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Item 11 of the provisional agenda*

Digital sequence information on genetic resources

Study on contribution rates, including implications for revenue generation and economic competitiveness and on national and international standards for the identification of the small, medium and large entities**

Note by the Secretariat

1. In decision 16/2, the Conference of the Parties to the Convention on Biological Diversity adopted the modalities for operationalizing the Multilateral Mechanism for the Fair and Equitable Sharing of Benefits from the Use of Digital Sequence Information on Genetics Information including a global fund, to be known as the Cali Fund, and set out its modalities in the annex to the same decision.
2. In paragraph 3 of this annex, the Conference of the Parties decided that 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, defines that 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, and add that the indicative list of sectors to which such users may belong is contained in enclosure I of the decision.
3. Additionally, in the same decision, the Conference of the Parties requested the Executive Secretary to prepare a study on national and international standards for the identification of the small, medium and large entities referred to in paragraph 3 of the annex to that decision (paragraph 5(d)) and to commission a study on contribution rates, including implications for revenue generation and economic competitiveness (paragraph 5(e)).
4. As such, the Secretariat issued notification [2024-116](#) inviting Parties other Governments, indigenous peoples and local communities and relevant organizations to submit information on national, regional or international standards on thresholds determining small, medium and large entities by 18 April 2025. The Secretariat received submissions from seven Parties and nine observers¹. The

* [CBD/COP/17/1](#).

** The present document is being issued without formal editing.

¹ Parties are Japan, United Kingdom of Great Britain and Northern Ireland, Brazil, Colombia, India, Republic of Korea, and the European Union and its Member States. Observers are KEIDANREN (Japan Business Federation), the UK BioIndustry Association (BIA), the Brazilian National Confederation of Industry (CNI), Grupo FarmaBrasil (GFB), the Brazilian Bioinnovation Association (ABBI), Nascimento e Mourão Sociedade de Advogados (in Portuguese, NMSA), the International Chamber of Commerce, Biz N Biodiversity Platform (BNBP), and the London School of Economics.

information submitted pursuant to this notification were integrated within this combined study, at section 5.3. Additionally, and considering the limited resources and the interlinkages between those two subjects, both studies were combined into one study, which was commissioned by the Executive Secretary to an external consultant. The outcome of the combined studies are presented within this document and an executive summary of the combined studies can be found at [CBD/COP/17/6/Add.3](#).

5. Finally, a peer review process for an initial draft of the combined studies was launched on 12 June through notification [2026-050](#). A total of 730 comments were received, 308 from 17 Parties and 422 from 17 rightsholders and observers.

6. The 729 comments received during the peer-review process cluster around seven main themes. As explained below, comments which presented factual or drafting issues were reflected accordingly in the revised text. Several comments reflected genuine policy disagreements, in particular around the design of the Multilateral Mechanism, or made points that, while valuable, were identified as outside of the scope of the study. These are briefly noted below.

(a) Clarity of key definitions: many comments related to use of terms: what counts as DSI, who is a "DSI provider," and how a corporate "entity" or "subsidiary" should be treated when it spans several countries. Definitions in the glossary were tightened in response, e.g. DSI and DSI provider. The decision to keep the study's scope limited to publicly available DSI was not changed, since this scope already reflects DSI covered by the Multilateral Mechanism, as found in paragraph 1 of the annex of decision 16/2.

(b) How the Fund compares to other schemes: many comments from both Parties and observers reflected on the comparison of the Cali Fund and other instruments, such as the International Treaty on Plant Genetic Resources for Food and Agriculture or the World Health Organization's pandemic frameworks (PIP Framework and the pandemic treaty) and indicated that some comparisons in the first draft were misleading. This led to significant redrafting, in particular of the sub-section on the International Treaty of Plant Generic Resources for Food and Agriculture.

(c) Whether the competitiveness assessment holds up: several comments queried the evidence behind the "limited competitiveness impact" conclusion, including reliance on a small 13-company consultation, on EU carbon-market literature, and on drawing conclusions for one sector from evidence about a different one. Feedback came mostly from observers, notably from the cosmetics sector, arguing that its numbers rest on the smallest, patchiest dataset and that their position as the sector with the highest effective contribution rate is really just a byproduct of the payment formula. Caveats to this effect were added.

(d) Whether the Fund is voluntary or binding: a number of comments, mostly from Parties, raised concerns regarding drafting seeming to imply that the Multilateral Mechanism is legally binding. Relevant paragraphs were redrafted to rectify this.

(e) Risk of contributions overlapping with other obligations: a recurring concern, mainly from observers but also from some Parties, related to the risk of double payments: once under national ABS law, and again under the Cali Fund. Unless this risk was addressed, several comments questioned whether the "compliance certificate" would actually motivate contributions. This reflects a genuine open-design question and has been reflected as such in the discussion on the overarching role of certificates on participation rates to the fund.

(f) How contributions are triggered and passed along: several comments, in particular from observers, raised concerns that under the multilateral mechanism, there is a risk that a single use of DSI could be charged more than once as it moves through a supply chain (say, from a raw ingredient supplier to a consumer brand) due to the terminology 'direct' and 'indirect' within decision 16/2. These comments are recorded here as a concern with the current design of the multilateral mechanism.

(g) Requests to go beyond the study's mandate: several comments, from both Parties and observers, requested that the study to expand its mandate and include information on the allocation formula, how disbursement should work, or broader conservation objectives. While these comments were

recorded as valid, they were identified as outside the scope of the present study as identified in paragraphs 6 of Decision 16/2.

7. The annex to this document present the final study as an information after the outcomes of the peer-review were reflected as described in paragraph 6.

Annex

Study on contribution rates, including implications for revenue generation and economic competitiveness and on national and international standards for the identification of the small, medium and large entities

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Acronyms

This study uses acronyms listed below:

ABS: Access and Benefit Sharing

AHTEG: ad hoc technical expert group

BBNJ: 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

BSF: Benefit-sharing Fund

CBD: Convention on Biological Diversity

COP: Conference of the Parties

DSI: Digital sequence information on genetic resources

ETS: European Union Emissions Trading System

GISRS: Global Influenza Surveillance and Response System

GBIF: Global Biodiversity Information Facility

IFC: International Finance Corporation

INSDC: International Nucleotide Sequence Database Collaboration

IP: Intellectual property

ISA: International Seabed Authority

ITPGRFA: International Treaty on Plant Genetic Resources for Food and Agriculture

KMGBF: Kunming-Montreal Global Biodiversity Framework

MAT: Mutually Agreed Terms

MLM: Multilateral mechanism

MLS: Multilateral System

MPTFO: Multi-Partner Trust Fund Office

NPV: Net Present Value

PABS: Pathogen Access and Benefit-Sharing

PC: Partnership Contribution

PIC: Prior Informed Consent

PIP Framework: Pandemic Influenza Preparedness Framework

SBA: Small Business Administration

SME: Small and Medium-sized Enterprise

SMTA: Standard Material Transfer Agreement

UN United Nations

UNCLOS: United Nations Convention on the Law of the Sea

WEOG: Western European and Other Group

WHO: World Health Organization

WIPO: World Intellectual Property Organization

Glossary

This glossary outlines the definitions and the assumed scope of the key terms used throughout the study.

Benefit-sharing Fund (BSF): the financial mechanism established under the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) is designed to receive and distribute monetary benefits generated from the commercial use of plant genetic resources originating from material accessed through the Treaty's Multilateral System. This mechanism is funded primarily by voluntary government contributions and, to a lesser extent, by user-based payments under the Standard Material Transfer Agreement (SMTA)², as well as voluntary contributions by the private sector and NGOs, international funds, and innovative initiatives. In this study, it is referenced as the closest operational precedent to the Cali Fund among existing international benefit-sharing mechanisms.

Digital Sequence Information on Genetic Resources (DSI): In Decision 14/20, the Conference of the Parties to the Convention on Biological Diversity noted that ‘the term “digital sequence information” may not be the most appropriate term and that it is used as a placeholder until an alternative term is agreed. Decision 15/9 then agrees on the continuing use of the term “digital sequence information” for further discussions. For the purposes of this study and in the absence of an internationally agreed meaning, DSI will be considered from non-human sources only, encompassing plants, fungi, animals, and microorganisms.

DSI intensity: the degree to which an entity’s commercial activities depend on publicly available DSI, relative to its total commercial activity. It varies considerably across and within Indicative Enclosure I sectors, with some entities using DSI directly and centrally in product and service development, and others relying on it only for a small subset of business activities. DSI intensity is distinct from being in scope of the multilateral mechanism (see “*eligible population*” below), which is determined by sector and financial thresholds rather than by the degree of DSI use.

DSI providers: Parties or indigenous peoples and local communities whose biological resources and associated genetic material are the origin of digital sequence information, irrespective of which entity subsequently sequences or deposits that information in publicly accessible databases, in compliance with national and international legislation.

DSI users: commercial and non-commercial entities that access and use digital sequence information on genetic resources in the scope of the Multilateral Mechanism on the Fair and Equitable Sharing of Benefits of the CBD in their research, development, or commercial activities.

Eligible population: The set of firms operating in Indicative Enclosure I sectors of the CBD Decision 16/2(CBD, 2024a), incorporated or principally operating in CBD Party jurisdictions, that meet at least two of the three financial thresholds (total assets of USD 20 million, annual revenue of USD 50 million, and annual profit of USD 5 million), averaged over the three most recent reporting years. These thresholds are indicative and adopted as interim parameters; Decision 16/2, Annex paragraph 4, provides that the Conference of the Parties will establish final thresholds and contribution rates at COP17, informed in part by this and other commissioned studies. Eligibility defines the scope of firms from which contributions to the Cali Fund are expected but does not imply participation.

² (ITPGRFA Secretariat, 2022; FAO, 2025c)

Entity: for the purpose of this study, unless specified otherwise, an *entity* refers to an individual legal entity, typically an operating for-profit company undertaking commercial activities. The treatment of entities in this study is further specified in Section 4.1 below.

Genetic resources: means genetic material of actual or potential value. These uses can range from basic research that seeks a better understanding of the world's natural resources to development for commercial products³.

Indifference margin: the profit margin at which a firm's contribution is identical under both the revenue-based and profit-based indicative rates in Decision 16/2, under the assumption, adopted in this study, that firms contribute on whichever base produces the lower amount. Decision 16/2 does not define 'revenue' as a payment base, nor its relationship to the 'sales' criterion used for eligibility; this study treats the two as equivalent and applies them at the individual legal-entity level. At the current indicative rates of 0.1% of revenue and 1% of profit, the indifference margin is 10%. Firms with profit margins above this threshold might choose to pay on revenue; firms below it might choose to on profit.

Multilateral Mechanism for the Fair and Equitable Sharing of Benefits from the Use of DSI (DSI MLM) was established at COP15 through Decision 15/9⁴, and later operationalised at COP16 through Decision 16/2⁵, this mechanism serves as the framework for the fair distribution of both monetary and non-monetary benefits generated from the use of DSI. The system for sharing monetary benefits is implemented through the Cali Fund.

Net Present Value: refers to the sum of a series of future cash flows discounted to their present value using a specified discount rate. In this study, NPV aggregates projected annual Cali Fund contributions over time into a single comparable figure, reflecting the principle that revenues received earlier have greater value than identical revenues received in the future.

Profit-base payer: a firm expected to contribute under the Cali Fund and whose profit margin falls between zero and the 10% indifference margin and therefore might choose to contribute 1% of profit under the minimum-of-two rule.

Revenue-base payer: a firm expected to contribute under the Cali Fund and whose profit margin exceeds the 10% indifference margin and therefore might choose to contribute 0.1% of revenue under the minimum-of-two rule.

UN Multi-Partner Trust Fund Office (MPTFO), hosted by UNDP, acts as the UN system's central administrative agent and technical hub for pooled funding mechanisms. It delivers independent fund design, financial management, as well as fiduciary oversight of multi-stakeholder trust funds. These funds are designed to drive humanitarian, development, and environmental results⁶.

³ Article 2, Convention on Biological Diversity (CBD, 2011)

⁴ (CBD, 2022)

⁵ (CBD, 2024a)

⁶ (UN MPTFO, no date)

1. Introduction

1.1. Mandate

Paragraph 6 of Decision 16/2⁷ requested the Executive Secretary, subject to the availability of resources, to commission analytical work ahead of COP17. This study responds to two of those requests, namely:

"Prepare a study on national and international standards for the identification of the small, medium and large entities referred to in paragraph 3 of the annex to the present decision."

Convention on Biological Diversity, Decision 16/2 paragraph 6(d)

and:

"Commission a study on contribution rates, including implications for revenue generation and economic competitiveness."

Convention on Biological Diversity, Decision 16/2 paragraph 6(e)

The direct relevance of the first study to COP17 is established in paragraph 4 of the annex to Decision 16/2, which states that:

"In the light of the studies on national and international standards for the identification of small, medium and large entities and on contribution rates, including implications for revenue generation and economic competitiveness, the Conference of the Parties will establish thresholds and contribution rates at its seventeenth meeting and review them periodically thereafter."

Convention on Biological Diversity, Decision 16/2 Annex paragraph 4

1.2. Scope and limitations

This study's focus on contribution rates and economic competitiveness reflects the specific mandate of Decision 16/2, paragraph 6(e). It should be read as one input among the fuller set of considerations set out in Decision 15/9 (see Background), including benefit-sharing, conservation, and support for the Convention's broader objectives, which this study does not independently assess. This study examines only the contribution aspect of the Cali Fund mechanism. It does not consider the allocation formula, distributional outcomes for recipients, or non-monetary benefit-sharing, or the governance, traceability, and disbursement arrangements of the Cali Fund itself, as these are out of scope and for some, addressed through separate intersessional processes. Any instances where the analysis addresses allocation, such as the interaction between contribution obligations and allocations, are explicitly stated. The study makes no finding on additionality, that is, whether funds raised through the mechanism would produce conservation outcomes that would not otherwise have occurred, or on the extent to which they complement rather than substitute for existing public conservation financing; the revenue estimates in Part II accordingly indicate what could be raised, not whether raising it advances the Convention's conservation objectives. The revenue estimates in this study should accordingly not be read as evidence that the mechanism will function as intended once operational; they describe potential contribution levels under stated assumptions, not the credibility or effectiveness of subsequent fund governance.

There are several important limitations to the contribution flow and competitiveness analyses, which are explained in detail in the relevant sections: Section 6.2 for contribution rate modelling and Section 7.2 for

⁷ CBD/COP/DEC/16/2 (CBD, 2024a)

competitiveness analysis. The impacts of those limitations on the interpretations of the results are explicitly addressed throughout the study.

1.3. Structure

The study starts with a background section, a review of other multilateral mechanisms concerned with the private sector, and the analytical framework assumed for the analyses.

The analyses are organised in three parts, each addressing a distinct element of the two mandates above.

Part I addresses paragraph 6(d). It examines national and international standards for entity size classification and assesses the Decision 16/2 financial thresholds against those standards. It also compares those standards to the current indicative threshold design.

Part II addresses the revenue generation dimension of paragraph 6(e). It presents firm-level data estimates of the Cali Fund's revenue potential under alternative participation scenarios. Furthermore, it examines the distributional properties of the current modalities on contribution across the indicative sector list.

Part III looks at the economic competitiveness and whether Cali Fund contributions might put participating firms at a disadvantage relative to non-participating firms. This part uses sector-level value chain analysis, compares financial burdens, and includes results from a dedicated industry consultation.

The discussion section brings together the findings from all three parts. The conclusion section presents elements that the Conference of the Parties might wish to consider at its seventeenth meeting.

1.4. Data and analytical inputs

Each section of the analysis uses different primary data sources. Part I uses submissions to the CBD Secretariat's [notification 2024-116](#), which requested information on how small, medium (SME), and large entities are classified at the national and international levels. These submissions came from Parties, other governments, indigenous peoples and local communities, and relevant organizations. Part II is based on Makowska-Curran⁸ a working paper from the Grantham Research Institute⁹ which analysed financial data from more than 20,000 eligible companies in 100 CBD Party jurisdictions to estimate potential Cali Fund contributions. Part III is supported by the results of an industry consultation of companies operating in eligible sectors and industrial association representatives. The consultation's questionnaire is provided in Annex B.

For all three parts, the main evidence comes from peer-reviewed literature. Where needed, the analysis also uses grey literature, other submissions to the CBD from Parties, indigenous peoples and local communities, observers, and non-Party stakeholders, and other official documents. All sources are cited throughout.

⁸ (2026)

⁹ Grantham Research Institute on Climate Change and the Environment; hosted by the Global School of Sustainability at the London School of Economics (<https://www.lse.ac.uk/granthaminstitute/about/about-the-institute/>).

2. Background: institutional and legal context

This section presents the institutional and legal context of the study, tracing the emergence of the multilateral mechanism for digital sequence information on genetic resources (DSI), and the core design features of the Cali Fund.

The term “DSI” remains a placeholder concept without an internationally agreed definition. Different international fora use varying terminology to refer to related forms of digitized genetic information and apply different scopes and governance approaches. Unless explicitly stated otherwise, this study uses the term DSI as it is discussed under the CBD framework (see glossary). 2.2

Terminology also varies across fora discussing related concepts. The CBD uses 'digital sequence information'; the BBNJ Agreement refers to 'digital sequence information on marine genetic resources of areas beyond national jurisdiction'; and discussions under the ITPGRFA and elsewhere have used 'genetic sequence data' to describe closely related material. This study uses 'DSI' throughout, consistent with the CBD framework, regardless of which term a particular source or instrument uses.

The long-term availability of publicly accessible DSI is not self-sustaining: it depends on continued investment in biodiversity conservation, species documentation, and sequencing infrastructure, work disproportionately carried out by megadiverse countries. This interdependence is part of the underlying rationale for benefit-sharing under the Convention, though assessing it in full is beyond the scope of this study's focus on contribution rates and competitiveness (see Scope and limitations).

2.1. Transition towards multilateral approaches for DSI

The Nagoya Protocol¹⁰ and other bilateral approaches, designed primarily for tangible genetic resources, raised practical challenges when applied to DSI. Among these challenges, as life science research came to depend increasingly on digitised sequence data stored in open-access repositories such as the International Nucleotide Sequence Database Collaboration (INSDC)¹¹, the bilateral access and traceability requirements underpinning the Protocol became difficult to apply at the scale and speed at which sequence data are generated, shared, and reused¹². This reflects a more fundamental distinction between the two mechanisms: unlike physical genetic material, which is finite and can in principle be tracked through a bilateral chain of custody, digital sequence data is non-rivalrous and can be replicated and accessed simultaneously by an unlimited number of users across multiple public repositories, making the bilateral, transaction-based model underlying the Nagoya Protocol structurally unsuited to DSI regardless of scale. This was one of several unresolved issues, alongside questions of attribution to a country or community of origin, the public-good character of open sequence databases, and disagreement over whether DSI constitutes utilisation under the Convention, that shaped the negotiations leading to Decision 15/9. The multilateral mechanism was developed as a pragmatic solution to be implemented alongside the Nagoya Protocol and other existing ABS instruments, rather than as a replacement for them. COP 15 in Montreal in December 2022, acknowledged this and adopted Decision 15/9, which formally established

¹⁰ Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (the Nagoya Protocol hereafter).

¹¹ (INSDC, no date)

¹² (Maia and Bourgeois-Gironde, 2025)

the multilateral mechanism for the fair and equitable benefit-sharing from the use of DSI and set out the main criteria that a solution for benefit sharing from the use of DSI should meet. It recognised the practical challenges associated with tracking and tracing DSI, established a multilateral approach as a practical response, and stressed that any benefit-sharing arrangement must be consistent with principles of open data. The decision also stated that the mechanism should deliver benefits that outweigh its costs, offer users legal certainty and clarity, not hinder research and innovation, align with international legal obligations, and respect the rights of indigenous peoples and local communities¹³. Establishment of the multilateral mechanism reflected not only these practical and technical considerations, but also the collective objective of addressing long-standing equity concerns raised by biodiversity-rich provider countries regarding benefit-sharing from DSI use, and of strengthening implementation of the Convention's third objective on the fair and equitable sharing of benefits.

Building on this and intersessional work, at COP16 in Cali in October 2024, Parties agreed on Decision 16/2(CBD, 2024a), which adopted the modalities for operationalizing the multilateral mechanism. This decision operationalised the global financing instrument, designated as the Cali Fund, to channel and distribute the monetary benefits arising from the use of DSI.

The Cali Fund was officially launched in February 2025, administered by the United Nations Multi-Partner Trust Fund Office (MPTFO). The MPTFO provides an institutional structure for receiving, managing, and disbursing resources at the global level.

2.2. The Multilateral Mechanism for the Fair and Equitable Benefit-sharing of Digital Sequence Information on Genetic Resources, and its Cali Fund

This subsection presents the institutional design and operational arrangements of the DSI MLM as established under decision 15/9 and operationalized under decision 16/2.

Scope of DSI

At the CBD as well as other international agreements, digital sequence information is a placeholder term, highlighting the lack of a commonly agreed definition (Houssen, Sara and Jaspars, 2020). Under the CBD, where most of the discussions on DSI's meaning and boundaries have taken place so far, it is understood as a broad umbrella covering a wide range of potential data types and uses, potentially due to the different uses of DSI in different scientific disciplines (Heinemann, Coray and Thaler, 2018; Smyth *et al.*, 2020). However, “the scope of each international ABS instrument is not delineated using the same characteristics or legal concepts” but rather set by jurisdictional boundaries, organism-specific characteristics and type, or its intended use of research and development outputs (Switzer, Rourke and Eccleston-Turner, 2025). Therefore, this subsection presents the scope of DSI under relevant mechanism and will not attempt to set out a single definition for this study. Note that these multilateral mechanisms are further analysed in Section 3, while Section 4.2.3 below explores the potential consequences of firms facing multiple DSI-linked commitments for the Cali Fund participation.

¹³ Full list of criteria can be found in Decision 15/9 paragraph 9.

Box 1: DSI scope in the multilateral mechanism

The primary scope of DSI used for the purpose of this study is determined based on the wording found in Decision 16/2:

[Decision 16/2 Annex para. 1(CBD, 2024a)] The multilateral mechanism for the fair and equitable sharing of benefits from the use of digital sequence information on genetic resources covers, without prejudice to national legislation, digital sequence information on genetic resources:

- That is made publicly available, in compliance with national legislation, where applicable;
- That is not subject to mutually agreed terms established at the time of access to the genetic resources from which the digital sequence information is derived, unless those terms allow for the making of the digital sequence information on genetic resources freely available;
- For which the fair and equitable sharing of benefits from the use of digital sequence information on genetic resources is not provided for under other international instruments

- **Multilateral Mechanism under the CBD:** The mechanism covers DSI that is publicly available, not subject to prior mutually agreed terms, and not already covered by other international instruments.
- **BBNJ Agreement**(UN General Assembly, 2023): The BBNJ Agreement applies to marine genetic resources found in areas beyond national jurisdiction and specifically refers to “*digital sequence information on marine genetic resources of areas beyond national jurisdiction*” while simultaneously acknowledging that the term DSI is not defined within the agreement. Under the BBNJ framework, benefit-sharing follows a multilateral approach and applies regardless of whether physical marine genetic resources or intangible DSI from MGRs are obtained.
- **The Plant Treaty (ITPGRFA)**(FAO, 2001): The FAO created a dedicated ABS system that governs a specific range of plant genetic resources for food and agriculture (Annex I). It grants facilitated access for research, breeding and training through a Standard Material Transfer Agreement (SMTA), which encourages all users to share non-monetary benefits resulting from the use of the genetic resource, and in certain instances of commercialisation triggers monetary benefit-sharing duties.
- **The Pandemic Influenza Preparedness (PIP) Framework** (WHO, 2021): A WHO-administered mechanism covering seasonal and pandemic influenza virus samples and associated sequence data shared through the Global Influenza Surveillance and Response System (GISRS). Manufacturers that rely on GISRS pay an annual Partnership Contribution equal to 50% of the System's operating expenses into a pooled fund, while benefit-sharing obligations under its Standard Material Transfer Agreement 2 (SMTA2) are arranged bilaterally between manufacturers and WHO and are largely in-kind, including vaccine donations and mutually agreed terms before technology transfer.
- **The WHO Pandemic Agreement** (WHO, 2025b): Recent discussions on the WHO Pandemic Agreement have introduced provisions for a Pathogen Access and Benefit-Sharing (PABS) System. This

system is meant to cover PABS Materials and Sequence Information defined in the Annex but broadly includes both physical pathogen materials with pandemic potential and the related sequence data for pathogens with pandemic potential, however at the time of writing is still under negotiation and therefore not yet defined.

