity

Joint
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JRC138679

PDF ISBN 978-92-68-19794-3 doi:10.2760/936096 KJ-02-24-835-EN-N

Luxembourg: Publications Office of the European Union, 2024

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How to cite this report: European Commission, Joint Research Centre, Weissgold, L., Switzer, S., Eccleston-Turner, M. and Scholz, A.H., *A technical and legal analysis of triggers for monetary benefit-sharing from digital sequence information on genetic resources*, Publications Office of the European Union, Luxembourg, 2024, <https://data.europa.eu/doi/10.2760/936096>, JRC138679.

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Abstract

This study is the result of a response to a policy request submitted by DG ENV to the Knowledge Centre for Biodiversity (KCBD) through the KCBD ticketing system. It provides a technical and legal analysis of six triggers for monetary benefit-sharing from the use of digital sequence information (DSI) on genetic resources, evaluated against the criteria in para. 9 of Decision 15/9 of the 15th Conference of Parties to the Convention on Biological Diversity (CBD/COP/DEC/15/9). This study suggests that a trigger based on commercial activity related to DSI (trigger 5) best meets the Decision's criteria, with secondary options being commercialisation of DSI products (trigger 4) and a micro-levy (trigger 6). A fee at the point of access (trigger 1) and licences associated with DSI records (trigger 2) were found to restrict open access and innovation, require significant cooperation from database managers and fail to meet several criteria. Licences combined with mandatory cloud service platforms (trigger 3) also raise privacy and competition concerns. The commercialisation of DSI products (trigger 4) avoids impacting research but requires clear definitions and reliable payment collection. A micro-levy on DSI-related products or services (trigger 6) is feasible but may not effectively link to DSI use. The study finds that trigger 5, potentially combined with some elements from triggers 2 and/or 6, could support the development of a DSI multilateral mechanism (MLM) that meets the criteria of para. 9 of Decision 15/9.

Acknowledgements

The authors thank Pablo Orozco for constructive conversations and analysis, as well as Mery Ciacci, Hugo-Maria Schally and Nadja Steinfort of the Directorate-General for Environment (DG ENV) for the review of drafts, and Paris Vasilakopoulos of the Joint Research Centre (JRC) for coordination, project management and editing the report.

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Executive summary

DG ENV submitted a policy request to the Knowledge Centre for Biodiversity (KCBD) through the KCBD ticketing system¹ to get a technical and legal analysis of triggers for monetary benefit-sharing from the use of digital sequence information (DSI) on genetic resources. The aim of this request was to inform the drafting of the EU position for the second meeting of the Ad Hoc Open-ended Working Group on Benefit-sharing from the Use of Digital Sequence Information on Genetic Resources (WG DSI 2) that will make recommendations to the 16th Conference of the Parties (COP) to the Convention on Biological Diversity (CBD). In response to that request, the KCBD identified and organised four experts to develop the current study.

This study analyses six triggers against the criteria laid out in para. 9 of Decision 15/9 of the 15th Conference of Parties to the Convention on Biological Diversity of 2022 (CBD/COP/DEC/15/9; 'Decision 15/9' hereafter). This study shows that a trigger based on commercial activity related to DSI best meets the criteria laid out in para. 9 of Decision 15/9. A trigger based on commercialisation of DSI products and/or a micro-levy are the second-best options. These could be complemented by the implementation of labels for DSI that have indigenous people or local community (IPLC)-provenance or cultural importance. Taken together, these measures could contribute to the creation of a DSI multilateral mechanism (MLM) that meets all the criteria in para. 9 of Decision 15/9.

Fee at the point of access (Trigger 1)

This trigger would take place at the point of access to DSI. There would be a paywall at the point of user and machine interaction with a public database containing DSI. This trigger will require significant cooperation with DSI database managers, who will need to overhaul their infrastructure to create new web interfaces, registration systems, payment collection abilities, monitoring mechanisms, data privacy measures and more. This trigger will significantly restrict open access and hinder research and innovation. The restrictions will also break the interoperability of DSI databases and may cause user avoidance. This trigger fails to meet criteria (a), (b), (e) and (f) of para. 9 of Decision 15/9.

Benefit-sharing licences associated with DSI records (Trigger 2)

This trigger attaches licences that require benefit-sharing to specific DSI records (e.g., sequence entries). For this trigger to function effectively, there would need to be a small number of standard licences agreed upon by the Parties. These licences would be the first to require monetary benefit-sharing associated with individual sequences and it is unclear if this would work for generating significant and predictable benefits. This trigger will likely result in jurisdiction shopping and avoidance. As with trigger 1, this trigger requires full cooperation from database managers, and may go against their stated operating policies. Licences fail to meet criteria (a), (b), (d) and (e) of para. 9 of Decision 15/9. They may also fail to meet criterion (f), depending on the terms of use embedded in the licence.

¹ https://knowledge4policy.ec.europa.eu/biodiversity/topic/kcbd%E2%80%99s-ticketing-system-policy-requests_en

However, while licences may not work for the DSI MLM, labels could provide a way for IPLCs to mark what DSI has provenance from their territories or is of cultural importance to them. This could help the DSI MLM meet criterion (i) of para. 9 of Decision 15/9.

Licences along with mandatory use of cloud service platforms (Trigger 3)

This trigger creates 'CBD-compliant' databases which would be housed alongside and integrated with pre-selected cloud computing services. The cloud computing services would charge users for the amount of DSI used or processed, upkeep of the data infrastructure, and bioinformatic analyses and support services run via the cloud. Like paywalls and licences, this trigger requires coordination and cooperation with database managers, as well as the cooperation of cloud service providers, who would also need to implement novel data privacy architecture. Creating CBD-compliant databases would restrict where DSI can be analysed and used. There are also significant privacy, innovation and competition concerns with mandating specific cloud computing platforms for entire sectors. If the cloud-based fees for the database infrastructure are charged at the point of access, all of the concerns from trigger 1 apply. However, if the fees are charged at a different point (e.g., decoupled from access and added as a surcharge to the use of commercial cloud computing services), they may not hinder scientific process and could be a part of a successful DSI MLM. We discuss further how this might work in trigger 6. Trigger 3 fails to meet criteria (a) and (e) of para. 9 of Decision 15/9. Also, depending on how it is implemented, it may or may not meet criterion (f).

Commercialisation of DSI-based products (Trigger 4)

To implement this trigger successfully, Parties would need to agree on a definition of a DSI-based product and create guidelines for implementation. For the purpose of this study, commercialisation of a DSI-based product means: *'placing on the market a product whose development and/or production involves access to, knowledge of, and/or use of digital sequence information'*. Parties could also use a standard product classification system, such as the United Nations Conference on Trade and Development (UNCTAD) Trade and Biodiversity (TraBio) classification, to support implementation and pre-define which products are likely to be considered DSI-based. However, it may be difficult to obtain accurate information on whether DSI was used in the production and/or development of a product. There may also be issues with obtaining figures for the sale of DSI-based products at a company level, potentially hampering the ability to ensure that the correct payments are made. This trigger may also re-ignite the debate about tracking and tracing, but it does not need to, and much will depend on its implementation. This trigger would not impact academic research, innovation or open access. Given that this trigger is not necessarily related to any kind of contractual relationship with users of DSI, Parties will need to further clarify how legal certainty is provided to users with respect to DSI usage. However, if it is implemented in a manner similar to commercial activity related to DSI (trigger 5) it could provide legal certainty. The Parties will also need to decide who will collect these payments, an issue common to several of the triggers discussed in this study. While national-level collection seems the most appropriate method for trigger 4, more consideration needs to be given by the Parties to the individual-country capacity to participate in the collecting, monitoring, compliance and enforcement aspects of the DSI MLM funds.

Commercial activity related to DSI use (Trigger 5)

This trigger would require those users engaging in commercial activity related to DSI to make DSI benefit-sharing payments. For the purpose of this study, 'commercial activity related to DSI' means: *'any activity in the nature of trade, commerce or business that involves the generation, storage and/or analysis of digital sequence information, or the development, production, transfer, exchange,*

and/or provision of products, assets, and/or services that involve access to, knowledge of, and/or use of digital sequence information'. Parties would likely need to agree on a definition of commercial activity and industry users would then, depending on how this trigger is operationalised, need to self-assess whether they are in scope. The Parties at COP, when defining the MLM modalities, would likely need to consider issues related to compliance. There are also several options (beyond the definition itself) for creating the obligation to share benefits: by posting terms of use in the public DSI databases; by posting terms of use in the DSI MLM and allowing users to self-assess, register, and pay directly to the MLM based on the commercial activity definition; and/or by identifying sectors obligated to share benefits and requiring those identified sectors to pay benefits. The Parties will need to decide who will collect these payments, if not sent directly to the DSI MLM. This trigger would not impact academic research and innovation or open access. Creating terms of use could provide legal certainty, but posting terms of use at the point of access to DSI would require coordination with public databases. Mechanisms for monitoring and for ensuring compliance with such terms of use would be required. Parties might also need to determine where along the value chain 'DSI-using' companies become obligated to share benefits (e.g., retail level, all along the value chain) although 'stacking' of obligations could also be an acceptable feature in order to assure wide participation in benefit-sharing. Depending on its operationalisation, this trigger could potentially meet all the criteria of para. 9 of Decision 15/9.

Micro-levy products or services associated with DSI generation, laboratory equipment, and/or cloud-computing fees (Trigger 6)

This trigger would be a micro-levy implemented at country level on products or services associated with DSI generation and/or storage. Micro-levies could be applied to any number of things: DSI sequencing or synthesis equipment, other lab equipment, or cloud computing services (see trigger 3). These levies would be collected by companies producing the equipment/services and sent to the global fund. Micro-levies are already standard practice in some parts of the world, but would require country-level changes in tax policy. This trigger will not restrict open access to DSI or research and innovation. Levies have the potential to garner significant, predictable monetary benefits, but political will is required to implement a levy at the national level, even if small and highly targeted. This trigger may fail to meet criterion (d) of para. 9 of Decision 15/9, depending on how it is implemented by Parties at the national level.

1 Introduction

At the 15th Conference of the Parties of the Convention on Biological Diversity (COP15), the Parties, in Decision 15/9 (CBD/COP/DEC/15/9; CBD, 2022; ‘Decision 15/9’ hereafter), decided to establish a multilateral mechanism (MLM) for benefit-sharing from the use of digital sequence information on genetic resources (DSI). They established a time-bound process ahead of the 16th Conference of the Parties (COP16) for further development and operationalisation of the MLM. As part of this process, Parties agreed to address a number of issues pertaining to the successful implementation of the DSI MLM. One of these is ‘triggering points for benefit-sharing’ (Decision 15/9: Annex, ‘Issues for Further Consideration’, (b)). A number of proposals for ‘trigger points’ were put forth in the run up to COP15 as well as during the current intersessional period. Some triggers are part of larger proposals for the DSI MLM, while others are standalone proposals. In para. 9 of Decision 15/9 (Box 1), Parties also agreed on a number of criteria for the MLM.

