RESOLVING ACCESS AND BENEFIT-SHARING FROM BIODIVERSITY: TOWARDS AN EFFECTIVE GLOBAL BENEFIT-SHARING MECHANISM ON DIGITAL SEQUENCE INFORMATION

BART VAN VOOREN AND YULIYA GEVRENOVA
Covington & Burling LLP, Brussels*

1. From Bilateral to Multilateral: The Troubled Evolution of the Global Access and Benefit-sharing Legal Regime

The Convention on Biological Diversity ('CBD') of 1992 recognises the sovereignty of countries over biological resources within their jurisdiction. The CBD has three main objectives: (1) the conservation of biodiversity, (2) its sustainable use, and (3) the fair and equitable sharing of benefits arising from the utilisation of genetic resources.

Even though 196 Parties have joined the CBD, by the mid-2000s only a handful had adopted rules on benefit-sharing from biodiversity. As a result, the Nagoya Protocol was introduced to support the CBD's third objective. Negotiations concluded in 2010 in Nagoya. Building on the CBD's recognition of national sovereignty over biological resources, it allows Parties to impose prior authorisation ('access') and payment requirements ('benefit-sharing') for commercial R&D on biological materials – a system known as access and benefit-sharing ('ABS'). The idea is to generate a new financing stream for Nagoya Parties, thereby incentivising biodiversity protection.

The Nagoya Protocol follows a seemingly simple bilateral model. Anyone seeking access to physical materials must obtain a permit from the country of origin. In issuing the permit, that provider country's authority can require benefit-sharing terms for the user. Since 12 October 2014, when it entered into force, 142 countries have ratified the Protocol, and more than 130 national ABS laws have been adopted worldwide.

When the Nagoya Protocol was negotiated, synthetic biology was still emerging, so the text focused mostly on physical biological materials. As science advanced, researchers increasingly relied on digital footprints of genetic resources (for example, genomics, transcriptomics, proteomics, metabolomics). Because the need to access materials physically diminished, and because open science principles encourage sharing genetic sequence data on public databases like GenBank, existing Nagoya Protocol laws risked becoming outdated. For some CBD Parties, digital sequence information ('DSI') became the new frontier of biopiracy. In 2016, at the 13th Conference of the Parties ('COP13') in Mexico, all 196 CBD Parties decided to 'consider any potential implications on the use of digital sequence information'.[1]

A period of six years followed; with studies, reports and discussions in bodies such as AHTEG[2] and SSBSTA,[3] negotiators were tasked to define alternate models to ABS for DSI. A major milestone were the four peer-reviewed studies of

* Bart Van Vooren PhD is a partner with Covington & Burling LLP. Yuliya Gevrenova is an associate with Covington & Burling LLP. For more than a decade, the team has advised innovative life science companies on ABS under the Nagoya Protocol, the Plant Treaty, CBD Cali Fund, the WIPO disclosure convention, the BBNJ and the upcoming WHO pandemic treaty PABS system. This contribution was written in their own name.

1) COP Decision 13/16, available at: https://www.cbd.int/doc/decisions/cop-13/cop-13-dec-16-en.pdf.

2) CBD/DSI/AHTEG/2020/1/7, Report of the ad hoc Technical Expert Group on Digital Sequence Information on Genetic Resources, 20 March 2020, available at: https://www.cbd.int/doc/c/ba60/7272/3260b5e396821d42bc210352a/dsi-ahteg-2020-01-07-en.pdf.

3) Subsidiary Body on Scientific, Technical and Technological Advice.

2019 on (i) the concept and scope of DSI, (ii) the traceability of DSI, (iii) the public and private databases holding DSI, and (iv) the national ABS measures applying to DSI.[4] It was broadly recognised among experts and diplomats alike that the above-mentioned bilateral, 'transactional approach' of the Nagoya Protocol was ill-suited to the digital age. For DSI, value does not lie in a single sequence, but in giga/petabytes of aggregate information. The maturation of generative AI in biology (for example, Google AlphaFold) has further illustrated the value of nature data in the aggregate. Therefore, an expert working group proposed alternate approaches to the bilateral ABS model of the Nagoya Protocol, including a flat-fee ('Netflix') access model, a model using database access agreements when downloading DSI, or a 'bounded openness model' where utilisation or commercialisation of products using DSI would trigger benefit-sharing.[5]

These proposed models share a key feature: they operate at the above-country ('multilateral') level, so individual DSI data points do not need to be traced back to a specific provider country – a complex and costly requirement. Under a multilateral system, any funds generated could flow into a global biodiversity 'honey pot' to support conservation and restoration. This multilateral concept differs sharply from the Nagoya Protocol's bilateral approach, setting up a fundamental contrast in DSI negotiations.

On 19 December 2022, in Montreal at COP15, CBD Parties agreed an ambitious new Global Biodiversity Framework with four goals for 2050 and 23 targets for 2030.[6] To finance these objectives, COP15 called for an urgent increase in funding from all sources – domestic, international, public, and private. One prominent strategy to raise private-sector contributions is the 'multilateral mechanism on benefit-sharing from the use of digital sequence information on genetic resources' ('MLM-DSI'), officially created by COP Decision 15/9 in December 2022.

After Montreal, the new global mechanism existed only on paper. Countries agreed on two more years of talks to define its payment terms and governance. Decision 15/9 stated in paragraph 9 that these 'modalities for operationalisation' of the MLM-DSI should meet ten key requirements. They include among other things that the system should be efficient, generate more benefits than costs, provide legal certainty to users of DSI, and not hinder research or innovation. Paragraph 6 notes that a multilateral approach for sharing benefits from DSI 'has the potential' to meet those criteria.[7] An earlier draft expressly stated that the multilateral approach was preferred over the bilateral approach of the Nagoya Protocol, but this was deleted in the final COP Decision 15/9. Still, the stage was set for an ambitious, truly global approach to financing biodiversity.

On 1 November 2024, COP Decision 16/2 adopted the 'modalities for operationalising' the new mechanism and called it the 'Cali Fund'.[8] Paradoxically, although it is labelled as a 'multilateral mechanism', it does not align neatly with multilateral principles. Nor does it implement the bilateral transactional model. Instead, negotiators produced a 'hybrid system' that arguably raises more questions than it answers.

Under this new system, large companies using DSI are 'invited' to contribute either 0.1 per cent of their total revenue or 1 per cent of their profit to the Cali Fund. Yet companies making these contributions may still face penalties under national ABS laws implementing the Nagoya Protocol. Furthermore, nothing prevents double payment under other specialised ABS regimes for plant genetic resources or marine biodiversity, meaning that companies could pay twice for the same DSI and there are no means to avoid double taxation.

In this article, we assess why this 'hybrid system' fails to fulfil the legal certainty criterion in paragraph 9 of Decision 15/9, and how CBD Parties can address the resulting flaws that

4) Available at: https://www.cbd.int/dsi-gr/2019-h021/studies.

5) Note 2 above, pages 12 to 13.