DSI multilateral mechanism

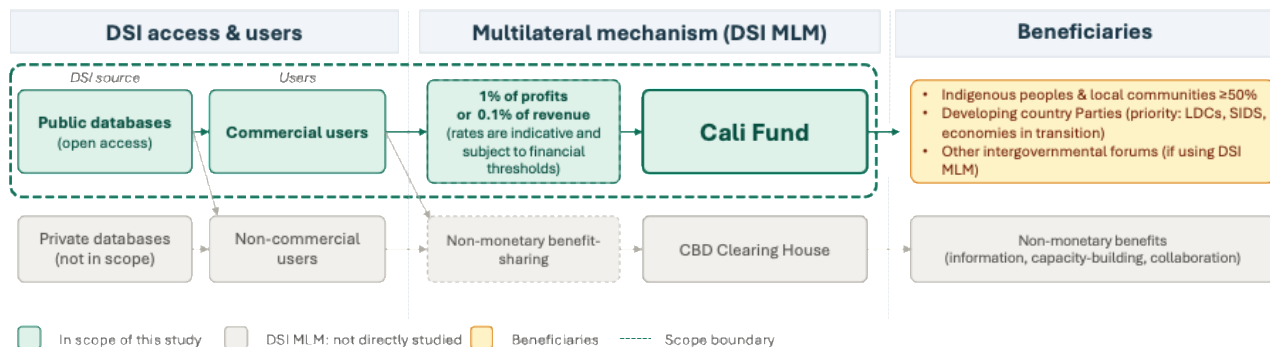
Decision 16/2 defines the operational framework for the DSI multilateral mechanism (DSI MLM). Open access to DSI is a foundational premise of this mechanism, not an outcome it protects: benefit-sharing obligations arise from the use of DSI rather than from access to it, which allows the mechanism to operate without restricting or gating access to sequence data. All users of DSI should share benefits, which can be monetary and non-monetary benefits. While all users should share non-monetary benefits, as appropriate (see para 6 of annex of decision 16/2), users in sectors that directly or indirectly benefit from the use of DSI should also share monetary benefits.

In practice, the boundaries between commercial and non-commercial use can blur. Academic research conducted with public grant funding is typically non-commercial, but the same research can shift in character once it feeds into a company-sponsored partnership aimed at eventual product development, even before any product exists (Vieira, 2015). A related case arises within commercial entities themselves: a company's early-stage R&D, such as screening DSI against a reference dataset to identify candidate compounds, is exploratory and produces no product, yet is conducted by a commercial entity with eventual commercial intent. Submissions to CBD Notification 2024-114 raised exactly this question, asking whether such early-stage use, distinct from use in a final product, should trigger the same benefit-sharing expectation as later-stage commercial use; this study does not resolve that question, treating R&D activities as in scope for the revenue analysis (see 4.1). A related boundary case concerns sequencing conducted for taxonomic identification, strain verification, or safety and regulatory compliance purposes, such as in probiotic, botanical, or microbial supplement production, where sequencing functions primarily as a quality assurance tool rather than a means of extracting commercially exploitable genetic information. Whether such use constitutes 'use' of DSI within the meaning of Decision 16/2 is, like early-stage R&D screening, not resolved by the current text.

The benefits generated through the DSI MLM are intended to be allocated to indigenous peoples and local communities, in both developing and, where appropriate, developed countries (with at least 50% of funding earmarked for their self-identified needs), and developing country Parties, in particular least developed countries, small island developing states and economies in transition. Other intergovernmental forums may also use the Cali Fund if they choose to. Decision 16/2 envisages that these benefits, monetary and non-monetary, should support biodiversity conservation, sustainable use, capacity-building, technology transfer, and scientific cooperation, contributing to implementation of the Kunming-Montreal Global Biodiversity Framework; this study's focus on the contribution side of the mechanism does not extend to assessing these downstream objectives (see Scope and limitations).

Figure 1 provides an overview of the DSI MLM's overall structure and indicates the elements that lie within the direct scope of this study.

Figure 1 Design of the DSI MLM



Notes: This study focuses on commercial users of publicly available DSI and their monetary contributions to the Cali Fund (teal, dashed border). The DSI MLM also covers non-commercial use and non-monetary benefit sharing via the CBD Clearing House¹⁴.

Source: Author's illustration adapted from Decision 16/2 and Orozco and Scholz (2025).

DSI MLM principles

The core design principles of the DSI MLM were initially set out in Decision 15/9 paragraphs 9 and 10. These paragraphs specify the main criteria that any DSI benefit-sharing solution should fulfil.

[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;*
- b) Generate more benefits, including both monetary and non-monetary, than costs;*
- c) Be effective;*
- 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;*
- g) Not be incompatible with international legal obligations;*
- h) Be mutually supportive of other access and benefit-sharing instruments;*
- 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;*

Convention on Biological Diversity, Decision 15/9 paragraph 9

¹⁴ Coverage by the multilateral mechanism is determined by the specific conditions laid down in Decision 16/2, and this simplification is used for illustrative purposes only.

[The Conference of the Parties] Recognizes that the monetary and non-monetary benefits arising from the use of digital sequence information on genetic resources should, in particular, be used to support conservation and sustainable use of biological diversity and, inter alia, benefit indigenous peoples and local communities;

Convention on Biological Diversity, Decision 15/9 paragraph 10

Contributions to the Cali Fund

This subsection outlines the modalities and indicative parameters adopted under Decision 16/2 for contributions to the Cali Fund and relevant for this study, covering who is expected to contribute, indicative contribution rates, exemptions, and payment modalities.

Box 2 summarises the key parameters derived from Decision 16/2 covering: (A) indicative criteria for the Fund's contributors' size and industrial activity (defined by sectors), and (B) indicative contribution rates.

Box 2: Scope of the Cali Fund contributions

A. Cali Fund contributors

As defined in Decision 16/2:

DSI use and type of activity: Users of digital sequence information on genetic resources in sectors that **directly or indirectly benefit from its use** in their **commercial activities** (...).

Company size: Entities that, on their balance sheet dates, **exceed at least two out of three thresholds** (namely, total assets: 20 million United States dollars, sales: 50 million United States dollars, and profit: 5 million United States dollars) averaged over the preceding three years.

Indicative list of sectors that may benefit from DSI:

Sectors that may benefit directly or indirectly from the use of digital sequence information on genetic resources include:

- a) Pharmaceuticals;
- b) Nutraceuticals (food and health supplements);
- c) Cosmetics;
- d) Animal and plant breeding;
- e) Biotechnology;
- f) Laboratory equipment associated with the sequencing and use of digital sequence information on genetic resources, including reagents and supplies;
- g) Information, scientific and technical services related to digital sequence information on genetic resources, including artificial intelligence.

B. Indicative contribution rates

(...) should contribute to the global fund **1 per cent of their profits or 0.1 per cent of their revenue**, as an indicative rate.

Notes: Emphasis added by the author.

Annex to Decision 16/2 on modalities for operationalising the DSI MLM, further clarifies the scope of entities that fall within the contribution modalities and expectations described in the Decision.

Paragraph 5 states that:

The 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.

Convention on Biological Diversity, Decision 16/2 Annex paragraph 5

Consequently, mere inclusion in a sector covered by Enclosure I does not, on its own, determine contribution expectations; instead, the expectation also depends on whether the entity benefits from its use of DSI in their commercial activities.

With no official definition or description of the term “direct or indirect” use of DSI, how this term is implemented in practice may differ between entities and jurisdictions.

Similarly, questions relating to the scope of participation and assessment level of an ‘entity’ may be interpreted differently. Section 4 revisits these ambiguities within the context of the analytical framework.

Additionally, paragraph 16 of the Annex encourages voluntary contributions from entities that fall outside the modalities specified in Decision 16/2. The classification of which entities this applies to is not free of ambiguity: because Enclosure I is described as an ‘indicative’ list and paragraph 1 uses non-exhaustive language (‘include’), it is not settled whether DSI-using entities outside the listed sectors fall under paragraph 16. For the purpose of this study, and pending clarification by the COP, this includes, among others, entities that use DSI but operate in sectors other than those listed in Enclosure I, paragraph 1; entities that use DSI but do not meet the “two out of three” financial threshold criteria set out in Annex, paragraph 3; and entities that benefit from the use of DSI in the context of non-commercial activities.

Furthermore, paragraph 15 of the Annex to Decision 16/2 specifies that contributing entities will receive a certificate, defined as:

For each year that users make monetary contributions to the fund in line with the modalities of the multilateral mechanism, they will be considered as having fairly and equitably shared monetary benefits arising from the use of digital sequence information on genetic resources under the multilateral mechanism and will receive a certificate accordingly. Such a certificate excludes the user from any expectation to share further monetary benefits from the use of such information within the scope of the multilateral mechanism for that year.

Convention on Biological Diversity, Decision 16/2 Annex paragraph 15

Finally, Decision 16/2 invites Parties and non-Parties to:

(...) 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 modalities of the multilateral mechanism.

Convention on Biological Diversity, Decision 16/2 Annex paragraph 13

Notably, as Parties design and implement such incentivization measures, any concern surrounding the ‘voluntary nature’ of contributions to the mechanism would diminish considerably. Legislative measures at the national level would alleviate any uncertainty. Moreover, other measures such as e.g. fiscal incentives, could incentivise contributions without affecting the voluntary nature of the Fund.

Cali Fund allocation formula

The allocation formula falls outside the primary scope of this study. Its potential relevance to participation incentives is discussed in Section 4 (section 'Who participates?', Allocation formula).

3. Contribution rate models in analogous monetary benefit-sharing mechanisms

This section reviews existing contribution rate models in international benefit-sharing mechanisms that rely on private sector monetary contributions. It covers how rates are determined, the revenues these mechanisms have generated, and the factors shaping revenue generation and compliance. The findings inform the assumptions used in the contribution rate analysis in Part II and the competitiveness framework in Part III.

3.1. The Multilateral Access and Benefit-Sharing System of the International Treaty on Plant Genetic Resources for Food and Agriculture

The Plant Treaty (ITPGRFA) which was adopted in 2001, entered into force in 2004 and the MLS of the Plant Treaty became operational in 2007, is the closest existing precedent to the Cali Fund, in that it established a multilateral system that governs monetary and non-monetary benefit sharing for PGRFA. The discussion below focuses specifically on the monetary benefit-sharing flows under the Standard Material Transfer Agreement (SMTA), as the closest available comparator for the Cali Fund's own contribution mechanism, rather than on the MLS's broader non-monetary architecture

Under the Treaty's Multilateral System (MLS), users who commercialise products developed from MLS material and restrict further access must pay into the Treaty's Benefit-sharing Fund (BSF) via the SMTA 1.1% of the sales of commercialised products, less a 30% deduction for commercialisation costs¹⁵ (Tsioumani, 2020), which gives an effective rate of approximately 0.77% of sales¹⁶. Recipients may instead opt into an alternative payment scheme under Article 6.11, paying a discounted 0.5% on gross sales of all Plant Genetic Resources for Food and Agriculture (PGRFA) products of the same species accessed from the MLS, regardless of restriction status, in place of the standard rate. Article 6.8, covering products made freely available without restriction, encourages voluntary payments but does not specify a rate. The Cali Fund's indicative rates of 1% of profits or 0.1% of revenue apply to a firm's total profit or revenue rather than to sales of a specific product, a materially broader base than the SMTA's product-specific payment obligation. Because the SMTA's 0.77% rate applies only to the sales of the specific commercialised product incorporating MLS material, while the Cali Fund's indicative rates apply to a firm's total revenue or profit, the two are not directly comparable in magnitude. If anything, this difference in base means the Cali Fund's effective burden relative to a firm's total economic activity is likely to be higher than the SMTA's, not lower, though no data exists to quantify this precisely. Whatever the true relative burden, income from user-based payments under the SMTA has remained minimal over fifteen years of operation: by May 2025, total SMTA receipts amounted to just USD 824,680 from six

¹⁵ This gives an effective rate of approximately 0.77% of sales (Switzer *et al.*, 2023).

¹⁶ Sales and revenue are used interchangeably here. This distinction is material for firms deriving significant income from non-sales sources such as licensing fees or royalties, which is a relevant consideration for the plant breeding sector specifically, where trait licensing and royalty income are a substantial part of large firms' revenue (see Animal and plant breeding, Section 7.10). The approximation is used here for the aggregate comparison across sectors and should be read with this caveat in mind.

companies, representing only 2.2% of the Benefit-sharing Fund's USD 36.9 million total (FAO, 2025b)¹⁷. The ITPGRFA's own commissioned analysis projected payments of USD 10 million per year by 2030¹⁸ (Moeller and Stannard, 2013); actual payments averaged approximately USD 55,000 per year over fifteen years, noting that the figures are not directly comparable due to different time spans. Consequently, the BSF remains financed almost entirely through governmental contributions. This shortfall reflects structural flaws rather than the payment rate itself. Obligations under the SMTA arise only upon commercialisation, a stage rarely reached given the lengthy interval between research and product development (Bassi, Sanchez-Garcia and Ortiz, 2024); companies can fully avoid these obligations by sourcing material outside the MLS; voluntary payments generated and thus an uneven playing field (ITPGRFA Secretariat, 2014; Tsioumani, 2020); and reform discussions have not resulted in a revised SMTA, despite the Enhancement Process having examined many of the same issues raised later in this study for the plant breeding sector, including early benefit-sharing payments, a possible subscription option, and the inclusion of licensing fees in the payment basis; the 11th Governing Body in November 2025 was unable to reach agreement on these proposals (FAO, 2025a).

Unlike the ITPGRFA, where payment under the standard SMTA route becomes a binding contractual obligation once a firm accesses Multilateral System material and commercialises a restricted product, the Cali Fund's contribution expectation under Decision 16/2 creates no equivalent binding duty; participation depends on the incentives available rather than an enforceable obligation, a deliberate design choice reflecting the voluntary nature agreed by Parties. This is a structural difference, not a shared feature, and one that plausibly makes the Cali Fund more exposed to the participation risks the ITPGRFA experience illustrates, not less. Beyond this, the Cali Fund exhibits two further structural weaknesses analogous to the ITPGRFA's: DSI can be obtained beyond the scope of Decision 16/2 via private databases, and the specific DSI uses that would trigger contributions are not explicitly defined.

The Pandemic Influenza Preparedness Framework

Adopted in 2011, the WHO Pandemic Influenza Preparedness (PIP) Framework obliges manufacturers that rely on the Global Influenza Surveillance and Response System (GISRS) to pay an annual Partnership Contribution (PC) equal to 50% of GISRS operating expenses (currently USD 33.7 million per year) managed as a pooled fund by WHO (WHO, 2021; Switzer *et al.*, 2023). In contrast to the Cali Fund, the benefits shared under the PIP framework's Standard Material Transfer Agreement 2 (SMTA2) are largely in-kind, including real-time vaccine donations and mutually agreed terms before technology transfer commitments, and arranged through bilateral, confidential agreements rather than through a centralised monetary fund (Rourke, 2019; Hampton *et al.*, 2023). Within its defined contributor base, the Framework has generated substantial participation: 17 manufacturers have entered into SMTA2 agreements, together accounting for roughly 85% of global pandemic vaccine manufacturing capacity, with total PC collections reaching USD 354.7 million for the period 2012-2025 (WHO, 2025a, 2026). This performance depended on structural factors that are not easily reproduced for the Cali Fund: manufacturers faced a clearly defined obligation; their operational reliance on GISRS-supplied candidate vaccine viruses created strong incentives to join; and the small, well-identified contributor group allowed costs to be distributed across competitors mitigating first-mover disadvantage (Rourke, 2019; Huvos, Solomon and Nannini, 2020). Neither of these enabling conditions are present for the Cali Fund, where the scope of the multilateral mechanism is limited to the use of publicly available DSI, users operate across several

¹⁷ Note that these payments are to be made once per year, for as long as access is restricted. The companies who started payments only recently will therefore continue to make payments, increasing the overall amount.

¹⁸ The study assumed that 50% of payments would be voluntary.

sectors, and the degree to which any particular firm's products rely on publicly available DSI is hard to determine (Sett *et al.*, 2024a). As a result, the main takeaway concerns structural prerequisites rather than specific contribution rates - to secure broad, voluntary financial participation in a multilateral mechanism, there must be a clearly bounded set of contributors, precisely defined obligations, and burden-sharing arrangements that offset first-mover disadvantage. All of those elements currently remain only partially addressed under the current Decision 16/2 modalities.

The WHO Pandemic Agreement

The WHO Pandemic Agreement, adopted in May 2025 (WHO, 2025b), represents a further shift away from the PIP model toward a binding, in-kind-first approach. Through its Pathogen Access and Benefit Sharing (PABS) framework it obliges pharmaceutical manufacturers to allocate 10-20% of their real-time pandemic production to WHO as a condition for gaining access to pathogen samples and sequence information. The practical implementation has been postponed to a PABS annex, which is still being negotiated. Decision 15/9 requires that any solution for benefit-sharing from DSI be mutually supportive of other international instruments and not incompatible with existing international legal obligations. Whether this is achieved in practice for the WHO Pandemic Agreement specifically remains to be seen, since implementation arrangements under its PABS framework are still under development. For this study, the Agreement matters primarily because of the overlap risk this uncertainty introduces: firms relying on pathogen DSI could, absent a coherence arrangements between the two mechanisms, incur parallel in-kind obligations under the Pandemic Agreement while also becoming subject to monetary benefit-sharing expectations under the Cali Fund for the same activity (Jon, 2025). The consequences for firm-level contribution choices are examined in Section 4.2.

3.2. The Agreement on Marine Biological Diversity of Areas beyond National Jurisdiction (BBNJ)

The BBNJ Agreement entered into force on 17 January 2026 (United Nations Treaty Collection, 2026). In its current form it creates a framework for future rulemaking rather than a fully operational payment system for private sector (Krabbe, 2025; Yu *et al.*, 2025; Krabbe and Wagenaar, 2026). At present, the most concrete financial obligations rest with developed States, which are required to make annual contributions to a dedicated fund equal to 50 per cent of each Party's assessed budget contribution¹⁹. The COP will later decide how monetary benefits arising from the commercial exploitation of marine genetic resources and related DSI should be allocated among downstream users (Krabbe, 2025; Whomersley, 2025; Krabbe and Wagenaar, 2026). BBNJ's significance for the Cali Fund lies in the way it highlights the challenges of converting broad political agreement on fair and equitable benefit-sharing into a workable payment mechanism; key elements, including contribution levels, payment triggers, and the legal nature of user obligations, are still unresolved, and the literature repeatedly emphasizes that any feasible system would need strong disclosure and traceability rules before obligations on private users could be effectively implemented (Humphries *et al.*, 2020; Humphries, Rabone and Jaspars, 2021; Yu *et al.*, 2025).

3.3. The International Seabed Authority

¹⁹ Article 14 paragraph 6

The International Seabed Authority (ISA) is not itself an access and benefit-sharing mechanism, but its payment system offers a useful reference point for designing private-sector contributions within an international regime (Feichtner, 2019; Willaert, 2022). An ISA-commissioned technical report recommended a tiered ad valorem royalty beginning at 2% of the total value of metals recovered in the initial production stages, increasing to 6% in later stages; however, exploitation rules were still being negotiated as of early 2026 (Kirchain *et al.*, 2019; Wilde *et al.*, 2023; IISD, 2026). The literature on rate design converges on a lar finding, that profit-based instruments are theoretically more equitable but vulnerable to transfer-pricing abuse and hard to verify when oversight capacity is limited, while straightforward ad valorem schemes are easier to implement and enforce, even though they tend to capture less value over the long term (Nijen *et al.*, 2019; Thiele, Damian and Singh, 2021). For the Cali Fund, the key lesson is that contribution levels must be evaluated together with the ease of measurement and the risk of avoidance, rather than in isolation; a seemingly lower but straightforward, verifiable rate may ultimately yield more revenue than a higher nominal rate that is open to dispute and manipulation.

3.4. Synthesis and implications for the Cali Fund

Table 1 summarises the key features of each mechanism.

Table 1 Comparison of analogous benefit-sharing and payment mechanisms

Mechanism	Legal status	Contribution basis	Rate	Observed participation	Key lessons
ITPGRFA / MLS (SMTA)	Binding treaty; contribution route itself voluntary/discretionary depending on option chosen	Sales of the specific commercialised product (not total firm revenue)	1.1% of product sales less 30% deduction ($\approx 0.77\%$ effective); or 0.5% alternative scheme on all PGRFA products of the species (Art. 6.11); voluntary, unspecified rate for unrestricted products (Art. 6.8)	USD 824,680 total from 6 companies since 2007 (2.2% of BSF); commissioned projection of USD 10m/year vs. actual $\sim$ USD 55,000/year	Obligation may be avoidable by sourcing outside MLS; narrow, rarely reached commercialisation trigger; no public-sector fallback if user income falls short
WHO PIP Framework	Binding on manufacturers relying on GISRS	Fixed Partnership Contribution tied to GISRS operating costs	50% of GISRS operating expenses ($\sim$ USD 33.7m/year, pooled)	17 manufacturers, $\sim 85\%$ of global pandemic vaccine capacity; USD 354.7m collected 2012-2025	Success depended on a clearly bounded contributor group, a precisely defined obligation, and burden-sharing that offset first-mover disadvantage — conditions the Cali Fund currently lacks
WHO Pandemic Agreement (PABS)	Binding (adopted May 2025); implementation details still being negotiated	In-kind: 10–20% of real-time pandemic production, as a condition of accessing pathogen samples/sequences	Not monetary	Not yet operational	Creates a direct overlap risk: firms using pathogen DSI may face both potential PABS in-kind obligations and Cali Fund monetary obligations for the same activity
BBNJ Agreement	In force (Jan 2026); private-sector payment system not yet designed	Currently government-only (developed States pay into a fund based on assessed budget contributions); private-sector mechanism still undecided	50% of assessed budget contribution (states only, for now)	Not yet applicable to private users	Illustrates how far broad political agreement can be from a workable private-sector payment mechanism; disclosure/traceability seen as a prerequisite before firm-level obligations can work
International Seabed Authority	Not an ABS mechanism, but a comparable royalty-design precedent	Ad valorem on value of resources recovered	Tiered, 2% rising to 6% (recommended, not yet finalised)	Rules still under negotiation as of 2026	Simple ad valorem designs are easier to enforce and audit than profit-based ones, though they may capture less value over time

The contrast between the ITPGRFA MLS and PIP experiences together points to the importance of structural conditions in determining whether private sector contributions materialise. The Cali Fund currently shares more structural features with the Plant Treaty's MLS than with the PIP Framework, and unlike both, lacks a comparable public sector fallback²⁰ to compensate for shortfalls in user-based income. The two mechanisms differ in legal basis, governance, and contributor base, so this comparison is used as the closest available reference point rather than a precise predictive model, except where explicitly used to calibrate the lower bound of the revenue scenarios in Part II, given the mechanisms' shared reliance on voluntary, non-binding contributions.

The design of the contribution rate and its measurement basis have, in comparable mechanisms, been closely linked to how readily the underlying obligation can be defined and verified. Under the Plant Treaty's SMTA, companies may source material from non-Party countries or private collections to sidestep obligations (Moeller and Stannard, 2013; Rabitz, 2017). The equivalent underlying genetic sequence information remains accessible through private databases outside the scope of Decision 16/2, even where publicly available DSI on the same resource is captured by the Cali Fund. The PIP experience adds a further dimension: when scope definitions are tied to physical material transfers rather than actual data use, companies relying on sequence data alone can fall entirely outside the contribution framework. The Cali Fund faces an analogous risk, as its contribution scope is broad in sectoral coverage but lacks clear definitions. Neither DSI itself nor the distinction between direct and indirect uses have been defined, which leaves room for contested interpretation.

The ISA literature underscores a related insight: relatively simple ad valorem contribution models tend to be more enforceable than profit-based arrangements, even if they capture less value over time. Their structure makes them less vulnerable to transfer pricing manipulation and easier to audit where monitoring capacity is constrained. The revenue effects of different rate designs are assessed in the contribution rate analysis in Part II.

Together, the evidence from all four mechanisms shows that rate levels must be assessed alongside measurement feasibility, avoidance risks, and the strength of institutional implementation. To address this, the indicative contribution rates under Decision 16/2 are adjusted for realistic compliance presented in Part II.

4. Analytical framework: implications of the DSI MLM design for economic assessment

²⁰ Decision 16/2 also encourages contributions from entities beyond those defined as commercial DSI users under Annex paragraph 3, including potential public sector contributors (Decision 16/2, paragraph 16). At the time of writing, no such commitments have been made. This distinguishes the Cali Fund structurally from the analogous mechanisms reviewed in Section 3. Under the Plant Treaty, several Parties provided the revenue floor that compensated for negligible user-based income. The PIP Framework similarly relies on a defined contributor base with operational incentives that limit total non-compliance. The Cali Fund has no comparable public sector fallback, making the mobilisation of private sector contributions more essential to its financial viability than in any of the reviewed analogues. This study treats the private sector contribution modelled in Part II as the Fund's primary revenue source.

This section translates the design of Decision 16/2 into the analytical parameters applied in Parts I (industry classification standards), II (contribution rates analysis), and III (competitiveness analysis). It identifies the modalities of the mechanism that require explicit methodological positions prior to empirical analysis and clarifies the rationale for presenting results across a range of scenarios due to several uncertainties around companies' eligibility, participation, and their ultimate level of contribution.

Figure 2 presents the participation decision framework that structures the analysis. The summary of all the identified uncertainties can be found in Table 2.

The factors identified in this section are derived from three primary sources: peer-reviewed literature evaluating the modalities of Decision 16/2, comparative analysis of multilateral contribution models presented in Section 3, and official submissions to CBD intersessional consultations from Parties, industry representatives, and other relevant stakeholders²¹. CBD notification submissions reflect positions in an ongoing negotiation process and are used here to corroborate factors identified in the academic literature and show relative salience of concerns among the relevant actors, rather than as independent evidence of how firms can be expected to behave.

Decision 16/2 sets out indicative parameters pending further development ahead of COP17, which once agreed, may determine entity eligibility, participation behaviour, and contribution burden. Where the decision provides a clear basis, this study makes transparent methodological choices, presented below. Where it does not, the underlying features are treated as uncertainties and reflected in the scenario analysis, because the existing evidence is often insufficient to assign them settled values. The volume of unresolved parameters reflects the early stage of the mechanism's implementation, and many of the elements discussed here are expressly identified in Decision 16/2 as pending further development ahead of COP17. Each such uncertainty has a direct impact on the revenue analysis in Part II, where the scenario range changes depending on how these parameters are defined, and on the competitiveness analysis in Part III, which examines how they influence the distribution and magnitude of firm-level burdens.