An analysis of the most commonly considered triggers against the criteria laid out in para. 9 of Decision 15/9 (Box 1), with both technical and legal assessments, is needed to support Parties in developing the MLM. For this reason, the Directorate-General for the Environment (DG ENV) submitted a policy request to the Knowledge Centre for Biodiversity (KCBD) through the KCBD ticketing system, for ‘*an assessment of the legal and technical impacts and implications for research and development of triggers at the commercial use of DSI, including legal/policy/administrative measures necessary for implementation and to ensure compliance*’, to support DG ENV at of the second meeting of the Ad Hoc Open-ended Working Group on Benefit-sharing from the Use of Digital Sequence Information on Genetic Resources (WG DSI 2). The present assessment complements an ongoing study requested by DG ENV on ‘DSI Triggers for a Multilateral Benefit-Sharing Mechanism’ by Pedro Batista, which has an economic and legal perspective. With its compact format, the current study also complements the more in-depth CBD-Commissioned Studies on revenue-generating measures further to Decision 15/9 (CBD/WGDSI/2/2/Add.2; CBD, 2024).

This study analyses six monetary benefit-sharing triggers for payment into the DSI MLM². These triggers are:

1. A fee at the point of access to DSI.
2. Licences associated with individual DSI records.
3. Licences associated with individual DSI records with mandatory use of cloud services related to DSI storage or processing.
4. A commercialisation fee based on individual DSI products.
5. A fee on commercial activity related to DSI.
6. A micro-levy on products and services associated with DSI generation.

The study analyses the technical and legal implications of implementation of these triggers and discusses the triggers with respect to the criteria laid out in para. 9 of Decision 15/9 (Box 1). It also discusses appropriate rate setting measures for each of the triggers. A technically focused traffic

² These triggers were pre-agreed with DG ENV during the study’s scoping phase in the interest of efficiency.

light analysis of triggers for benefit-sharing, based on para. 9 of Decision 15/9, is set out in Annex 1.

Box 1. Para. 9 of Decision 15/9 (CBD/COP/DEC/15/9; CBD, 2022) with added notes in italics, where applicable, of the authors' interpretation of the relevant criteria (a) - (i).

9. [The Conference of the Parties] Also agrees that a solution for fair and equitable benefit-sharing on digital sequence information on genetic resources should, inter alia:

(a) Be efficient, feasible and practical;

Efficient, feasible and practical to implement and enforce from a legal and technical standpoint.

(b) Generate more benefits, including both monetary and non-monetary, than costs;

(c) Be effective;

Be an effective MLM in which monetary benefits from the use of DSI are collected and shared at sustainable and predictable rates.

(d) Provide certainty and legal clarity for providers and users of digital sequence information on genetic resources;

(e) Not hinder research and innovation;

(f) Be consistent with open access to data;

Defined in Sara et al. (2022) as embodied by five properties: anonymous access, free of charge, free of restrictions, interoperable, transparent and reproducible.

(g) Not be incompatible with international legal obligations;

(h) Be mutually supportive of other access and benefit-sharing instruments;

This includes the Nagoya Protocol and therefore national Access and Benefit Sharing (ABS) legislation as well as other multilateral instruments, such as, for instance, the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) and the Agreement under the United Nations Convention on the Law of the Sea on the Conservation and Sustainable Use of Marine Biological Diversity of Areas beyond National Jurisdiction (BBNJ Agreement).

(i) Take into account the rights of indigenous peoples and local communities, including with respect to the traditional knowledge associated with genetic resources that they hold.

1.1 Terminology

There are a number of terms that must first be defined for the purpose of this study. First, unless otherwise indicated, 'Parties' refers to CBD Parties. Additionally, the term 'trigger', is potentially confusing as, legally, it refers only to the moment when users *must* begin to share benefits; however, in common CBD parlance, 'trigger' can also be understood to include the *creation* of an obligation to share benefits and/or the time point and location of (monetary) benefit collection. For this reason, we propose an expansion of the 'trigger' concept. For the purpose of this study, any 'trigger' in the CBD DSI sense includes three elements: an obligation, the trigger for payment itself, and the point of benefit collection.

— **Obligation:** the moment a duty to share benefits with the DSI MLM is created.

- **Trigger:** when users have a duty to begin the sharing of benefits with the DSI MLM. The trigger may happen at a later point in time than the creation of the obligation to share benefits. It could be an activity or a specific point in time.
- **Benefit collection:** the point at which money enters the fund (e.g., start of the next financial reporting year). This may occur at a later point in time than the creation of an obligation to share monetary benefits, as well as of the trigger to start sharing monetary benefits.

The analysis of triggers in this study will take into account the three elements of the monetary benefit-sharing trigger concept. For example, a paywall (trigger 1) has all three aspects occurring simultaneously, whereas triggers based on an annual operating figure require further discussion on what exactly obligates users, as well as the applicable benefit collection point. Discussion of triggers also requires an understanding of to whom any such obligation to share benefits should apply and at what rate payment is to be made. These issues are also discussed in Chapter 2.

The criteria of para. 9 of Decision 15/9, with added notes of the authors' interpretation of these criteria, are listed in Box 1.

2 DSI monetary benefit-sharing trigger analysis

In this chapter, the triggers selected during the scoping phase of the study are described and analysed from both technical and legal perspectives. Their compatibility with the criteria set forth in Decision 15/9 is also assessed. For reference, if criteria are not listed in the summary, we deemed them as potentially met or at least not adversely impacted. There are common elements that must be identified and agreed across all triggers to ensure a functional DSI MLM, including payment rates and obligated users. These issues are discussed in Chapter 3 ('Rate setting') and within the trigger analyses (Chapters 2.1 - 2.6), respectively. The discussion of each trigger also unpacks the distinction between obligation, trigger and benefit collection points. Finally, although the triggers are discussed separately, they are not mutually exclusive.

Following the trigger analysis (Chapter 2) and rate setting discussion (Chapter 3), we provide an overview of common legal issues (Chapter 4) that ought to be considered across all triggers.

2.1 Trigger 1 - Fee at the point of access

Headline messages:

- This trigger will require significant cooperation with DSI database managers.
- Database managers will need to overhaul their infrastructure to create new web interfaces, registration systems, payment collection abilities, monitoring mechanisms, data privacy measures, advanced programmer interfaces (APIs), file transfer protocols (ftps) and more.
- Paywalls significantly restrict open access, hinder research and innovation and put the value of scientific reproducibility at risk. They will have particularly strong impacts on low and middle income country (LMIC)-based scientists.
- This trigger will break the interoperability of DSI databases that automatically exchange DSI amongst thousands of independently run databases.
- In a new financial model, databases would need to recuperate their own operating costs (50 million - 1 billion USD/year globally) before being able to share benefits, as their funding is contingent on them providing open access.

Analysis by criterion of para. 9 of Decision 15/9 (Box 1):

- (a): the reliance on public databases to implement, enforce, track, and collect benefits makes this trigger neither feasible nor practical to implement, meaning that criterion (a) is not met.
- (b) & (c): the recoupment of operating costs and the high likelihood of avoidance mean that criteria (b) and (c) are not met.
- (e) & (f): the severe limitations on open access and potential destruction of existing data interoperability mean criteria (e) and (f) are not met.
- (h): this trigger appears to conflict with a number of international ABS regimes, as well as domestic regimes that have sought to regulate DSI through ABS laws at the national level³.

2.1.1 Description of trigger

This trigger would take place at the point of access to DSI. There would be a paywall at the point of user and machine interaction with a public database containing DSI. The applicable list of fees for access would need to be determined by the Parties (see Chapter 3 on rate setting).

The obligation, trigger, and benefit collection point are all the same moment; i.e., when accessing DSI in a public database and encountering a paywall. Essentially, the technological barrier of a paywall manages, enforces, and collects benefit-sharing.

2.1.2 Technical feasibility

While the mechanics of putting in place a paywall are technologically feasible, doing so would require the cooperation of database owners/managers, as well as their funders. Paywalls would severely disrupt the flow of DSI between databases, hinder innovation and research, and restrict open access.

Public DSI databases such as those within the International Nucleotide Sequence Database Collaboration (INSDC) are free to users, with the INSDC premised upon '*free, unrestricted access to all of the data records in their database*' (CBD, 2018;⁴). Should this trigger be introduced, database managers who do not voluntarily comply with its requirements may need to be made to do so by the national law of the jurisdiction in which they are domiciled. New and existing databases could forum shop to avoid these national law obligations and domicile in a non-Party (see also Chapter 4.1). A large DSI database such as Genbank, based in the US, seems unlikely to change its fundamental US Federal Government funding structure to accommodate the CBD. It is also of course possible that certain CBD Parties will not take action to ensure the enforceability of the trigger. On the other hand, public databases in non-Parties might be willing to voluntarily update their terms of use to point to the DSI MLM to maintain a high level of scientific integrity, as they have to require provenance (geographical and temporal) information⁵.

³ This may be an issue common to a number of triggers, depending on their design and operationalisation, see Chapter 4.

⁴ <https://www.cbd.int/dsi-gr/2019-2021/studies>

⁵ <https://www.insdc.org/news/insdc-spatiotemporal-metadata-minimum-standards-update-03-03-2023/>

From the perspective of a database manager, implementing a paywall requires changing the web interface as well as any automated access points to DSI such as their ftp sites or advanced programmer interfaces (APIs). An additional technological layer would also be needed to require registration, payment and a back-end system to track registrants and payments and an accounting system to pass funds to the MLM for further distribution. The scale and cost of changes to web interfaces is unknown, and it is unclear if all the big public databases have the capability or the capacity to track, monitor, and communicate with the MLM or national governments regarding benefit-sharing from the use of DSI. Beyond tracking and communication, in implementing a paywall, databases would also need to create infrastructure and measures to comply with data privacy laws, including the European General Data Protection Regulation (GDPR). Potential frictions may arise depending on where databases are hosted, the nature of the data they collect, the manner in which such data is processed, and how (and where) it is stored.

Implementing paywalls would restrict open access and put the fundamental value of scientific reproducibility at risk, hindering research and innovation. In addition, paywalls would severely disrupt the automatic flow of data between databases. There are at least 2,000 databases, of which 50-60 are core databases with large international footprints, which automatically pull from the 3 INSDC databases. This trigger would likely have a cascade effect where smaller databases need to charge for access and require each of the thousands of databases to put up their own paywalls and then perhaps also pay each other in order to exchange DSI. Alternatively, they would simply stop exchanging DSI to the detriment of science and innovation.

In addition, given the unlikelihood of universal adoption across databases, users could simply avoid databases with paywalls, which would further limit open access to data. Users may also move their operations to private databases. Consideration will need to be given as to the inclusion of publicly accessible private databases within the DSI MLM. The Parties could encourage private databases to implement paywalls, but, similarly to public databases domiciled in non-Party states, uptake is unlikely in the absence of a requirement to do so under national law. Alternatively, private databases could be seen as providing a DSI-based service and fall under other triggers such as trigger 5.