6) COP Decision 15/4 on the Kunming-Montreal Global Biodiversity Framework: https://www.cbd.int/doc/decisions/cop-15/cop-15-dec-04-en.pdf.

7) Draft on file with author.

8) COP Decision 16/2 on modalities for operationalising the multilateral mechanism for the fair and equitable sharing of benefits from the use of digital sequence information on genetic resources, including a global fund: https://www.cbd.int/doc/decisions/cop-16/cop-16-dec-02-en.pdf.

undermine the Cali Fund's functionality. The paper has eight further sections:

In section 2 we first explore what characterises 'bilateral', 'multilateral' and 'hybrid' ABS systems. In section 3 we recall the EU Court of Justice's definition of the principle of legal certainty, which we will be using as the baseline of our analysis. We also explain how life sciences companies typically make R&D decisions to illustrate what the principle of legal certainty implies for ABS laws in a real-world context. Thereafter, we examine key unknowns for companies covered by the MLM-DSI, and where they need legal certainty: first, how much is a company expected to pay (section 4); second, what activities trigger the invitation to pay (section 5); third, what is digital sequence information (section 6); fourth, are companies legally obligated to pay (section 7); and fifth, does payment grant freedom to operate (section 8). Finally, in section 9, we conclude with recommendations on how to resolve the MLM-DSI's legal certainty issues.

2. Distinguishing between the Bilateral, Multilateral and Hybrid ABS Approaches

This section defines three types of ABS systems: a bilateral, national ABS system; a multilateral, supranational system; and a hybrid of the two. Each type requires different measures to achieve legal certainty, so we first clarify what we mean by each category.

2.1 Bilateral ABS system

The following characteristics define a 'bilateral' ABS system: (i) sovereignty over biological diversity is exercised at national level, so that users need to negotiate with the competent national ABS authority of each country (and not a supranational body); (ii) it is built on the assumption that the system will apply to physical samples or information where there is absolute certainty on the origin from that country; (iii) a legal agreement covering every single sample or sequence of the genetic resource is required; and (iv) an ABS payment must be made to every individual country in line with their national ABS laws.

Under this national approach, a country's sovereignty over its biodiversity is enforced via bilateral agreements between the 'provider country' (for example, Afghanistan, Zambia, Zimbabwe) and the company seeking to access and utilise the genetic resources. These agreements typically take the form of prior informed consent ('PIC') and material transfer agreements ('MAT'). Because there are as many potential bilateral ABS systems as there are CBD Parties, this approach inevitably leads to a proliferation of national ABS laws.

The Nagoya Protocol attempted to harmonise these national ABS frameworks by setting general principles for legislatures. However, since its entry into force in 2014, over 100 ABS laws have emerged among the 141 Parties to the Protocol, each with its own definitions, permit requirements, and enforcement mechanisms. Additionally, some CBD Parties that have not joined the Nagoya Protocol still maintain their own ABS measures (for example, Australia and, until 2021, Brazil). Even the United States, not a party to the CBD or Nagoya, imposes ABS rules in its National Parks. Some Nagoya Protocol Parties, such as Austria, Germany, and the Netherlands, have chosen not to adopt ABS laws at all; others, like Switzerland, have partial measures (registration in case of genetic resources originating from Switzerland but no benefit-sharing), or even varied laws within a single country (as in Belgium). Thus, the Nagoya Protocol created a complicated Harlequin's costume of national ABS laws, where no two sets are identical.

Nearly all these national ABS laws assume that sovereignty must be exercised over every single transaction involving every single genetic resource. Users attempting to comply must track each physical genetic resource or snippet of DSI they access – a complex and costly process.

A decade of applying this approach under the Nagoya Protocol shows that navigating this patchwork of national ABS laws is challenging for anyone conducting R&D in the life sciences – companies large and small, but also universities, government research institutes, botanical gardens, zoos, philanthropic research organisations, and so on. Typical questions these entities need to examine are: where does my genetic resource 'originate'? What if my resource is indigenous to multiple

countries that each have ABS laws? Where do I find these ABS laws? Can I trust the ABS clearing house to be up-to-date and complete? Is the law available in a language I understand? Is my activity 'utilisation' that triggers a permit or payment requirement under that ABS law? Will I be (criminally) liable if I misunderstand the ABS law? Such realities are an everyday burden under a purely bilateral system.

2.2 Multilateral ABS system

In contrast, 'multilateral' ABS systems are characterised by the following characteristics: (i) sovereignty over genetic resources is exercised at international level, so that users must only interact with a supranational body; (ii) rather than discrete permits for each resource or sequence, users obtain a broad authorisation for R&D; and (iii) users make one ABS payment to one international body, thus eliminating conflicting claims under national laws and/or other international bodies.

The 'multilateral approach' presumes that obligations are imposed on users in a single legal instrument that exists at above-country level. In principle, this system imposes fully harmonised requirements at international level, and it excludes any national authorisation requirement. At most, national laws may be adopted to give legal binding force to the global system, because international public law is not itself binding on citizens or legal entities. Countries can make such 'transfer' of sovereignty under Article 10 of the Nagoya Protocol, which introduces an opportunity for the Parties to set up a 'global multilateral benefit-sharing mechanism' that occurs in transboundary situations or where it is not possible to grant or obtain PIC.

A truly multilateral ABS system is rare – if it exists at all. The WHO's Pandemic Influenza Preparedness ('PIP') framework offers the closest example, established through a non-binding 2011 resolution of the Assembly of Members of the World Health Organization.[9] Under PIP, access to pandemic influenza samples from the WHO's Global Influenza Surveillance and Response System ('GISRS') by, for example, companies benefits from a presumption of prior informed consent, on the condition that benefit-sharing is arranged through standard contracts between the WHO secretariat and the company. This single-stop approach avoids 196 individual bilateral negotiations with parties to the CBD. The PIP framework is an imperfect example, because in reality it creates a complex hybrid system: *physical, seasonal* influenza samples may fall under the Nagoya Protocol implementing ABS laws, whereas *physical, pandemic* influenza falls under the PIP framework. Digital sequence information of influenza is not covered by the PIP framework, so that DSI may be covered by national ABS laws, or now the Cali Fund. In short, three different ABS regimes may apply to influenza products. The WHO's pathogen ABS system being negotiated under the Pandemic Treaty, and possibly adopted in May 2025, may further develop and rectify some of these flaws towards a truly global, multilateral ABS system.

2.3 'Hybrid' ABS system

Finally, 'hybrid' ABS systems are characterised by the following three criteria: (i) sovereignty is exercised both nationally and internationally, so users may need to deal with both national ABS authorities and a supranational body; (ii) multiple permits or contracts, so users could face legal obligations at both levels; (iii) double payment is likely because national and international entities both levy claims.

For a user of genetic resources, a 'hybrid' ABS system means that there are potentially multiple, co-existing bilateral or multilateral legal sources for ABS obligations that could apply to the same activity or genetic resource, at a given moment in time. Whether one or more ABS requirements apply could depend on material (for example, physical vs digital), geographic (for example, territorial sea vs high sea), temporal (before or after 12 October 2014), or personal (public or private entity) 'triggers' that determine the applicability of the ABS instrument. As we will further explore in sections 4 to 8 below, such assessment is often not straightforward at all.