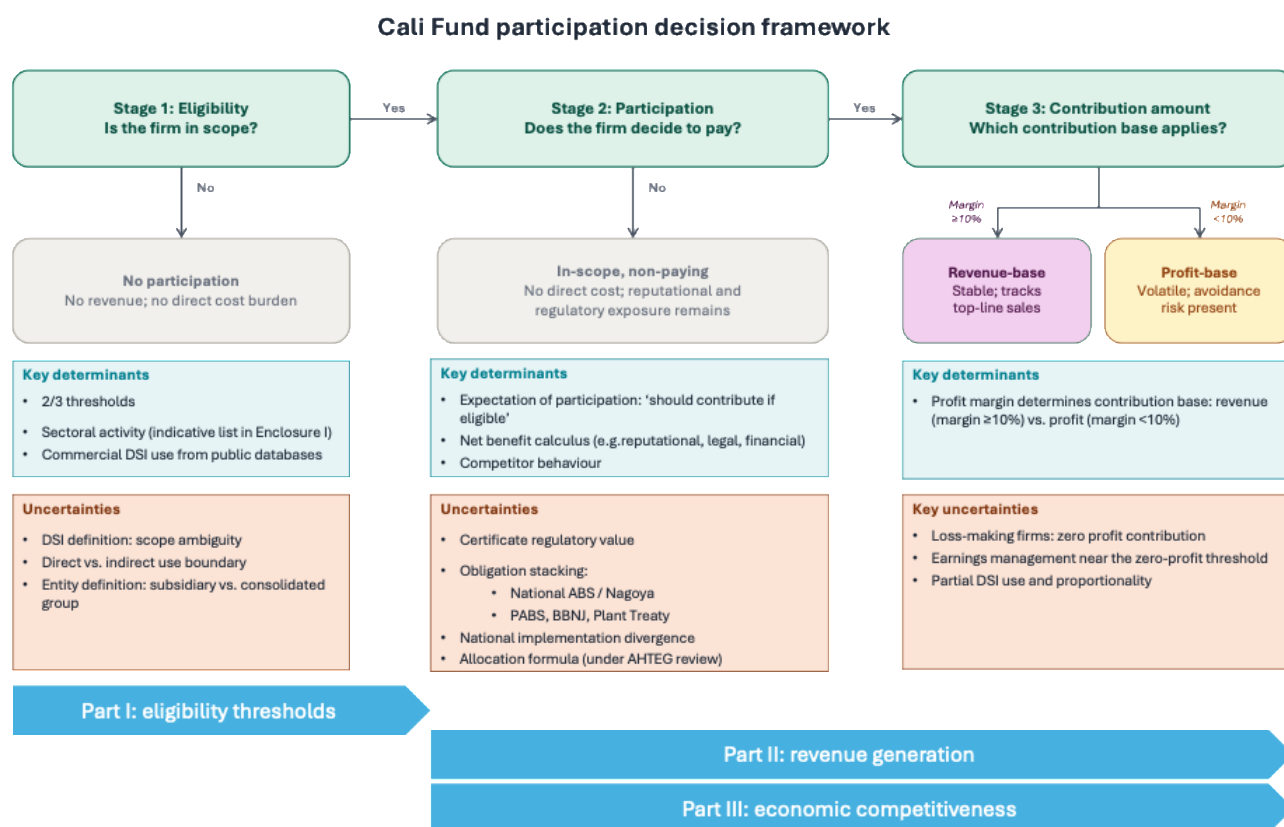
Figure 2 organises the three analytical stages that structure this section, each corresponding to firm-level decisions occurring before any contribution into the Fund is made:

- Stage 1: a firm self-identifies as eligible or non-eligible (i.e. Who is eligible?);
- Stage 2: an eligible firm decides to participate or opts out (i.e. Who participates?); and,
- Stage 3: a participating firm determines its contribution (i.e. How much do they contribute?).

Sections 4.1 to 4.3 examine each stage sequentially, identifying the key determinants and uncertainties that inform scenario construction in Parts II and III. Section 4.4 provides a summary of the key analytical parameters and their treatment.

²¹ All relevant submissions were reviewed in full: 35 received in response to CBD Notification 2024-114 and 9 in response to CBD Notification 2026-019.

Figure 2 Participation decision framework for the Cali Fund under Decision 16/2 and corresponding sections of the study



Notes: The framework maps the sequential firm participation logic that structures the analysis in Parts I-III. Key determinants reflect the mechanism's design as specified in Decision 16/2 and core factors shaping firms' participation decisions (the list is illustrative rather than exhaustive); key uncertainties identify unresolved features that may alter firms' decisions to participate. In-scope, non-paying firms enter Part III as non-contributing competitors. Blue arrows map the stages onto the relevant parts of the analysis they feed into.

4.1. Who is eligible?

The entities expected to contribute to the Cali Fund under Decision 16/2 are defined by three criteria: sectoral activity, entity size, and commercial use of DSI in scope of the MLM. Each subsection explains the methodological approach for this study and points out to uncertainties potentially affecting which firms are expected to contribute.

Sectoral activity

This study covers the indicative sectors listed in Decision 16/2 Enclosure I, as set out in Box 2. Enclosure I is explicitly described as an 'indicative' list, and in principle, any DSI-using entity could fall within scope regardless of sector. This study nonetheless focuses on these seven sectors for analytical tractability, since reliably identifying DSI use outside them is not feasible at this scale; the choice should be read as a practical boundary, not an authoritative statement of scope. The detailed mapping of Indicative Enclosure I sectors to official industrial classifications is described in Part II, and should not be read as this study's own assessment of sector reliance on DSI

Throughout the analysis, selected Indicative Enclosure I sector names are abbreviated for brevity. Full designations are as follows:

- Information and AI refer to information, scientific, and technical services related to DSI including artificial intelligence;
- Laboratory equipment refers to laboratory equipment related to sequencing and DSI use including reagents and supplies.
- Pharmaceuticals, biotechnology, nutraceuticals, cosmetics, and animal and plant breeding correspond directly to their Enclosure I names.

The indicative list of Enclosure I brings uncertainty as to the inclusion of additional sectors or the deletion of existing ones in the future. Additionally, these sectors are broadly defined, so that some sectors are contesting their status as ‘DSI-reliant’ (see CBD notification 2024-114(CBD, 2024b)). The common use of industrial classification codes was used in this study in order to refine some sectors such as ‘information and artificial intelligence’ but should not be interpreted as a study on sector reliance on DSI.

This subjectivity has consequences beyond definitional debate. Because sector membership is used as a proxy for DSI reliance, firms with genuinely low DSI use may be grouped with, and treated on the same basis as, firms with high reliance, or vice versa, which can create inconsistencies in how the mechanism's obligations map onto actual DSI use. This can also lead to an incomplete capture of genuinely DSI-reliant firms whose sector classification places them outside Enclosure I.

Financial thresholds and entity definition

The thresholds presented in Box 2 are designed to restrict the expectation to larger commercial entities. Large companies often operate through multiple subsidiaries, which are separate legal entities that may each focus on a different business activity or operate in a different country. For the purpose of applying the Decision 16/2 financial thresholds, this study assesses each subsidiary individually rather than treating an entire corporate group as one entity. This approach better reflects where DSI-related activity actually occurs. For example, a large technology multinational corporation may have a subsidiary specialising in bioinformatics that crosses the eligibility thresholds on its own, even though the parent company’s overall revenues are dominated by DSI-unrelated business activities. Assessing the subsidiary separately captures DSI-relevant activity more accurately than looking at the group as a whole. This approach is consistent with the methodology adopted in Makowska-Curran (2026), whose firm-level estimates inform the revenue analysis in Part II.

The threshold design raises three analytical issues. The first concerns calibration and is addressed directly in Parts I and II. For the former, Decision 16/2 explicitly requests a study on standards for identifying small, medium, and large entities [paragraph 6(d)], acknowledging that the current thresholds may be considered further for a global mechanism. For the latter, the potential revenue analysis in Part II (“Uncertainty-adjusted revenue range”) tests how sensitive the projected revenues are to the current indicative thresholds.

The second issue concerns threshold volatility. Because eligibility is assessed as a three-year average, firms whose financials fluctuate significantly across years may find their eligibility status change between reference

periods, introducing some instability into the Fund's revenue base over time. The sensitivity of the eligible population²² and their revenue estimates is also examined in Part II ("Rate and base design sensitivity").

The third source of uncertainty relates to the definition of the contributing entity. Decision 16/2 does not clarify whether the contributing entity is a subsidiary or a consolidated corporate group. Under subsidiary-level assessment, a multinational is represented as multiple contributing entities across several jurisdictions, while group-level assessment treats the same firm as a single entity. The absence of a clearly defined boundary enables firms to effectively minimise contributions²³, as the evidence from the analogous tax literature shows that separate-entity approaches facilitate the shifting of profits and costs, which would reduce the contribution base of the eligible entity²⁴ (Morgan, 2016; Picciotto, 2019; Beer, de Mooij and Liu, 2020). Firms may also simply choose not to join unless the mechanism offers a clear advantage or stronger incentives; for example, studies of optional EU corporate tax consolidation find that firms opt into optional regimes only when doing so lowers their burden, while optional participation can reduce overall revenue (van der Horst, Bettendorf and Rojas-Romagosa, 2007; Devereux and Loretz, 2008). On the other hand, a subsidiary-level eligibility assessment may support more accurate targeting, by allowing firms to contribute only through subsidiaries that directly use DSI. The net effect on Fund revenue is ambiguous and cannot be determined *ex ante*. Part III examines the competitive implications of entity-level assessment, including whether the absence of ownership and affiliation conditions, equivalent to those in the EU and US frameworks, creates asymmetries between corporate groups that restructure to minimise contributions and those that do not, and what this implies for the level playing field among competing firms in the same sector.

Commercial DSI use

Several aspects of the current scope of DSI under the MLM may create uncertainty about which firms are truly eligible, each explored below.

Public DSI

The mechanism only applies to publicly available DSI not under other obligations, which narrows down the scope of the mechanism. For the purposes of eligibility, however, this restriction creates limited uncertainty in practice; firms that use publicly available DSI can reasonably self-identify as eligible under the current binary threshold implicitly imposed by Decision 16/2²⁵ (users vs. non-users). For most, it will be clear²⁶ whether public DSI plays a role in their research and innovation operations or not.

²² Eligible population here refers to the firms in-scope of the DSI MLM (see glossary).

²³ Note that the current modalities do not determine whether companies choose their contribution base representing the total revenue or profit for the entire corporate group or its portion corresponding to each of its subsidiaries.

²⁴ Note that in certain cases, it may be possible for companies to minimise their contributions by choosing their corporate group revenues/profit instead of using the accounts of its individual subsidiaries; for instance, whenever the corporate group profits are lower than those reported by a single subsidiary.

²⁵ The more analytically consequential question, how much of a firm's activity depends on public rather than private DSI, and whether contributions should reflect that proportion - is a contribution base question rather than an eligibility question and is addressed in Section 0.

²⁶ The lack of a universally agreed definition of DSI creates some ambiguity at the margins. During the AHTEG process, three different scope options were examined, ranging from a narrow definition limited to DNA and RNA sequences, to broader scope that also include other forms of molecular information (such as proteins or metabolites) (CBD, 2020b). Firms whose activities rely mainly on data types that fall outside these narrower definitions can experience uncertainty about whether they are covered. The direction and size of any resulting misclassification are hard to assess and are not reflected in these estimates. This paper assumes firms generally know whether DSI, at least in the narrower sense, is used in their operations - an assumption that seems reasonable but may not hold across all sectors or firm types.

Determining exactly how much they depend on it is more difficult, and the degree of dependence matters. The current all-in contribution design applies the same rates to total revenues or profits regardless of how intensively a firm uses DSI relative to its overall commercial activity. This means that a firm deriving only a small share of its commercial value from DSI contributes on the same basis as one whose entire operations rely on it. This difficulty has a direct bearing on participation: a firm deriving only a marginal share of its commercial value from DSI has an incentive to avoid the mechanism altogether rather than contribute on a basis it considers disproportionate to its actual DSI-derived benefit, since the current design offers no way to contribute proportionally instead. In practice, companies typically combine public and proprietary (private) sequences in shared internal databases, and the reported ratios of public to private data that are self-declared might be inexact (CBD, 2020a). The current modalities do not specify whether contributions need to be aligned with the proportion of public DSI used in a company's activities, possibly due to the fact that tracking and tracing DSI was recognized as impractical (decision 15/9 para 5). Firms are generally able to determine whether DSI was used in the development of a specific product, and in principle could aggregate this determination across their product portfolio to approximate the share of commercial activity attributable to DSI use, without following individual sequences through a supply chain. A proportional design based on this kind of product-level self-declaration would face its own practical and verification challenges but is conceptually distinct from the tracking and tracing problem Decision 15/9 addressed.

This design also carries a structural risk in the opposite direction: because the contribution obligation attaches specifically to public DSI use, firms may have an incentive to rely more heavily on privately negotiated sequence access or proprietary databases to reduce their exposure, which would run counter to Decision 15/9's own principle that the mechanism be consistent with open data. Neither the current DSI intensity multipliers nor the underlying literature distinguish contributions by source (public versus private database), meaning this risk cannot currently be assessed empirically. Note that COP17 will consider possible additional modalities, including a product or service-based payment into the Cali Fund.

Direct vs. indirect use boundary

Decision 16/2 refers to entities benefiting directly or indirectly from DSI use, without defining this term. In conventional value chain analysis, the differentiation between direct and indirect corresponds to where a firm is situated in the chain in relation to the activity that produces the value added (McCormick and Schmitz, 2001). To exemplify this logic: a firm that accesses DSI sequences to develop a new drug is directly connected to the value-generating activity; a retailer selling that drug is not, even though it benefits commercially from the same chain. Applying this reasoning to DSI, direct users would be those whose commercial goods or services rely directly on sequence data e.g. pharmaceutical companies identifying compounds via genomic screening, or biotech companies designing sequences for particular uses. Indirect users would include downstream firms that use inputs produced from DSI, despite not working directly with sequence data. Under this interpretation, upstream enablers, such as manufacturers of laboratory equipment, would usually be excluded from the scope, since indirect benefits generally accrue downstream. Note that including the laboratory sector in Enclosure I does not clearly fit this framework, except where such companies use DSI in their own research or production processes, in which case they would qualify as direct users. The interpretation set out above is offered for analytical purposes only. It does not reflect an agreed understanding under the Convention, nor is it intended to narrow or predetermine the scope of contributors; the definition of direct and indirect use remains a matter for the Conference of the Parties to determine.

For this study, eligibility is defined by primary sectoral activity rather than value chain position. Mapping indirect inter-firm links across supply chains is infeasible at the scale of the firm-level analysis used for the revenue estimates in Part II, hence the sector-based approach in Enclosure I is used as a practical criterion. As a result, the direct/indirect distinction set out above does not operate as a separate filter in the revenue estimates that follow. Any firm meeting the sectoral and financial threshold criteria is treated identically for eligibility purposes, whether its use of DSI would be classified as direct or indirect under the value-chain reasoning above. This reflects two compounding constraints rather than a single practical shortcut: Decision 16/2 does not define what distinguishes direct from indirect use, and even under a working definition, mapping individual firms' inter-firm value-chain links at the scale of a 21,690-firm sample would not be feasible with available data. The DSI intensity and participation multipliers applied in Part II (Table 47 and Table 49) vary by sector, not by an individual firm's position within that sector's value chain. The analytical implications of this choice, especially for upstream and downstream firms whose links to DSI are mediated through the value chain, are examined in Part III.

Submissions to CBD Notification 2024-114 from seed industry and bio-business representatives raised a related concern: under a broad interpretation, multiple actors in the same value chain could fall within the scope, so a single use of DSI might be counted repeatedly at different stages of the chain (CBD, 2024b). Part III examines the competitive implications of how this boundary is ultimately defined. This risk compounds with a separate feature of the contribution design. Because each eligible entity contributes on the basis of its own total revenue or profit rather than a DSI-attributed share, a firm identified as an indirect user can be captured twice: once directly, through its own contribution obligation, and again indirectly, to the extent that an upstream direct user passes its own contribution cost forward through input pricing (see Cost of intermediate consumption, Part III). Sector-level and aggregate contribution totals in this study do not net out this potential overlap, since doing so would require value-chain-level data on inter-firm cost pass-through that is not available at the scale of this analysis.

Other submissions to CBD Notification 2024-114 questioned whether early-stage DSI use, typically in R&D screening rather than in final products, creates the expectation of monetary benefit sharing as intended by Decision 16/2 (CBD, 2024b). This question reflects the scientific nature of DSI, where value arises from comparative analysis against the global dataset rather than from use in discrete final products (Scholz *et al.*, 2022a). This study does not answer that question, which depends on how the benefit-sharing trigger is interpreted. For the revenue analysis, R&D activities are treated as in scope, consistent with the full-sector approach in Enclosure I and with comparable studies (CBD, 2024d; Menon Economics, 2025). Revenue sensitivity to a narrower interpretation cannot be isolated from the broader uncertainty around DSI intensity²⁷ and participation rates in Part II, since firms holding that view are unlikely to see themselves as eligible or to contribute.

A further issue arises for firms that use DSI in only a subset of their commercial activities. Decision 16/2 does not clarify how these firms should be treated in comparison to those whose entire commercial output depends on DSI. The contribution consequences of partial DSI use are discussed in Section 4.3.

²⁷ See the glossary

4.2. Who participates?

Decision 16/2 states that eligible entities "should contribute", which sets an expectation for participation but does not create a legal requirement (Blom *et al.*, 2025; Muñoz-García *et al.*, 2025). As a result, the expected participation rate is the central factor in the overarching economic analysis. Section 3 shows mixed results across the two active analogous mechanisms, with the lesson learned that, under voluntary schemes, the funding gap may be driven primarily by low participation rather than contribution rate design, which becomes a secondary question²⁸. The main scenario in Part II is based on these findings.

A number of elements influence whether eligible firms choose to participate. First, Decision 16/2 itself creates an expectation: once firms have determined they fall within its scope, they are expected to contribute, and opting out (though not prohibited) carries reputational and regulatory risk. Research on voluntary environmental programmes shows that firms respond to pressure from consumers, investors, communities, and civil society, as well as to the implicit threat of more stringent regulation if voluntary measures are judged insufficient. As a result, even when participation is formally voluntary, there can still be strong incentives for firms to take part (Arora and Cason, 1996; Segerson and Miceli, 1998; Maxwell, Lyon and Hackett, 2000; Khanna, 2001; Prakash and Potoski, 2012)

Those incentives are linked to the second element: a net benefit assessment, comparing costs of non-participation to the benefits associated with compliance. Again, the evidence on this trade-off is well-established in the literature on private sector voluntary environmental programmes. It suggests that firms make a decision to participate if the expected benefits of joining, such as public recognition, brand and legitimacy gains, and potential regulatory relief, outweigh the compliance and administrative costs of participation (Arora and Cason, 1996; Khanna, 2001; Potoski and Prakash, 2005). Applying this to the Cali Fund implies that eligible firms face direct costs in the form of the contribution and indirect costs linked to participation, for instance administrative costs of compliance. On the other hand, those costs will be weighed against possible benefits such as obtaining a certificate of contribution, achieving greater legal clarity in relation to CBD ABS requirements, and securing reputational benefits from a visible commitment to biodiversity finance. However, even if those aspects were resolved, participation would also depend on a third factor, namely, what their competitors do.

Because the mechanism is not legally binding, firms decide collectively and contributing when competitors do not create a cost disadvantage that affects participation decisions. The literature finds that engagement in voluntary environmental programmes is frequently driven by collective-action dynamics and peer behaviour rather than individual firm preferences (Prakash and Potoski, 2007; Contreras, Bos and Kleimeier, 2019; Han and Ito, 2024), competitive pressures, collaborative networks, and supply-chain requirements, meaning that participation is partly dependent on whether competitors, customers, and other market actors are likewise moving in this direction (Delmas and Montiel, 2009; Contreras, Bos and Kleimeier, 2019; Han and Ito, 2024). Evidence from comparable multilateral benefit-sharing mechanisms points in the same way. In examining the ITGPFRA, Halewood *et al.* (2023) observe that very few companies have been willing to make voluntary payments into the fund in the absence of a requirement for others to do so, citing concerns about competitive disadvantage. Notably, this reluctance appears specific to individual firm-level payments: the BSF has received

²⁸ Note that low participation could also be affected by the contribution rate design e.g. in case the contribution rates are set too high. As discussed in Part III, the indicative rates are unlikely to deter participation due to economic reasons.

voluntary contributions from industry associations, including the European Seed Association, SEMAE, the Federation of Seed Industry of India, and the International Seed Federation (FAO, 2025). This suggests that collective, association-level contributions may offer one route around the first-mover disadvantage facing individual firms, since no single company bears a competitive cost relative to others within the same association. The analogy to the Cali Fund is clear: under a non-binding scheme, any given firm's decision to participate depends on its expectations about how its competitors will behave. At the time of writing, no systematic data on participation intentions across eligible sectors is available, meaning that expectations about competitor behaviour must be treated as unobservable and are incorporated into the scenario range in Part II rather than as a point estimate. Those collective decisions are also assessed in detail in Part III.

These three factors affect firms differently depending on their size and market position. Large, publicly listed multinationals will likely face more reputational pressure and investor scrutiny than mid-sized firms that are just above the financial thresholds (Lee, 2009; Luo, Lan and Tang, 2012; Rasche *et al.*, 2022). For these mid-sized firms, the burden of contributing may seem larger compared to the expected benefits. Similarly, sectoral affiliation can determine each firm's public scrutiny, regulatory exposure, and DSI use intensity, meaning that the three elements will carry different weights across listed sectors. This across-firms and across-sectors heterogeneity is accounted for throughout the three main parts of the study.

Information asymmetry and participation

A fundamental constraint on participation is that firm eligibility cannot be verified externally: there is no obligation for firms to disclose their (often commercially sensitive) DSI use. Currently, registration requirements for public DSI users varies greatly across the platforms. For instance, the INSDC, which is considered to be the core public DSI database, does not collect information about users or their institutions, making it impossible to tell commercial from non-commercial access at the database level (CBD, 2020a). On the contrary, platforms such as Aotearoa Genomic Data Repository (Te Aika *et al.*, 2025) and GISAID (Re3data.Org, 2012) make user registration mandatory. Those discrepancies in the degree of user information which can be retained from the public DSI databases makes any potential user verification challenging, though this reflects current database architecture rather than an inherent feature of DSI itself. Furthermore, Decision 16/2 also does not require databases to enforce benefit-sharing terms to grant access (Rouard, Scholz and Halewood, 2025). This is a deliberate design choice rather than an oversight: gating access to DSI on proof of benefit-sharing compliance would function as a potential barrier to open research and innovation, in tension with Decision 15/9's own requirement that the mechanism be consistent with open data principles and not hinder research. This unobserved attribution problem can be further exacerbated by the large-scale use of artificial intelligence and the derivation of new, synthetic sequences. In their latest study, Sett *et al.* (2024a) warn that "synthesising new sequences could incentivise DSI mechanism avoidance". Regardless of whether they are using DSI downloaded directly from public databases or its synthetic derivatives, firms that do not participate, or underreport, cannot be easily challenged by Parties or the CBD Secretariat. Equally, this asymmetry presents challenges for firms attempting to demonstrate compliance. In the absence of a standardised method for attributing commercial activity to specific DSI inputs, firms are unable to verify that their contributions accurately reflect their DSI use.

Patent disclosure is a partial exception, as it may link DSI to specific commercial uses (WIPO, 2025), but this applies only to sectors and applications where DSI use leads to patentable inventions, such as in pharmaceuticals and biotechnology (Oldham, Hall and Forero, 2013). This information asymmetry implies that both the true

population of eligible firms and any future observed participation rate are inherently uncertain. Firms that are genuinely eligible may not self-identify as such, and non-participation cannot be straightforwardly distinguished from ineligibility. This is arguably one of the principal sources of uncertainty in this study.

Certificate regulatory value

Private companies are more likely to join voluntary environmental schemes when membership provides a clear, externally validated benefit, particularly a credible certificate or comparable signal that communicates sound environmental practice to customers, regulators, and other stakeholders in situations where actual performance is otherwise difficult to observe (Khanna, 2001; Potoski and Prakash, 2005; Toffel, 2005). Participation is also more appealing when these programs deliver reputational benefits such as public recognition, or tangible legal or regulatory advantages such as regulatory relief, reduced sanctions, lower likelihood of enforcement actions, or streamlined administrative procedures (Khanna and Damon, 1999; Khanna, 2001; Wätzold *et al.*, 2001; Stafford, 2007; Short and Toffel, 2008). Firms with pre-existing public commitments on biodiversity or sustainability may also be more inclined to participate for reasons of reputational consistency with those commitments, independent of the certificate's own legal value.