An additional consideration is that large public DSI databases are entirely funded with taxpayer money so that they can provide open access to data in support of scientific reproducibility and integrity. If databases ceased to provide open access, governments currently carrying the bill would likely pull their public funding. This means that any money collected by the databases for benefit-sharing could plausibly first need to offset their operating costs (\$50 million USD/annum for the INSDC and upwards of \$500 million - \$1 billion globally for all public DSI databases)⁶ before they could pass on benefits to the DSI MLM. Around 50% of INSDC users live in countries whose governments do not contribute to Nucleotide Sequence Database (NSD) infrastructure costs so a discontinuation of public funding would no longer subsidise their use.

2.1.3 Legal feasibility

Prima facie this appears legally straightforward. This is because the obligation, trigger and benefit collection all occur simultaneously through one focal point - the database itself. Presumably, the

⁶ Financial estimates based on informal discussions with DSI database managers (Global Biodata Coalition, 2024, *personal communication*).

terms and conditions of payment, if any further terms were to apply (for example, if this trigger was combined with other options for further benefit-sharing in the event of commercialisation), would be communicated by way of a click-through user agreement when registering on the database. The collecting body, which in this case appears to be the databases themselves, needs to ensure it has legal personality to form legal relations with end users in all relevant jurisdictions around the world. Databases would also require the capacity to monitor and verify users, to eliminate free riders or fraudulent users. They would furthermore need the ability, capacity and resources to instigate legal proceedings against those who breach the terms of the database on behalf of the DSI MLM. Verification and monitoring of access would be required if, for example, the Parties decide to institute a system of tiered fees for access by LMIC-based users and/or academia; or tiering based on the amount of use.

Alternatively, a third party could be tasked with the above responsibilities, acting as the collecting, monitoring and enforcement agent on behalf of the DSI MLM, but this will require close collaboration with databases, which could result in additional running costs. It will also require the formation of, among other things, data sharing agreements (see Chapter 4.6). Regardless of the body nominated with collection, monitoring and enforcement - and these could potentially be separate entities - sufficient resources will need to be given to this task. As noted above, the scale of this task should not be underestimated; there are around 10 to 15 million users of INSDC alone.

2.2 Trigger 2 - Licences associated with individual DSI records

Headline messages:

- This trigger creates the conditions for jurisdiction shopping and avoidance resulting in less monetary benefits shared.
- Parties would need to agree to a limited number of licences, which will likely take a significant amount of time.
- Existing Creative Commons (CC) licences do not have monetary benefit-sharing terms embedded so unclear if DSI use and benefit-sharing licences would deliver as hoped.
- This will require full cooperation from database managers and attachment of licences restricting use explicitly contrary to INSDC operating policy.
- DSI database architecture changes would need to be widespread.
- Retroactive application would make this trigger most effective but free access countries would have little motivation to do so.
- There is a need to consider the role for IPLC *labels* in public DSI databases.

Analysis by criterion of para. 9 of Decision 15/9 (Box 1):

- (a): the reliance on databases across the world to add monetary benefit-sharing licences to individual sequence records, particularly if the changes result in use restrictions is neither feasible nor practical to implement, meaning criterion (a) is not met.
- (b): the high likelihood of avoidance means that criterion b is not met.
- (d) & (e): use restrictions on data would hinder research and innovation and potentially cause a lack of legal certainty for users, meaning that criteria (d) and (e) are not met.
- (f): depending on the terms of the licences, some of them will likely restrict open access to some data meaning criterion f is not met.
- (i): labels provide one of the best ways for IPLC rights to be made transparent and thus respected. However, the aspects of this trigger that can best address IPLC rights can be included in the DSI MLM without also being a trigger for benefit-sharing, or restricting use.

2.2.1 Description of trigger

This trigger attaches licences - in essence, a contract setting out terms and conditions of use - to specific DSI records (e.g., sequence entries). In order for this trigger to function effectively there would need to be a small number of standard licences agreed upon by the Parties. The licence trigger is modelled on the use of CC licences as used by, among others, the Global Biodiversity Information Facility (GBIF)⁷ which, since 2014, has allowed uploaders to assign one of three CC licences to their data. However, licences for DSI benefit-sharing would differ from the GBIF model by requiring (or not) monetary and/or non-monetary benefit-sharing from the use of individual DSI records. This trigger is based on the model put forth by Kindness and Oldham (2022).

Much will depend upon the terms and conditions of the agreed licences. For example, some DSI might receive a licence with no restrictions and no benefit-sharing obligations. This could apply to, for example, DSI from the United Kingdom, which has granted free access to its genetic resources through national legislation and is currently the leading provider country⁸ in the INSDC with 20% of all DSI records with a 'country tag'⁹. Some DSI might allow for non-commercial use only. Some licences might require monetary benefit-sharing by all or only by commercial users and so on. While we assume under this trigger that most DSI currently in public databases would have no benefit-sharing licences, as they are already in the public domain under terms of use that specify they are free and open for re-use, there may be practical benefits to the retroactive application of licences to older DSI (see Chapter 2.2.2).

The obligation under this trigger is the licences associated with individual pieces of DSI, the trigger itself would be defined within the licence, and the benefit collection point would again need to be defined within the licence. Notably, there could be variability between licences on both trigger and benefit-collection, increasing legal uncertainty.

⁷ <https://www.gbif.org/publishing-data>

⁸ Where sampling of the genetic resource that gave rise to DSI took place.

⁹ <https://apex.ipk-gatersleben.de/apex/wildsi/r/wildsi/overview-dsi?session=11526737469995>

2.2.2 Technical feasibility

While this trigger may be feasible to implement from a technical standpoint, it would create the perfect tool for jurisdiction shopping and avoidance behaviour by users. This, in turn, would lead to a lack of monetary benefit-sharing. Depending on the terms of the licence, it may require the user to track and trace the use of individual DSI records.

As noted earlier, the Parties would need to agree to a limited number of licences. These could be built off of the CC licences or other existing licencing/labelling schemes, such as Local Contexts,¹⁰ or they could be novel and fit for purpose, but ultimately they would need to allow for monetary benefit-sharing. The licence would need to lay out exactly who is obligated to share benefits, how they must do so, at what rate, and with whom and when the benefits must be shared (see triggers 4 and 5 for further discussion on identifying users/products to obligate). Although reference is often made to GBIF and its use of CC licences, there are no CC licences in place that require monetary benefit-sharing; thus, it is unclear whether the success of CC licences (which have no financial implications at all) are comparable to licences for benefit-sharing. Additionally, the application of benefit-sharing licences which have embedded use restrictions will result in some data no longer being open access, as defined by Sara et al. (2022), since they will no longer be ‘free of restrictions’.

Like a paywall, implementing this trigger would also require full cooperation from database managers/owners. Databases would need to put in place architecture to associate a licence to a DSI record. In the past, the INSDC has been amenable to updating their metadata fields and their requests for information on uploaded DSI (e.g., country of origin). However, labels which restrict use would directly contradict the INSDC’s 2002 policy which reads:

*‘The INSD will not attach statements to records that restrict access to the data, limit the use of the information in these records, or prohibit certain types of publications based on these records. Specifically, no use restrictions or licensing requirements will be included in any sequence data records, and no restrictions or licensing fees will be placed on the redistribution or use of the database by any party’.*¹¹

Implementing licences as a trigger would necessitate changes in database architecture far beyond the INSDC, as the licences would likely need to travel with the piece of DSI through to its final use. To encourage this, the Parties would need to ask for a change in the architecture of scientific and private databases around the world. Universal implementation is unlikely and even less likely if the licences restrict the use of data. The terms and conditions contained within the licences would also need to determine how minor modifications to DSI are to be dealt with; there needs to be legal certainty as to which terms carry forward.

Even if licences were successfully implemented across a majority of databases, they could still engender the avoidance of obligations, wherein tagged data could simply be sorted out and avoided. For comparative analysis, users will seek to use data that all have the same legal conditions to avoid confusion and ambiguity. Users would avoid tagged data to minimise their benefit-sharing obligations and would likely be unsure of how to treat a larger dataset when only

¹⁰ <https://localcontexts.org/>

¹¹ An exception to this is in respect of data for human genetic material covered by patient prior informed consent requirements. This exception does not relate to licences, but rather to restrictions on access to use until a patient privacy committee has evaluated requests for access.

one labelled piece is used in data analysis. User avoidance of DSI with restrictive licences would lead to jurisdictions that have lots of licenced DSI but little research output and international collaboration. This would be a particular problem for jurisdictions with high biodiversity and limited scientific research output. The more DSI is avoided, the fewer benefits there are to share. If licenced DSI is not avoided, users will likely need to track and trace licences throughout their use of DSI in order to determine if their ultimate use: a) is compatible with the licence, b) obligates them to share benefits, and/or c) necessitates that they add the licence terms on to their own work.

For this trigger to be more effective, it would need to be retroactively applied to existing data -- or at least this option would need to exist. For this to be workable, the Parties would need to determine who would be allowed to licence 'old' DSI, and would need to ensure that any retroactive licensing of DSI was fair and legitimate. There would also need to be a process in place to enable countries that have granted 'free access' to their genetic resources (GR) also to grant free access to their DSI. However, it cannot be guaranteed that such retrospective application will be acceptable to all Parties (see also Chapter 4.4).

It is important to note that even if *licences* which require benefit-sharing are impractical for all the reasons discussed above, *labels* or metadata fields offer a way for IPLCs to potentially identify data that is relevant to them. Also, if not connected to benefit-sharing or legal restrictions on use, labels could be a good way for the DSI MLM to meet the provisions regarding IPLCs in Decision 15/9. Implementing these labels would require coordination with databases to request that they make metadata fields for Indigenous labels and/or expand existing provenance metadata fields. The simpler and more homogenous the labels, the more easily they could be implemented since data infrastructure required to hold and transmit heterogeneous tags is technically complicated.

2.2.3 Legal feasibility

The legal feasibility of this option is highly connected to the terms of the licences, or what we may think of as the 'terms and conditions of use', created to operationalise this trigger. These licences would set out the potential obligation of the user to pay at some future point in time and would also need to specify the relevant trigger point. Accordingly, the licence is not the trigger, but rather sets out the terms by which benefit-sharing would be triggered at some future point in time, and when and under which conditions such payments may be required. This is an important distinction and the relevant licences will therefore need to specify the relevant trigger point, such as those set out in triggers 4 and 5, as well as when benefit collection will take place. The licence would also need to specify or provide some sort of schedule for users to work out the rate at which payments would be owed, and to whom payments would need to be made (see Chapter 3).