The PIP framework has features of a hybrid system, though arguably it edges closer to multilateralism. A good example of a hybrid ABS system is the International Treaty on Plant

9) WHA64.5 A64/VR/10, available at: https://apps.who.int/gb/ebwha/pdf_files/wha64/a64_r5-en.pdf.

Genetic Resources for Food and Agriculture ('ITPGRFA' or 'Plant Treaty'). It has elements of multilateralism and global harmonisation, like the standard material transfer agreement and the common fund under the FAO. However, the multilateral system only applies insofar as Plant Treaty State Parties have expressly designated which of their collections of plant genetic resources are within the scope of the Plant Treaty. Thus, the applicability of ABS obligations depends on which genebank a user has acquired the plant genetic resource from. If the national genebank is not within the scope of the Plant Treaty, ABS under the Nagoya Protocol may apply. Moreover, the Plant Treaty does not apply to utilisation of a plant genetic resource that is used for purposes other than food and agriculture. Instead, ABS under the Nagoya Protocol may apply. That is the essence of a hybrid ABS system: depending on the purpose of the use, the physical or digital nature of what has been accessed, and the entity that provides or accesses the genetic resource, the applicable ABS requirements will be different.

3. The Principle of Legal Certainty in Law and Practice

3.1 Legal certainty and fiscal legality in EU law

Legal certainty is a general principle of law in the European Union ('EU'). The Court of Justice of the European Union ('CJEU') has long applied this principle across legal areas, including taxation. We adopt the CJEU's approach as our benchmark for evaluating whether the 'modalities for operationalising' the MLM-DSI meet paragraph 9 of Decision 15/9.

According to the CJEU, legal certainty requires that:

> *rules of law be clear, precise and predictable in their effect, especially where they may have negative consequences for individuals and undertakings, so that persons may ascertain unequivocally what their rights and obligations are and may take steps accordingly.*[10]

The CJEU also adds that legal certainty implies non-retroactivity:

> *in accordance with settled case-law, whilst the principle of legal certainty precludes a new legal rule from applying retroactively, namely to a situation established prior to its entry into force, that same principle requires that any factual situation should normally, in the absence of any express contrary provision, be examined in the light of the legal rules existing at the time when the situation obtained.* [11]

In the area of taxation, the CJEU consistently holds that it 'is apparent from the constitutional traditions common to the Member States, [that] the principle of fiscal legality may be regarded as forming part of the EU legal order as a general principle of law'.[12] The CJEU will determine the nature of a tax, duty or charge according to 'objective characteristics by which it is levied',[13] and the principle of fiscal legality requires that 'all the essential elements defining the substantive features thereof must be provided for by law'. Concretely, according to the CJEU's Advocate General Sharpston, a tax should be:

> *defined in legally binding rules accessible to taxable persons in advance in a manner that is sufficiently clear, precise and exhaustive so as to allow the taxable person in question to foresee and determine the amount of tax due at a given point in time on the basis of the texts and data available or accessible to him or her.*[14]

In conversations with some negotiators, the authors have been challenged when characterising the MLM-DSI as a global tax on innovation. According to a diplomat of an EU Member State, it should be viewed as a fee, or an invitation to contribute to a worthy goal. This article will not enter that debate. According

10) C–72/15 *Rosneft* (Judgment of 28 March 2017) EU:C:2017:236, para 161; C–611/17 *Italy v Council (Fishing quota for Mediterranean swordfish)* (Judgment of 30 April 2019) EU:C:2019:332, para 111; C–39/20 *Jumbocarry Trading* (Judgment of 3 June 2021) EU:C:2021:435, para 48.

11) C–89/14 A2A (Judgment of 3 September 2015) EU:C:2015:537, para 37; C–496/18 and C–497/18 *Hungeod and Others* (Judgment of 26 March 2020) EU:C:2020:240, para 94.

12) C–566/17 *Związek Gmin Zagłębia Miedziowego w Polkowicach* (Judgment of 8 May 2019) para 39.

13) C–446/04 *Test Claimants in the FII Group Litigation* (Judgment of 12 December 2006) EU:C:2006:774, para 107; C–338/08 and C–339/08 *P Ferrero e C. and General Beverage Europe* (Judgment of 24 June 2010) EU:C:2010:364, para 25.

14) Opinion of Advocate General Sharpston in C–566/17 *Związek Gmin Zagłębia Miedziowego* EU:C:2018:995, point 114.

to the OECD, taxes are defined as 'compulsory, unrequited payments to general government'.[15] First, the COP Decisions establishing the Cali Fund are indeed not legally binding. As such, they do not meet the requirement that a tax should be 'compulsory'. However, as we explain in section 7 below, the EU's Corporate Sustainability Due Diligence Directive ('CS3D') may result in the enforcement of the DSI payment. This makes the CJEU case law directly relevant in assessing the legality of the MLM-DSI. Second, the payment organised by the MLM-DSI is unrequited (that is, not reciprocated or returned in kind), as it is not connected to a specific service provided by the government, but is meant to finance biodiversity conservation. Such parallels with tax law justify applying the legal certainty standard to the MLM-DSI.

Hence, we assume that COP Decision 15/9 implicitly requires legal certainty in the MLM-DSI; the 0.1 per cent of revenue or 1 per cent of profit contribution resembles a tax; and it may meet OECD or CJEU criteria for taxation when implemented or enforced under national or EU law. Consequently, the MLM-DSI should be foreseeable, clear, exhaustive, and precise to fulfil legal certainty.

3.2 Legal certainty on ABS obligations in the context of life sciences R&D decision-making

Alongside legal certainty, according to paragraph 9 of Decision 15/9, the Cali Fund must also be efficient and not hinder research and innovation. To achieve these three principles, the mechanism must accommodate the realities of life sciences R&D across the public and private sector. In our definition, the life sciences sector comprises companies active in various areas, including cosmetics, food and feed, human and veterinary medicines, biotechnology, plant breeding, animal breeding, and biocontrol. All life sciences companies constantly need to innovate to respond to changing needs: climate change requires drought-resistant agricultural crops; anti-microbial resistance requires new antibiotics; consumers want natural instead of synthetic cosmetic ingredients; clean labels on food; and so on. These research and development cycles typically range from five to seven years in cosmetics, 10 years in food, 10 to 15 years in pharmaceuticals and 15+ years in plant breeding.

Companies will consistently have a tailored project management process to manage these long innovation cycles. This process typically consists of clearly identifiable moments on the path of an R&D project that represent the completion of a significant activity and the beginning of a new phase. For example:

- For a food company, phase 1 might be to define consumer trends and needs; phase 2 to explore potential ingredients to address this need; phase 3 to develop the ingredient and product to incorporate it; phase 4 to upscale for industrial production; and phase 5 to commercialise the product.