Decision 16/2 introduces a certificate of contribution as a benefit for participants²⁹, but several design aspects remain unresolved. For instance, its legal status under domestic legal systems is still uncertain (Blom *et al.*, 2025). Blom *et al.* (2025) suggest that the certificate will incentivise participation, but only if it provides genuine legal certainty in comparison with national ABS regulations. Beyond legal certainty over DSI use, the credibility of the Cali Fund's own governance and disbursement arrangements is itself a participation precondition rather than a downstream question. A firm weighing whether to contribute is likely to consider not only the rate and the certificate's legal value, but whether funds are disbursed transparently and traceably to their intended purpose; the ITPGRFA and WHO PIP comparators discussed above suggest this credibility, not the payment rate itself, is often the more decisive factor in whether voluntary contributions materialise. Where the certificate succeeds in providing this legal certainty, participation may also generate compliance cost savings for firms that would otherwise need to navigate separate bilateral or national ABS arrangements for the same genetic resources or DSI. This claim is consistent with several submissions to CBD Notification 2024-114 made by commercial actors, representing pharmaceutical, seed, biotech, and cosmetics sectors, who repeatedly emphasised that the capacity of certificates to incentivise firm participation relies on an explicit exemption from national ABS requirements, which in turn increases legal uncertainty (CBD, 2024b). Responses from several Parties to CBD Notification 2026-019 also show that this equivalence has yet not been recognised at the national level. As a result, the value of the certificate is treated as an unresolved parameter throughout this analysis and is reflected in the scenario range in Part II.

Obligation stacking

Benefit-sharing under the Cali Fund applies only in cases where DSI (monetary) benefit-sharing is not already addressed by other international instruments³⁰. This issue, referred to as 'obligation stacking', was identified as a challenge in the literature (Berman and Vooren, 2025; Blom *et al.*, 2025), by the pharmaceutical, seed, biotech,

²⁹ Decision 16/2, Annex, paragraph 15

³⁰ Decision 16/2, Annex, paragraph 1(c)

and cosmetics industries in submissions to the CBD(CBD, 2024b), and a concern of Parties in their implementation of the MLM (CBD, 2026).

In practice, firms may be subject to multiple overlapping international rules, such as the WHO PABS system or the ITPGRFA' MLS as well as the Cali Fund and potential national legislation. The position with respect to the ITPGRFA is narrower than for WHO PABS: since the Multilateral System currently governs physical genetic material rather than DSI, the two instruments' obligations are generally distinct, and stacking would arise only where a firm accesses both physical material under the MLS and DSI relating to the same genetic resource under the Cali Fund. Should DSI be formally incorporated into the ITPGRFA's own scope in future reform, a clear interaction clause with the Cali Fund would be needed at that stage to avoid stacking. The overlap risk with WHO PABS is more direct, since pathogen DSI use could trigger both mechanisms simultaneously for the same activity.

The composition of the INSDC database gives some indication of how publicly available DSI is distributed across international agreements: Sett *et al.* (2024a) estimate that the genetic resources underlying 56% of INSDC sequences fall under CBD scope, 10% within ITPGRFA Annex I, and 3% within the WHO framework³¹; DSI-specific obligations under these instruments remain unresolved or absent. In practice, however, a single commercial activity may draw on sequences from multiple frameworks simultaneously. For instance, vaccine development, may require sequences governed by both WHO and CBD mechanisms within a single product development process (Berman and Vooren, 2025).

Decision 16/2 recognises this risk and calls for the establishment of a mechanism that avoids overlapping benefit-sharing obligations, while also encouraging cooperation with other relevant international frameworks³² (Muñoz-García *et al.*, 2025). This uncertainty is incorporated into the broad revenue uncertainty range presented in Part II. Parties should be encouraged to ensure coherence and interoperability between the multilateral mechanism and existing national access and benefit-sharing (ABS) frameworks, with a view to minimizing duplicative obligations, reducing compliance costs, and enhancing legal certainty for participating entities. A good example of such action is the pledge made in June 2026 by a coalition of governments, the 'Friends of the Cali Fund,' to work toward avoiding duplication of benefit-sharing expectations and the stacking of obligations across international instruments (UK Defra, 2026).

National implementation divergence

Decision 16/2 invites Parties to adopt measures that support contributions but does not prescribe a specific approach. The literature on the analogous Nagoya Protocol³³ indicates that how countries implement ABS obligations³⁴ can influence firm behaviour, because national laws determine how ABS principles are translated into regulatory mechanisms and, in many jurisdictions, link them to binding compliance procedures and sanctions (Sirakaya, 2019; Michiels *et al.*, 2022; Ljungqvist *et al.*, 2025). The level of national ABS legislation

³¹ Note that, currently, there are no benefit-sharing obligations for the use of DSI under the ITPGRA or the WHO.

³² Decision 16/2, paragraphs 1(c) and 27

³³ The Nagoya Protocol provides a legally binding basis for national ABS implementation, which distinguishes it from Decision 16/2, where national measures are encouraged rather than required. It is used here to illustrate potential effects of national implementation measures on compliance.

³⁴ Note that the Nagoya Protocol is a legally binding treaty, meaning its legal character is also transferred to national-level implementation. For the non-binding Cali Fund, national implementation may take different forms, including soft laws or other non-regulatory measures, which could have more limited effects on firm behaviour and compliance rates than binding instruments.

varies across Parties, and this variation has been found to extend to DSI, where national laws diverge in their treatment of sequence data which can be problematic for users and affect their compliance (Sirakaya, 2019; Michiels *et al.*, 2022; Ebert *et al.*, 2023). This may lead to additional obligation stacking across jurisdictions capturing DSI under their ABS laws, with some already explicitly regulating DSI (Gunnar V Ljungqvist *et al.*, 2025). When such national rules apply to the same uses of DSI, companies contributing to the Cali Fund may be subject to obligations under both systems at the same time.

Applied to Decision 16/2, national implementation is therefore likely to affect participation in two directions: jurisdictions with active domestic regulatory frameworks may give firms stronger incentives to engage with the Fund, while significant divergence across jurisdictions could create uneven competitive conditions for firms operating in one or the other jurisdiction, or across them.

Submissions to CBD Notification 2026-019 confirm that implementation of Decision 16/2 remains at an early stage, with most responding Parties being in awareness-raising or exploratory phases, and with no legislative measures targeting the Cali Fund contributions specifically having been adopted at the time of submission (CBD, 2026). Cross-jurisdictional variation in implementation has therefore not yet materialised in practice. The analytical implications, for participation rate uncertainty in Part II and for cross-border competitive asymmetries in Part III, are noted here as potential channels should national measures diverge ahead of or following COP17.

This dynamic is already visible in practice: the United Kingdom's Biodiversity Beyond National Jurisdiction Act 2026 (Meaning of "Digital Sequence Information") Regulations 2026 define DSI, for the purposes of implementing the BBNJ Agreement nationally, as "DNA or ribonucleic acid (RNA) sequences in digital form" (SI 2026 No. 521) ([UK, 2026](#)). This is a useful early reference point, and illustrates the more general risk that, absent a shared definition at the multilateral level, Parties are likely to develop national definitions independently and potentially divergently, which is the same fragmentation risk this section identifies for the Cali Fund's own undefined terms.

Allocation formula

A fourth unresolved issue is the allocation formula. Decision 16/2 established an Ad Hoc Technical Expert Group (AHTEG) to develop allocation options ahead of COP17 (CBD, 2025). The AHTEG is still developing the method for distributing Cali Fund resources among Parties, and it has not yet been finalised at the time of writing. Participation assumptions in Part II do not depend on a specific formula, but the scenario range implicitly captures differences in how potential contributors view its potential distributional impacts. This sensitivity has a basis in the wider literature; research on voluntary collective efforts shows that people are more likely to contribute when they perceive the benefits as shared fairly (Persson and Remling, 2014; Droste *et al.*, 2019), suggesting that how the allocation formula is ultimately designed could materially affect participation, independent of the certificate's legal value discussed above.

Private sector contributions are treated as the Fund's sole revenue source; although Decision 16/2 encourages contributions from other sources³⁵, which could entail public sector contributions, none had been made at the time of writing. No additional sources of funding have been captured in the revenue modelling.

³⁵ Decision 16/2, Annex, paragraph 16.

4.3. How much do they contribute?

For firms that fall within the scope and participate, the contribution amount is determined by the indicative rates specified in Decision 16/2 and by how the contribution base is chosen. This study calculates contributions as a proportion of total financials, consistent with the language of Decision 16/2 (i.e. applying the indicative rates directly to revenue or profit). Two elements of the current design create uncertainty about the total contribution and its allocation among firms, each affecting the revenue analysis in Part II and the competitiveness assessment in Part III.

Indicative rates and contribution base

Decision 16/2 sets indicative contribution rates of 1% of profit or 0.1% of revenue and it does not specify how these two rates relate to one another, or which applies in a given case. One assumption, and the one adopted in this study, is that entities contribute whichever of the two amounts is lower in order to minimise their cost burden. The rates are explicitly described as indicative and subject to revision at COP17; this study takes them as given for the baseline analysis, while Part II also presents results under alternative rate assumptions.

The profit and revenue bases generate structurally different contribution profiles. For firms earning profit margins below 10%, the mechanism in practice functions as a profit levy; once that level is exceeded, it effectively turns into an ad valorem charge on revenue. Two implications follow. The Fund's income will be more sensitive to earnings cycles than a uniform ad valorem system would be, since firms reporting losses contribute nothing under the profit base regardless of their revenue or DSI activity (Kirchain *et al.*, 2019). Second, using profit as the base creates incentives for earnings management, meaning that reported profits may only imperfectly reflect the firm's underlying economic performance. This phenomenon is widely documented for profit taxation, to which the contribution levy is structurally similar (Sahay, 2013; Choi, Furusawa and Ishikawa, 2020; Sebele-Mpofu, Mashiri and Schwartz, 2021); whether it materialises here depends partly on how firms respond to a mechanism that sets an expectation rather than a legal requirement. Both questions are examined in Part II.

Partial DSI use and proportionality

Decision 16/2 ties both eligibility and the contribution amount to financial metrics, namely assets, sales and profit, rather than to digital sequence information use itself. No data source currently observes how much of a firm's financial activity is attributable to DSI use, and this is a limitation of the underlying data landscape rather than of any single study. In the absence of such a measure, the analysis in Part II approximates DSI use through sector membership under the Enclosure I list, combined with assumed participation rates and DSI intensity multipliers; these are proxies for DSI use, not measurements of it, and this distinction should be borne in mind in using the results as a basis for policy. Decision 16/2 explicitly excludes entities that do not use DSI, however, it does not specify the treatment of entities whose commercial activities depend on public DSI only partially. The Decision, as currently written, can be interpreted as applying contribution rates to the overall financial figures. This interpretation creates a proportionality issue that commercial users from various sectors have repeatedly highlighted in their submissions to CBD Notification 2024-114: companies that rely on DSI for only a portion of their products or services are subject to the same contribution base as those that employ it across all of their operations. While this 'all-in' approach partially helps address the issue of unobservable public DSI use (as explained in Section 0, it is reasonably easier to observe public DSI use compared to the *extent* and

*effect*³⁶ of that use), it can impose a disproportionate burden on firms for which DSI constitutes only a marginal input compared to their overall business activity. While this ‘all-in’ approach partially helps address the issue of unobservable public DSI use (as explained in Section 4.1, it is reasonably easier to observe public DSI use compared to the *extent* and *effect*³⁷ of that use), it can impose a disproportionate burden on firms for which DSI constitutes only a marginal input compared to their overall business activity. This reasoning can be easily illustrated with an example: a pharmaceutical company deriving one product from genomic screening and ninety-nine from conventional chemistry would contribute on the same total revenue or profit base as one whose entire portfolio is DSI-dependent, despite fundamentally different levels of DSI reliance.

This study bases its calculations on contributions as a share of total financials, in line with the wording of Decision 16/2. Part II analyses how sensitive revenues are to the DSI attribution issue, presenting a lower-bound scenario that uses sector-level DSI intensity adjustments alongside the total-financials reference estimate³⁸. Beyond this, any additional, unobserved DSI-use uncertainty is captured within the broad estimated revenue bounds. Part III explores the implications for proportionality, including how the all-in approach affects the allocation of contribution obligations among firms with varying degrees of DSI reliance, and what this implies for competitive dynamics within listed sectors.

4.4. Summary of analytical parameters and uncertainties

Sections 4.1 to 4.3 highlight several parameters that require methodological decisions before starting the analysis in the parts that follow. These parameters are treated here as given inputs for analytical purposes only, not as a judgement that they are settled; several are explicitly indicative and subject to revision by the Conference of the Parties. In this study, the main choices are as follows:

- All indicative Enclosure I sectors are included in the reference scenario, with detailed mapping to official industrial classifications as explained in Part II;
- Entities operating in several Indicative Enclosure I sectors are identified based on their primary sectoral activity;
- Financial thresholds from Decision 16/2 are set at the subsidiary level using a three-year reference average;
- Contributions are based on total financials, matching the wording of Decision 16/2;
- The reference scenario provides a theoretical maximum revenue assuming full participation;
- For the baseline analysis, the indicative rates are used as given, while alternative rate assumptions are explored in Part II; and,

³⁶ The ‘extent’ refers here to the scale of public DSI use e.g. the number of sequences, while the ‘effect’ covers the impact that DSI use has on a company’s operations (incl. commercial value derived from DSI).

³⁷ The ‘extent’ refers here to the scale of public DSI use e.g. the number of sequences, while the ‘effect’ covers the impact that DSI use has on a company’s operations (incl. commercial value derived from DSI).

³⁸ Note that the ‘total-financials’ approach also reflects a practical constraint: apportioning contributions to the share of activity attributable to DSI use is currently not possible, as this information is not observable.

- Entities are assumed to pay the contribution on the base which leads to lower costs (choose profit *or* revenue).

These choices are made when the Decision's text provides a basis for a clear methodological choice³⁹. When it does not, the underlying features create uncertainty about revenue potential and company burden, which cannot be resolved *ex ante*. Table 2 outlines these uncertainties, their likely impact on the Fund's revenue, and how each is addressed in the analysis. Most of these factors lower the realistic revenue estimate compared to the theoretical maximum. Their combined effect is highly uncertain, and hence, shown in the scenario range in Part II, rather than being modelled separately. Their effects at the firm and sector levels are discussed in Part III.

Table 2 Uncertainty register

ID	Factor	Direction of effect on revenue	Mechanism	Basis for inclusion	Treatment in analysis
Stage 1: Who is eligible?					
U1	Sector list boundary	Compresses	Narrower interpretation reduces eligible population	Literature + submissions	All indicative sector reference scenario, additionally broken down by sector in Part II
U2	Threshold volatility over time	Ambiguous	Firms near boundary move in and out of eligibility	Literature	Explicit sensitivity in Part II
U3	Entity definition: subsidiary vs. group	Ambiguous	Subsidiary branch vs group level affects count and the level of contributions	Literature	Subsidiary-level assessment adopted throughout; subsidiary vs. group-level contribution implications discussed in Part III
U4	Direct vs. indirect use boundary	Ambiguous	Broader interpretation expands scope; value chain double-counting possible	Literature + submissions	Supply chain implications in Part III
Stage 2: Who participates?					
U5	Information asymmetry and participation	Compresses	Eligible firms may not self-identify; non-participation unverifiable	Literature + submissions + analogous mechanisms	Reflected in scenario range in Part II
U6	Certificate regulatory value	Compresses	Low regulatory value reduces participation incentive	Literature + submissions	Reflected in scenario range in Part II; impact on competitiveness effects in Part III
U7	Obligation stacking	Compresses	Unresolved overlap with national/international instruments deters participation	Literature + submissions (identified as the most frequently cited barrier in submissions to CBD Notification 2024-114)	Reflected in scenario range in Part II; impact on competitiveness effects in Part III
U8	National implementation divergence	Ambiguous	More implementation increases participation; divergence creates asymmetries	Literature + submissions	Not yet materialised; flagged as potential channel for scenario range in Part II and cross-

³⁹

ID	Factor	Direction of effect on revenue	Mechanism	Basis for inclusion	Treatment in analysis
					border asymmetry in Part III
U9	Allocation formula	Ambiguous	Perceived distributional outcomes may affect participation	Analogous mechanisms	Reflected in scenario range in Part II
U10	Competitor participation	Ambiguous	Low sector uptake deters individual participation; high uptake encourages it	Literature + analogous mechanisms	Scenario range in Part II; competitive asymmetry analysis in Part III
Stage 3: How much do they contribute?					
U11	Profit base: earnings volatility and management	Compresses	Loss-making firms contribute nothing; earnings management possible	Literature	Empirical distribution documented in Part II; management risk reflected in scenario range
U12	Partial DSI use and proportionality	Compresses	Same contribution base regardless of DSI intensity; low-DSI firms face disproportionate burden, reducing participation incentive	Literature + submissions	Explicit sensitivity: DSI intensity lower bound in Part II; proportionality in Part III
Note: 'Compresses' indicates the factor is expected to reduce Fund revenue below the theoretical maximum under full compliance⁴⁰. 'Ambiguous' indicates the direction depends on how the parameter resolves. The basis for inclusion column indicates the type of evidence supporting each factor: peer-reviewed literature, official submissions to CBD intersessional consultations, analogous mechanisms, or a combination. No formal ranking of factors by importance is assigned. Factors marked 'reflected in scenario range' contribute to the cumulative downward adjustment from the theoretical maximum documented in Part II but are not modelled separately. Factors marked 'explicit sensitivity' are tested through specific alternative assumptions in Part II.					

⁴⁰ Full compliance' (S0) is defined as 100% participation by the eligible population, where eligibility is determined by sector membership (Enclosure I) and the financial thresholds in Annex, paragraph 3, not by verified DSI use; the eligible population therefore includes firms that meet these criteria regardless of whether they in fact use DSI (see 'Financial thresholds and entity definition,' Section 4.1). This study does not distinguish direct from indirect users for eligibility purposes: any firm meeting the sectoral and financial threshold criteria is treated identically, whether its use of DSI would be classified as direct or indirect (see 'Commercial DSI use,' Section 4.1).

5. Part I: Eligibility thresholds

This part responds to paragraph 6(d) of Decision 16/2, which requested the CBD Executive Secretary to commission a study on national and international standards for identifying small, medium, and large entities. To support this process, the Secretariat issued notification 2024-116 to call for submissions from Parties, other Governments, indigenous peoples and local communities and relevant organizations, to submit on outstanding design elements of the DSI Multilateral Mechanism (MLM), including how company size should be defined (CBD, 2024c).

The analysis draws on submissions received and a desk-based review of existing international frameworks for firm size classification to present:

- the rationale for defining entity size for the Cali Fund;
- common themes across submissions on this definition; and,
- international standards on defining company size and comparing that against the submissions.

Its purpose is to assess whether the current financial thresholds in Decision 16/2 are appropriately calibrated for a global benefit-sharing mechanism and to identify options for consideration by the Conference of the Parties.

5.1. Rationale for defining company size

The Cali Fund applies a "two-out-of-three" financial threshold model based on total assets, sales, and profits, to clarify which commercial users of DSI are expected to contribute a proportion of their profits or revenue to the Cali Fund⁴¹. Under this model, an entity is in scope, if it exceeds at least two of the following:

- Total assets: more than USD 20 million
- Annual sales (revenue): more than USD 50 million
- Profit: more than USD 5 million

These values are assessed as an average over the preceding three years.

How entity size is defined is therefore central to the Cali Fund's design. Understanding company scope is essential to ensure that contributions to the mechanism are proportionate to the scale of benefits companies derive from biodiversity. Submissions to Notification 2024-116 demonstrated broad agreement that company size differentiation is necessary but diverged on how best to define the actual size of small, medium, and large companies. Existing SME frameworks offer tested, administratively workable benchmarks, yet they were not

⁴¹ Decision 16/2 Annex paragraph 3

designed for benefit-sharing or biodiversity governance. Submissions identified the need for thresholds that balance:

- a) simplicity in implementation;
- b) sufficient robustness to ensure funds are raised; and,
- c) sufficient flexibility not to deter innovation or undermine equity.

5.2. Common themes in submissions on defining company size

The following section synthesises submissions received in response to CBD Notification 2024-116, covering Party submissions first, followed by those from observers.

Main themes emerging from submissions

Parties and observers generally favoured the use of already-established frameworks, such as the EU SME definition or national business classification systems. There was broad agreement that a CBD-specific system was unnecessary, as it would add administrative burden and reduce compatibility with existing tax and accounting frameworks.

A dominant position across submissions was a preference for financial thresholds over employee-based thresholds, which target revenue and/or profit as the primary determinant of company size. The rationale was that the Cali Fund contribution is a financial commitment, so ability to pay is the most relevant metric; an employee count in isolation was claimed to be misleading in this context. Parties stated that financial metrics are auditable and internationally comparable and correlate more directly with DSI-related commercial activity, whereas employee figures do not adequately reflect digital or IP-intensive business models. Some observers proposed a simplified, single-metric approach, such as annual revenue alone, to avoid frequent reclassification and unnecessary administrative complexity. Overall, financial metrics should therefore be prioritised, though some submissions noted that both systems could be combined.

Several Parties stressed that company size cannot be defined uniformly across sectors, noting significant differences between the biotechnology and pharmaceutical sectors and others such as cosmetics, food, AI, and life-science service providers. Proposals included sector-adjusted thresholds or tiered expectations to reflect these structural differences.

Private sector observers consistently warned against overly broad or rigid definitions of company size. The primary concern was that many companies use DSI only indirectly, and not across all their revenue streams or product lines. It was argued that rigid definitions could capture firms with limited biodiversity dependence, and that the resulting legal uncertainty could negatively affect R&D investment, particularly in emerging economies.

Non-governmental and academic observers expressed a preference for activity-based criteria, suggesting measures such as the value derived from DSI, the degree of dependence on biodiversity, and profit margins rather than absolute turnover.

A recurring theme was the need for flexibility and adaptation to national economic contexts, including the size and share of SMEs in Indicative Enclosure I sectors, with recognition of the differences between developed and

developing countries. Submitters consistently raised the need to avoid excessive burdens on SMEs, calling for either full exemption or simplified and reduced contribution modalities. This was seen by Parties as essential so as not to stifle innovation through additional compliance costs, particularly in the biotech and research sectors, and similarly by observers as a way of preserving innovation systems and sustaining opportunities for North-South research collaboration. Hence, special consideration may be given to start-ups, research institutions, and early-stage biotechnology firms, including transitional arrangements, deferred contribution schemes, or innovation-sensitive thresholds, particularly where such entities demonstrate high levels of DSI use but limited financial capacity.

5.3. International standards of company size

Submissions to Notification 2024-116 reflect broad agreement that company size differentiation is necessary, but they show some divergence on how to define it. Existing SME global frameworks offer tested, administratively workable benchmarks, yet they were not designed for benefit-sharing or biodiversity governance. The frameworks most commonly referenced in submissions are reviewed below, supplemented by additional examples to illustrate the range of approaches adopted across different economic and regional contexts. The review is not exhaustive but aims to provide useful benchmarks for the assessment of the existing eligibility thresholds indicated in Decision 16/2.

European Union

This widely referenced international standard, drawn from Commission Recommendation 2003/361/EC (European Commission, 2003), applies a dual criterion covering both an employee threshold and a financial threshold (see Table 3). It is also used by the United Kingdom and several non-EU international organisations.

The Cali Fund uses three indicators - annual sales, total assets, and annual profit - with a two-out-of-three threshold. Annual sales and turnover refer to the same concept, namely total revenue generated from business operations in a given year. Total assets and balance sheet total are also equivalent. Unlike the EU SME framework, which relies only on turnover and balance sheet total, the Cali Fund adds profit as a third criterion, making its indicator set closely related but slightly broader by capturing financial performance as well as scale.

A key element is the independence requirement: companies in which a larger enterprise holds 25% or more of the capital or voting rights are typically not considered SMEs, no matter their individual financial size⁴². This rule is designed to stop large corporate groups from reorganising their subsidiaries in order to obtain SME advantages.

Table 3 EU definition of small and medium-sized enterprises

Category	Employees	Turnover	Balance sheet
Micro	< 10	≤ €2M (~\$2.3M)	≤ €2M (~\$2.3M)
Small	< 50	≤ €10M (~\$11.6M)	≤ €10M (~\$11.6M)
Medium	< 250	≤ €50M (~\$58.1M)	≤ €43M (~\$50.0M)

⁴² Commission Recommendation 2003/361/EC, Annex, Article 3(2) and (4).

Note: EUR thresholds converted to USD at €1 = \$1.162, spot rate mid-May 2026 (Trading Economics, 2026c). To be classified as an SME, a business must remain below the employee limit and satisfy at least one of the two financial criteria. Businesses where 25% or more of the capital or voting rights are owned by a larger company are typically not eligible for SME status, no matter what their individual size is.

Source: (European Commission, no date).

China

China's definition of SMEs is detailed, sector-specific, and multi-criteria, making it more complex than most systems globally (Ecovis, 2021). It is based on the amended China's SME Promotion Law (2017)⁴³. Enterprises are classified using a combination of three indicators: number of employees, annual business revenue, and total assets (EU SME Centre, 2021; Chen, 2023). However, the relevance of each indicator varies by sector (e.g. total assets feature only in construction, real estate and leasing).

Unlike many countries, China's thresholds vary significantly by industry to reflect differences in labour intensity and capital requirements. For instance, in manufacturing, a firm may be considered small with fewer than 300 employees, while in retail the equivalent ceiling can be as low as 50 to 100 employees. Another distinctive feature is the qualification logic: medium and small enterprises must typically meet all relevant thresholds, while micro enterprises generally need to satisfy only one. Agriculture is an exception, being classified by revenue alone with no employment criterion. Table 4 also reports SME ceilings, above which companies are classified as large.