Perhaps the biggest issues from a legal feasibility perspective are those associated with monitoring, compliance and enforcement (see Chapter 4.2). While clearly this trigger draws inspiration from the use of licences under the GBIF, as explored above, these licences do not make provision for monetary benefit-sharing and the GBIF is not involved in enforcement. Indeed, for the most restrictive of the three CC licences, CC BY-NC - which requires attribution and mandates non-commercial use - the GBIF notes that it *'has neither the interest nor the resources to enforce CC BY-NC by legal means. If users severely infringe upon these licences or act in bad faith, publishers may*

choose to pursue legal actions; GBIF will not participate in them.¹² This is not to say that such licences are unenforceable, but rather that consideration needs to be given both to the ‘how’ and ‘when’ of monitoring, compliance and enforcement (see Chapter 4.2), as well as the quality and quantity of information available to assist with these processes. Furthermore, the resources required for monitoring, compliance and enforcement should not be underestimated, especially given the hundreds of millions of DSI and the exponential growth rate of biological data of all types. As with the first trigger point (payment upon access), consideration also needs to be given to which body will be responsible for monitoring, compliance and enforcement, with the same considerations regarding jurisdiction shopping and free-riding also applicable here.

More generally, the use of licences is intrinsically linked to the question of copyright. In essence, licences of this kind operate ‘*alongside*’ copyright, ‘*allowing authors to keep their copyrights while permitting others to use their works*’ (Sara et al., 2022). However, there are questions around whether research data, and DSI in general, ‘*always meet the minimum criteria for copyright protection in a creative work. This renders the permissions and restrictions embodied in an open licence unenforceable as a content creator cannot enforce rights they do not have*’ (Sara et al., 2022).

2.3 Trigger 3 - Licences associated with individual DSI records with mandatory use of cloud services related to DSI storage or processing

Headline messages:

- This trigger requires coordination and cooperation with database managers and cloud service providers, who would also need to implement novel data privacy architecture.
- Creating CBD-compliant databases housed on specific platforms and if use of such databases is mandatory, would restrict where DSI can be analysed and used, as it would require a wholesale shift of ‘compliant’ research to specific platforms.
- Many private and public entities do not use external cloud computing services (and could not be compelled to do so), nor do they use DSI through web interfaces.
- There are significant privacy, innovation and competition concerns with mandating specific cloud computing platforms for entire sectors.
- If the cloud-based fee for the database infrastructure is set up as a paywall or mandate, all of the same concerns from trigger 1 apply.
- If it is set up as a de-coupled micro-levy, scientific progress will not be as hindered (see Chapter 2.6).

¹² <https://www.gbif.org/terms>

Analysis by criterion of para. 9 of Decision 15/9 (Box 1):

- (a): the implicit reliance on databases and cloud service providers to implement, track, and collect benefits make this trigger neither feasible nor practical to implement, meaning that criterion (a) is not met.
- (e) & (f): the severe limitations on open access and potential destruction of existing data interoperability mean criteria (e) and (f) are not met.

2.3.1 Description of trigger

This trigger goes beyond the description laid out in trigger 2 to create ‘CBD-compliant’ databases where users could upload DSI with a CBD-DSI-licence. These CBD-compliant databases would be housed together with pre-selected cloud computing servers. The cloud computing services would charge users for the amount of DSI used or processed, upkeep of the data infrastructure, and genomics analyses and support services run via the cloud. Like trigger 2, this trigger is based on some of the discussion put forth by Kindness and Oldham (2022).

Using CBD-compliant databases could be implemented without the obligatory use of licences. In our technical assessment, we focus on only the implementation of the CBD-compliant databases.

The obligation under this trigger is the use of CBD-compliant databases. The trigger would be the use of the for-cost DSI infrastructure. For the use of CBD-compliant databases, the benefit collection point is the payment for cloud services, either at the point of access or as a back-end micro-levy.

2.3.2 Technical feasibility

This trigger will be technically challenging to implement for the same reason as trigger 1: many DSI databases would be required to implement a rather dramatic and widespread change in technology. This trigger goes beyond coordination and cooperation with databases and requires cooperation with cloud service providers, many of whom are domiciled in the US, a non-Party. As with the paywall, mandating database/cloud provider use requires novel data privacy architecture, especially where industry use of DSI is concerned and significant legal liability around concerns about corporate espionage and trade secrets, which would require very high levels of data security and privacy.

Furthermore, obligatory use of cloud services would restrict how and where DSI can be analysed and used. Most use of DSI is not via web interfaces but rather through large downloads and automated exchanges of DSI across and between databases. The cloud-based-fee proposal assumes that many/most users of DSI use and want cloud services. However, many private and even public institutes download data directly to their local servers/hardware in order to use in-house software pipelines and analysis tools. Public scientists also use government-paid-for cloud services; for example, in Germany, the deNBI cloud¹³ (paid for by the Germany Ministry of Research and Training) or in the EU, the European Open Science Cloud¹⁴ (funded by the European Commission).

¹³ <https://www.denbi.de/about>

¹⁴ <https://digital-strategy.ec.europa.eu/en/policies/open-science-cloud>

These specialised scientific cloud services were developed both because of privacy concerns raised by for-profit cloud services and because research funders determined that these solutions can be cost-efficient when funding large research portfolios.

There is also an industry innovation concern with the mandatory cloud computing platform; businesses are worried about their competitors gaining access to their confidential activities. Requiring use of CBD-compliant databases might have anticompetitive effects if all DSI from many sectors were stored in one central location and would likely need to be investigated by the European Directorate-General of Competition (DG COMP), as well as national competition authorities around the world before this trigger could be operationalised.

Even if the infrastructure is set up, user uptake of the system might be low, particularly if it is slow to start, confusing, easy to avoid, and presents competitive concerns. Additionally, this trigger would not capture the use of DSI by institutions which have closed private databases, as COP could not force industry to use specific tools/platforms to conduct their business.

This trigger restricts open access to data and potentially limits non-commercial research and innovation. Even if the fee is charged on *cloud computing costs* and not for *access* to the DSI itself, it may ultimately function like a paywall (see discussion in chapter 2.1 for the infeasibility of paywalls). However, it is possible that the cloud-based fee could function as a de-coupled micro-levy (i.e. not associated with public DSI databases). This will be discussed Chapter 2.6.

2.3.3 Legal feasibility

The legal feasibility of this option very much depends upon its operationalisation. Issues to be clarified include: how and where disputes are to be settled in respect of services rendered and the fees charged; the applicable law that will govern such disputes; liability and indemnification for such services where error, negligence or related deficiencies are alleged, as well as who will underwrite associated costs, including transition to the cloud infrastructure; and issues around data protection, security, and competition. Considerable concern is likely to exist around corporate espionage and trade secrets, which would require very high levels of guarantee on data security and privacy, with associated indemnification and insurance required. As with several of the triggers discussed in this study, any personal data will require a privacy notice and processing in line with applicable law, including the GDPR (see also Chapter 4.6).

In terms of benefit collection, who will charge the fee and when will also need to be clarified. If it is the cloud service provider, this is placing the likely success of the DSI MLM in the hands of Amazon, Microsoft or Google¹⁵, or another large multinational corporation. Safeguards will be required to ensure that the cloud service host does not have access to use such data for any activities related to their own business interests, e.g., training artificial intelligence models and machine learning.

¹⁵ Who between them account for over 60% of the cloud computing market; <https://uk.pcmag.com/old-cloud-infrastructure/131713/four-companies-control-67-of-the-worlds-cloud-infrastructure>

2.4 Trigger 4 - Commercialisation fee based on individual DSI products

Headline messages:

- This trigger would not impact academic research and innovation or open access.
- Parties would need to agree on a definition of DSI-based product and create guidelines for implementation.
- This trigger will require definitions on what counts as 'DSI-based'. The UNCTAD TraBio product classification could support implementation although complexity might be a drawback.
- This trigger may re-ignite the debate about tracking and tracing.

Analysis by criterion of para. 9 of Decision 15/9 (Box 1):

- (d): given that this trigger is not necessarily related to any kind of contractual relationship with users of DSI, Parties will need to further clarify the way in which legal certainty is provided to users in respect of DSI usage.

2.4.1 Description of trigger

This trigger would require those commercialising DSI-based products to share benefits. For this study, 'commercialisation of a DSI-based product means: *'placing on the market a product whose development and/or production involves access to, knowledge of and/or use of digital sequence information'*.

While the above definition is relatively clear, given that there is no current list of 'DSI products', significant effort would be needed to define, create and regularly update a definition and potentially a list or database of DSI-based products.

The obligation would need to come through a Decision of CBD Parties on the DSI MLM, the trigger would be the commercialisation of the product, with the benefit collection point at a later point such as n months after the end of the financial year for each country if fees are collected on a country-specific basis, or at another date agreed by the Parties if fees are collected on a regional or international level.

2.4.2 Technical feasibility

This trigger would not impact academic (non-commercial) research and innovation or open access to DSI. To implement this trigger at the most basic level, Parties would need to agree on a definition for DSI products, i.e., what 'counts' as a DSI-based product. A consensus-based definition accompanied by guidelines for users might suffice for implementation. These guidelines could be suggestive; i.e., providing categories that DSI products may fall into, or prescriptive; i.e., containing a specific list of product classes or even individual products that are 'DSI products'. The suggestive approach has the benefit of being theoretically easier to negotiate while the prescriptive approach will provide legal clarity to users and therefore likely generate more predictable benefits.

Parties will need to consider what product classes 'count,' even if they do not end up negotiating a specific list. This identification could be done using the UNCTAD TraBio product classification

(UNCTAD/DITC/TED/2023/4; UNCTAD, 2023). The TraBio database outlines categories of biodiversity products. These could potentially qualify as 'DSI products', and include:

- A. Live animals and plants
- B. Food and beverage
- C. Agricultural inputs
- D. Natural ingredients
- E. Perfumery, cosmetic, personal care and room care preparations
- F. Pharmaceuticals
- G. Hides, skins, leather, furskins and products thereof
- H. Natural fibres and articles thereof
- I. Wood and derived products
- J. Vegetable plaiting materials and articles thereof
- K. Other products of animal origin
- L. Other products of plant origin
- M. Miscellaneous

However, as this dataset has over 2,220 rows of data identifying different biodiversity-based goods, it would be difficult for any individual to identify which of these specific goods are definitively 'DSI products' and reaching consensus on a list of these products amongst Parties would be even more difficult. However, this list or other regional lists might be useful for national or regional implementation.

It is also unclear if and how companies use these classifications for their own product portfolios, so there would need to be further investigation into how UNCTAD is implemented in corporate workflow systems. The list of products and/or guidelines would potentially need to be updated regularly to account for technical and scientific innovation.

This trigger could reignite the tracking and tracing discussion. Parties that wish to have benefits returned directly to them on a bilateral basis without going through the global fund, might use this trigger to require DSI-based products be labelled with country of origin so that benefits can be shared back bilaterally. This would require users to track the country of origin of specific DSI for all DSI-based products to determine which should be paid at the national level and which at the global level. Parties would need to determine whether such an approach, if broached, would be compatible with para. 5 of Decision 15/9¹⁶.