- A typical pharmaceutical company process would be to begin with the exploratory stage to examine, for example, in the pre-clinical phase the identification of a target for addressing a specific disease, to understand its mechanism of action and to develop compounds to interfere with this mechanism in the desired way, which could include the preparation of thousands of compounds, and finally the selection of a few compounds for further development followed by the clinical development with a single active pharmaceutical ingredient. Clinical development will typically comprise phase 1, phase 2 and phase 3 clinical trials, as well as post-commercialisation phase 4 clinical trials. The overall process is characterised by significant investments and high failure rates.[16]

At any milestone from one phase to the next, a company will make the decision whether to proceed, or not, with a given R&D project. For instance, a project may be cancelled because a new nature-based flavour is not well received by the tasting panel; because a pharmaceutical compound turns out to be no more effective than a placebo; or because

15) See, for example, OECD *Revenue Statistics, Interpretative Guide* (2023) available at: https://www.oecd.org/content/dam/oecd/en/topics/policy-sub-issues/global-tax-revenues/oecd-classification-taxes-interpretative-guide.pdf as well as OECD iLibrary, available at: https://www.oecd-ilibrary.org/taxation/tax/indicator-group/english_76e12892-en.

16) See, for example, 'Why 90% of clinical drug development fails and how to improve it?' (2022) available at: https://pmc.ncbi.nlm.nih.gov/articles/PMC9293739/#:~:text=Analyses%20of%20clinical%20trial%20data,(10%25)2%2C4.

regulatory compliance presents an insurmountable hurdle to market access. The risk of failure is real and exists in all life sciences sectors. But even for R&D projects for which there may be clear consumer demand, there are other reasons for a company to decide (or not) to dedicate limited financial and human resources to the next phase of the R&D process. Companies will look at a variety of financial and non-financial criteria, including the size of the business opportunity, critical performance criteria of the product, projected sales upon commercialisation, positive impact on the environment or public health, and so on. In this cost-benefit analysis, a company will seek to predict costs as early as possible, and with the highest degree of certainty. This includes legal, regulatory and compliance costs.

When a proposed R&D project relies on non-human biological materials, or DSI (typically both), ABS is simply yet another compliance requirement to be integrated into the company's cost-benefit analysis. In doing that analysis, companies will want the 'clarity, precision and predictability' referred to by the EU Court of Justice. Since committing to an R&D innovation cycle can take upwards of 10+ years of investment, in practice, the principle of legal certainty translates as follows in decision-making on ABS:

- First, an upfront, clear and reliable determination as to which benefit-sharing rules will apply to a given R&D project: the Nagoya Protocol, the Cali Fund, the Plant Treaty and/or any national ABS measures.
- Second, how much the company will be expected to pay, at what time, how it will be calculated, and to whom they should pay.
- Third, this information will need to be certain early in the R&D process and typically many years before the eventual commercialisation of a final product.
- Fourth, the payment requirements should be stable and not change during the innovation process.
- Fifth, companies are under pressure to make R&D decisions quickly – often in a matter of months, weeks, or days. Thus, they must be able to ascertain their benefit-sharing obligations within a short timeframe.
- Finally, payment should legally guarantee the freedom to operate – meaning that companies are at liberty to file a patent, sign a licence deal, and commercialise the product or service resulting from their R&D once obligations are met.

Bilateral and hybrid ABS systems create significant uncertainty in responding to all these questions, with a negative impact on R&D. A well-designed global ABS system could overcome these hurdles, and actually result in tangible benefits for biodiversity.

4. How Much is a Company Expected to Pay?

Paragraph 3 of the Annex to Decision 16/2 reads as follows:

> *Users of digital sequence information on genetic resources in sectors that* directly or indirectly benefit from its use in their commercial activities *should contribute a proportion of their profits or revenue to the global fund,* according to their size. *Having regard to paragraph 13, entities that, on their balance sheet dates, exceed at least two out of three of thresholds (namely, total assets: 20 million United States dollars, sales: 50 million dollars, and profit: 5 million dollars) averaged over the preceding three years* should contribute to the global fund 1 per cent of their profits or 0.1 per cent of their revenue, as an indicative rate. *An* indicative list of sectors *to which such users may belong is contained in enclosure I.* (emphasis added)

Users are indicatively given the option to pay 1 per cent of profit, or 0.1 per cent of revenue.

At this stage, it is not possible for companies to determine the amount of the DSI payment with any degree of clarity, precision, or foreseeability. The basis for calculation is unclear. The percentage is uncertain and fundamental concepts such as 'use', 'benefit', and 'DSI' remain undefined. In addition, companies will need to make payments in perpetuity in order to assure compliance.

The expectation to pay into the Cali Fund applies to companies that belong to a sector 'that directly or indirectly benefit[s] from [DSI] use in their commercial activities'. There is a presumption

that companies in sectors listed in Enclosure I meet this requirement. We quote the list in full for the reader's benefit: '(i) pharmaceuticals; (ii) nutraceuticals (food and health supplements); (iii) cosmetics; (iv) animal and plant breeding; (v) biotechnology; (vi) laboratory equipment associated with the sequencing and use of digital sequence information on genetic resources, including reagents and supplies; and (vii) information, scientific and technical services related to digital sequence information on genetic resources, including artificial intelligence'.

A commonly heard question is how the negotiators reached agreement on the seven sectors covered and how much countries expect to collect in the Cali Fund.

Lengthy discussions on which entities should be covered were held in the two years leading to COP16. Negotiators were exploring two broad approaches. The first, the product definition suggested that any company which commercialises a product or process (as in service) that 'has benefited from the use of DSI' should share benefits. However, negotiators considered that this would require defining complex terms, and would also require determining whether a product has been developed through the use of DSI. Therefore, the second and supposedly 'easier' sectoral route considered options to define sectors that were, for example, 'highly reliant on' DSI.

In 2024, the CBD Secretariat commissioned two studies with the aim of clarifying how DSI is used across different business activities. It is a public secret that it proved extraordinarily difficult to gather comprehensive and verifiable information. Eventually, a Big Four consultancy was retained. However, it was obliged to work with an extremely compressed timeline, and was likely under significant pressure to provide tangible input to the negotiators. This resulted in the two tables in the study, quoted below, which have been subject to heavy criticism from negotiators and industry alike. Nevertheless, these figures did set expectations for the negotiations at COP16 in November.[17]

Table 1
Total annual revenue generated by sectors that use digital sequence information on genet resources: estimates for 2024 and projections for 2030[a]

Sector	*Billions of dollars*	
	2024	*2030*
Pharmaceutical	593.24	836.60
Cosmetics	333.90	474.00
Plant and animal breeding and agricultural biotechnology	581.62	904.23
Laboratory equipment associated with the use of DSI	43.36	66.40
Information, scientific and technical services related to DSI	7.65	22.44
Total	**1 559.77**	**2 330.67**

Table 2
Illustrative annual contributions to the global fund based on sector revenue or an assumed net profit of 12.5 per cent[a] (2024)

	Contribution based on total revenue across relevant sectors of 1,559.77 (in billions of United States dollars) and assuming a levy on sector revenue		*Contribution based on total net profit across relevant sectors of 12.5 per cent (194.97 (in billions of United States dollars)) and assuming a levy on sector net profit*	
	Percentage levy	*Billions of United States dollars*	*Percentage levy*	*Billions of United States dollars*
(a)	0.10	1.56	1.00	1.95
(b)	1	15.60	10	19.50
(c)	0.64	10.00	5.13	10.00
(d)	1.28	20.00	10.26	20.00

[a] A 12.5 per cent average net profit across the sectors is assumed. Although research suggests that this varies between and within the sectors under consideration, it was not possible to identify net profit estimates for each sector.

