
BIA response to CBD consultation on possible additional modalities of the multilateral mechanism¹

About the BIA

The UK BioIndustry Association (BIA)² is the voice of the innovative life sciences and biotech industry, enabling and connecting the UK ecosystem so that businesses can start, grow and deliver world changing innovation. Our members include start-ups, biotechnology and innovative life science companies, large pharmaceutical companies, universities, research centres, tech transfer offices, incubators and accelerators, and a wide range of life science service providers: investors, lawyers, IP consultants, and IR agencies. We promote an ecosystem that enables innovative biotech companies to start and grow successfully and sustainably.

The BIA has always supported the biodiversity objectives of the CBD. We are invested in assisting in the development of a solution for the sharing of benefits arising from the use of Digital Sequence Information (DSI) on genetic resources while safeguarding biotech companies' ability to innovate, scale, and succeed.

Key points

BIA welcome the voluntary nature of the new mechanism. In this submission, we address outstanding concerns over some of the modalities of the multilateral mechanism as outlined in decisions 16/2. If unaddressed, these concerns may undermine incentives to contribute to the Cali Fund.

¹ See <https://www.cbd.int/doc/notifications/2024/ntf-2024-114-dsi-en.pdf>

² See <https://www.bioindustry.org/>

These outstanding points to be addressed by the CBD and its Parties include:

- A recognition of biotech's contributions to biodiversity and sustainability
- Clarification of terms, particularly on the meaning of 'direct' and 'indirect' benefit as well as 'use' of DSI
- Sector limitations
- Expectations of the funds to be raised by the Cali Fund
- Obligation stacking across international and national benefit sharing agreements
- The explicit exclusion of human and human-derived DSI
- Further clarification and monitoring of the use and disbursement of funds from the Cali Fund
- The review timelines for the mechanism and Fund

BIA welcome the opportunity to submit views on this matter to the CBD, and are committed to supporting the CBD and working with its Parties and other stakeholders in addressing these outstanding issues.

Views on current & additional modalities

Biotech's contribution to biodiversity

A fact that has thus far not been adequately recognised in the CBD's discussions on a mechanism for benefit sharing over the use of DSI is the positive contributions commercial users of DSI in the biotech sector make to biodiversity through their innovative products and processes, and the nature of their business. It is important that these are recognised.

The life sciences and biotech industry have always been supportive of the biodiversity aims of the CBD. Those who innovate using genetic resources and digital sequences, which includes many companies in our sector, are not the driving force behind biodiversity loss. On the contrary, innovation delivered by the life sciences and biotech sector is necessary for economic growth, public health and the delivery of solutions to problems which cause biodiversity loss.

Our industry has a long history of non-monetary benefit-sharing initiatives, including donations, technology transfer and voluntary licensing, capacity-building, and public health partnerships

that improve healthcare systems globally. These efforts represent significant contributions to global health security, ensuring that benefit-sharing does not come at the expense of innovation.

In addition, small biotech companies develop novel biosolutions³ with the direct goal to safeguard biodiversity and building a sustainable bioeconomy, by reducing our reliance on large-scale land use, fossil fuels, and environmental pollutants. The following is a non-exhaustive list of examples of UK-based solutions developed by small biotech companies which reduce the environmental impact of various sectors:

- An SME pioneering the first entirely biological process to dye textiles. Their technology harnesses nature's own processes, and offers substantial reductions in chemical use, carbon emissions, and water consumption compared to conventional dyeing processes.
- A startup that uses CRISPR-based gene-editing to control insect populations that harm health, food security and biodiversity.
- A startup that uses microbial engineering to create new biomaterials to replace animal and fossil fuel derived alternatives in the fashion industry.
- A startup using enzyme carbonic anhydrase to reduce and remove CO2 emissions.
- A university spin-out which uses clostridia bacteria to convert whisky co-products into biofuels and other green chemicals.
- A startup developing cell growth medium for lab-grown meat production, which avoids the animal welfare issues of conventional farming, and promises multiple environmental benefits.
- A startup leveraging synthetic biology and AI to decarbonise chemicals using a cyanobacterial platform.

For further examples of the positive impact of biotech companies towards the world's sustainability and biodiversity goals, please see our Deep Biotech⁴ and Power of Biology⁵ reports.

³ See <https://www.eubiocoalition.eu/what-are-biosolutions/>

⁴ See <https://deepbiotech.org/>

⁵ See <https://www.bioindustry.org/resource/engineering-biology.html>

The COP16 decision on DSI

While we welcome the voluntary nature of the new multilateral mechanism on DSI, concerns and a lack of clarity remain over some provisions of the decision and the operationalisation of the Fund.

- **Realistic expectations of funds to be raised.** Any consideration of the amount of funds mobilised through the Fund will necessarily involve comparing that which has been raised against the expectations of the Parties. The CBD's expectations are currently unrealistically high⁶. A realistic expectation has to be set about the funds to be raised, against which success of the Fund and mechanism can adequately be measured. Should these unrealistic expectations remain, the review to be conducted at COP18 may inevitably perceive any level of contributions reached by the Fund as inadequate. A realistic expectation should be driven by a bottom-up approach, through a full and appropriate assessment of the impact of levels of contributions *on innovators*.

In turn, appropriate and sustainable contribution rates, and the method for calculation thereof, should be arrived at through thorough and evidence-led assessment, working closely with commercial users and wider industry.