¹⁶ <https://www.cbd.int/doc/decisions/cop-15/cop-15-dec-09-en.pdf>

2.4.3 Legal feasibility

If benefit collection takes place based on a fee charged on individual DSI products, this raises three potential legal issues. First, it may be difficult to obtain accurate figures on, for example, the sale of DSI products at a company level, significantly hampering the ability to ensure that the correct payments are made. The Parties will need to decide whether companies will be allowed to self-report on such figures; publicly available balance sheets do not typically provide such granularity of detail. Second, as noted above, countries may wish to have monetary benefits returned directly to them from DSI generated from their own sovereign GR, with benefits from products generated from DSI generated from non-national GR (including DSI generated by AI) then returned to the MLM global fund. This would clearly require tracking and tracing to ensure that funds are allocated appropriately between the relevant national DSI mechanism and the DSI MLM. While this is largely a technical issue, national legislation may be required to arbitrate on which mechanism (national or global) payments should be made, particularly if there is a difference in fees due. On a related note, consideration will also need to be given to where and on what basis benefit-collection will take place. National level collection seems the most appropriate method here, but issues around individual country capacity to participate in the collecting, monitoring, compliance and enforcement aspects of the DSI MLM funds, especially in Least Developed Countries (LDCs; see Chapter 4.5) need further consideration.

Finally, as also discussed in Chapter 4, there will not be universal adoption of the DSI MLM, and therefore, the possibility of border checks on goods leaving a non-Party and entering a Party may be required to ensure consumers/wholesalers do not seek to avoid the fee by way of imports. This would be particularly important where the fee is charged on intermediate products which are then imported into another country for formulation into a finished product. Companies, when faced with a choice between import of an intermediate product from a non-Party which does not charge the fee, and a country which does, would, if acting in an economically rational sense, choose to import from the non-Party to the extent the fee makes the product in question more expensive. This clearly has the potential to lead to unintended trade distortion.

2.5 Trigger 5 - Commercial activity related to DSI

Headline messages:

- This trigger would not impact academic research and innovation or open access.
- Global terms of use could be housed within the DSI MLM or linked to point of access to DSI.
- Terms of use could provide legal certainty; however, posting terms of use would require coordination with public databases.
- Parties could decide on a definition of commercial activity. Industry users would need to self-assess whether they are in scope.
- Parties could also identify specific companies or sectors as 'DSI-using,' and could use International Standard Industrial Classification (ISIC) codes. Again, coming to consensus on specific sectors will be complicated.
- Parties will also need to determine where on the value chain 'DSI-using' companies who are obligated to share benefits should be (e.g., retail level, all along the value chain).

Analysis by criterion of para. 9 of Decision 15/9 (Box 1):

— From a technical standpoint, this could meet all the criteria.

2.5.1 Description of trigger

This trigger would require those users engaging in commercial activity related to DSI to make DSI benefit-sharing payments. For this study, ‘commercial activity related to DSI’ means: *‘Any activity in the nature of trade, commerce or business that involves: the generation, storage and/or analysis of digital sequence information, or the development, production, transfer, exchange and/or provision of products, assets and/or services that involve access to, knowledge of and/or use of digital sequence information’.*

Under this option, the obligation would need to come through a Decision of CBD Parties on the DSI MLM, the trigger would occur at the point of commercial activity (as defined above), while the benefit-sharing collection point would need to be defined by the Parties but would likely be on an annual (or recurring) basis.

There are several options for creating the obligation to share benefits:

- by posting terms of use in the public DSI databases;
- by posting terms of use in the DSI MLM and allowing users to self-assess, register, and pay directly to the MLM based on the above definition;
- by identifying sectors obligated to share benefits and requiring those identified sectors to pay benefits.

Depending on implementation, these ‘obligation-creating’ options are not necessarily mutually exclusive.

2.5.2 Technical feasibility

2.5.2.1 Global terms of use linked to access

Global terms of use could be added or linked to the point of access to DSI (i.e., DSI databases) to notify users that commercial activity will likely incur benefit-sharing obligations. The terms of use would guarantee commercial users of DSI from public databases legal certainty for their use of DSI,¹⁷ provided they pay the required amount of money into the global fund. However, it is possible that commercial users would begin to avoid public databases.

There are a range of technical options for implementing terms of use, ranging from heavy to lightweight. A simple ‘pointer’ to the MLM and global fund would likely be received differently, and have different legal implications, than a registration-based system that requires databases to disclose user information. The discussion of technical feasibility in respect of triggers 1 and 2 (Chapters 2.1.2 and 2.2.2) is relevant here in terms of providing further elaboration on the

¹⁷ Provided there are no overlapping additional DSI ABS schemes in operation such as national schemes

difficulties of identifying appropriate databases and coordinating with them on use of the DSI ecosystem.

2.5.2.2 DSI MLM-based system

A further option is that Parties could simply decide on a definition of commercial activities related to DSI, and commercial DSI users would then determine for themselves if they fall under the definition provided. This self-assessment may cause some confusion and could lead to avoidance of obligations, though national level legislation may help to obviate this somewhat (see Chapter 2.5.3).

To ensure legal clarity for commercial users, global terms of use could be housed within the DSI MLM as a part of a registration system with notices posted to databases and other websites to increase user awareness of the MLM and associated obligations. Users could then register with the system, and thereby ensure legal certainty for their use of DSI if they signed up and complied with terms set by the Parties.

This option preserves open access to DSI for non-commercial users and does not hinder scientific research and innovation, or impact DSI interoperability and exchange. The system would present the benefit-sharing terms to users, including their obligation to pay an amount of money (fee or percentage) annually into the global fund as their monetary benefit-sharing. As noted above, signing up to this registration system could provide users legal certainty for their use of DSI.

2.5.2.3 Set list of DSI-using entities

Alternatively, Parties could identify companies as ‘DSI-using’ (although a clear and transparent process for doing so would be required) and declare that they are obligated to share benefits. For example, this could be done using the United Nations’ ISIC codes, which are, according to the United Nations Department of Economic and Social Affairs (UN/DESA), used by the majority of countries as they are written at the international level or in country-specific implementations. ‘*ISIC is a standard classification of economic activities arranged so that entities can be classified according to the activity they carry out*’¹⁸. The DSI MLM could focus, for example, on specific sections from the 4th ISIC revision (ST/ESA/STAT/SER.M/4/Rev.4; UN/DESA, 2008) including:

- A: agriculture, forestry and fishing,
- C: manufacturing (including pharmaceuticals, medicinal chemical and botanical products),
- G: wholesale and retail trade,
- J: information and communication, and
- M: professional, scientific, and technical activities.

This list is not exhaustive and, similar to the UNCTAD codes discussed earlier, there are thousands of ISIC codes. Parties (or national/regional implementation efforts) would need to select the appropriate codes. The more activities included at the section level (rather than on the more granular levels), the more commercial entities will be obligated to share benefits. ISIC codes are more widely used than the TraBio classification. For this reason, this trigger will be slightly easier

¹⁸ <https://ilostat.ilo.org/methods/concepts-and-definitions/classification-economic-activities/>

for companies to understand and comply with, than if they have to analyse their product portfolio. This will also make the development of a monitoring framework more straightforward.

Parties may also need to determine if there is a point on the value chain where users should be obligated to pay or if all users along the value chain need to pay. If companies across the value chain are obligated to pay, there may be accumulation of DSI benefit-sharing costs, resulting in more expensive consumer products on the market. However, analysing the value chain and picking a singular point would be very difficult unless Parties decide to exclusively obligate users operating at the retail level. Parties will also need to decide if there should be differentiated obligations for companies of differing sizes or sectors. Each additional level of granularity requires further negotiations and work on who precisely is 'in' and under what terms.

2.5.3 Legal feasibility

As noted above, there are a number of ways to identify those obligated to pay. We deal with the legal implications and legal feasibility of each in turn.

2.5.3.1 Global terms of use linked to access

As set out above, the obligatory element of this trigger could be operationalised in at least two ways; a simple 'pointer' to the DSI MLM and global fund, which would then signpost users to register with the DSI MLM, and a registration-based system that requires databases to disclose user information. Both will have different legal implications. For the latter option, as with triggers 1 and 2, hosting terms of use within databases would require those databases to build infrastructure to retain the details of those agreeing to the specified terms as well as share these details with the DSI MLM (and potentially onwards to Parties if monitoring, compliance and enforcement is operationalised at national level). There may also need to be mechanisms in place to verify users when accessing DSI. Data processing agreements will need to be agreed upon in order for this information to be shared in a legal way. One advantage this option has over several other options (notably triggers 1 and 3) is that databases, or another third party, e.g., cloud computing companies, would not be involved in any collection of fees, thereby mitigating against some of the legal difficulties associated with such third-party entities performing such a function.

For this analysis, we assume that identified companies or sectors would be presumed to have used DSI. This presumption, and legal consequences of access to DSI, will need to be set out in the terms of use, and has some legal challenges. The option of a rebuttal to this presumption, where companies can demonstrate that they did not use DSI and therefore are not liable to the Fund, may also need to be explored when operationalising the DSI MLM. The lack of a rebuttable presumption raises general concerns around natural justice, and may conflict with domestic regimes around the protection of property rights and expropriation of investments. Accordingly, if this presumption is retained it should be subject to rebuttal, and a process for adjudication on this issue should also be provided. As with many of the different options discussed in this study (see also Chapter 4), consideration will also need to be given to issues of monitoring, compliance and enforcement. For this and the other options under this trigger, the Parties will also need to decide who will collect these payments, if they are not made directly to the DSI MLM fund (see also Chapter 3). Where funds are collected nationally, issues around individual country capacity to do so need further consideration by the Parties (see Chapters 3 and 4).

2.5.3.2 DSI MLM-based system

The DSI MLM-based system would operate in a broadly similar way to the ‘pointer’ to the MLM/global fund, discussed earlier. Processes would need to be put in place to monitor such registrations, together with the introduction of mechanisms for compliance and enforcement. National legislation to require registration by companies under the specified circumstances, together with penalties in the absence of registration, may be the preferred choice here, and mechanisms to rebut the presumption of use (discussed earlier) should be considered. As with triggers 4 and 6, Parties will need to decide who will collect these payments, if not paid directly to the DSI MLM fund.

2.5.3.3 Set list of DSI-using entities

If Parties instead opt to identify companies as ‘DSI-using entities’ and declare that they are obligated to share benefits, as with the previous options, this would likely require national legislation to implement but would not require any changes to database operations. For the latter option, the discussion earlier on the possibility of introducing a process for rebuttal of DSI use is also relevant here, as are the previous considerations in respect of monitoring, compliance and enforcement, as well as the need to decide who will collect these payments, if they are not made directly to the DSI MLM fund.

2.6 Trigger 6 - Micro-Levy on products or services associated with DSI generation, laboratory equipment, and/or cloud-computing fees activity related to DSI

Headline messages:

- Already standard business practice in some parts of the world, but would require country-level changes in tax policy.
- Will not restrict open access to DSI or research and innovation.
- Micro-levy could be applied to any number of things: DSI sequencing or synthesis equipment, other lab equipment, or cloud computing services.
- Cost would theoretically be passed down to the final consumer.
- Levies have the potential to garner significant, predictable monetary benefits. Copyright-based levies generate ca. €500 mil. annually in Europe alone.

Analysis by criterion of para. 9 of Decision 15/9 (Box 1):

- (d): given that this trigger is not necessarily related to any kind of contractual relationship with users of DSI, Parties will need to further clarify the way in which legal certainty is provided to users in respect of DSI usage.