Table 4 China's definition of small and medium-sized enterprises

Category	Industry		Agriculture		Information transmission		Software & IT	
	Emp.	Rev.	Emp.	Rev.	Emp.	Rev.	Emp.	Rev.
Micro	< 20	or < \$440K	—	< \$73K	< 10	or < \$147K	< 10	or < \$73K
Small	≥ 20	and ≥ \$440K	—	≥ \$73K	≥ 10	and ≥ \$147K	≥ 10	and ≥ \$73K
Medium	≥ 300	and ≥ \$2.9M	—	≥ \$734K	≥ 100	and ≥ \$1.5M	≥ 100	and ≥ \$1.5M
SME ceiling	< 1,000	or < \$58.7M	—	< \$29.4M	< 2,000	or < \$146.8M	< 300	or < \$14.7M

Note: CNY thresholds converted to USD at ¥6.81/\$, the onshore PBoC-referenced spot rate for mid-May 2026 (Trading Economics, 2026b). Agriculture is classified by revenue only; no employment criterion applies. Industry covers pharmaceuticals, biotechnology, cosmetics, nutraceuticals, and laboratory equipment. Both digital sectors are classified by employment and revenue jointly. The classification covers more sectors: the scope of the table was limited to those most relevant to the Cali Fund's monetary benefit-sharing scope.

Source: (MIIT *et al.*, 2011; Standing Committee of the National People's Congress, 2017).

Japan

Japan's SME definition is sector-specific and based on a dual criterion of capital and employee numbers. Under the Small and Medium-sized Enterprise Basic Act, a firm qualifies as an SME if it meets either, not necessarily both, of the thresholds set for its industry (Small and Medium Enterprise Agency, 1999). A distinctive feature

⁴³ Originally implemented in 2003 (Chen, 2023)

is this either/or approach combined with strong sector differentiation, which allows firms with low capital but larger workforces, or vice versa, to still qualify as SMEs. Unlike most jurisdictions, Japan uses capital⁴⁴ rather than revenue as its financial indicator.

Japan also defines a sub-category of small enterprises within the broader SME population, with employee counts below 20 or fewer employees, reflecting the prevalence of micro and family-run businesses. For Cali Fund purposes, the most relevant sectors are manufacturing, which covers pharmaceuticals, biotechnology, and cosmetics, and services, which covers software and information-related activities.

Table 5 Japan's definition of small and medium-sized enterprises

Sector	Capital threshold	Employee threshold
Manufacturing, construction, transport and others	≤ ¥300M (~\$1.9M)	≤ 300
Wholesale	≤ ¥100M (~\$631K)	≤ 100
Retail	≤ ¥50M (~\$315K)	≤ 50
Services	≤ ¥50M (~\$315K)	≤ 100
Small enterprise sub-category (within SMEs)		
Sector group	Employee threshold (small enterprise)	
Manufacturing and others	≤ 20	
Commerce and services	≤ 5	

Note: JPY thresholds converted to USD at ¥158.5/\$, spot rate mid-May 2026 (Trading Economics, 2026d). An enterprise qualifies as an SME by meeting either the capital or employee criterion. The small enterprise sub-category is employee-only; no capital criterion applies at that tier.

Source: (Small and Medium Enterprise Agency, 1999)

United States of America⁴⁵

The United States does not apply a single universal threshold. Instead, thresholds are industry-specific, based on NAICS codes, and expressed in terms of either average annual revenue or number of employees, depending on the sector. There is no defined category of medium or large business, only small. “Small” business thresholds typically range from \$2.25 million to \$47 million in annual turnover depending on sector, while employee-based thresholds, applied primarily in manufacturing and IT services, range from 500 to 1,500 employees. A firm exceeding its sector threshold is classified as other than small, as the system does not define a medium category.

It should be noted that the US system applies an affiliation rule which, similarly to the EU classification, requires that 50% or more of a business be assessed together with any other entities it controls or is controlled by, rather than on a standalone basis, based on ownership, management control, or other forms of influence. These rules are designed to prevent large corporations from restructuring into smaller units to qualify for

⁴⁴ Capital here refers to paid-in capital which is a single line position on the balance sheet, unlike the Cali Fund's total assets, which include everything a company owns (incl. fixed assets).

⁴⁵ The United States is not a Party to the CBD but is included here given the significant presence of US-headquartered firms among Cali Fund-relevant sectors, particularly in pharmaceuticals, biotechnology, and information technology.

benefits reserved for small businesses, ensuring that size classifications reflect the true economic scale of the entire corporate group.

Brazil

Brazil classifies enterprises by annual gross revenue under Lei Complementar 123/2006 (Brazil, 2006), which is the primary framework used for tax and regulatory purposes. Table 6 sets out the classification thresholds, converted to United States dollars. Annual gross revenue as used in the Brazilian classification is equivalent in scope to the annual sales indicator used in the Cali Fund.

Table 6 Brazilian classification of micro and small-sized enterprises

Category	Gross revenue
Micro	< BRL 360,000 (~USD\$71,146)
Small	BRL 360,000 to BRL 4.8 million (~USD\$71,146 to ~USD\$948,617)

Note: Converted from original thresholds using a spot exchange rate as of June 2026: 5.06 BRL/USD (Trading Economics, 2026a).

Source: (Brazil, 2006)

The Cali Fund financial thresholds are substantially higher than Brazil's small enterprise ceiling of approximately USD 1 million in annual revenue. The Brazilian classification system does not define a medium-sized enterprise category, meaning there is no domestic benchmark between the small enterprise ceiling and the Cali Fund's revenue threshold of USD 50 million. Hence, a firm considered as large under Brazilian legislation may fall below the Cali Fund eligibility threshold.

India

Under the MSME Development Act 2006, India categorizes enterprises as micro, small, medium enterprises based on two simultaneous composite criteria: the level of investment in plant and machinery and the value of annual turnover. An enterprise must satisfy both conditions to fall within a given category. Annual turnover under the Indian framework is equivalent in scope to the annual sales indicator used in the Cali Fund's two-out-of-three eligibility threshold, making the two frameworks directly comparable on this dimension. These limits were raised in April 2025, and the updated classification is presented in Table 7.

Table 7 Indian classification of micro, small and medium-sized enterprises

Category	Investment	Turnover
Micro	< INR 2.5 crore (~\$262,254)	< INR 10 crore (~\$1,049,017)
Small	< INR 25 crore (~\$2,622,542)	< INR 100 crore (~\$10,490,169)
Medium	< INR 125 crore (~\$13,112,710)	< INR 500 crore (~\$52,450,847)

Note: Converted from original thresholds using a spot exchange rate as of June 2026: 95.3370 INR/USD (Trading Economics, 2026a). 1 crore = 10 million.

Source: (India, Ministry of MSME, 2025).

The Cali Fund revenue threshold of USD 50 million falls just below the Indian medium enterprise turnover ceiling of approximately USD 52.4 million. This means that some firms classified as medium enterprises under

Indian legislation could fall within the Cali Fund thresholds for contribution if they also meet two of the three financial criteria. Nonetheless, the two classification systems are not directly comparable, since India uses both investment and turnover simultaneously while the Cali Fund applies a two-out-of-three rule across revenue, assets, and profit.

Organisation for Economic Co-operation and Development

The OECD does not impose a single legally binding definition of business size but provides a widely used statistical classification framework based primarily on employee numbers, used for cross-country comparison and analysis. Through its standard classification, enterprises are grouped into micro (1-9 employees), small (10-49), medium (50-249), and large (250 or more) categories.

Table 8 OECD definition of small and medium-sized enterprises

Category	Employees
Micro	< 10
Small	< 50
Medium	< 250

Note: The OECD SME classification is based solely on employee numbers.

Source: (OECD, no date a).

The OECD framework is designed for analytical and comparative purposes rather than regulatory application. It does not typically include financial thresholds (such as turnover or assets), nor does it differentiate by sector, meaning it cannot fully capture differences in capital intensity or market structure between industries. Several submissions noted that this feature limits direct applicability as a contribution eligibility criterion.

International Finance Corporation (World Bank Group)

The World Bank Group's operational definition of enterprise, applied via the International Finance Corporation (IFC), classifies firms as micro, small, or medium based on a combination of employees, annual sales, and total assets. Unlike the EU model, these thresholds are not applied uniformly and are often adjusted to reflect country income levels, sector characteristics, and national definitions. The primary purpose of the framework is operational and analytical, supporting development finance, SME access to credit, and economic analysis. As a result, it prioritises local relevance over strict international comparability.

Table 9 World Bank definition of small and medium-sized enterprises

Category	Employees	Annual sales	Total assets
Micro	< 10	< \$100,000	< \$100,000
Small	< 50	< \$3 million	< \$3 million
Medium	< 300	< \$15 million	< \$15 million

Note: An enterprise qualifies as micro, small, or medium if it meets two out of three criteria: number of employees, total assets, and annual sales. A loan size proxy is also used as an operational classification tool by IFC financial intermediaries but is not applicable to the Cali Fund context, and hence not presented in the table.

Source: (ICF, no date)

The comparisons above use point-in-time spot exchange rates (June 2026) to convert national thresholds into USD.

5.4. Assessment of the Decision 16/2 thresholds

The thresholds established in Decision 16/2 can be assessed against both the submission positions summarised in Section 5.2 and the international frameworks reviewed in Section 5.3.

Overall, the use of financial rather than employee-based criteria aligns with the dominant Party preference, and the two-out-of-three structure partially reflects calls for multi-metric approaches. However, the thresholds are not sector-differentiated, which sits in tension with the concerns raised in submissions about structural differences across DSI-reliant industries. There is also no explicit lower boundary protecting micro enterprises, SMEs, or early-stage firms, despite broad support in submissions for such protection. The profit criterion stands out in the threshold design because, unlike other frameworks, it does not measure size by assets, revenue, or employees but by financial performance. The two-of-three structure helps protect firms that are not making a profit but using absolute profit as a requirement makes the system sensitive to different margin structures and how profits are reported. Parts II and III look more closely at how threshold calibration affects the Fund's potential revenue and what the profit criterion means for coverage across different sectors.

When compared to international frameworks, the Cali Fund thresholds broadly match the criteria for large enterprises, though with some differences. According to the World Bank IFC framework, a company meeting the Cali Fund thresholds would be considered large, as it surpasses the medium-enterprise limits. The Cali Fund revenue threshold of USD 50 million is similar to the EU's medium-enterprise turnover ceiling of about USD 58 million. However, its assets threshold of USD 20 million is considerably below the EU's medium balance sheet ceiling of about USD 50 million. This means a company could meet the Cali Fund's assets requirement but still be considered medium-sized in the EU. Similarly, for India, some firms classified as medium-size under its legislation might be captured under the fund's scope (approx. \$52.5 million ceiling vs. \$50 million for the fund), however its investment criterion cannot be benchmarked against the two-of-three criteria. In China, the classification depends on the sector: the Cali Fund thresholds are above the SME limits in digital sectors but not in manufacturing. For Brazil, a direct comparison is not possible, given the absence of thresholds for a medium-sized company. The OECD and Japanese frameworks are also not directly comparable, since the OECD uses only employee numbers and Japan focuses on paid-in capital instead of revenue or assets. Unlike all the frameworks reviewed, the Cali Fund does not include an employee criterion, which makes it diverge from almost all international SME classification frameworks. This divergence has a practical implication for national implementation. Many government economists rely primarily on employee data to assess domestic firm size and may have more limited access to consolidated data on assets or profit, particularly for privately held companies. Whether to introduce an employee-based criterion, and how it might interact with the existing financial thresholds, is a matter for the Conference of the Parties to consider; this study does not take a position on it.

Separately, two of the frameworks reviewed, namely the EU and the US, include ownership or affiliation conditions that prevent large corporate groups from restructuring subsidiaries to access preferential treatment. No equivalent provision exists in the current Decision 16/2 threshold design. As the Cali Fund's contribution obligations are entity-level, this raises a related question of whether the definition of a qualifying entity is sufficiently robust to prevent the creation of separate legal entities structured primarily to isolate DSI-related

activity and report lower revenues or assets. This issue is examined further in the analytical framework and may represent an additional design element for consideration by the Conference of the Parties, independently of the threshold calibration questions above.

Under several of the frameworks reviewed, firms meeting the current Decision 16/2 revenue and assets thresholds would be classified as medium-sized rather than large. Parties may wish to consider whether the current thresholds are calibrated at the intended level in light of this comparison. The following options address this and related design questions:

- 1) The current thresholds could be supplemented by an explicit SME exemption or reduced requirement tier, using a definition from existing international or national frameworks (e.g. EU or World Bank). Although Decision 16/2 thresholds already tend to exclude smaller firms, setting a formal lower limit would fill a gap that several submissions pointed out. This option keeps the current threshold levels but adds another layer, which would require agreement on which reference framework to apply.
- 2) A second option is to revisit the profit criterion, which has no direct parallel in the reviewed frameworks and was not specifically proposed in Party submissions. Several observer submissions suggested profit margins as an alternative to absolute profit, on the basis that margins better account for structural differences in profitability across sectors. Whether this would represent a meaningful change in practice depends on where any margin threshold is set. Profit is also a performance metric rather than a size metric, and is subject to earnings management and cyclical volatility in ways that revenue and assets are not, which is a further consideration in assessing its suitability as a contribution-basis criterion. The implied margin structure of the existing thresholds is examined in Part II.
- 3) Parties may wish to apply calibrated adjustments to eligibility thresholds at the national level, taking into account structural characteristics such as firm size distribution and sectoral composition. Similarly, introducing sector-adjusted thresholds may be most appropriate where a sector is a financial outlier relative to the rest, rather than a general principle. Financial characteristics of eligible entities differ across Indicative Enclosure I sectors, as documented in Part II. Pharmaceuticals exhibit substantially higher median revenue, assets, and profit margins compared to all other sectors, while the remaining six sectors display a relatively narrow range of financial metrics. Hence, sector adjustments to thresholds are most analytically justified for pharmaceuticals specifically, rather than for a broad manufacturing-versus-digital distinction. However, submissions have raised concerns regarding both approaches due to potential administrative complexity and reclassification risk.
- 4) Parties may wish to consider whether the current entity-level design is sufficiently robust to prevent the creation of separate legal entities structured to isolate DSI-related activity. This could involve including ownership and affiliation conditions applied in the EU and US frameworks.
- 5) Introducing an employee count criterion, alone or alongside the current financial thresholds, would align the Fund's design with most other frameworks reviewed and ease domestic estimation of exposure by Parties. However, Party submissions consistently viewed financial metrics as more relevant than employee numbers for determining contribution capacity, and this option was not raised in submissions received.

- 6) Considering periodic revision of the thresholds, comparable to the EU's practice of updating its equivalent thresholds through Commission delegated legislation, since the Decision 16/2 thresholds are currently fixed in nominal USD terms rather than indexed to inflation or exchange rate movements.
- 7) Parties may wish to consider transition arrangements, such as a phase-in period or reduced initial rate, for firms newly meeting the eligibility thresholds or with historically low DSI intensity, to ease the administrative and financial adjustment to first-time contribution.

6. Part II: Revenue potential and contribution structure

This part provides the evidence to support the analysis of the revenue generation dimension of paragraph 6(e) of Decision 16/2. It draws on firm-level financial estimates from an independent study and extends the analysis drawing on the comparative mechanism review in Section 3 and the current Cali Fund design analysis in Section 4. The analysis follows the three-stage participation framework set out in Section 4: Section 6.3 describes the eligible population, participation assumptions, and contribution mechanics before any results are presented; Section 6.4 presents the revenue estimates and their sensitivities; and Section 6.5 synthesises findings.

6.1. Data and methodology

Estimating Cali Fund revenue at the entity level requires firm-by-firm financial data across all seven Indicative Enclosure I sectors and CBD Party jurisdictions. Using publicly available sectoral aggregates would not allow to apply Decision 16/2 thresholds and contribution bases, as both require firm-level data. Such data are commercially sensitive and not publicly available. While individual Parties might have access to relevant financial information through domestic tax records or company filings, creating a global dataset would, at a minimum, require data-sharing agreements with each Party. Currently, there is no such system at the CBD, and direct access to external proprietary financial databases was not available for this study. As a result, the revenue estimates presented here are based on Makowska-Curran (2026), a working paper from the Grantham Research Institute on Climate Change and the Environment at the London School of Economics and Political Science. The paper provides global bottom-up estimates of the Cali Fund's contributions, using firm-level financial information for 21,690 eligible firms spanning over 100⁴⁶ CBD Party jurisdictions. The full methodological detail and sensitivity analysis are documented in the working paper itself. Eligibility in this analysis is assessed against the total assets, revenue and profit criteria specified in Decision 16/2. Employee count is not part of this threshold design and is therefore not used as a basis for determining eligibility here. This is a reflection of the current Decision text rather than a methodological choice made for this study; were the Conference of the Parties to include an employee-based criterion at COP17, the eligible population and revenue estimates in this Part would need to be reassessed accordingly.

The estimates are based on the Orbis database (Moody's Analytics, 2025), a commercial firm-level financial database widely used in cross-country economic analysis (Gal, 2013; Bajgar *et al.*, 2019; Kalemli-Özcan *et al.*, 2024), providing the balance sheet and income statement data required to apply the Decision 16/2 eligibility thresholds and compute contributions at the entity level.

⁴⁶ A full breakdown of CBD Party coverage status, including which Parties have no coverage within the database and which have coverage but no eligible firms meeting the thresholds, is provided in Annex reproduced from Makowska-Curran (2026).

The sector mapping translates the Enclosure I list into the standard international industry activity classifications, namely NACE Rev.2⁴⁷, ISIC Rev.4/5⁴⁸, and NAICS⁴⁹. For ISIC, it uses the classification by Oldham (2025), for NACE, it follows Menon Economics (2025), while NAICS matching was done specifically for that study. The classification is applied at the most granular available level, usually the 4-digit NACE class or its equivalent, to avoid including firms whose main activity does not involve DSI use. This helps prevent counting companies that are in a broad industry group but are not actually involved in DSI-related activities.

Data coverage varies considerably across jurisdictions. For EU member states and a limited number of other OECD economies, firm-level samples are validated against official structural business statistics and treated as broadly representative. For the majority of CBD Parties, coverage is partial and official sectoral benchmarks were unavailable for validation; those estimates are treated as conservative lower bounds. Of the 196 CBD Parties, 100 have at least one eligible firm in the data. Where gaps exist, they most likely reflect genuine database under-coverage in Sub-Saharan Africa, parts of Asia-Pacific and selected large OECD economies, including Canada (Bajgar *et al.*, 2019; Kalemli- Özcan *et al.*, 2024) rather than an absence of eligible firms, though for small island states and least-developed countries the reverse is the more plausible interpretation given the scale of the financial thresholds involved.

Each firm's annual contribution is calculated using the lower of two indicative rates applied to its 2023 financials (the most recent complete year⁵⁰), since firms are expected to choose the option that results in a smaller expectation. Firms with losses do not contribute. The revenue analysis covers five scenarios, described below.

6.2. Limitations

Several features of the underlying data and methodology limit the interpretation of the results. Database coverage gaps in Sub-Saharan Africa, parts of Asia-Pacific, and selected large OECD economies mean the 100-Party sample likely understates the true eligible population, and estimates for those regions should be treated as conservative lower bounds. Switzerland and Canada are identified as probable undercounts due to incomplete coverage of unconsolidated accounts for large multinationals headquartered in those countries; their true contribution potential is higher than reported (seed data validation in Makowska-Curran (2026)). On the contrary, the United Kingdom figure is sensitive to the inclusion of consolidated accounts and should be treated as an upper bound. Taken together, country-level estimates are less reliable than the aggregate, and the disaggregation should be interpreted as indicative rather than precise. Similarly, Makowska-Curran (2026) provides more detail on coverage by Indicative Enclosure I sector (see Figure 9 of that study); overall, the tested sectoral coverage for large companies in scope in selected OECD countries is good, nonetheless, due to gaps in validation data for other countries, sectoral coverage may be lower for those remaining countries.

⁴⁷ NACE stands for "statistical classification of economic activities in the European Community" (translated from French "Nomenclature statistique des activités économiques dans la Communauté européenne"). It is the classification of industrial activities used in the European Union (European Commission, 2008).

⁴⁸ ISIC is the International Standard Industrial Classification of All Economic Activities, the United Nations reference framework for classifying economic activities by productive type (UNSD, 2026).

⁴⁹ NAICS refers to the North American Industry Classification System, the standard classification framework used by United States federal statistical agencies to categorise business establishments for statistical purposes (U.S. Census Bureau, 2022).

⁵⁰ Where firms have data for fewer than all three threshold years, the average is computed over available years only. This is a conservative choice that avoids excluding firms with incomplete Orbis coverage rather than genuine recent entry. Full methodological detail is in Makowska-Curran (2026).

The sector mapping applies standard industrial classification codes at the most granular available level, but cannot cleanly separate directly DSI-relevant firms from those in adjacent segments within the same code. In particular, the eligible population count reflects sector and financial-threshold criteria only; paragraph 5 exclusions for entities that do not use DSI at all are not applied at the firm-count level, and are instead captured indirectly through the DSI intensity adjustment to contribution amounts in Stage 3.

Firm-level financials are expressed in nominal USD terms over 2021-2023, consistent with the fixed nominal thresholds set by Decision 16/2. As with comparable frameworks, exchange rate movements and inflation will affect the real value of both thresholds and estimated contributions over time unless the thresholds are periodically revised.

Several of the parameters underpinning the central scenario are not observed directly and are instead inferred from adjacent literature or sector-level proxies, which is itself a source of uncertainty. Participation rate assumptions are calibrated from published literature on voluntary environmental schemes that does not cover a mechanism with the Cali Fund's specific design features, and no direct evidence on participation intentions across eligible sectors is currently available.

A related but distinct constraint applies to DSI intensity: Decision 16/2 ties both eligibility and the contribution amount to financial metrics rather than to DSI use itself, and no data source currently observes the share of a firm's financial activity attributable to DSI use. In the absence of such a measure, the DSI intensity adjustments applied in the central scenario rely on sector-level proxies rather than observed firm-level data. The sector-level DSI intensity multipliers do not net out potential overlapping obligations under other instruments relevant to particular sectors, such as the WHO PIP Framework and Pandemic Agreement for pharmaceutical firms working with influenza and pandemic pathogen sequences, the ITPGRFA's Benefit-sharing Fund for plant breeding, or a future BBNJ benefit-sharing mechanism for biotechnology firms using marine genetic sequences, which remains government-donor funded and not yet operational. No data exists to estimate the scale of this overlap by sector, and it is addressed only at an aggregate level through the ITPGRFA-based lower-bound revenue scenario in this Part. Participation rates and DSI intensity are therefore both treated as the most uncertain parameters in the analysis, and the wide scenario range is designed specifically to reflect this reliance on inferred rather than observed values, rather than being an artefact of modelling choice. All figures presented in this study are illustrative analytical scenarios developed to inform policy discussion, not forecasts or expected outcomes. Actual Cali Fund revenue will depend on the Conference of the Parties' eventual decisions on thresholds and rates, subsequent national implementation measures, actual participation levels, and how corporate behaviour evolves once Decision 16/2 is operational. As corporate disclosure requirements evolve and Decision 16/2 is implemented, data availability on firm-level DSI use is likely to improve, which should reduce the estimation uncertainty reflected in this study's wide scenario range over time.

6.3. Applying the analytical framework

The three-stage framework introduced in Section 4 (

Figure 2) structures the analysis here. Stage 1 concerns eligibility: which firms meet the Decision 16/2 thresholds and fall within the indicative Enclosure I sector list. Stage 2 looks at participation: what share of eligible firms may actually contribute, and under what assumptions. Stage 3 concerns contribution amounts: how much participating firms pay, given the current contribution base and their DSI use. Each stage is described below before results are presented.

Stage 1: The eligible population

The eligible population is defined by the two-of-three financial threshold rule in Decision 16/2, applied at the subsidiary level (matching the entity definition applied in this study), and across all seven Indicative Enclosure I sectors, determined by primary sectoral activity (i.e. excluding relevant secondary activities). Applying these thresholds to firm-level financial data for CBD Party jurisdictions yields 21,690 eligible entities spanning 100 Parties. Table 10 provides their total number and median values for each relevant financial indicator. The full distribution of financial characteristics, including the spread around those medians, is shown in Figure 3. The remaining Parties either have no coverage in the data or no firms meeting the eligibility criteria, with coverage gaps discussed in Section 6.1 and full breakdown by Party in the Annex

With a median revenue of USD 95 million and median total assets of USD 111 million, the typical eligible firm sits well above the Decision 16/2 assets threshold of USD 20 million (5.5 times the threshold) but only moderately above the revenue threshold of USD 50 million (1.9 times) and marginally above the profit threshold of USD 5 million (1.3 times, or USD 6.5 million in absolute terms)⁵¹. As shown in Figure 3, the spread around these medians differs substantially across the three indicators. Total assets are distributed well above the threshold across the full range of the sample, with the lower end of the distribution remaining above the USD 20 million boundary in every sector (for 90% of eligible firms). Revenue and profit show a different pattern. The lower ends of both distributions get close to or fall below their thresholds. Profit is particularly sensitive: in every sector, at least one in four eligible firms reports profit at or below USD 5 million, indicating that many clear this criterion only marginally, if at all. This pattern means that eligibility depends primarily on revenue and profit in terms of variation within the sample, while the assets threshold creates less differentiation within the eligible population since most firms clear it by a substantial margin.

While all sectors behave similarly, pharmaceuticals stand apart on every dimension; it has the highest median revenue, assets, and profit. It is also the only sector where the 25th percentile of profit meets or exceeds the Decision 16/2 profit threshold of USD 5 million, suggesting that the financial capacity to contribute is more broadly distributed within that sector than in any other. The implications of these characteristics for revenue estimates and participation are discussed in Stages 2 and 3.