17) Available at: https://www.cbd.int/doc/c/2236/870d/df42fo0e104ad6a48d1d4d9/wgdsi-02-02-add2-en.pdf.

Negotiators used these figures to produce a draft text by August 2024, and leading up to COP16, countries were considering four payment options:

- Option A: a percentage of profits or revenue from DSI-based products.
- Option B: a percentage of companies' profit or revenue in sectors heavily reliant on DSI.
- Option C: a 1 per cent contribution based on retail value.
- Option D: a voluntary contribution by companies actively using DSI.

At Cali, options C and D failed to gain traction, and options A and B were merged into option E that required a contribution based on entity size, in certain sectors, with higher rates for large entities and exemptions for smaller ones. Two days before the end of COP16, the diplomats from the UK and Malawi that led the DSI negotiations added specific contribution rates for large entities, namely 1 to 2 per cent of profits or 0.1 to 0.2 per cent of revenue. They introduced these numbers without any negotiation between the Parties, and in spite of push-back by, for example, Switzerland and the EU, the final COP Decision retained the 1 per cent of profit, and 0.1 per cent of revenue. Reflecting Table 2 above, it was thus assumed that the Cali Fund could generate between 1.56 and 1.95 *billion* USD.

Finally, COP Decision 16/2 states that the percentages are currently only 'indicative'. Given some countries' push-back against including the percentages, the compromise was that yet another study would be commissioned on 'contribution rates, including implications for revenue generation and economic competitiveness'. On that basis, COP17 will establish the contribution rates and 'review them periodically thereafter'.[18]

5. What Activities Trigger the Expectation to Pay?

A core question is whether a company's activities constitute 'use' of DSI and thus trigger the invitation to pay into the MLM. In 2022, COP Decision 15/9, at paragraph 16, stated that the MLM-DSI will apply to the 'use' of DSI on genetic resources. Decision 16/2 expanded on the trigger in paragraph 3, stating that companies 'in sectors that directly or indirectly benefit from the use of DSI in their commercial activities' are expected to contribute to the Cali Fund. The progressively broader scope of the mechanism was due to significant pressure by the African Group that pursued an ever-broader payor base for the Cali Fund.

As mentioned, paragraph 3 of Decision 16/2 establishes a presumption that companies operating in the seven identified sectors are 'using' DSI. Paragraph 5 states that '[t]he provisions of paragraph 3 do not apply to entities active in the sectors listed in Enclosure I that do not directly or indirectly use digital sequence information on genetic resources'. This raises a number of questions, for example: (i) If 'DSI' and 'use' are not defined, how does one prove that these criteria do not apply to a company? (ii) To whom does the company provide proof, and who decides – for example, national authorities that apply their ABS laws to DSI, those that participate in the Cali Fund, or the CBD Secretariat? (iii) How does one prove a negative, without disclosing commercially sensitive information? (iv) If a company proves that it does not 'use' DSI, could it still 'benefit' from it? (v) Since payments are annual, must proof be provided annually as well?

As to the definition of 'use', negotiators could not reach agreement at COP16, though attempts were made. During the negotiations, other triggers such as 'utilisation' or 'accessed' were also explored. These terms are very familiar from the Nagoya Protocol to the CBD, which defines utilisation as '[to] conduct research and development on the genetic and/or biochemical composition of genetic resources',[19] whereas 'access' is traditionally understood as physically acquiring genetic resources. From having attended the negotiations, it became clear to these authors that 'use' should be understood as being narrower than 'access' – so that the mere download of DSI from public databases in itself should not trigger any obligations – but broader than 'utilisation' under the Nagoya Protocol. However, that is not written down anywhere.

18) COP Decision 16/2, para 6(e) and Annex para 4.

19) Nagoya Protocol, Article 2.

From a legal certainty perspective, it is important to have a definition of 'use'. University and company researchers in the life sciences conduct all kinds of 'research and development' on DSI from genetic resources. For instance, they may test how much annatto to add to colour Cheddar cheese;[20] they may examine whether dog food containing essential oils of cloves, rosemary and oregano is good for a pet's health;[21] they may test whether quadrivalent mRNA vaccines protect against certain influenza B strains;[22] they may research the safety of naturally sourced chlorophyl as a green food colorant;[23] they may test the type or quantity of enzymes necessary for washing detergents to function;[24] and so on. This means that users must determine whether their 'research and development' in the *colloquial* sense will fall under the definitions of 'use' or 'utilization' in the *legal* sense as defined in the relevant ABS regime.

The absence of definitions of 'use', '(in)directly benefit from', and 'commercial activities,' creates major uncertainties for companies wishing to comply with the Cali Fund requirements, especially as and when they are implemented into national law. The multilateral mechanism would be much better served with using the term 'utilisation' of the Nagoya Protocol. Rather than reinventing the wheel and agreeing new terms devoid of meaning, the Cali Fund should build on 10+ years of experience with 'utilisation.' The Nagoya Protocol is by no means perfect, but the term could provide a useful starting point. For example, Switzerland's definition of 'utilisation' is identical to that of the Nagoya Protocol. In contrast, India's ABS law defines 'commercial utilisation' so widely that almost any form of trade in biological resources is in scope. In our view this likely violates WTO trade law, but that is the topic of another paper altogether. Similarly, France's ABS law defines 'utilisation of genetic resources' as R&D on the genetic resources, as well as the 'valorisation of genetic resources, the applications and commercialisation that results from it'. Finally, the European Union in 2021 published a guidance document of 68 (!) pages to explain the meaning of 'utilisation' under its Regulation 511/2014 that requires users to conduct due diligence to ensure compliance with ABS laws of provider countries.[25]

Based on 130+ national ABS regimes that have implemented this term, the Cali Fund could provide an opportunity to build a global consensus on the meaning of 'utilisation'. This would be a uniquely valuable effort of international law-making, and is absolutely essential for the Cali Fund to function. This harmonisation effort could be the beginning of harmonising the global ABS framework, so that the Cali Fund could over time incorporate genetic resources, thereby absorbing and displacing national ABS laws, as well as replacing other international ABS regimes such as the Plant Treaty or the BBNJ.