2.6.1 Description of trigger

This trigger would be a micro-levy implemented at country level on products or services associated with DSI generation and/or storage. These levies would be collected by companies producing the equipment/services and sent to the global fund.

The obligation would be a State creating a new tax. The trigger would be the purchase of relevant items and the benefit collection point would be set by the State.

2.6.2 Technical feasibility

Technically, these levies are already standard business practice in some parts of the world. For example, Germany provides copyright holders small financial returns on a levy placed on the purchase of copy machines and printers. Micro-levies would not hinder open access or scientific research and innovation, and in most cases they would not hinder research in high-income countries in a significant way. Depending on how (or if) they are set at the state level, they might impact research in LMICs. This trigger may fail to meet criterion (d) of para. 9 of Decision 15/9, as, depending on how it is implemented at the national level, it may not provide legal certainty for users.

We define micro-levies as, *'small charges on high-volume purchases that should not impact the behaviour of the purchasing customer'* (Scholz et al., 2020). According to a 2020 WiLDSI report (Scholz et al., 2020), the DSI micro-levy could be linked to aspects of DSI generation and be applied to DNA sequencing/synthesis services, laboratory reagents, or equipment, among other things. In addition, as discussed in trigger 3, a micro-levy could also be applied to the use of cloud services (not connected to DSI databases) related to biological resources or by the sectors identified in trigger 5. Such a micro-levy could be captured and paid for by cloud service providers (and then passed on to consumers through their bill) on all biological resource-related users, thereby contributing additional money to the DSI MLM. This levy, since it would not be charged at the point of access, would not restrict access to data.

If this trigger was put in place, companies would, in practice, pass on the final cost to consumers. Existing examples of these levies are the private copy levy (Wijminga et al., 2017) as well as the solidarity levy in some countries on airline tickets which supports Unitaid. These micro levies garner significant benefits; in 2015, private copying levies generated revenue of over 580 million euros in the EU (Wijminga et al., 2017).

2.6.3 Legal feasibility

From a legal perspective, this option is perhaps the most straightforward to implement, particularly since there are examples of successful micro-levies in operation in several countries. If implemented at national level - and we would suggest this is the most straightforward of options - national legislation would likely be required. There may also be issues with implementation/compliance capacity, something we discussed above in several of the triggers. Potential deficiencies in implementation/compliance could arise here. Not all countries will, for example, have the necessary capacity to implement micro-levies, and this may impact the success or otherwise of this option.

3 Rate setting

Any trigger chosen would require the Parties to suggest, if not determine, appropriate rates for benefit-sharing. These rates could take the form of predetermined fees or a rate based on a percentage of some operating value, depending on the trigger. For both forms of rate setting, Parties will need to take into account a variety of variables, enumerated later. Some triggers could only function with a set of fees and some could function with either set fees or a rate based on a percentage of an operating value (Table 1).

For triggers 1 and 3 Parties would need to determine a set of fees for benefit-sharing. For triggers 2, 4 and 5, rates for benefit-sharing could take the form of set fees determined by the Parties, or percentages by which users would determine their own obligations. For trigger 6, Parties could suggest rates, but it would be entirely up to States to determine how to set the micro-levy; for this reason, we will not address rates for trigger 6 here.

Table 1. Possible rate setting forms by trigger.

Trigger	Set Fee	Percentage of Operating Value
1. Payment at access	✓	
2. Licences associated with DSI records	✓	✓
3. Fee on cloud service provision (if applied at point of access)	✓	
4. Commercialisation of DSI product	✓	✓
5. Commercial activity related to DSI	✓	✓
6. Micro-levy (and a fee on cloud service provision, if applied on the back-end)	Set by states	

Source: own elaboration

More discussion is needed as to who will collect these payments, with this question raising several legal issues for consideration by the Parties (see Chapter 4). Under certain triggers, and depending on their operationalisation, payments could of course be collected by relevant national or regional authorities. Tax authorities would be well placed to collect such a fee, though of course, as discussed in trigger 4, not all countries will have the necessary capacity to participate in the collecting, monitoring, compliance and enforcement aspects of the DSI MLM funds, especially in LDCs (see Chapter 4.2).

3.1 Considerations for triggers 1 and 3

For triggers 1 and 3 (if implemented at the access point), Parties would need to determine a set of fees for benefit-sharing. Factors for consideration for a set list of fees are: individual or institutional

charges; tiered fees or exemptions for access by those in LMICs and/or academia; or tiering based on the amount of DSI use. In practical terms, the lines between commercial and non-commercial use are often blurred with, for example, research undertaken by universities 'spun out' into commercial enterprises.

Fees set, published, and monitored by the MLM would be fairly easy to evaluate. In addition, predicting long-term monetary benefit-sharing amounts would be simple, resulting in sustained, predictable benefit-sharing. The set list of fees would need to be periodically updated by the Parties or include an automatic ratcheting mechanism.

3.2 Considerations for triggers 2, 4 and 5

For triggers 2, 4 and 5, Parties could either set rates through set fees or as a percentage of some operating value. There are pros and cons to both options.

3.2.1 Percentage-based

PROS: simple way for users to calculate their owed benefits; theoretically net the most benefits; fair way to calculate benefits; responsive to changes in the market (company growth/sector growth etc.).

CONS: monitoring will be difficult; depending on the metric chosen, forum shopping/avoidance might be easy.

Calculating annual benefit-sharing amounts based on percentages of a commonly used accounting metric, such as turnover (meaning gross income after deductions for VAT, taxes and trade discounts), earnings before interest and taxes (EBIT), etc., is a simple way for commercial users to calculate their owed benefits. In determining the appropriate metric, the Parties need to take into account how to handle multinational subsidiaries of companies which may be registered in several jurisdictions.

Calculating benefits from a percentage of an accounting metric could theoretically net more money than fee payments, as it captures company growth and innovation quickly. It is also a fairer way to calculate owed benefits, as fees will undercharge and overcharge some users. However, percentage-based payments will be difficult to monitor without auditing financial statements of companies.

One proposal is to calculate benefit-sharing obligations based on the average of the last three years of global turnover. This proposal has the advantage of excluding start-ups and other new companies, though this could also create the perverse incentive encouraging companies to fold and re-establish to escape this obligation and wouldn't capture - or at least would lag in capturing - high growth companies. It also adds an additional layer of accounting that would make it even more difficult to monitor and ensure compliance.

3.2.2 Set list of fees

PROS: easy for users to quickly understand what they owe; easy to monitor by the MLM; easy to predict long-term, sustainable benefit-sharing.

CONS: likely will have to be set at a rate lower than percentage; set list would need to be updated periodically.

Alternatively, Parties could decide to calculate owed benefits by creating a set list of fees for obligated users to quickly understand how much they need to send to the global fund annually. Given their unequal application, fees would likely have to be set at a rate lower than the percentage that users would tolerate. When there is an option between set fees and percentage-based payments, fees set, published, and monitored by the MLM would be easier to monitor. In addition, predicting long-term monetary benefit-sharing amounts would be simpler, resulting in sustained, predictable benefit-sharing. As mentioned earlier, the set list of fees would need to be periodically updated by the Parties or include an automatic ratcheting mechanism.

3.2.3 Level of granularity

In setting the basis for both kinds of rates (percentage or set fees), the Parties will need to decide on the level of granularity of the rate list. For trigger 4, they will need to determine if they will base the rate on a per-product basis or on aggregate product portfolios. For trigger 5, they could choose to have varied payment amounts based on product portfolios, specific products, size and/or sectors of the obligated users.

Additional consideration will need to be given to the possibility of differential fees based on the economic position of the respective country. This is because ultimately these fees, particularly if applied to consumer-based products, will be passed onto the end consumer. Furthermore, Parties will need to decide if there is a point on the value chain which triggers payment, or whether all users along the value chain need to pay.

3.3 Legal analysis

On a legal note, the issues around company self-reporting, monitoring, compliance and enforcement discussed in trigger 4 are also relevant here. Payment based on national metrics might result in forum shopping, and registration of business in non-Party jurisdictions in order to avoid any fee is a considerable risk with this option. Global turnover is a useful alternative, and would ameliorate, at least to an extent, the risk of forum shopping. However, it is important to note that verification of (global) turnover figures for non-publicly listed companies will be difficult, raising the possibility of avoidance. The question of 'who' will verify any self-reported figures and ensure compliance here also needs to be considered. Additionally, where a fee is based on global turnover (as discussed above), national authorities can still charge the fee, but consideration needs to be given to how such fees will be disaggregated across jurisdictions.

4 Common legal issues

There are a number of legal challenges present across each or a number of the triggers discussed earlier, which may be inherent to any effort to create a DSI MLM. This Chapter therefore provides a discussion of ‘common legal issues’ present across all or several triggers.

4.1 Forum shopping

Any DSI MLM system, no matter how carefully designed and worded, will not have universal application as there will be countries which remain non-Parties and hence outside of the jurisdictional scope of the system. Depending on the design of the DSI MLM, this would mean that: a) databases hosted within these countries, b) end users accessing the database, and/or c) products for sale or revenues generated in that jurisdiction, would fall outside of the scope of the DSI MLM, and therefore any obligation with respect to benefit-sharing under the mechanism. This could result in the creation of what can be thought of as ‘DSI safe havens’, incentivizing databases and/or companies to be domiciled in these countries to escape any obligations within the mechanism, in much the same way that tax havens operate to attract companies based on their low rates of corporate tax. The creation of DSI safe havens is all the more likely if the ‘safe havens’ in question already have large amounts of research and development (R&D) capacity, or host large databases; e.g., the US, which is a non-Party and highly unlikely to become Party to the CBD and therefore, *de facto*, not part of the MLM irrespective of its design. This could in turn incentivise end users wishing to avoid any benefit-sharing obligations, to seek to access DSI through a database hosted in a safe haven, knowing that it will not enforce revenue collection on behalf of the DSI MLM. The choice of trigger for benefit-sharing as well as add-on incentives or disincentives may increase or decrease the likelihood of such forum shopping, depending on their ultimate design. For example, for globally-operating companies seeking freedom-to-operate and legal certainty for their global portfolio, incentives (and corresponding disincentives) that enable a US-based branch to join the MLM should logically be preferred over triggers that cannot offer this inclusion. The design of the DSI MLM should therefore be sufficiently open to allow for voluntary compliance. This may, for example, be best operationalised via direct payments to the DSI MLM, rather than (exclusively) via State authorities.