The eligible population described above reflects specific methodological choices about sector scope and threshold application. As noted in the uncertainty register in Section 4 (Table 2), sensitivity of revenue estimates to different thresholds is examined in Section 6.3.

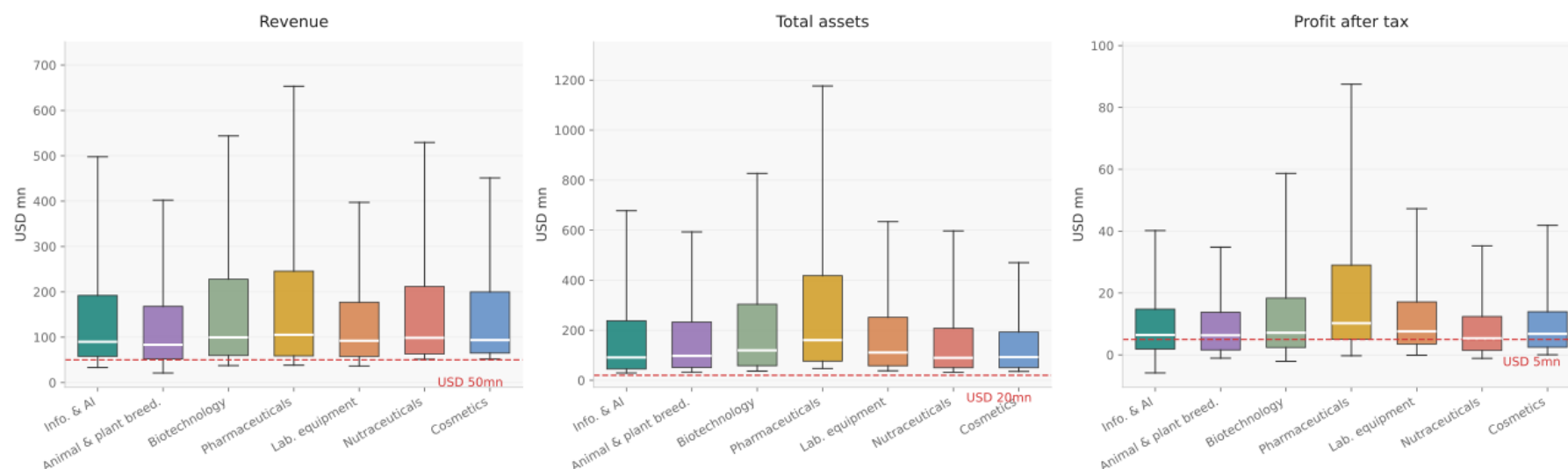
⁵¹ Note that those estimates use 2023 as the reference year, rather than 3-year averages reported in Figure 3. The latter is more aligned with the Decision 16/2 thresholds.

Table 10 Eligible entity characteristics by sector

Sector	No of entities	Share of total (%)	Median revenue (USD million)	Median assets (USD million)	Median profit (USD million)
Information and AI	5,217	24.1	96	95	6.4
Animal and plant breeding	4,256	19.6	83	97	4.6
Biotechnology	3,709	17.1	96	120	5.7
Pharmaceuticals	3,401	15.7	105	165	10.2
Laboratory equipment	2,846	13.1	93	114	7.4
Nutraceuticals	1,513	7.0	104	91	5.0
Cosmetics	748	3.4	100	97	7.4
All sectors	21,690	100.0	95	111	6.5

Note: Median revenue, total assets and profit in nominal USD millions, reference year 2023.

Source: Adapted from Makowska-Curran (2026).

Figure 3 Distribution of financial characteristics of eligible entities by Indicative Enclosure I sector

Note: Boxes show P25–P75; whiskers extend to P10–P90; values in nominal USD millions, three-year average 2021–2023; dashed red lines show Decision 16/2 thresholds. *Source:* Author's calculations based on Makowska-Curran (2026).

Stage 2: Participation

Stage 2 looks at how many eligible firms may be willing to contribute. Since participation under Decision 16/2 is encouraged, rather than mandatory, this creates the main source of uncertainty in the revenue analysis and is the principal driver for the gap between the full compliance estimate and the more realistic revenue range.

Makowska-Curran (2026) estimates Cali Fund contributions through a Monte Carlo simulation that draws on the empirical literature on voluntary environmental schemes. The simulation combines three sector-level parameters: a participation rate reflecting reputational exposure and investor scrutiny, an adjustment for differences between publicly listed and unlisted firms, and an estimate of the share of activity in each sector that depends on DSI. This calibration is appropriate for benchmarking the Cali Fund against the general population of voluntary environmental initiatives but does not fully reflect the uncertainties specific to the mechanism identified in Table 2.

This study addresses the research question from two additional perspectives. Section 3 presents a comparative review of private sector monetary contributions that have emerged in mechanisms most structurally similar to the Cali Fund. The mechanisms examined differ significantly in their compliance outcomes: the ITPGRFA' MLS, where user-based payments remained significantly below projected levels over fifteen years due to structural features that closely align with the unresolved uncertainties identified in Section 4; and the PIP Framework, where a clearly defined and operationally dependent contributor pool achieved broad and sustained financial engagement over a comparable period. In the absence of direct evidence on the behaviour of Cali Fund-eligible firms, these mechanisms serve as the most relevant empirical benchmarks. The ITPGRFA' MLS informs the lower bound of the plausible range, while the PIP Framework illustrates the outcomes under more favourable conditions. Section 4 introduces an analytical framework that identifies specific features of Decision 16/2 likely to deter participation, which are not present in either the voluntary scheme literature or analogous mechanism evidence. These include obligation stacking, uncertainty about the legal value of the certificate of contribution, and information asymmetry regarding self-identified DSI use. Together, these two directions inform the uncertainty-adjusted revenue range and timing variants presented in Section 6.4. As the results show, the range is wide, reflecting the number of design parameters that remain open under Decision 16/2.

Table 11 describes the five modelling scenarios used as the basis for the revenue analysis. S1 through S3 apply empirically calibrated adjustments for sector-level participation variation, firm ownership type, and DSI use intensity respectively. S4 adds a temporal dimension, modelling participation as building gradually over time.

Table 11 Revenue estimation scenarios

Scenario	Description
S0: Full participation	The theoretical upper bound. Every eligible entity (as defined in this study, i.e. using publicly available DSI, operating in one of the indicative Enclosure I sectors, and meeting the 2-of-3 thresholds) is assumed to participate, with no adjustment for differences in the likelihood of engagement across sectors, firm types, or levels of DSI use.
S1: Sector variation	Participation rates vary by sector, reflecting differences in voluntary engagement incentives calibrated from published evidence on comparable environmental programmes. Carries moderate uncertainty: the empirical evidence on sector-level participation in voluntary environmental initiatives is well-established but not specific to the Cali Fund. Firm type and DSI use intensity are held constant across the eligible population.
S2: Sector and firm variation	Extends S1 by additionally differentiating participation rates between publicly listed and unlisted firms. Listed firms are assigned a higher participation probability, reflecting stronger disclosure

Scenario	Description
	pressure and investor scrutiny. The listed-unlisted distinction is the best-evidenced parameter in the analysis, drawing on a broad empirical literature on corporate environmental disclosure. DSI use intensity held constant.
S3: Sector, firm, and DSI adjustment	Extends S2 by scaling participation to reflect the share of each sector's commercial activity that can plausibly be attributed to DSI use. Carries the highest uncertainty of the three calibrated parameters: direct firm-level evidence on DSI use is not currently available, and sector-level estimates rest on indirect proxies. Central modelling scenario.
S4: Progressive uptake	Applies the same sector and firm participation rates as S2 but models engagement as building gradually over time, starting at 10% of the mature-state rate in year one and reaching the full S2 level by 2035, consistent with slow early adoption observed across voluntary environmental schemes.

Note: S3 and S4 are designated as central scenarios for annual revenue analysis and NPV projections respectively. Adjustment factors in S1 through S3 are calibrated from peer-reviewed literature on voluntary environmental programme participation and DSI use. Central modelling scenario highlighted in light grey (shaded).

Source: Adapted from Makowska-Curran (2026).

Full sensitivity results across alternative contribution years, averaging windows, rate combinations, contribution bases, discount rates, and Monte Carlo parameter shifts are reported in Makowska-Curran (2026).

The sector-level participation rates, ownership multipliers, and DSI intensity parameters used in Scenarios S1 through S3 are calibrated from peer-reviewed literature on voluntary environmental scheme membership and DSI use patterns. Central values and supporting justifications for all three parameters are provided in Annex A.

Uncertainty-adjusted revenue range

The upper bound of the range is the central scenario (S3), representing the revenue the fund could approach if the identified uncertainties are substantially resolved and participation converges toward what the voluntary scheme literature predicts, conditional on DSI intensity of eligible firms. Hence, S3 is not a near-term projection but a ceiling conditional on favourable resolution of those risks.

The lower bound estimate is calculated by applying the ITPGRFA' MLS' observed payment ratio to the S3 central estimate. The ITPGRFA's own commissioned analysis projected conservative near-term user-based payments of USD 10 million per year; actual payments averaged approximately USD 55,000 per year over fifteen years, a ratio of roughly 0.5%. Applying this ratio to the S3 central estimate of USD 929 million yields a lower bound of approximately USD 5 million per year. This approach assumes that the structural features suppressing ITPGRFA' MLS' user-based payments, including first-mover problem, and avoidance, repeat under the Cali Fund. The distance between the two bounds reflects the degree to which the identified uncertainties need addressing. The revenue analysis in Section 6.4 presents result across this range.

Within the uncertainty-adjusted range, three alternative timing pathways are tested. The lower bound shows what happens when the ITPGRFA' MLS' ramp-up pattern is applied to S2. In this scenario, revenue stays near zero in the early years and then grows very slowly, mostly among a few firms with high reputational exposure. This delayed uptake trajectory keeps the same mature-state ceiling (USD 7 million) but assumes that this ceiling is not reached until well after the 2035 horizon used in S4.

Three timing variants bracket the plausible range:

- Fast: following the S4 path as already modelled (10% increase every year);

- Moderate: with near-zero in years one through three, before an S4-style ramp from year four, reflecting partial early resolution of the most critical identified uncertainties; and,
- Slow: with near-zero in years one through nine, consistent with the ITPGRFA BSF's first decade, followed by very slow growth.

The NPV⁵² implications of the three timing variants are examined in Section 6.4, applied to both the S3 ceiling and the lower bound of the uncertainty-adjusted range.

Stage 3: Contribution amounts

Stage 3 concerns how much participating firms actually pay. Under Decision 16/2, each cost-minimising, eligible entity contributes whichever of two indicative rates produces the smaller obligation: 1% of profit after tax or 0.1% of revenue. This minimum-of-two design divides the eligible population into two groups with structurally different contribution profiles.

The dividing line follows mechanically from the ratio of the two rates. Firms whose profit margin exceeds 10% will always find the revenue-based obligation smaller and so pay a flat 0.1% of revenue, regardless of how profitable they are. Firms below that margin pay on profit at a fixed rate of 1%, or nothing if they report a loss. The 10% indifference point is an arithmetic consequence of the indicative rates, and it would shift if either rate were revised independently.

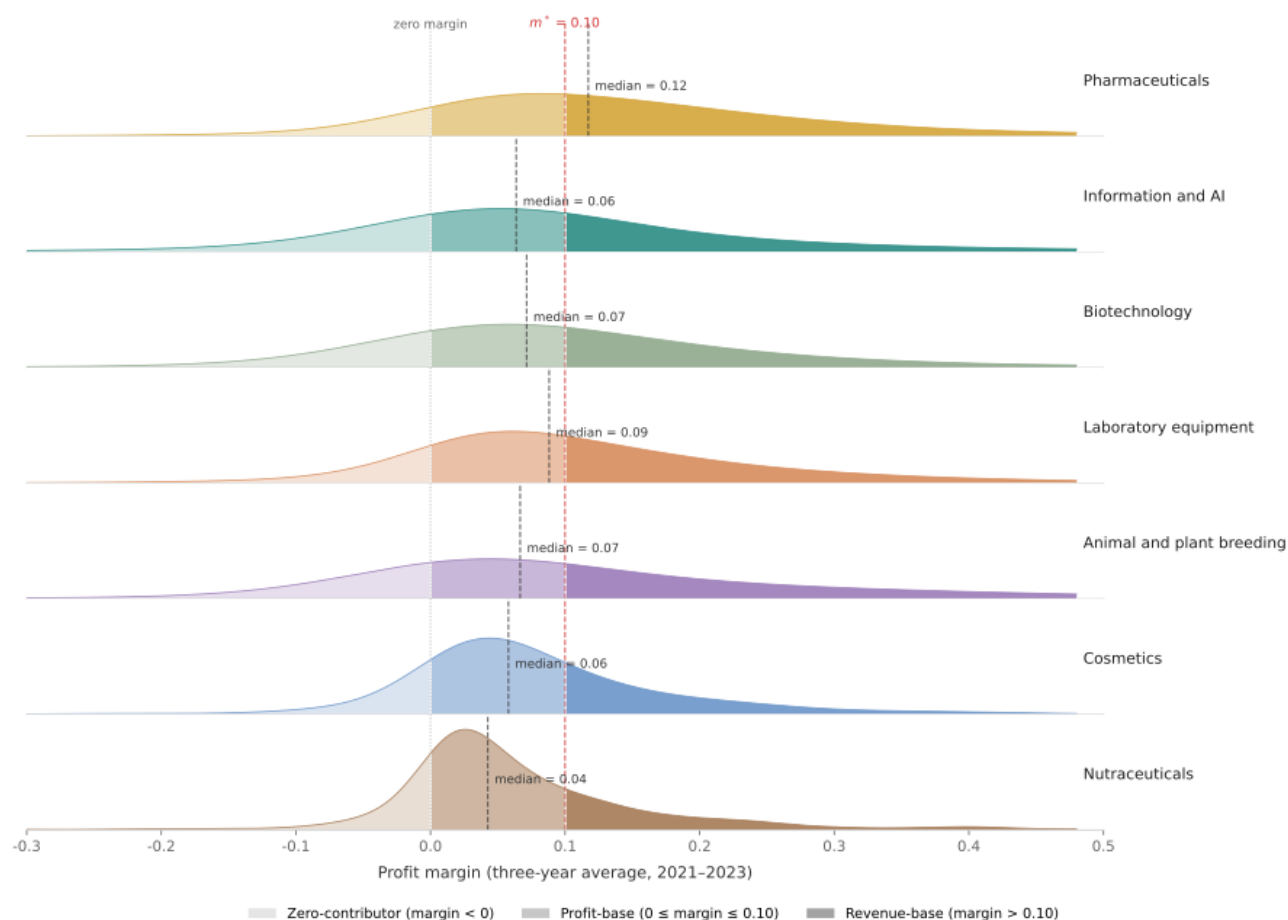
The median eligible firm has a profit margin of 6.8%⁵³, placing the majority of the eligible population in the profit-base group. Figure 4 and

Table 12 show the distribution of firms across contribution regimes by sector, and their corresponding share by contribution base. Pharmaceuticals is the only sector where the majority of eligible firms exceed the 10% indifference threshold, with a median margin of 11.7% and 51% of firms in the revenue-base group, giving it a structurally more stable and predictable contribution profile than all other sectors. In every other sector, the majority of firms fall in the profit-base or zero-contributor group, meaning aggregate sectoral contributions are sensitive to annual earnings fluctuations. Hence, the fund's revenue stability depends disproportionately on whether pharmaceutical firms choose to participate, a point that connects directly to the participation discussion in Stage 2.

Above the threshold, the effective contribution rate as a share of profits declines continuously as profitability rises: a firm at 45% margin pays an effective rate of 0.22% of profits, against 1.0% for a firm at exactly 10%. In absolute terms, the higher-margin firm still contributes more to the fund; the declining effective profit rate is an inherent property of the minimum-of-two design and cannot be addressed through proportional rate revisions alone.

⁵² Net Present Value (see the glossary).

⁵³ See Table 10

Figure 4 Smoothed distribution of eligible entities by profit margin and sector

Note: Curves show the smoothed distribution of firms by profit margin within each sector, based on three-year average financials 2021-2023. Shading indicates contribution regime under the Decision 16/2 contribution structure: light shading denotes zero-contributors (margin below zero), medium shading denotes profit-base payers (margin between zero and 10%), and dark shading denotes revenue-base payers (margin above 10%). The dashed red line indicates the indifference threshold $m = 0.10$; the dotted grey line indicates zero margin. Extreme values below -0.30 and above 0.50 are excluded for display clarity.

Source: Author's calculations based on Makowska-Curran (2026).

Table 12 Distribution of eligible entities by contribution base and sector

Sector	n	Revenue-base (%)	Profit-base (%)	Zero-contributor (%)
Information and AI	5,217	36.0	45.0	19.0
Animal and plant breeding	4,256	37.0	42.0	21.0
Biotechnology	3,709	36.0	43.0	21.0
Pharmaceuticals	3,401	51.0	36.0	13.0
Laboratory equipment	2,846	43.0	43.0	13.0
Nutraceuticals	1,513	25.0	59.0	16.0
Cosmetics	753	32.0	57.0	11.0
All sectors	21,690	38.6	43.8	17.5

Note: Revenue-base payers are firms with a three-year average profit margin exceeding 10%, for whom the revenue levy is cost-minimising under the current contribution structure. Profit-base payers report margins between 0% and 10%. Zero-contributors report negative average profits and pay nothing under the profit base. Shares may not sum to 100% due to rounding. Three-year average financials 2021-2023.

Source: Author's calculations based on Makowska-Curran (2026).

The contribution structure also produces two distinct regime-switching risks across reference periods. The first concerns firms near the zero-profit boundary moving from profit-base contributor to zero-contributor status if profitability falls in the contribution year, without any change in their underlying DSI activity. The second, less severe but worth noting, concerns firms near the 10% threshold moving from the stable revenue-base regime into the more volatile profit-base regime if their margin compresses. Both dynamics introduce an inherent tension between the protective function of the contribution structure (i.e. exempting genuinely loss-making firms) and the predictability of the fund's revenue base. The revenue stability findings are examined in Part II (Section “Minimum-of-two design and revenue stability”).

The contribution structure produces a set of trade-offs that reflect the broader design challenge of balancing revenue generation against the protection of firms facing genuine financial constraints. The profit floor means that firms reporting losses contribute nothing regardless of their revenue or DSI activity. Submissions from Parties and industry stakeholders noted that this protects early-stage firms, particularly in the biotechnology and pharmaceutical R&D from obligations arising before commercial returns materialise. At the same time, as noted in the uncertainty register and conditional on participation, the same feature creates a structural incentive for profit management among firms with low but positive margins, a phenomenon well documented for profit-based taxation and systems generally (Sahay, 2013; Choi, Furusawa and Ishikawa, 2020; Sebele-Mpofu, Mashiri and Schwartz, 2021), though existing financial reporting standards, audit requirements, and tax transparency measures in many jurisdictions may limit the scope for such behaviour in practice. The revenue implications of which are discussed in Section 6.4. The broader distributional implications of the contribution structure across firm types and sectors are examined in Part III.

6.4. Results

Table 13 shows revenue estimates from Makowska-Curran (2026) for five scenarios, along with NPV projections at a 3% discount rate. These estimates draw on the best available evidence, but because no voluntary scheme with the Cali Fund's specific design features has been observed, the participation assumptions behind them are necessarily calibrated from other contexts rather than the Fund itself. The range presented here should be read as the plausible bounds implied by that evidence, not as a forecast of what the Fund will raise. Actual outcomes will depend on the Conference of the Parties' eventual decisions on thresholds and rates, subsequent national implementation measures, and how participation and corporate behaviour evolve once Decision 16/2 is operational. If all 21,690 eligible entities fully comply, they would contribute approximately USD 3.6 billion each year (S0,

Table 13). The central S3 estimate is USD 929 million, which is about one quarter of the full compliance figure. This reduction reflects differences in sector-level participation, ownership, and DSI intensity across the eligible

population. The S1 and S2 estimates of approximately USD 1,2 billion are somewhat higher than S3 because they do not include the downward DSI intensity adjustment. For the S4 scenario, which assumes a gradual increase in participation, the total revenue by 2035 (discounted at 3%) is USD 4.3 billion. This is USD 3.9 billion less than the USD 8.2 billion projected under the static S3 scenario, showing the impact of slower early participation compared to steady-state involvement.

Table 13 Estimated annual contributions and NPV projections

Scenario	Annual mean (USD billion)	P5-P95 range	% of S0	NPV to 2030 (USD billion)	NPV to 2035 (USD billion)
S0 Full participation	3.65	—	100.0	17.2	32.0
S1 Sector variation	1.16	0.81-1.53	31.9	5.5	10.2
S2 Sector and firm variation	1.20	0.83-1.60	33.0	5.7	10.6
S3 DSI adjustment	0.93	0.59-1.30	25.5	4.4	8.2
S4 Progressive uptake	—	—	—	1.3	4.3

Note: The participation share for each sector is calibrated from the empirical literature on voluntary environmental schemes, drawing on evidence from comparable mechanisms (ABS bilateral agreements, voluntary sustainability initiatives, and private-sector environmental disclosure frameworks). Because the Cali Fund has no direct precedent, this calibration carries genuine uncertainty: the P5 and P95 columns indicate the range within which participation rates plausibly fall, based on 10,000 simulation draws over the parameter distributions. The mean column is the central estimate; P5 represents the more cautious bound (lower participation), P95 the more optimistic bound (higher participation). NPV at 3% discount rate. S4 applies a participation scalar rising linearly from 10% of S3 rates in 2026 to 100% by 2035.

Source: Makowska-Curran (2026).

The revenue estimates mask a highly uneven distribution across the eligible population. Pharmaceuticals and information and AI services together contribute approximately half of all revenues under full compliance, despite representing only 40% of eligible firms. In the central S3 scenario, the sectoral composition changes significantly: pharmaceuticals increase from 26.3% to 49.6% of total contributions, reflecting a relatively high participation rate, high DSI intensity calibration, and stable revenue-base payers within the sector. In contrast, information and AI declines from 25.2% to 11.1%, consistent with its low participation calibration due to its high volatility.

Figure 5 illustrates this shift.

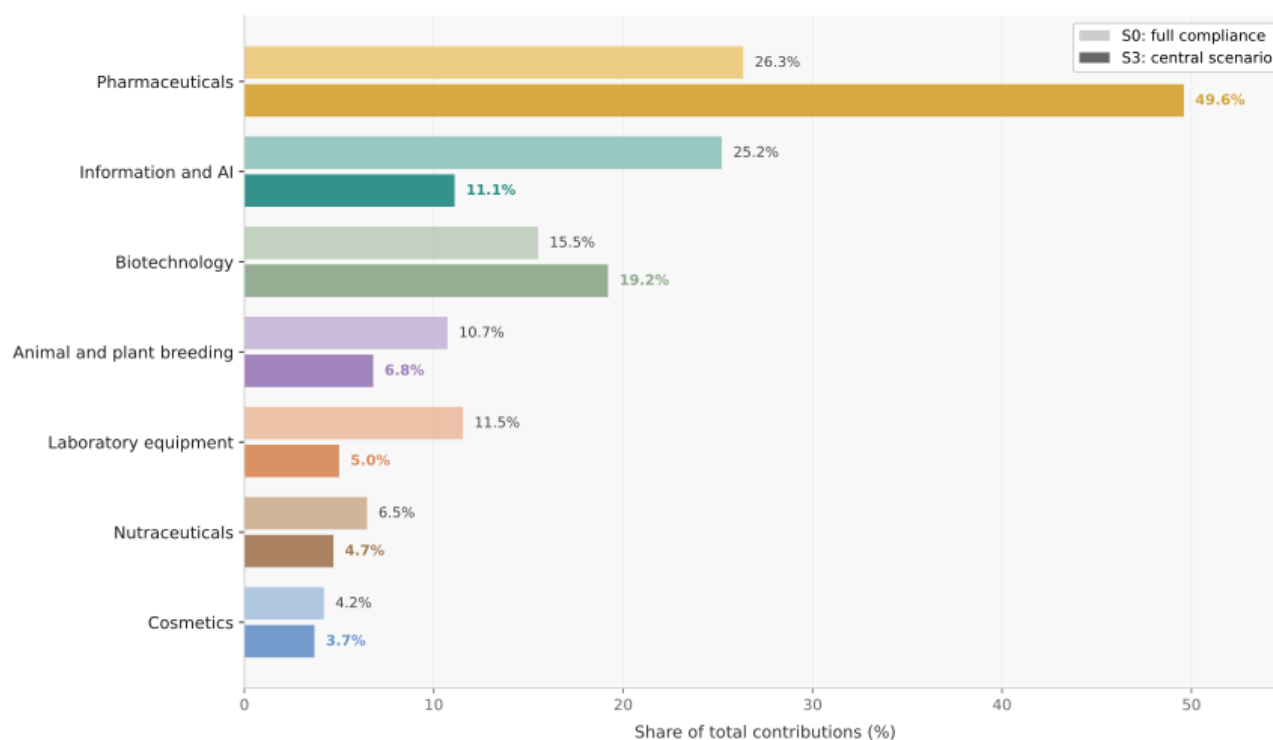
This concentration produces significant effects on the fund's financial characteristics. The pharmaceutical sector is the largest contributor to total revenue under the more realistic participation scenarios, the only sector in which most eligible firms contribute based on a stable revenue base rather than a volatile profit base. These two factors are mutually reinforcing. On the one hand, pharmaceutical participation increases revenue but also stabilises it. In contrast, low participation from the pharmaceutical sector would decrease total revenue, increase annual volatility, and weaken the revenue base essential for the mechanism's predictability. No other sector simultaneously exhibits all three effects. Note that Cosmetics is the smallest Enclosure I sector by firm count

(748 eligible firms), so its total is more sensitive than other sectors to which firms the underlying database happens to capture.