Further complication is introduced by the terms 'use "directly" or "indirectly"'. This topic was not subject to in-depth discussions at COP16. It raises a significant concern that any entity in the supply chain of a product developed with the use of DSI could be considered to be within its scope. As pointed out by Halewood *et al*. in a November 2023 *Science* article, '[l]ife scientists use hundreds of millions of sequence, protein, small-molecule, structural, and pathway data points to decide what hypotheses to pursue'.[26] Against that background, every life sciences company 'indirectly' likely benefits from the use of DSI. Without any criteria to demonstrate that an entity does not 'use' DSI under paragraph 5, it is also impossible to rebut it.

6. What is Digital Sequence Information?

Decisions 15/9 and 16/2 do not provide a definition of 'digital sequence information'. In addition, the countries attached certain conditions to the DSI covered by the Cali Fund. First, the Cali Fund only applies to DSI that is 'made publicly available', and not to DSI that is privately held. Second, the public DSI must have been uploaded in compliance with national laws, creating an obligation for users to verify compliance. Third, no other international ABS mechanism may apply to the DSI, unless that mechanism has chosen to opt in to the Cali Fund.

20) https://pubmed.ncbi.nlm.nih.gov/38608957/.

21) https://pubmed.ncbi.nlm.nih.gov/32602378/.

22) https://pubmed.ncbi.nlm.nih.gov/36322769/.

23) https://pubmed.ncbi.nlm.nih.gov/36322769/.

24) https://pubmed.ncbi.nlm.nih.gov/33184763/.

25) Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union, available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52021XC0112(02)&from=EN.

26) M Halewood, M Bagley, M Wyss *et al.* 'New benefit-sharing principles for digital sequence information' *Science* vol 382 issue 6670.

6.1 No definition of DSI despite years of negotiation

At COP14, the Parties decided to establish a science-based process to resolve their divergence of views on benefit-sharing from DSI. In March 2020,[27] AHTEG recognised that '[a]chieving conceptual clarity regarding digital sequence information is important to ensure legal clarity in all circumstances'. While the group did not define DSI, the experts did agree that the three groups in the table below 'could be considered' as DSI. This table was never formally adopted, in part due to Covid-19 derailing the COP that was due to take place in China at the end of 2020. We reproduce the table below because its approach to defining DSI is widely accepted among experts and negotiators as a 'common understanding' of what DSI may encompass – even if this is not immediately clear to those new to the Cali Fund.

At COP15, certain parties did attempt to include a definition. On 17 December 2022, a draft of Goal C of the Global Biodiversity Framework read:

> *[The monetary and non-monetary benefits from the utilization [of genetic resources in any form including digital sequence information]* [, only including nucleotide sequence data and excluding any information and data belonging to the group 1, 2, 3 contained in the outcome of the 2020 DSI AHTEG] *[including digital sequence* information]/[biological

Table 1. Clarifying the scope of digital sequence information on genetic resources

	Information related to a genetic resource			
	Genetic and biochemical information			Associated information
Group reference	*Group 1*	*Group 2*	*Group 3*	
High-level description of each group	DNA and RNA	Group 1 + proteins + epigenetic modifications	Group 2 + metabolites and other macromolecules	
Examples of granular subject matter	• Nucleic acid sequence reads; • Associated data to nucleic acid reads; • Non-coding nucleic acid sequences; • Genetic mapping (for example, genotyping, microsatellite analysis, SNPs, etc.); • Structural annotation.	• Amino acid sequences; • Information on gene expression; • Functional annotation; • Epigenetic modifications (for example, methylation patterns and acetylation); • Molecular structures of proteins; • Molecular interaction networks.	• Information on the biochemical composition of a genetic resource; • Macromolecules (other than DNA, RNA and proteins); • Cellular metabolites (molecular structures).	• Traditional knowledge associated with genetic resources • Information associated with digital sequence information Groups 1, 2 and 3 (for example, biotic and abiotic factors in the environment or associated with the organism) • Other types of information associated with a genetic resource or its utilization.

27) Note 2 above.

> diversity, including digital sequence information] … . (emphasis added)

The italicised language was eventually deleted, and the final COP15 Decision establishing the MLM-DSI simply stated that Parties '[agreed] on the continuing use of the term DSI for further discussions'. Between 2022 and 2024, no further attempt was made to define DSI. In fact, in the months leading up to COP16, countries coalesced around a view that no definition of DSI was required. It became widely accepted that not defining the open-ended term DSI would ensure a broad interpretation resulting on a broad payor base among private companies. Thus, the issue was intentionally left unresolved.

6.2 'Publicly available' DSI

Although DSI itself was not defined, countries attached conditions to the concept to ensure that their national ABS laws remained unaffected. As a first condition, they sought to ensure that the Cali Fund would relate only to data that is already beyond the grasp of national governments. Therefore, the MLM-DSI applies only to DSI that is made 'publicly available'. Significant effort was expended at COP16 on trying to define which databases are considered public (for example, providing free access to users or supported through public funding) or when data would be considered publicly available. The Parties could not reach an agreement. Instead, COP Decision 16/2 puts the compliance burden on 'entities operating databases, tools and models that are dependent on DSI and that make such information publicly available'[28] to make their own assessment whether they host 'publicly available' DSI. If they do, the database should inform its users that they may have to pay to the global mechanism when using the information from those databases. We are concerned that this could result in fragmentation of databases, and a push away from open access.

6.3 Scope limited only to DSI compliant with National ABS Laws

As a second condition, the MLM will only apply to DSI that was made publicly available 'in compliance with national legislation' or 'that is not subject to mutually agreed terms agreed to at the time of access to the genetic resources from which the DSI is derived, unless those terms allow for the making of the digital sequence information freely available'.

This provision was introduced in response to concerns raised by some governments at COP16 that certain DSI had been uploaded to public databases in violation of national ABS laws under the Nagoya Protocol. Regardless of whether that assertion is correct, for companies using DSI from public databases, this provision creates a major compliance challenge:

- If, on the one hand, a data entry lacks metadata on its country of origin, it is impossible to verify whether it was uploaded in compliance with national laws. To avoid non-compliance, the company may choose not to use such information, rendering the data useless for R&D.

- If, on the other hand, a data entry does contain data on the country of origin, companies will need to verify whether national ABS laws apply to DSI, and if so, whether they were complied with at the time of data upload. At present, there are at least 100 national ABS laws governing physical genetic resources in CBD member states, and at least 39 of these laws explicitly or indirectly apply to DSI, including in Brazil, Uruguay, Malawi, Malaysia, Costa Rica, Kenya, South Africa, Uganda, India, Colombia, and Peru.

As a result, in one fell swoop, the Cali Fund has made *all* public DSI containing terabyte after terabyte of data, suspect. The requirement to confirm compliance with national ABS laws of DSI is covered by the MLM-DSI fundamentally contradicts the goal of establishing a simplified, globally harmonised system. It perpetuates and amplifies the fragmented ABS landscape created by the Nagoya Protocol. Moving forward, we call on the Parties to correct this fundamental error in the set-up of the Cali Fund. One approach is to recognise that payment to the Cali Fund covers all DSI, in all 196 Parties to the CBD, and that it is presumed to have corrected any absence of PIC and/or MAT, as well as any non-compliance with PIC and/or MAT if they were in place.