4.2 Compliance/enforcement

A central issue for the effectiveness of the DSI MLM is how benefit-sharing revenues will be collected and by whom. While discussions may proceed on the basis that all users who ought to pay will indeed do so, consideration needs to be given to what happens when users are obligated to provide funds to the MLM but do not pay, and how the obligation to pay is created and enforced. This requires strong oversight and governance whereby the collecting entity (which could under certain triggers be the DSI MLM), must have the capacity to form legal relations, monitor compliance, and seek enforcement if necessary (Rourke et al., 2019). For enforcement to occur, for at least some of the triggers discussed, legal relations must have been formed between the collecting party and the end users accessing DSI, accompanied by a clear and enforceable legal obligation to pay. This gives rise to a number of issues including how legal relations are to be formed, who will be responsible for enforcement, in what jurisdiction this ‘legal obligation’ actually originates and whether the relationship aligns with notions of natural justice found in contract law (Switzer et al., 2024). In the absence of strong, enforceable legal obligations, the DSI MLM will be relying partially on goodwill to ensure any revenues owed are actually paid into the fund, which is a high-risk strategy, and from a practical perspective will make forecasting projected income difficult,

if not impossible. Given the need for predictable and sustainable financing for biodiversity, this would clearly be a suboptimal outcome. This could potentially be overcome, however, if the incentives for participation in the MLM are sufficient to make the system attractive to join; i.e., if they provide legal certainty and ‘amnesty’ in respect of enforcement of national DSI legislation, where the latter exists.

As noted above, enforcement can only occur on the basis of a clear, enforceable legal obligation. However, while enforcement for all triggers will require effective monitoring of compliance, certain triggers will also require tracking of DSI usage. In essence, depending on the trigger, we might need to know who has accessed and/or used DSI, and if this use has resulted in the commercialisation of a product, so as to be able to know if end users have fully paid what they are obligated to, as well as to have the capacity to instigate legal proceedings against those who do not pay. Whilst monitoring and tracking is, primarily, a technical issue, it does give rise to legal issues around who will be responsible for monitoring, as well as what happens if the responsible person/body does not engage in monitoring, and the level of information they are provided with in order to undertake monitoring and compliance. The cost of monitoring and enforcement also needs to be considered, as these certainly are not cost-neutral activities. However, as discussed earlier, incentives that encourage participation in the DSI MLM and make the system attractive for users to participate may reduce the costs associated with monitoring and enforcement, to the extent that such incentives make obligated users more likely to comply than to avoid their obligations. Where such incentives lower the cost of compliance and monitoring, they may also make the system more attractive for Parties who already have, or are considering, their own domestic ABS legislation on DSI. Finally, assuming that for at least some of the triggers payments will be made in arrears, consideration needs to be given to how debts will be recovered in the case of non-payment.

4.3 Overlap with other ABS systems/fragmentation

Different triggers for benefit-sharing have different risks of increasing regime overlap and fragmentation. This is a significant problem, as it risks the ability of any DSI MLM to meet the requirements of para. 9 (h) of Decision 15/9 (Box 1), and is likely to become more difficult to resolve, given the number of ongoing DSI ABS negotiations, as well as national ABS systems that already capture DSI. Notably, the ‘interface between national systems and the multilateral mechanism on benefit-sharing’ is noted in the Annex to Decision 15/9 (k) as an issue for further consideration. Given this multiplicity of potentially overlapping DSI ABS schemes, including national legislation, there are practical and of course legal issues associated with such overlap. Considerable efforts will be required to harmonise the DSI MLM instrument with other DSI benefit-sharing regimes to bring about legal certainty, predictability and avoid inviting users paying twice (or indeed, more than twice)¹⁹. It is difficult to make general recommendations in terms of how to ensure such harmonisation since much will depend on the scope of application of the different DSI ABS regimes/legislation at issue. However, where a country has national DSI ABS legislation, it seems difficult to see how this could operate at the same time as the DSI MLM without considerable confusion – and hence lack of legal certainty – arising as to ‘who’ to pay and how much to pay. Such overlaps may also work to disincentivise users from participating in the fund, or slow down the generation of benefits to the fund. Such countries may therefore need to make a choice between

¹⁹ https://www.dsiscientificnetwork.org/wp-content/uploads/2023/12/1.-Amber-Scholz_DSI_harmonization_DSISN_Geneva_Nov2023.pdf

national DSI ABS legislation and the DSI MLM. The use of country tags to filter out DSI from such jurisdictions could support this, although this could have the perverse incentive that users filter out such tagged sequences if the terms of any national scheme are seen as less favourable than those applying to the DSI MLM. The reverse could, in theory of course, also hold true and negatively impact the monetary benefits accruing to the DSI MLM.

4.4 Scope

The scope of the DSI MLM, both in terms of material and temporal scope, is directly relevant to its legal feasibility. For example, if it is determined that the scope of the DSI MLM includes all DSI in publicly available databases, then this will lead to the inclusion of DSI which would not otherwise fall within the CBD; e.g., human sequence data (9.3% of the INSDC dataset), and/or DSI from areas beyond national jurisdiction, such as the High Seas (0.6% of the INSDC dataset) and Antarctic, or plants listed in Annex 1 of ITPGRFA (9.9%). Ultimately, the modalities of the DSI MLM will determine the material scope of application of the DSI MLM, but from a legal perspective it should not be forgotten that DSI in publicly available databases may fall under other, non-CBD legal regimes, which could result in frictions between different legal regimes (see also discussion earlier). This risk could, however, be ameliorated if the CBD DSI MLM were sufficiently open to include other ABS regimes and/or if all DSI-regulating mechanisms acknowledged that payment in one DSI regime 'counted' (and provided legal certainty) for use of the global public DSI dataset (Sett et al., *in review*). Technical and legal architecture would then need to be built to both allow for and ensure mutual recognition across regimes of this single payment.

In terms of temporal scope, it could be assumed that the DSI MLM only applies to DSI created after the adoption of the Decision 15/9, though this will present difficulties in operationalising the mechanism (see trigger 2 earlier on the difficulties posed by non-retroactive application). A number of alternative temporalities of scope could, however, be suggested by the Parties. In addition, even if we assume that the DSI MLM applies to DSI created after Decision 15/9, this raises the question of how to treat DSI accessed prior to Decision 15/9, but in respect of which a product is only developed and brought to market after the introduction of the mechanism itself. The Parties will need to decide whether this would be considered to fall within or outside the scope of the DSI instrument. Furthermore, DSI generated prior to Decision 15/9, but only accessed and used after the mechanism is introduced, raises similar legal issues for consideration by the Parties. If the instrument applies only to sequences uploaded *after* the mechanism comes into force, then there will be a strong incentive to bypass these samples, in favour of sequences uploaded *before* the mechanism which do not have any benefit-sharing obligations attached to them, but still have scientific utility for the process/R&D in question. In any case, the temporal scope of the instrument needs to be agreed by the Parties to ensure legal certainty as well as uniformity in compliance and implementation. The task of agreeing the temporal scope of the DSI instrument should not, however, be underestimated. Notably, the Nagoya Protocol is silent on its temporal scope, not because the issue was not considered during its negotiation, but rather due to the inability of negotiators to agree on this matter (see chapter 3 of Morgera et al., 2015). However, the BBNJ

Agreement has an explicit presumption in favour of the retroactive temporal application for marine genetic resources (MGR) and DSI²⁰.

Of course, scope also goes to the more practical issue of which type of databases will be covered by the DSI MLM. While much of the analysis above is based on the presumption that the scope of the DSI MLM applies to all DSI in publicly available databases currently widely used by both non-commercial and commercial users, it is possible (as noted, for example, earlier at trigger 5) that industry would avoid public databases once the DSI MLM comes into force, and use and develop their own private (internal) databases with a mix of both company generated DSI as well as publicly available DSI that was previously downloaded. Such activity, to the extent it leads to commercial activity/income generation, is captured in certain triggers discussed above (triggers 4 and 5). Accordingly, even if private databases retained by companies are determined as being outside the formal legal scope of the DSI MLM, they can be captured indirectly under certain triggers.

4.5 Capacities to monitor, collect and enforce

Further consideration needs to be given as to the extent to which developing and least-developed countries are able to participate in the collecting, monitoring, compliance and enforcement aspects of the DSI MLM funds. Some developing and least-developed countries, though by no means all, may have limited capacity to do so. This is especially pertinent if these activities are to be done either by the country of origin of the DSI, or at the point of sale for products associated with DSI. In this regard, Article 20(1) of the CBD text²¹ in respect of '*financial support and incentives in respect of those national activities which are intended to achieve the objectives of this Convention*', and particularly Article 20(5) on the '*specific needs and special situation of least developed countries*' in respect of funding, should be considered with a view to ensuring that all Parties can adequately participate in the collection, monitoring and compliance activities which are required under the DSI MLM. Similarly, not all commercial users have the same ability to monitor DSI usage, a point that needs to be reflected upon in the design of different triggers (see e.g., the discussion of tracking and tracing under trigger 4 earlier).

4.6 Data

The collection of names, email addresses and relevant financial data under any of the options outlined raises issues of personal data protection. Any personal data will require a privacy notice and processing in line with applicable law, including the EU GDPR²². Relevant questions for data controllers are the purpose for which personal data is collected, and the legal basis for such

²⁰ BBNJ Agreement, Article 10 (1); '*The provisions of this Agreement shall apply to activities with respect to marine genetic resources and digital sequence information on marine genetic resources of areas beyond national jurisdiction collected and generated after the entry into force of this Agreement for the respective Party. The application of the provisions of this Agreement shall extend to the utilisation of marine genetic resources and digital sequence information on marine genetic resources of areas beyond national jurisdiction collected or generated before entry into force, unless a Party makes an exception in writing under article 70 when signing, ratifying, approving, accepting or acceding to this Agreement*'. <https://www.un.org/depts/los/XXI10CTC%28EN%29.pdf>

²¹ <https://www.cbd.int/convention/articles/default.shtml?a=cbd-20>

²² For a useful overview, see [EU data protection rules - European Commission \(europa.eu\)](https://european-commission.europa.eu)

processing. Where data is shared with third parties, GDPR-compliant data protection agreements will need to be created.

5 Conclusions

Each trigger discussed in this study presents potential technical and legal problems. While none are perfect, there are some triggers that are better suited to the DSI MLM than others. In terms of meeting the criteria laid out in para. 9 of Decision 15/9 (Box 1), trigger 5: ‘commercial activity related to DSI’ stands out. Triggers 4 and 6: ‘commercialisation fee based on individual DSI products’ and ‘a micro-levy on products or services associated with DSI generation, laboratory equipment, and/or cloud-computing fees’, respectively, meet many of the criteria. Triggers 1, 2, and 3 (paywalls, licences, and mandatory cloud services) meet fewer criteria. However, the triggers are not mutually exclusive and certain aspects could be combined to create the DSI MLM to best achieve some of the criteria of para. 9 of Decision 15/9. Parties may want to consider combining different triggers (e.g., commercial activity and a micro-levy implemented by willing states) so that there are multiple streams of benefit-sharing.