In terms of the across-sector concentration, at the firm level, the ten largest contributors account for 8.6% of the S0 (full participation) scenario in

Table 13, while the top 100 account for 27.6% (Makowska-Curran, 2026). This indicates that the fund's revenue base is concentrated within a small and identifiable group of firms. Under more realistic participation assumptions, this concentration intensifies (12.2% and 32.3%, respectively), making the fund's revenue prospects increasingly dependent on the engagement of large pharmaceutical firms.

Figure 5 Sectoral distribution as a % share of total estimated contributions under full compliance (S0) and the central participation scenario (S3)

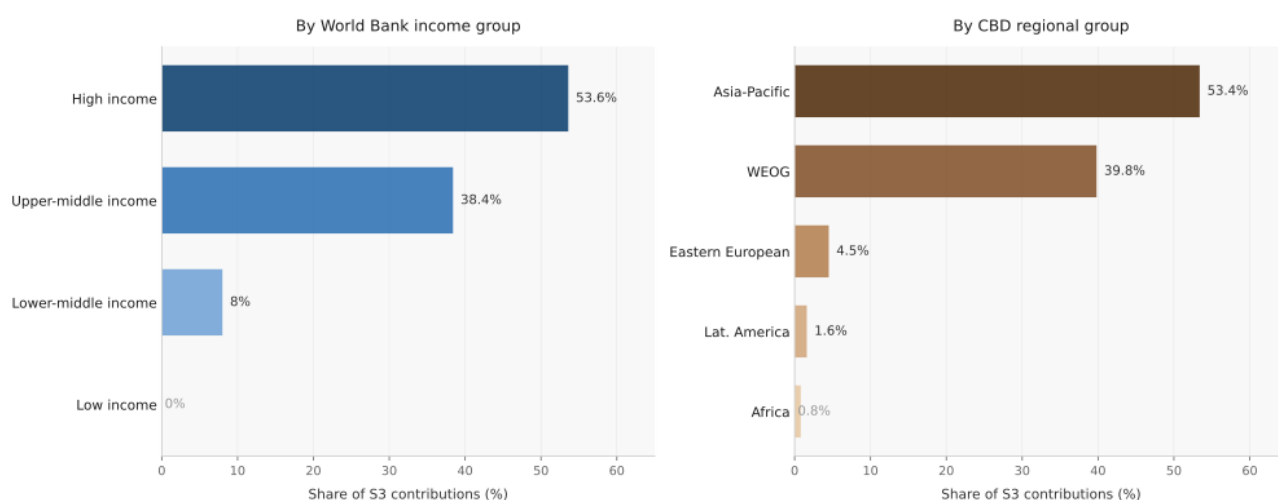


Note: Each sector shows two bars: lighter shading represents the share of total S0 contributions under full compliance; darker shading represents the share under S3, which applies sector-level and ownership-type participation rates calibrated from the voluntary scheme literature. Percentage labels are shown for sectors with a contribution share of 5% or above. Sector totals should be read with the possibility of double counting in mind: where a firm is treated as an indirect user because contribution expectations are assumed to pass through the value chain from an upstream direct user, the same underlying DSI use may be reflected in more than one sector's estimated contribution.

Source: Author's calculations based on Makowska-Curran (2026).

Figure 6 presents the geographic distribution of S3 contributions by World Bank income group and CBD regional group. High-income countries represent approximately 54% of the central scenario total, while upper-middle-income countries contribute an additional 38%. Lower-middle-income and low-income countries collectively account for the remainder, which reflects the limited presence of firms meeting the Decision 16/2 eligibility thresholds in these economies⁵⁴. The CBD regional breakdown is similarly concentrated: the Asia-Pacific region and the Western European and Others Group (WEOG) together account for approximately 93% of central scenario contributions, primarily due to large DSI-dependent industries in China, Japan, Germany, the United Kingdom, and Switzerland (Makowska-Curran, 2026). African States contribute very little in comparison under the central scenario, which is consistent with the low number of eligible firms in the region. This regional concentration should be read alongside the data coverage limitations discussed in Section 6.2: under-coverage in Sub-Saharan Africa and parts of Asia-Pacific likely understates the true eligible population in these regions, which risks understating their share of contributions relative to their actual economic exposure to DSI-dependent activity.

Figure 6 Estimated S3 contribution shares by World Bank income group and CBD regional group



Note: Bars show each group's share of total S3 contributions (\$929m). S3 applies sector-level participation rates, ownership-type multipliers, and DSI intensity adjustments to the eligible firm population. WEOG refers to Western European and Other Group; Eastern European refers to the CBD's Central and Eastern European regional group (CEE); Lat. America refers to the CBD's Group of Latin American and Caribbean States (GRULAC).

Source: Adopted from Makowska-Curran (2026).

The ten largest contributing jurisdictions collectively account for an estimated 74% of the fund's total annual revenue under more realistic participation assumptions (S3). Contributions are highly concentrated: China alone accounts for over a quarter of the total, and the top four jurisdictions (China, the United Kingdom, India, and Japan) together represent more than half.

⁵⁴ Note that the author of the study also points to firm-level data limitations for those regions.

These figures should be interpreted with caution. The estimates are based on contributions from entities registered in each jurisdiction, not on the location of actual commercial operations or ultimate ownership. When multinationals register subsidiaries in specific countries for tax or administrative reasons, the figures may overstate those countries' true economic exposure to the mechanism. Ireland's estimate of USD 52 million illustrates this, as the underlying study attributes it mainly to multinational registration activity rather than commercial presence.

The United Kingdom estimate is particularly uncertain. When limited to unconsolidated accounts, which better align with the subsidiary-level scope intended by Decision 16/2, the UK figure drops significantly. The headline figure should be considered an upper bound, rather than a reliable point estimate.

Some major source jurisdictions are likely underrepresented for the opposite reason. The underlying study identifies Switzerland and Canada as probable undercounts due to incomplete coverage of unconsolidated accounts for large multinationals headquartered in those countries. Their true contribution potential is higher than reported, but the gap cannot be quantified without better firm-level data. Hence, their contribution flow estimates should be treated as a conservative lower bound.

The country-level breakdown should be viewed as an indicative jurisdictional mapping, not a precise attribution of contribution flows. The aggregate figure of USD 929 million is more reliable than individual country estimates, so the disaggregation should be interpreted with appropriate caution.

Table 14 Estimated S3 annual contributions by top 10 countries (S3 central scenario)

CBD Party	Estimated annual contribution (USD million)	Share (%)
China	248	26.6%
United Kingdom†	90	9.7%
India	79	8.5%
Japan	65	7.0%
Ireland‡	52	5.6%
Germany	39	4.2%
France	38	4.1%
Russia	29	3.1%
Belgium	23	2.4%
Singapore	21	2.3%
Top 10 total	684	73.6%
S3 full sample	929	100%

Note: Figures represent estimated contributions from eligible entities registered in each jurisdiction, not contributions attributable to the country of ultimate economic activity. Contributions from multinationals are allocated to the jurisdiction of entity registration, which may differ from the location of DSI-dependent commercial operations or the headquarters of the ultimate parent. Values derived by applying each jurisdiction's S0 contribution share to the S3 central scenario total of \$929 million; country-level breakdowns from the Monte Carlo simulation are not separately reported. † UK figure sensitive to inclusion of consolidated-account (C1) entities;

unconsolidated-only estimate is \$170 million. ‡ Ireland figure may primarily reflect multinationals registered for tax purposes. The United States is excluded as a non-Party to the CBD.

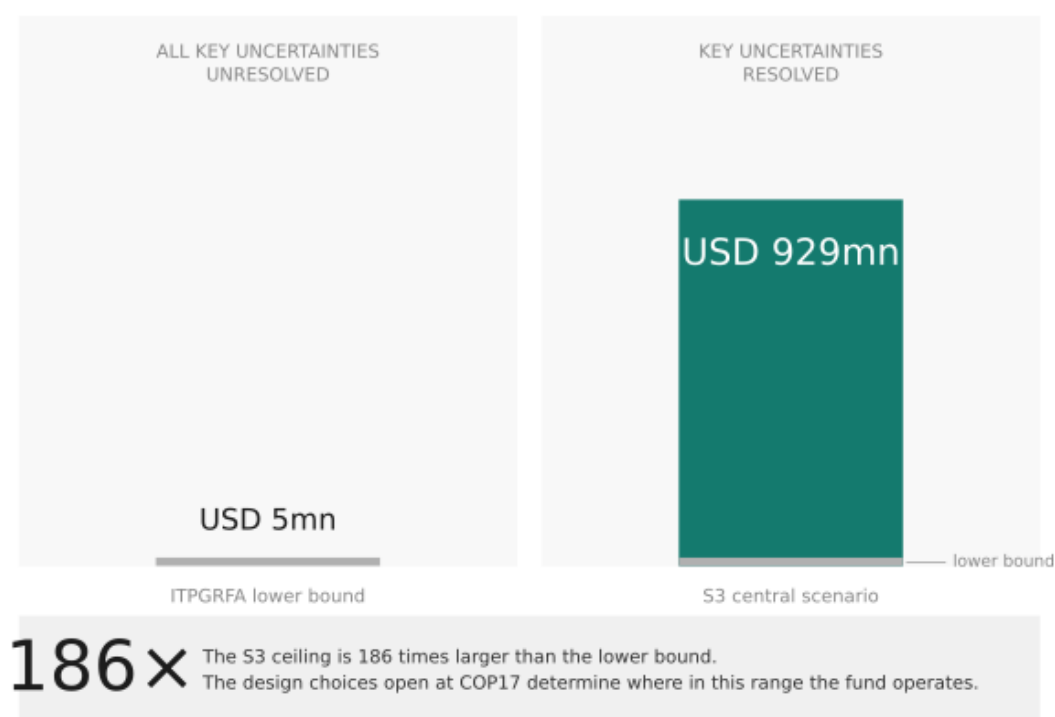
Source: Author's calculations based on Makowska-Curran (2026).

Uncertainty-adjusted revenue range

The uncertainty-adjusted range derived spans from approximately USD 5 million per year at the lower bound to USD 0.9 billion at the S3 ceiling. As illustrated in

Figure 7, the two bounds differ by a factor of 186, and represent two, radically different scenarios, rather than a statistical interval around a central estimate. The range presented here should be read as the plausible bounds implied by that evidence, not as a forecast of what the Fund will raise. The lower bound reflects what the fund could collect if the structural features that suppressed ITPGRFA' MLS' user-based payments over fifteen years were to repeat under the Cali Fund, while the upper bound reflects the revenue achievable if the key uncertainties identified in Table 2 are substantially resolved by the COP. The distance between the two bounds is therefore determined by design choices, many of which remain open. The S2 ceiling is expressed under the current Decision 16/2 modalities, which do not include a DSI attribution mechanism; with such an adjustment, the effective ceiling would shift downward toward the S3 estimate.

Figure 7 Estimated annual Cali Fund revenue at maturity under alternative resolution of key design uncertainties



Note: Bar heights are illustrative; scale is not preserved owing to the magnitude of the difference between the two estimates. Lower bound derived by applying the ITPGRFA MLS' observed payment ratio to the S3 central estimate. S3: central participation scenario, assuming key design uncertainties are substantially resolved.

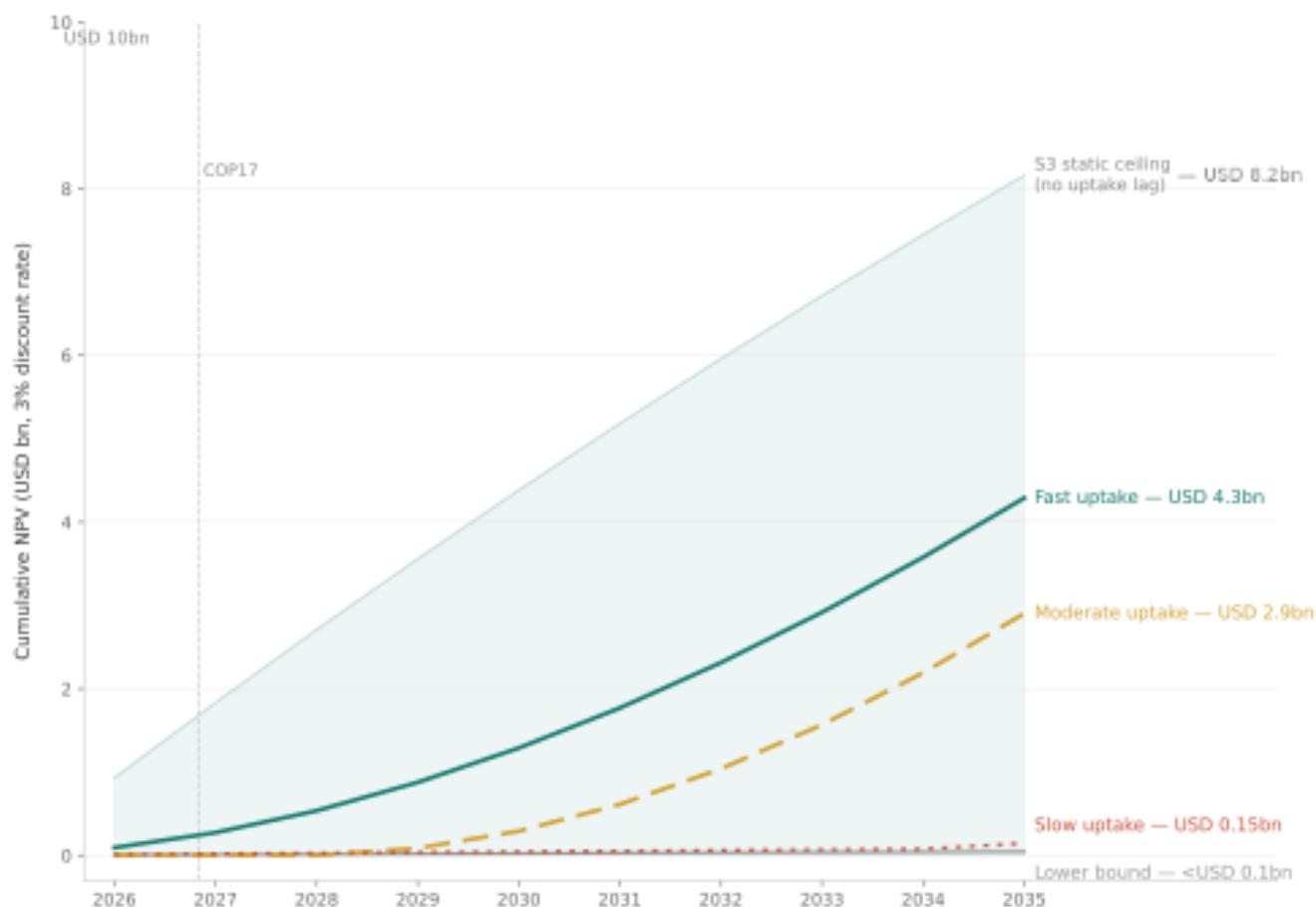
Source: Adopted from Makowska-Curran (2026).

The timing of how quickly participation materialises compounds the effect of the annual revenue level. Even where the long-run ceiling is identical, slow early adoption carries a substantial NPV cost. Within the 2035 projection horizon, the timing of participation has a compounding effect on cumulative value that is independent of the eventual full-maturity revenue level. Design parameters that shape early participation, such as the operational value of the certificate and the clarity of contribution scope, carry revenue implications that extend beyond their direct effect on the annual ceiling.

Figure 8 presents cumulative NPV projections to 2035 for three timing variants applied to the S3 ceiling, along with the lower-bound trajectory for reference. Under fast uptake, cumulative NPV reaches USD 4.3 billion by 2035. Moderate uptake, with near-zero participation in years one through three, reduces this to USD 2.9 billion. Slow uptake, consistent with the ITPGRFA BSF's first decade, yields only USD 0.15 billion - a reduction of over 90% relative to the fast scenario, despite the same theoretical annual maximum. The lower bound produces negligible NPV under any timing assumption. Table 12 summarises the underlying figures.

Design parameters that shape early participation, such as the operational value of the certificate and the clarity of contribution scope, carry revenue implications that extend beyond their direct effect on the annual ceiling.

Figure 8 Cumulative NPV of Cali Fund contributions to 2035 under alternative timing variants (3% discount rate, USD billion)



Note: Fast uptake follows the S4 maturation path (10% of the S2 participation rate in 2026, rising linearly to 100% by 2035). Moderate uptake assumes near-zero participation in years one to three, followed by an S4-style ramp from year four. Slow uptake assumes near-zero participation through year nine, consistent with the ITPGRFA BSF's first decade, followed by very slow growth. The lower bound applies the ITPGRFA' MLS' observed payment ratio to the S2 estimate throughout. The dotted line shows the S2 static ceiling assuming no uptake lag. The shaded band spans the full uncertainty range.

Source: Author's calculations based on Makowska-Curran (2026).

Table 15 NPV projections under alternative timing variants (S3 ceiling, 3% discount rate)

Timing variant	NPV to 2030 (USD billion)	NPV to 2035 (USD billion)
S3 static ceiling (no uptake lag)	4.4	8.2
Fast uptake (S4 path)	1.3	4.3
Moderate uptake	0.3	2.9
Slow uptake (ITPGRFA-like ramp)	0.04	0.15

Timing variant	NPV to 2030 (USD billion)	NPV to 2035 (USD billion)
ITPGRFA lower bound (reference)	0.02	0.04

Source: Author's calculations based on Makowska-Curran (2026).

Rate and base design sensitivity

Threshold sensitivity analysis demonstrates a structural characteristic of the Cali Fund's eligible population with potential implications for future design decisions (

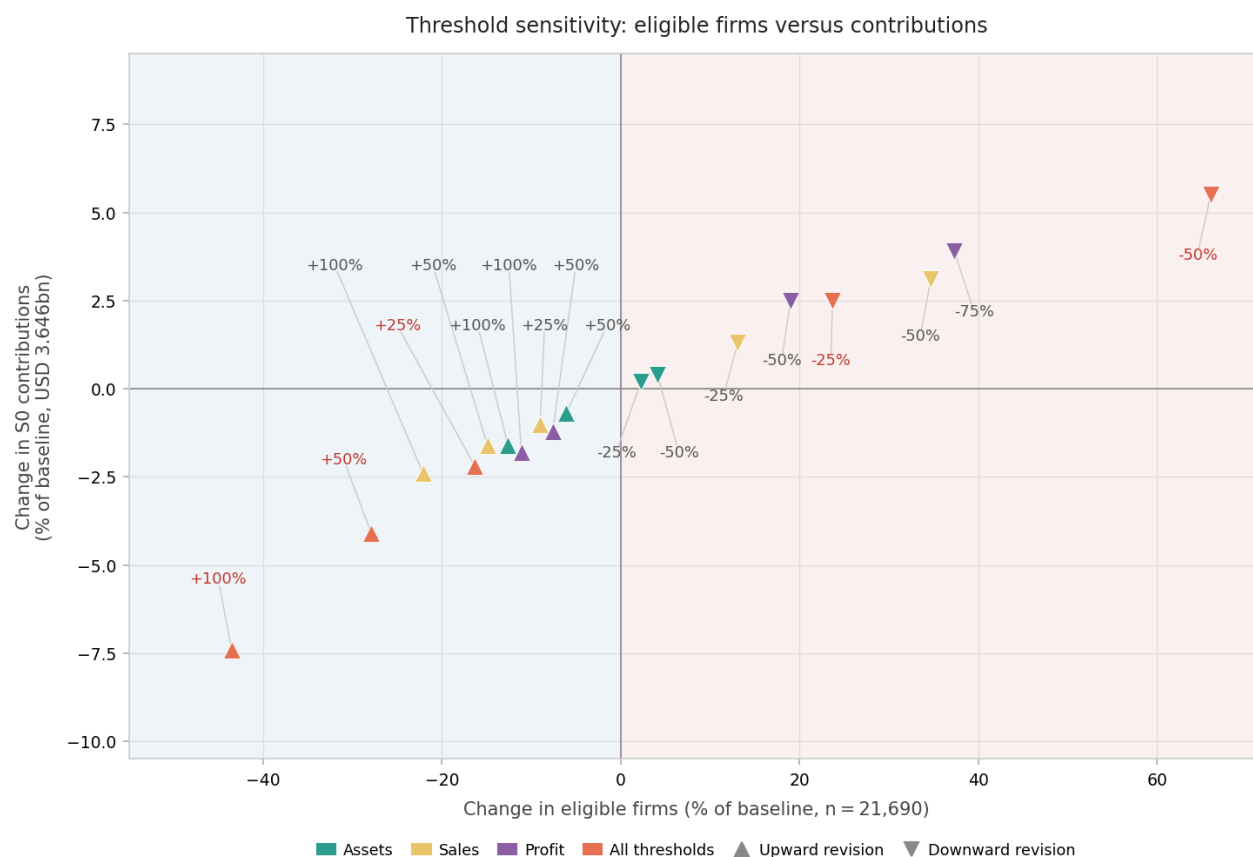
Figure 9). Contributions are predominantly concentrated among the largest firms, resulting in a revenue base that remains stable across various threshold adjustments. Doubling all three Decision 16/2 thresholds to USD 40 million in assets, USD 100 million in sales, and USD 10 million in profit would exclude approximately 9,441 firms, reducing the eligible population by 43.5%, yet S0 contributions would decrease by only 7.4%, from USD 3.65 billion to USD 3.38 billion. Firms excluded under higher thresholds are significantly smaller than those retained, and the revenue base is sustained primarily by large pharmaceuticals.

A similar pattern emerges when thresholds are lowered. Halving all thresholds would more than double the number of in-scope firms, adding 14,317 entities, yet full-compliance contributions would increase by only 5.5%. Newly eligible firms near the lower end of the distribution are too small to significantly impact aggregate revenues.

This asymmetry underscores a structural feature of the eligible population relevant to threshold design. Higher thresholds limit the contributor pool to the largest and most commercially prominent firms, which the voluntary scheme literature associates with stronger reputational scrutiny for their biodiversity practices. However, increasing thresholds also reduces sectoral diversity among contributors, as smaller firms in sectors such as nutraceuticals, cosmetics, and animal and plant breeding are increasingly excluded from the mechanism's scope. This shift increases the mechanism's dependence on a limited range of industries. These two effects partially counterbalance each other in terms of participation: there are fewer firms, but they may become more visible and more easily targeted, with the additional reputational pressure providing stronger individual

incentives to participate. The overall impact on fund revenue depends on which effect prevails and cannot be determined based on the current evidence. In contrast, lower thresholds substantially expand the contributor pool by including more smaller firms across all sectors. Nonetheless, this expansion could result in higher administrative costs for a larger number of companies, without potentially generating proportional revenue gains.

Figure 9 Sensitivity of eligible firm counts and contributions to alternative eligibility threshold combinations



Note: Each point represents one threshold scenario. The horizontal axis shows the percentage change in the number of eligible firms relative to the Decision 16/2 baseline of 21,690 firms; the vertical axis shows the corresponding percentage change in S0 contributions relative to the baseline of USD 3.646 billion. Upward-pointing triangles denote scenarios where thresholds are raised; downward-pointing triangles denote scenarios where thresholds are lowered. Labels show the percentage revision applied to the relevant threshold. Colour identifies the threshold revised: assets (green), sales (yellow), profit (purple), all three thresholds simultaneously (orange). The shaded band spans the full range of contribution outcomes across all scenarios. Downward revision scenarios are computed from the full in-scope firm population; upward revision scenarios are computed from the baseline eligible sample. S0 assumes full participation at the indicative contribution rates of 0.1% of revenue and 1% of profit.

Source: Author's calculations based on Makowska-Curran (2026).

The contribution rate sensitivity analysis looks at how the hypothetical full eligible sample (S0) contributions change when the indicative rates are adjusted.