- **Clarification needs to be reached, by COP17 at the latest, on the meaning of 'direct' and 'indirect' benefits derived from the 'use' of DSI in commercial activities** (see Annex 16/2, Article 3⁷). It is currently unclear how commercial users who are asked to contribute to the Cali Fund should identify whether they directly or indirectly benefit from, or 'use', DSI that is within scope of the CBD. The meaning of the terms will also have consequences for how far the expectation of payments reaches through to companies within the supply or distribution chains of the development of a commercial product or process, that is, all actors involved in the development or 'commercialisation' of a product from research to development, manufacture and end-use. In particular, it is unclear whether those who use products that were made 'using' DSI are expected to share benefits, and contribute to the Cali Fund.

In addition, further clarity needs to be provided on the point in time at which profits or revenue to be shared over 'use' of DSI that took place at a given point in time would fall under the scope of the multilateral mechanism and therefore warrant a contribution to be made to the Fund.

⁶ See <https://www.cbd.int/doc/press/2024/pr-2024-06-30-dsi-en.pdf>

⁷ See <https://www.cbd.int/doc/decisions/cop-16/cop-16-dec-02-en.pdf>

- Sector limitations:** Decision 15/9 sets out the agreement of the Parties to the CBD that “benefits from the use of digital sequence information on genetic resources should be shared fairly and equitably”⁸. The mechanism decided at COP16 **limits the main contributions to be made to the Fund to users from a select few ‘indicative’ sectors**. It is illogical that users from only a few sectors should primarily contribute financially to the Fund while other users who benefit from DSI in other sectors are not. This is particularly true in that contributions are currently asked primarily of bio-innovators, many of whose innovations (as exemplified above) already contribute to global sustainability and biodiversity. To create a fair and equitable system, all users of DSI, regardless of the sector they operate in, should be encouraged to contribute to the Fund.
- Obligation stacking:** Article 15 in COP16.2⁹ states that the certificate received upon contributing to the Fund in line with the modalities of the multilateral mechanism excludes the user from any expectation to share further monetary benefits from the use of DSI within the scope of the multilateral mechanism for that year. This provision does not go far enough. Commercial users should only be required to share benefits of the use of DSI under one international instrument. Otherwise, industry could be subject to multiple obligations, including under the BBNJ, PIP and WHO pandemic accord PABS. They could also be obliged to pay under national ABS laws. This stacking would result in aggregated payment obligations that are not only difficult to navigate but have a significant impact on prices, innovation, etc. Moreover, the possibility of stacking at international and national levels is a significant disincentive to contribute to the Cali Fund.

This could be avoided by providing that any monetary contribution under one scheme satisfies benefit sharing requirements under all international schemes. We recognise that this is something that, as an institution, the CBD cannot mandate without agreement of other institutions, but we encourage all relevant organisations to agree on a way forward so to avoid obligation stacking and create legal certainty.

⁸ See <https://www.cbd.int/doc/decisions/cop-15/cop-15-dec-09-en.pdf>

⁹ See <https://www.cbd.int/doc/decisions/cop-16/cop-16-dec-02-en.pdf>

- **Human and human-derived DSI, including DSI from the human microbiome, should be explicitly excluded from the new mechanism.** That is, companies who only use human DSI should be excluded from the request to contribute to the Cali Fund, and from making non-monetary contributions, as they are not users of DSI that lies within the scope of the CBD or the decision made at COP16. This will create certainty for users of DSI that is not within scope of the CBD.
- **Further clarification is needed over the use and disbursement of funds from the Cali Fund to monitor its impact.** This is particularly important to commercial entities contributing to the Fund to show the impact and success of contributions made. It will also play an important role in incentivizing further contributions.
- **A review of the multilateral mechanism and Fund at COP18 is premature.** Whilst we understand the desire to review the effectiveness of the system, a review with the possibility of adjustments to the mechanism (as outlined by Articles 29 to 30 of decision 16/2) will be impractical, as many elements set out in decision 16/2 and Enclosure VI will be difficult if not impossible to judge in such a short time frame of the mechanism and Fund having been operational. The issues we outline above reduce the likelihood of contributions being made to the Fund, and need to be addressed before or as part of a first review of the mechanism and Fund.

In addition, for industry to be faced with the possibility of significant changes to the multilateral mechanism in as little as two years' time creates legal and commercial uncertainty. Any review should be done in a reasonable timeframe, and include a review of the impact of the multilateral mechanism *on those making contributions* to the Fund in order to ensure long-term feasibility, practicability, and minimised burden, particularly on the levels of contributions expected.

Accordingly, we propose that the review at COP18 should not be used as the basis for any *substantive* changes to the multilateral mechanism or Fund at that stage, but rather to identify areas of potential concern or opportunities for improvement. No substantive changes to the multilateral mechanism should be decided at COP18 itself, but issues identified should be

addressed in intersessional work following COP18 and proposals for any necessary changes reviewed at the following COP.

For the mechanism and Fund to succeed in the long term, the above points need to be addressed and clear incentives be created for biotech companies to be able to contribute. As exemplified above, commercial bio-innovators in our sector are not the drivers behind biodiversity loss. Those who already contribute to biodiversity and a sustainable bioeconomy through their innovative products and processes may find it difficult to contribute financially in addition.

BIA welcome further consultation by the CBD on the modalities of the mechanism and Cali Fund, and are keen to continue the important engagement between the CBD, its Parties, and the UK's life sciences and biotech industry.