Triggers 4 and 5 stand out as the most technically appropriate for the DSI MLM because they maintain open access, do not restrict research and innovation, have the potential to generate significant benefits and, depending on their operationalisation, have the potential to provide users the legal certainty they need for their operations. However, there are elements that will be difficult to find agreement on: the respective definitions of DSI products and commercial activities related to DSI, potentially the list of products and/or sectors that are considered ‘in’ the benefit-sharing system, and the rate of benefit sharing, to name but a few. While it may be more straightforward for the Parties to come to a simple definition and let users determine whether or not they are ‘in’, consideration would need to be given to how to ensure compliance under such a circumstance; i.e. if users are allowed to self-assess their liability to make benefit-sharing payments, this will need to be monitored to guard against avoidance. Users will have the most legal certainty for both triggers 4 and 5 if Parties can come to an agreement on, at a minimum, what sectors should be obligated and if their place on the value chain should be taken into account. In addition, if trigger 4 or 5 is chosen, Parties will need to figure out how to take into account the rights of IPLCs in other parts of the DSI MLM, perhaps in fund disbursement, or in the request for implementation of IPLC labels (further discussed later).

While triggers 4 and 5 have similar technical impacts (they retain open access and do not necessarily hinder scientific progress), trigger 5 will likely be less complex to implement. Implementing trigger 4 will require that companies first understand that they are ‘in’ the CBD DSI system and then conduct further analyses on their supply chains to understand their benefit-sharing obligation. This second level of analysis will make company implementation and DSI MLM monitoring and compliance quite difficult. For this reason, we believe that trigger 5 will be the simplest to implement.

There are several triggers (2, 3, potentially 4) that will likely require tracking and tracing in their implementation. This should be avoided and minimised as much as possible, because of the compliance issues that will arise.

For certain triggers, national-level legislation may be required which could give rise to uncertain and uneven implementation. In addition, triggers which require the significant involvement and cooperation of external stakeholders to implement may be considered less appropriate for the DSI MLM. Again, triggers 1, 2, and 3 are not recommended in our analysis since they require cooperation of databases and cloud service providers, many of which are domiciled in a non-Party. Triggers 4 and 5, if they obligate users through the creation of global terms of use, could potentially be implemented without the need for Parties to put in place national laws and would likely provide

users legal certainty in their operations. However, other aspects of triggers 4 and 5 may require national legislation, and much will depend on the design of their operationalisation.

Trigger 6 would require national-level implementation but such levies could be implemented by a coalition of willing states to provide additional funding to the DSI MLM, since it has the potential to generate significant and predictable resources. In addition, as mentioned earlier, the cloud service providers discussed in trigger 3 could be a part of the micro-levies implemented by willing states under trigger 6. These states could charge a micro-levy on cloud service providers on their biodiversity-related work. This levy would then be passed on to paying users of these platforms. While technically feasible, trigger 6 also has some issues in that it may fail to meet criterion (d) of para. 9 of Decision 15/9 (Box 1) as it may fail to provide legal certainty for users depending on how it is implemented by Parties at the national level. It is also not an appropriate sole trigger, as it is predicated on national-level tax policy changes.

Even though triggers 1, 2 and 3 are less compatible with para. 9 of Decision 15/9 than the other triggers, they still have aspects that meet criteria laid out there where more overall feasible triggers fall short - particularly criterion (i) (Box 1). In particular, as mentioned in the technical analysis of trigger 2, there is merit in labels that offer a way for IPLCs to potentially identify data that is relevant to them. If they are not connected to benefit-sharing or legal restrictions on access and use, labels could be a good way for the DSI MLM to meet criterion (i) of para. 9 of Decision 15/9. Implementing these labels would require coordination with databases to request that they make metadata fields for IPLC labels but would not require databases to implement paywalls, registration systems, or GDPR compliance measures.

This study of triggers for benefit-sharing for the DSI MLM is meant to provide a technical and legal analysis to aid policy makers in their decision making ahead of the DSI Open Ended Working Group 2 and COP16 meetings. When looking exclusively at the triggers, there are clearly some which better fit the needs of the DSI MLM, as identified in Decision 15/9. That said, triggers cannot be considered in a vacuum and the other parts of the MLM including governance, non-monetary benefit-sharing, fund distribution requirements, and the relationship of the mechanism to other approaches and systems need to be taken into account when Parties determine the appropriate trigger(s) for the DSI MLM. Parties should also consider appropriate monitoring, learning, evaluation and adaptation mechanisms to ensure that whatever trigger(s) are chosen, they are future proof, responsive, and generate more benefits than costs.

References

Convention on Biological Diversity - CBD, *Digital Sequence Information on Genetic Resources*, 2022, CBD/COP/DEC/15/9

Convention on Biological Diversity - CBD, *Executive summary of the studies commissioned pursuant to decision 15/9 on digital sequence information on genetic resources*, 2024, CBD/WGDSI/2/2/Add.2

Convention on Biological Diversity - CBD, Laird, S. and Wynberg, R., *A Fact Finding and Scoping Study on Digital Sequence Information on Genetic Resources in the Context of the Convention on Biological Diversity and Nagoya Protocol*, 2018, CBD/DSI/AHTEG/2018/1/3

Morgera, E., Tsioumani, E. and Buck, M., *Unraveling the Nagoya Protocol: a commentary on the Nagoya Protocol on access and benefit-sharing to the Convention on Biological Diversity*, Brill, 2014.

Oldham, P. and Kindness, J., 'Sharing Digital Sequence Information', *Zenodo*, 2022, <https://doi.org/10.5281/zenodo.6557191>

Rourke, M.F., 'Access by design, benefits if convenient: a closer look at the pandemic influenza preparedness framework's standard material transfer agreements', *The Milbank Quarterly*, Vol. 97, No. 1, 2019, pp. 91-112. <https://doi.org/10.1111/1468-0009.12364>

Sara, R., Hufton, A.L., Sett, S. and Scholz, A.H., 'Open access: a technical assessment for the debate on benefit-sharing and digital sequence information', *Zenodo*, 2022, <https://doi.org/10.5281/zenodo.5849643>

Scholz, A.H., Hillebrand, U., Freitag, J., Cancio, I., dos S. Ribeiro, C., Haringhuizen, G., Oldham, P., et al., *FINDING COMPROMISE ON ABS & DSI IN THE CBD: REQUIREMENTS & POLICY IDEAS FROM A SCIENTIFIC PERSPECTIVE*, WiLDSI, 2020, <https://doi.org/10.13140/RG.2.2.35180.80001>

Sett et al., 'Harmonise rules for digital sequence information benefit-sharing across UN frameworks', *Nature*, May 2024, *in review*

Switzer, S., Eccleston-Turner, M., Rourke, M., Hampton, A.-R., M.F. *Comments on Article 12: Pathogen Access and Benefit Sharing (PABS) of the "REVISED Draft of the negotiating text of the WHO Pandemic Agreement, 13th March 2024"*, 15 March 2024, https://www.graduateinstitute.ch/sites/internet/files/2024-03/GHC_Comments%20on%20Article%2012%20-%20PABS%20-%2013%20March%202024%20draft%20treaty.pdf

United Nations Conference on Trade and Development - UNCTAD, *The Trade and Biodiversity product classification. Measuring trade in products with a biological origin*, United Nations Publication, 2023, UNCTAD/DITC/TED/2023/4

United Nations Department of Economic and Social Affairs - UN/DESA, *International Standard Industrial Classification of All Economic Activities, Revision 4*, United Nations Publication, 2008, ST/ESA/STAT/SER.M/4/Rev.4

Wijminga, H., Klomp, W., van der Jagt, M. and Poort, J., *World Intellectual Property Association International Survey on Private Copying: Law and Practice 2016*, WIPO Publication No. 1037E/17, 2017, <https://www.wipo.int/publications/en/details.jsp?id=4183>

List of abbreviations and definitions

Abbreviations	Definitions
ABS	Access and Benefit Sharing
API	Advanced Programmer Interface
BBNJ Agreement	Agreement under the United Nations Convention on the Law of the Sea on the Conservation and Sustainable Use of Marine Biological Diversity of Areas beyond National Jurisdiction
CBD	Convention on Biological Diversity
CC	Creative Commons
COP	Conference of the Parties
DSI	Digital Sequence information
EBIT	Earnings before interest and taxes
EC	European Commission
EU	European Union
ftp	File transfer protocol
GBIF	Global Biodiversity Information Facility
GDPR	General Data Protection Regulation
GR	Genetic Resources
INSDC	International Nucleotide Sequence Database Collaboration
IPLC	Indigenous Peoples and Local Communities
ISIC	International Standard Industrial Classification
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
KCBD	Knowledge Centre for Biodiversity

Abbreviations	Definitions
LDC	Least Developed Country
LMIC	Low and Medium Income Countries
MGR	Marine Genetic Resources
MLM	Multilateral Mechanism
TraBio	Trade and Biodiversity
UN/DESA	United Nations Department of Economic and Social Affairs
UNCTAD	United Nations Conference on Trade and Development
WG DSI	Ad Hoc Open-ended Working Group on Benefit-sharing from the Use of Digital Sequence Information on Genetic Resources

List of boxes

Box 1. Para. 9 of Decision 15/9 (CBD/COP/DEC/15/9; CBD, 2022) with added notes in italics, where applicable, of the authors' interpretation of the relevant criteria (a) - (i)..... 9

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Table 1. Possible rate setting forms by trigger. 29

Annexes

Annex 1. Traffic light analysis

This traffic light analysis (Table S1) of the criteria of para. 9 of Decision 15/9 (Box 1) by trigger is based on the analysis as put forth in this study. Others may have different analyses and interpretations of the criteria.

Table S1. Traffic light analysis of the six triggers for benefit-sharing for the digital sequence information multilateral mechanism (DSI MLM) from a technical perspective, with regards to the criteria of para. 9 of Decision 15/9 (Box 1). Bright reds and greens indicate a strong probability of failing or meeting a criterion, respectively, while lighter reds and greens indicate a possibility. Light yellow indicates that further discussion is needed, or that other parts of the MLM can address the criteria better than triggers.

Criteria of para.9 of Decision 15/9 (CBD/COP/DEC/15/9)	Fee at access	Licences associated with DSI records	Mandatory cloud service use	Commercialisation of DSI products	Commercial activity related to DSI	Micro-levy
(a) Be efficient, feasible and practical	Bright red	Bright red	Bright red	Light yellow	Light yellow	Light yellow
(b) Generate more benefits, including both monetary and non-monetary	Bright red	Bright red	Light yellow	Light yellow	Light yellow	Light yellow
(c) Be effective	Bright red	Light yellow	Light yellow	Light yellow	Light yellow	Light yellow
(d) Provide certainty and legal clarity for providers and users of DSI on genetic resources	Light green	Bright red	Light yellow	Light green	Bright green	Light red
(e) Not hinder research and innovation	Bright red	Bright red	Bright red	Bright green	Bright green	Bright green
(f) Be consistent with open data	Bright red	Light red	Light red	Bright green	Bright green	Bright green
(g) Not be incompatible with international legal obligations	Light yellow	Light yellow	Light yellow	Light yellow	Light yellow	Light yellow
(h) Be mutually supportive of other access and benefit-sharing instruments	Bright red	Light yellow	Light yellow	Light yellow	Light yellow	Light yellow
(i) Take into account the rights of IPLCs	Light yellow	Bright green	Light yellow	Light yellow	Light yellow	Light yellow

Source: own elaboration

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