28) COP Decision 16/2, para 10(a) to (e).

6.4 Overlap with other international ABS regimes

Fourth and finally, the MLM-DSI will apply to DSI 'for which the fair and equitable benefit-sharing is not provided for by other international agreements on ABS, except if those instruments chose the MLM for that purpose'. There are four international ABS regimes that co-exist with the Cali Fund:

- First, the International Treaty on Plant Genetic Resources for Food and Agriculture, where the application to DSI is being considered.
- Second, the new regime on ABS from Marine Biodiversity of Areas Beyond National Jurisdiction ('BBNJ') that applies to DSI.
- Third, the PIP Framework that does not apply to DSI but mentioned 'Genetic Sequence Data' as an issue to take into account.
- Fourth, the new Pathogen ABS ('PABS') regime that is being negotiated as part of the WHO Pandemic Treaty and that expressly applies to DSI.

The Cali Fund allows those other treaty regimes to opt for contributions under the CBD, but we consider it is very unlikely that, for example, the World Health Organization would reject the opportunity to receive financing from the private sector. As a result, companies will continue to face multiple ABS regimes that may apply to the same activities and/or products.

7. Are Companies Legally Obligated to Pay to the MLM-DSI?

As a general principle, instruments of international public law that are agreed between states do not bind companies or citizens. Some form of national implementation is necessary to make the international Decision binding on individuals. Decision 16/2 paragraph 13 states that:

> *Parties and non-Parties* are invited *to take administrative, policy or legislative measures, consistent with national legislation,* to incentivize users in their jurisdiction to contribute to the global fund in line with the present modalities. (emphasis added)

Countries can choose to enact legislation to operationalise the 'invitation' to contribute to the Fund, but without such national implementation and/or enforcement, companies are currently not legally required to make any payments. Incentives for companies to voluntarily contribute lie in the reputational realm, and incentives may be positive (for example, collaboration between a country and company for sustainability brownie points in the form of a label or some other recognition) or negative (for example, pressure from NGOs alleging that companies engage in biopiracy).

At present, we are not aware of any national law that has directly implemented payment into the Cali Fund. The only legal obligation that we have identified so far stems from the EU's CS3D.

On 5 July 2024, the EU published the CSD3. Unless this is amended during the 'omnibus process' underway since early 2025, from 2027 the CS3D will apply to EU companies with a worldwide turnover of 1.5 billion and 5000 employees, and non-EU companies of a turnover of €1.5 billion generated in the EU. Later deadlines apply to companies meeting progressively lower thresholds. The CS3D contains due diligence obligations for companies to manage, for example, environmental law compliance in their own operations, as well as those of their subsidiaries, and direct and indirect business partners.

Article 3(1)(b) of the CS3D defines '*adverse environmental impact*' as:

> *an adverse impact on the environment resulting from the breach of the prohibitions and obligations listed in Part I, Section 1, points 15 and 16, and* Part II of the Annex to this Directive*, taking into account* national legislation linked to the provisions of the instruments listed therein. (emphasis added)

Articles 5 to 16 of CS3D require EU Member States to adopt laws that will ensure that companies conduct environmental due diligence to identify and assess actual or potential adverse environmental impacts, to prevent and mitigate them, to bring actual adverse impacts to an end, to engage with stakeholders, to establish a notification and complaints procedure, monitor their due diligence, and publicly communicate on it.

The CS3D contains an elaborate and strict regime to enforce companies' due diligence obligations as regards adverse environmental impacts:

- First, Article 26 requires member states to create a system where natural and legal persons can 'submit substantiated concerns, through easily accessible channels, to any supervisory authority when they have reasons to believe, on the basis of objective circumstances, that a company is failing to comply… .
- Second, Article 27 requires member states to lay down rules on pecuniary penalties for infringements. Article 27(4) states that '[w]hen pecuniary penalties are imposed, they shall be based on the company's net worldwide turnover. The maximum limit of pecuniary penalties shall be not less than 5 per cent of the net worldwide turnover of the company in the financial year preceding that of the decision to impose the fine.'
- Third, Article 29 requires member states to ensure that a company can be held liable for damage caused to a natural or legal person if the company intentionally or negligently failed to prevent potential adverse impacts, or bring actual adverse impacts to an end, 'when the right, prohibition or obligation listed in Annex is aimed at protecting the natural or legal person'.

We consider it likely that the obligations to prevent, mitigate and/or correct adverse impacts, and related sanctions for failing to do so, extend not only to the first two objectives of the Convention on Biological Diversity (that is, conservation and sustainable use of biodiversity), but also to the third objective on 'the fair and equitable sharing of the benefits arising out of the utilization of genetic resources'. This follows from Part II of the Annex to the CS3D which reads:

> *Part II – PROHIBITIONS AND OBLIGATIONS INCLUDED IN ENVIRONMENTAL INSTRUMENTS*
>
> *1.* The obligation to avoid or minimize adverse impacts on biological diversity, interpreted in line with Article 10, point (b) of the 1992 Convention on Biological Diversity and applicable law in the relevant jurisdiction, including the obligations *of the Cartagena Protocol on the development, handling, transport, use, transfer and release of living modified organisms and* of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits *Arising from their Utilization to the Convention on Biological Diversity of 12 October 2014*. (emphasis added)

Admittedly, this Annex does not expressly refer to the MLM-DSI, but it likely includes it through principles of public international law. The Vienna Convention on the Law of Treaties ('the Vienna Convention') is an international agreement adopted in 1969, which entered into force in 1980. Articles 31 and 32 of the Vienna Convention set forth generally accepted principles of treaty interpretation. Article 31(3) of the Vienna Convention provides that subsequent agreements concluded by the parties to a treaty, and the context in which they exist 'shall be taken into account' in the interpretation of the CBD. In order to have such an effect, subsequent agreements must be undertaken by all States Parties to a treaty. COP Decision 15/9 establishing the MLM-DSI, and COP Decision 16/2 were both adopted by consensus. Aside from the requirement that the agreement should be a joint action by all treaty parties, subsequent agreements do not need to meet any other particular formal requirements so that a COP Decision is sufficient under the Vienna Convention. Accordingly, the MLM-DSI can be considered to constitute a subsequent agreement to the Convention on Biological Diversity. Thus, although countries are currently not legally obliged to implement the MLM-DSI, it should be considered as an authoritative means of achieving the third objective on fair and equitable benefit-sharing.

In conclusion, the CS3D, with its combined references, first, to the CBD (with the MLM-DSI as subsequent agreement), second, to the Nagoya Protocol, which is a binding additional

agreement to the CBD, confirming that CS3D intends to encompass the CBD's third objective, and third, to 'applicable law in the relevant jurisdiction' implementing the CBD and Nagoya Protocol, in our view, most likely extends the various due diligence obligations and related sanctions to the 'voluntary' MLM-DSI. While this should not amount to a payment obligation *per se* (but does require a degree of due diligence – to be assessed on an individual company basis), the CS3D does extend to national laws in the 196 CBD parties implementing the MLM-DSI. As a result, if those laws impose a binding payment requirement on companies, we conclude that there is a real likelihood that NGOs and authorities could argue that CS3D effectively enforces compliance with those national MLM-DSI payment obligations. In what follows, we suggest various approaches to curtailing this conclusion.

Ultimately, companies assessing whether to comply with the MLM-DSI must weigh legal, policy, reputational, and financial considerations. While voluntary contributions are the stated expectation, the increasing integration of ABS compliance into corporate due diligence laws suggests that companies will face growing indirect pressures to participate. Whether these pressures will remain voluntary in practice, evolve into indirect enforcement via corporate accountability laws, or lead to more explicit national legislative measures will need to be monitored in the months and years to come.

8. Does Payment into the Cali Fund Provide Freedom to Operate from ABS Obligations?

A truly multilateral, above-country mechanism would ensure that once users make a payment to the Cali Fund, they should be shielded from competing national ABS obligations. Indeed, had the MLM-DSI replaced or superseded national laws, it would have offered a single, universally recognised compliance pathway for ABS. However, the final text of Decision 16/2 leaves open the possibility that entities could still face overlapping legal and financial obligations. Paragraph 15 of Decision 16/2 states:

> *[F]or each year that users make monetary contributions to the fund in line with the modalities of the MLM, they are considered to have fairly and equitably shared monetary benefits arising from the use of DSI under the MLM and will receive a certificate accordingly. Such a certificate excludes the users from any expectation to share further monetary benefits from the use of DSI within scope of the MLM for that year.*

While this language suggests that companies could receive a certificate relieving them from further monetary obligations for that year, it neither guarantees that the scope of such relief covers all forms of DSI nor that national authorities will respect the certificate in lieu of domestic ABS laws. Early drafts of Decision 16/2 contained proposals by industry to include bracketed text stating that 'users that make monetary contributions … are considered to be in [compliance][conformity] with requirements on fair and equitable benefit sharing.' However, these proposals were not retained in the final decision. Moreover, the last-minute insertion of the phrase 'DSI within the scope of the MLM for that year' further narrows the certificate's coverage.

We have already addressed the co-existence with other international regimes that apply to DSI (horizontal overlap), but an equally pressing concern, if not more so, is the vertical overlap between the new global mechanism and existing national ABS legislation adopted pursuant to the Nagoya Protocol. Decision 16/2 fails to harmonise these two layers of obligations, instead 'inviting' – but not obligating – national governments to align their rules with the MLM-DSI. Specifically, paragraph 26 of Decision 16/2 provides:

> Without prejudice to national access and benefit sharing measures*, where Parties put in place national measures on access and benefit-sharing from digital sequence information on genetic resources, they are* invited to align *them with the multilateral mechanism, such that there is* no duplication of expectations *to share the benefits arising from the use of digital sequence information on genetic resources under the multilateral mechanism*. (emphasis added)

The language 'are invited to align' remains non-binding. Thus, national ABS frameworks can continue to impose additional obligations on top of any payment made to the Cali Fund. The situation worsened in the final hours of COP16, when India

successfully insisted on adding 'without prejudice to national legislation'. Taken together, these changes effectively allow states to retain (or enact) national laws that duplicate or even exceed the financial obligations imposed by the MLM-DSI.

From a user perspective, this creates the risk that – despite paying into the Cali Fund – companies remain exposed to national ABS claims in jurisdictions that choose not to align or harmonise their legislation. For instance, a multinational corporation with an annual revenue of USD 50 billion might owe an MLM-DSI contribution of USD 50 million per year, only to find that it must pay further ABS fees or enter additional negotiations with multiple national authorities, receiving no definitive release from these parallel obligations.

The MLM-DSI, as established by Decision 16/2, was ostensibly designed to simplify and harmonise benefit-sharing for digital sequence information on a global scale. In practice, however, it operates vertically alongside national ABS laws – over which it has no supremacy – and horizontally next to other specialised ABS mechanisms, such as the ITPGRFA, the PIP framework, and the forthcoming WHO Pandemic Treaty. This overlapping legal environment raises the following core problems.

- *No single compliance pathway.* Making an annual contribution to the Cali Fund provides very limited value, as it only covers 'DSI within scope' and only for one year – without guaranteeing freedom from national ABS claims or compliance requirements under other international regimes.

- *Double (or multiple) payments*. Users can be compelled to pay more than once for access to the same DSI if national law requires separate payments or if other international treaties impose their own access and benefit-sharing obligations.

- *Uncertain scope of protection*. The MLM-DSI does not offer a definitive means of determining precisely which DSI falls within its coverage. Nor does it create a mechanism by which national authorities must align their legislation.

- *Administrative and financial burden*. Companies must navigate different legal regimes, check the legal provenance of each dataset they use, and potentially face overlapping fees. This undermines the objective of promoting research and innovation through a clear, predictable framework.

By requiring payment without conferring robust legal certainty, the MLM-DSI disincentivises participation. Rational businesses will avoid significant annual contributions that do not alleviate the broader risk of compliance failure or mitigate exposure to penalties under national laws or competing international regimes. Consequently, unless the MLM-DSI is reformed to address these critical gaps, its capacity to serve as a meaningful compliance mechanism for DSI benefit-sharing remains severely limited.

9. Fixing the MLM-DSI: A Last Chance at COP17 and COP18

The MLM-DSI was intended to provide a harmonised, legally certain and efficient approach to benefit-sharing at the global level. However, as structured under COP16, it falls short of delivering on that promise. Instead of a true multilateral system that simplifies compliance, the hybrid system created under Decision 16/2 introduces a new layer of complexity – one that fails to provide legal certainty, does not eliminate national ABS obligations, and risks creating overlapping or even contradictory compliance requirements.

Despite these shortcomings, the system is not beyond repair. CBD Parties still have an opportunity to fix fundamental flaws through the scheduled operationalisation of the Cali Fund leading up to COP17 and the scheduled review of the mechanism's effectiveness at COP18.[29] These meetings provide critical moments for countries to address key gaps in the MLM-DSI's structure, including:

- clarifying the definition of 'use', 'DSI', 'directly or indirectly use', 'directly or indirectly benefit' to prevent a fragmented regulatory landscape;

- ensuring that payments to the Cali Fund provide legal certainty and freedom to operate, so that companies contributing are not subject to additional ABS claims at the national or international level;

- aligning national ABS laws with the MLM-DSI to eliminate double payment obligations and conflicting compliance requirements;

29) Decision 16/2 para 29.

- establishing a universally recognised compliance certification that ensures that once a company contributes, it has met all its benefit-sharing obligations under the mechanism;

- creating a governance framework that ensures transparency, efficiency, and fairness in how funds are collected and distributed.

As countries move toward implementation, it is imperative that they take these issues seriously. If left unaddressed, the MLM-DSI risks becoming another administrative layer that fails to generate meaningful biodiversity funding. However, if properly restructured, it could still become the first truly multilateral ABS system that finally unlocks private monetary contributions towards biodiversity stewardship.