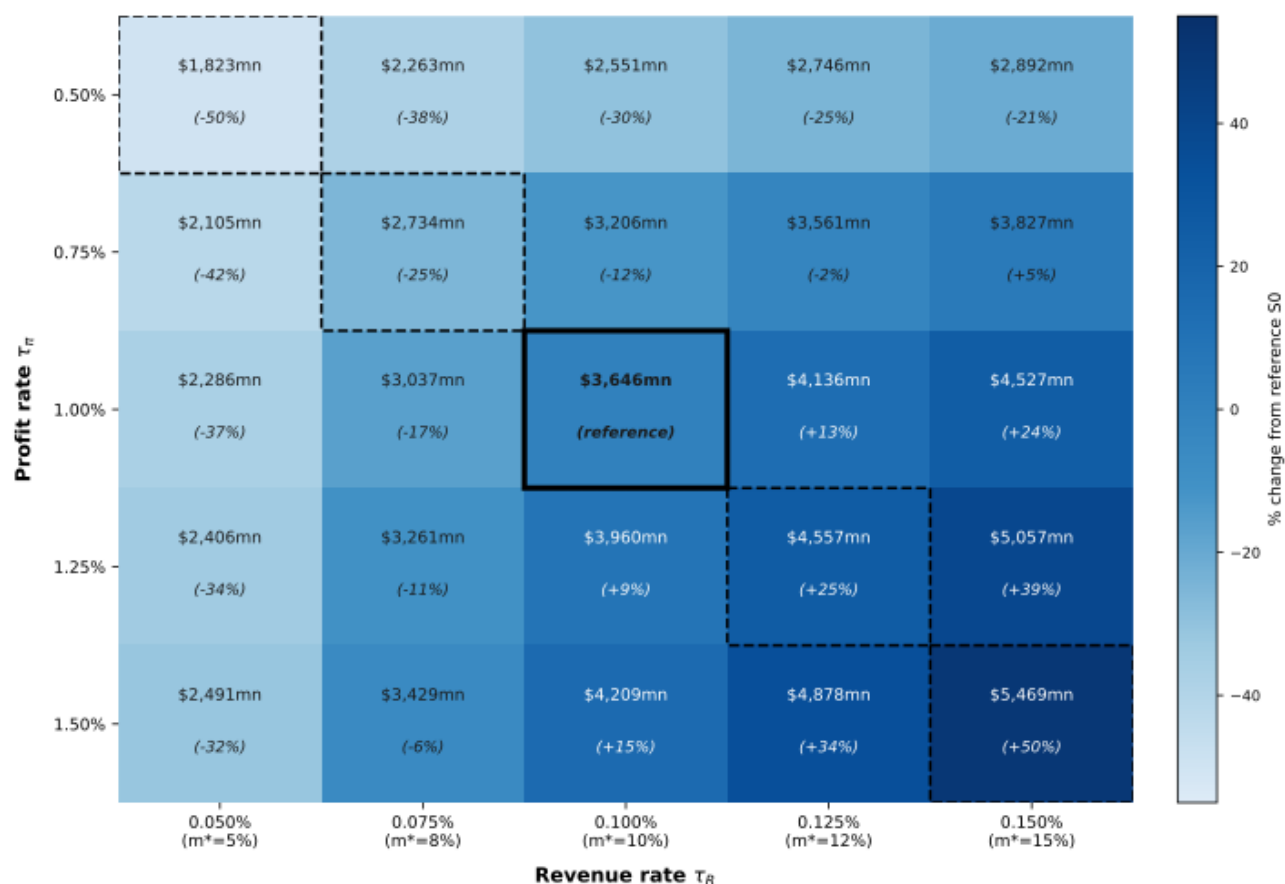
Figure 10 shows that if both rates are scaled up or down by the same proportion, revenue changes linearly. For example, at 50% of the indicative rates, S0 drops to about USD 1.8 billion, and at 150%, it increases to USD 5.5 billion. These changes are mostly balanced because scaling both rates by the same amount keeps the 10% indifference margin the same. This means the group of contributing firms does not change, only the amount each firm pays.

Changing only one rate at a time, instead of both together, has a bigger impact on how revenue is collected. Increasing the profit rate while keeping the revenue rate the same lowers the indifference margin, so more firms move to the 'stable' revenue base. If only the revenue rate goes up, the effect is reversed. When only one rate is revised, the revenue gain is smaller than proportional scaling of both rates would produce, because the minimum-of-two structure automatically re-routes firms to whichever base becomes cheaper as the indifference margin shifts. The decision to potentially reconsider the contribution rate at COP17 could affect not just the

total amount raised, but also which firms pay more and how steady those payments are over time. Section 6.4 (“Minimum-of-two design and revenue stability”) looks at these stability issues in more detail.

These rate sensitivities describe mechanical effects on total revenue; established economic principles suggest the rate level would also be expected to influence contributor behaviour more broadly. On the consumer side, standard price pass-through theory implies that as firms pass a larger share of a higher rate through to prices, demand for the affected goods or services would be expected to soften somewhat, though the extent depends on demand elasticity in each sector. On the firm side, the compliance and avoidance literature on voluntary schemes and taxation generally finds that higher effective costs increase the incentive to avoid or minimise exposure, whether by restructuring activity, relocating, or declining to participate altogether. These general principles are explored empirically for the Cali Fund’s current indicative rates in Part III, which examines competitiveness and behavioural responses sector by sector; this section’s rate sensitivities should be read alongside that discussion rather than in isolation.

Figure 10 Estimated contributions under alternative contribution rate combinations (% of Decision 16/2 baseline, full eligible sample)



Note: Each cell shows total estimated S0 contributions as a percentage of the baseline of USD 3.646 billion, computed under the corresponding combination of revenue rate (τ_R) and profit rate (τ_π). The baseline reference cell ($\times 1.00$, $\times 1.00$), corresponding to the indicative rates of 0.1% of revenue and 1% of profit, is outlined in bold. Proportional rate changes for both indicators are highlighted in dashed boxes across the diagonal. S0 assumes full participation.

Source: Adopted from Makowska-Curran (2026).

Finally, the minimum-of-two design, detailed in the subsequent section, affects total revenue in ways that go beyond just the rate. Since this rule picks the lower payment for each firm, the total collected is much less than what either base would bring in on its own. If the minimum rule were replaced with a pure revenue levy at 0.1%, S3 would rise to about USD 1.6 billion. A pure profit levy at 1% would bring in USD 2.0 billion (Makowska-Curran, 2026). Both options would roughly double the revenue compared to the minimum rule. If the goal is to collect more revenue without changing the rate, using a single base could achieve this. However, this would take away the protection the minimum rule gives to firms close to zero profit and would also remove the revenue stability benefit discussed in Section 6.4 (“Minimum-of-two design and revenue stability”) (only if choosing only a profit base).

Minimum-of-two design and revenue stability

The contribution structure results in two groups of contributors, each with different potential revenue stability patterns. Of the eligible firms, 6.7% went from making positive contributions to none between the averaging period (2021-2023) and 2023 alone (Makowska-Curran, 2026). These firms had profit margins just above zero during the averaging period, but reported losses in 2023. The decline in their contributions to zero resulted not from changes in DSI activity, but from the profit base being influenced by short-term earnings fluctuations rather than sustained changes in eligibility. Note however, that it is not possible to determine from a single cross-sectional comparison whether this dropout is a temporary fluctuation or a sustained decline in the contribution base. Multiple years of observation are needed to make this distinction.

Firms with revenue-based contributions above the 10% indifference margin stayed much more stable during this period. In the pharmaceuticals sector, most eligible firms are in this stable group, with a median margin of 10.2% and 51.0% paying based on revenue. In other sectors, most firms are below the indifference margin, so total contributions from those sectors change with yearly earnings. As a result, the fund’s revenue predictability may rely heavily on pharmaceutical firms, which increases the sector concentration risk discussed at the start of Section 6.4.

The literature highlights structural differences between profit-based and revenue-based contribution systems. An assessment for the UK Department for Environment, Food and Rural Affairs in the DSI context found that profit-based levies create year-to-year revenue volatility and risk profit-shifting to jurisdictions that do not implement these measures. This is especially relevant since one of the major DSI-using economies, the United States, is not a CBD Party. In contrast, revenues are more consistently and publicly disclosed than profits, making ad valorem systems easier to monitor and enforce (Bassford *et al.*, 2024). A similar economic assessment arises in the context of the ISA’s payment regime for deep-sea mining, where trade-offs between revenue stability and risk-sharing with contributors have been extensively analysed (Kirchain *et al.*, 2019). Those studies also show that profit-based systems are more open to earnings management and reporting discretion, while simpler ad valorem systems are easier to enforce when disclosure and monitoring are limited. Hybrid ISA royalty designs try to balance these issues by requiring the higher of a value-based or profit-based payment, which protects the authority’s revenue floor and shares commercial risk with contractors (Li *et al.*, 2021). The Cali Fund’s minimum rule takes the opposite approach: it uses the lower of the two amounts, protecting the contributor instead of the theoretical stability of the fund’s revenues. This fits the non-binding nature of the mechanism, but it leads to the instability described above and consistently lowers total revenue compared to either single-base system, as shown in Section 6.4 (“Minimum-of-two design and revenue stability”).

These stability properties are, however, conditional on participation having occurred in the first place. In a mandatory tax system, switching between regimes causes real volatility in collections. In a voluntary system, the main source of instability is whether eligible firms choose to contribute at all, which is a more fundamental issue than the stability dynamics discussed here. The closer assessment of how the choice of contribution base affects firm-level burden across the eligible entity population, together with other consequences of firms choosing between the two bases, is taken up in Part III.

6.5. Discussion and implications

The findings in Section 6.4 point to four key implications for the design decisions open ahead of COP17. They are presented here not as recommendations but as analytical observations about the consequences of the choices before Parties. It should be noted that all implications are conditional on a prior question: whether eligible firms choose to participate. Participation decisions depend on firms' assessment of the net costs and benefits of contributing. The rate level, threshold design, and contribution base all influence the cost-benefit calculation, but their impact on revenue only matters if firms actually participate. Part III looks at whether contribution requirements put participating firms at a disadvantage compared to those that do not join.

- **Participation is the binding constraint, not the rate level:** the uncertainty-adjusted revenue range spans from approximately USD 5 million to USD 929 million per year under the same indicative rates, a factor of 186. The range presented here should be read as the plausible bounds implied by that evidence, not as a forecast of what the Fund will raise. This range reflects unresolved design features rather than rate calibration, principally the operational value of the certificate of contribution, the clarity of contribution scope, the resolution of obligation stacking and the information asymmetry around DSI use, all of which may affect the decision to participate. Because the width of the range is determined by participation uncertainty rather than the rate level, revising rates without addressing those structural features would not materially change the fund's position within it. The rate level determines how much eligible participating firms contribute; the structural conditions for participation determine how many firms contribute at all.
- **Threshold design is a governance and inclusivity decision, not primarily a fiscal one:** if all thresholds are doubled, 43.5% of eligible firms are removed, but contributions drop by just 7.4%. Cutting thresholds in half adds 14,317 eligible firms, yet contributions only rise by 5.5%. This means that changing thresholds has a limited impact on revenue, since most contributions come from the largest firms no matter where the cutoff is set. Because of this, threshold changes may be a way to decide how many private sector firms are involved, not just as a way to maximise revenue.
- **Rate and base design affect who pays and how stable the contributions are, not just how much they pay:** if both profit and revenue contribution rates are increased proportionally, revenue rises linearly because the indifference margin stays the same and each firm's contribution grows by the same amount. If only one rate changes, the 10% indifference margin shifts, moving firms between contribution categories. This reduces the revenue impact and changes the stability of the contributor group. Using only a revenue base would remove the profit-based instability discussed, but it would also take away protection for firms that are making losses. Under full compliance, a pure profit levy would bring in the most revenue at current rates, although this may not hold under realistic participation given the greater volatility of profit-base contributors. The minimum rule is a middle

ground, offering protection to contributors but making revenue less predictable. However, as quantified in Section 6.4 (“Minimum-of-two design and revenue stability”), the revenue cost of this design is substantial (conditional on eligible firm participation): replacing the minimum rule with either a pure revenue levy or a pure profit levy at the current indicative rates would approximately double fund revenue under full compliance, from USD 0.9 billion to USD 1.6 billion and USD 2.0 billion respectively.

- **Pharmaceutical concentration is structural and compounds across all design dimensions:** if all eligible firms comply, pharmaceuticals make up 26.3% of contributions. In the central S3 scenario, this increases to 49.6%. The pharmaceutical sector also offers the most stable revenue, with a typical eligible firm paying on revenue, rather than profit. This concentration comes from how the mechanism is designed; none of the threshold, rate, or scope changes considered in this analysis significantly reduce this effect. Pharmaceutical sector participation represents the most significant determinant of fund revenue under realistic participation scenarios. Both the concentration and revenue stability identified in Section 6.4 (“Minimum-of-two design and revenue stability”) reflect the same underlying structural feature, that, under the scenarios analysed: the majority of pharmaceutical firms exceed the 10% indifference threshold which would likely make them choose revenue base instead of a volatile profit base. As a result, pharmaceutical participation is projected to have a substantial influence on both the level and predictability of fund revenue. However, these findings remain conditional on the assumptions underpinning the scenario analysis, particularly the assumed participation rates, DSI intensity calibration and firms' contribution behaviour. As DSI use expands in emerging fields such as artificial intelligence and synthetic biology, and as national implementation measures and participation evolve following COP17's decisions, the sectoral composition of Cali Fund contributions may shift over time.
- **Geographic concentration and early operationalisation:** The top ten jurisdictions account for an estimated 74% of central scenario revenue, with China alone representing 26.6%, though these country-level estimates are indicative and subject to the data limitations discussed in Section 6.2 (jurisdictional mapping reflects entity registration rather than actual commercial operations or ultimate ownership). As a result, the fund's early revenue depends largely on the engagement of a few Parties. With that caveat in mind, the general pattern suggests the fund's early revenue may depend disproportionately on the engagement of a small number of Parties, and design features that support participation in these jurisdictions, such as clear contribution scope and certificate value, could plausibly matter more for early revenue than for the aggregate estimate as a whole.

7. Part III: Competitiveness implications of Cali Fund contributions

This part responds to the economic competitiveness dimension of Decision 16/2 paragraph 6(e), which requested a study on the implications of contribution rates for economic competitiveness of firms operating in Indicative Enclosure I sectors. It examines whether the Cali Fund contribution requirements might put participating firms at a competitive disadvantage relative to non-participating competitors and assesses how the distributional implications of the current contribution structure vary across sectors and firm types.

Part III is subject to greater data limitations than Parts I and II because the Cali Fund is not yet operational and contribution behaviour cannot be directly observed. The analysis is therefore prospective and produces a structured, expert-judged qualitative assessment with quantitative anchors where data permit.

7.1. Key concepts and definitions

Competitiveness vs. competition

Competitiveness is a multidimensional concept, without a single, universally accepted definition in the academic or policy literature. Davidson, Kauffmann and de Liedekerke (2021) identify four common factors in existing definitions: an entity (typically a firm, but sometimes a sector or nation), a growth element (such as profitability or productivity), a geographical dimension, and a timeframe. In this assessment, competitiveness is defined at the firm level as the ability of individual eligible firms to sustain profitability, market position, and investment capacity in response to the contribution payment, evaluated across global product markets over both short-term and medium- to long-term horizons.

In this context, competitiveness is distinct from competition. Competitiveness refers to a firm's relative position or strength compared to its competitors, while competition refers to the market state as a whole and the interactions among competing firms (Khemani, OECD, and Centre for Co-operation with European Economies in Transition, 1993; Davidson, Kauffmann and Liedekerke, 2021). The Cali Fund may influence both dimensions: contributions can modify individual firm cost structures and investment capacity (competitiveness effect), and under partial participation, may impose differential burdens on firms within the same market (competition effect). This analysis addresses both aspects, prioritising firm-level competitiveness and considering market structure effects as a secondary focus, for instance, when looking at the payments' impact on firms' international competitiveness.

DSI as a public good

Digital sequence information that has been made publicly available in open-access databases, which constitutes the scope of the Cali Fund, exhibits the economic characteristics of a non-rivalrous and non-excludable public good once deposited: on one user's access to a sequence record does not limit another's access, and it costs almost nothing for an additional firm to use a public database. In contrast, commercial sequence databases and company-specific datasets do not have these features. This is a description of the good's consumption

characteristics only and does not bear on the legal status of digital sequence information or of the genetic resources from which it derives, both of which remain governed by each Party's domestic legislation and by the Convention's provisions on sovereign rights over genetic resources.

The Cali Fund does not charge for DSI access. Instead, contributions are based on the revenue or profit of companies that make commercial use of DSI. This difference is important. Charging for DSI access would act like a tax on *inputs*, raising the cost of using DSI for all purposes, including non-commercial research, and could reduce efficiency and hinder scientific innovation (ICF *et al.*, 2020; Scholz *et al.*, 2022b; Sett *et al.*, 2024b). A contribution based on commercial *output* does not change the cost of accessing DSI, but it does impose a financial cost on firms that benefit commercially from DSI use. This direct cost burden can affect pricing, margins, and investment decisions, and is the principal economic channel examined in Part III. A secondary effect is that the reduction in expected returns on DSI-based commercial activity may, at the margin, influence firms' decisions to initiate DSI-based research projects. This *innovation effect* is weaker and more indirect than a direct charge on DSI access. Both channels are analysed in the pillar assessment. Preserving open, non-restrictive access to DSI, and avoiding indirect disincentives to its legitimate use in research and the development of sustainable, biodiversity-relevant solutions, is accordingly treated as a design constraint on the mechanism as a whole, not only a feature of how access itself is priced.

Key economic mechanisms

The competitiveness analysis in this part identifies several economic mechanisms used to assess potential competitive effects resulting from Cali Fund contributions. Brief definitions are provided here, and discussed in more detail in subsequent sections.

Several of the mechanisms examined below rely on how a firm's contribution payment responds when its revenue or profit changes. This responsiveness is the *marginal effect* of the payment: the way it adjusts when the underlying variable (here, one of the contribution bases, revenue or profit) increases or decreases. This idea is key to understanding whether the contribution functions like a levy on output, a levy on profit, or some other cost. This in turn helps evaluate the impact contributions may have on firms' choices about pricing, R&D spend, and market entry.

Pass-through and consumer demand

Pass-through describes the extent to which a firm transfers cost increases to consumers by increasing prices. The extent of pass-through depends on demand elasticity, which measures how responsive consumer demand is to any such price changes. When demand is inelastic and consumers continue purchasing despite higher prices, pass-through is more feasible. Conversely, when demand is elastic and consumers significantly reduce purchases in response to price increases, pass-through is constrained and firms are more likely to absorb costs. Market structure is also relevant; concentrated markets generally permit greater pass-through than highly competitive markets.

Burden (cost) incidence

Incidence refers to the distribution of the economic burden of a payment among customers, shareholders, suppliers, and employees; this acknowledges that the entity formally responsible for the payment may not ultimately bear the cost. Pass-through constitutes one aspect of incidence; the remaining burden can be absorbed by shareholders through lower margins or, over time, by labour and other stakeholders through reduced investment.

Reputational benefits from participation, discussed in Section 4.2 as a driver of firms' willingness to contribute, could in principle also partially offset the cost-based competitive disadvantage relative to non-Party competitors discussed above, where markets, investors, or consumers specifically reward Cali Fund participation. Whether this occurs in practice, and to what extent, cannot currently be assessed given the mechanism's lack of operating history.

Investment distortion

This concept addresses how a payment influences the expected return on investment (ROI) and, subsequently, any future decisions to initiate, continue, or expand research and development (R&D) activities. A payment that diminishes post-commercialisation returns increases the implicit hurdle rate⁵⁵ for marginal investment projects. This effect is most significant for firms with forward-looking strategies and long-term development pipelines. However, R&D is only one of several budget lines a payment could affect; firms may instead adjust dividends, sales and marketing spend, or pricing before reducing R&D, and the empirical evidence reviewed in Sections 7.7-7.13 indicates that large, well-capitalised firms, including pharmaceutical innovators, do not scale back R&D in direct proportion to revenue changes at burden levels of this magnitude.

Comparison to other economic mechanisms

References to taxation and royalty design literature here are used only for their economic properties - how revenue- or profit-based structures affect incidence, pass-through, and enforceability - not as a claim that the Cali Fund shares a tax's legal basis or objectives. The Cali Fund is a multilateral benefit-sharing mechanism under the CBD, not a fiscal instrument; these comparisons are illustrative economic analogies, not models for its legal character.

7.2. Scope and limitations

The Cali Fund is a benefit-sharing mechanism to mobilise private sector contributions for biodiversity and DSI providers. The mechanism is better understood as implementing the fair and equitable benefit-sharing objective of the CBD established in Section 0, which channels resources from commercial users of publicly available DSI to provider countries and communities.

This framing leads to an important scope clarification. Describing contributions as benefit-sharing transfers rather than additional costs reflects the mechanism's intended purpose, but it does not change how competitive effects operate in practice. For an eligible firm, a contribution reduces available resources in the same way as any other cost obligation, regardless of its characterisation. The benefit-sharing framing remains relevant in two respects: it shapes how firms may present participation to their stakeholders, and it supports the interpretation of findings, since not all cost effects observed in this assessment necessarily represent unintended consequences of the mechanism's design. The competitiveness analysis is carried out on this basis.

This analysis focuses on eligible firms within each Indicative Enclosure I sector, as identified in Part II. Eligible firms within each sector are heterogenous across multiple dimensions, including their use of DSI, financial profiles, market exposure, and value chain position. Furthermore, firms operating in the same sector do not always compete in the same product markets. All these differences influence the competitive effects of contribution payments. The analysis accounts for this heterogeneity as far as the available data and evidence

⁵⁵ Hurdle rate can be defined as *"the minimum required return on an investment or project to be deemed acceptable, typically adjusted for risk"* (Kenton, 2025).

permit, with any material differences in conditions across the firms within the same sector highlighted explicitly. The results of the assessment are presented in Sections 7.7 to 7.13.

This assessment is based on the mechanism's current non-binding design. If the results depend on this assumption, such as when a move to stricter implementation e.g. via national legislation could change competitive effects, this is mentioned where relevant. The analysis does not assess competitiveness impacts on non-eligible firms, defined as those below the financial thresholds, outside the indicative Enclosure I sector list, or operating outside the CBD Parties jurisdictions. The competitive effects on these firms are considered indirectly under Pillar 4 (SME competitiveness).

Administrative and compliance costs assessed in this Part reflect conditions during the mechanism's initial implementation phase. Consistent with experience from other newly operational international regimes, such costs would generally be expected to decline over time as national implementation frameworks mature, reporting and certification procedures become standardised, and further guidance from the Conference of the Parties becomes available. The materiality ratings in this Part should accordingly be read as reflecting early-implementation conditions rather than a stable long-term characteristic of the mechanism.

This assessment is prospective, as the Cali Fund became operational in February 2025, and contribution behaviour has not yet been observed⁵⁶. The analysis identifies the potential channels through which competitive effects may arise and evaluates their plausibility based on sector characteristics and analogous instrument evidence. It also qualifies their magnitude where data are available, rather than quantifying impacts as a post-implementation evaluation would. While broader welfare impacts, including consumer price pass-through and forgone innovation, are acknowledged in the relevant pillar, they do not constitute the primary focus of this assessment.

In terms of the geographic scope, competitive effects are assessed at the global sector level by considering eligible firms across CBD Party jurisdictions. This approach reflects the global scope of the mechanism and acknowledges the practical limitations of conducting cross-country analysis at this scale. National competitive dynamics, such as domestic market concentration and price regulation all influence how global sector-level effects may manifest across individual jurisdictions. These national factors are highlighted where analytically significant. However, a country-by-country assessment falls outside the scope of this study. As a result, the findings should be interpreted as identifying structural patterns and risk channels likely to affect the eligible population as a whole, rather than as predictions for specific jurisdictions. Compliance cost and administrative burden assessments in this Part reflect gross costs under the current mechanism and do not net off any costs a firm might otherwise incur under bilateral ABS arrangements for the same genetic resources, which the multilateral mechanism was partly designed to avoid (Decision 15/9).

7.3. Data and methodology

Methodological approach

No internationally agreed framework for competitiveness assessment exists at the UN level. In the absence of such guidance, this assessment follows the detailed guidance from the 2021 OECD report reviewing regulatory

⁵⁶ As of the time of writing, publicly available information indicates that one company, TierraViva AI, has made a voluntary contribution of GBP 1,000 to the Cali Fund. This represents the only known instance of private sector contribution since the mechanism became operational in February 2025 (UN MPTFO, 2026).

impact assessments (Davidson, Kauffmann and Liedekerke, 2021). The framework also aligns with the impact pillars structure found in the European Commission's Better Regulation Toolbox series (Tool #21 competitiveness check) which is one of the most systematically developed frameworks for regulatory competitiveness assessment currently available (European Commission, 2025).

This study classifies competitiveness impacts across three dimensions (referred to as 'pillars' henceforth):

- a) cost and price competitiveness;
- b) capacity to innovate⁵⁷; and,
- c) international competitiveness.

The three pillars structure the assessment into distinct but related aspects of competitive performance. Cost and price competitiveness evaluates whether contribution obligations alter the relative cost position of participating firms and whether those changes translate into price effects that influence market share. Innovation competitiveness considers whether contributions limit investment capacity and hinder the development of new products or processes. International competitiveness examines whether firms face greater burdens than competitors in non-CBD Party jurisdictions and how this affects their global market position. Each pillar is evaluated separately, but the competitive mechanisms are interconnected. For example, cost burdens that reduce margins may also limit R&D investment, influence pricing, and affect firms of different sizes.

Before presenting the pillar-by-pillar assessment, empirical literature on the magnitude of regulatory cost effects on competitiveness is reviewed in order to establish the evidence basis for the materiality assessments that follow.

For each pillar, the analysis begins by characterising the firms in scope, followed by an identification of the competitive asymmetries each firm faces given the non-binding character of the mechanism. The findings from those two steps inform the detailed analysis by pillar. This competitiveness assessment framework is fully described in Section 7.5.

Data sources

Part III draws on five main sources:

Rapid literature review findings: examines peer-reviewed literature on the impact of regulatory cost burdens on competitiveness, including compliance cost thresholds, innovation investment, international competitiveness, and voluntary mechanism participation. The review is not a systematic literature review but a structured assessment of the most relevant empirical evidence to inform the significance assessments in the pillar analysis.

Sector-level estimates of eligible firm financial profiles: including total revenue, margin distributions, contribution base predominance, and eligible firm counts by sector, are drawn from Makowska-Curran (2026) described in Part II (Section 6.1). The same data limitations described in Part II apply.

⁵⁷

Sector-level R&D intensity data: taken from the OECD ANBERD database, supplemented by sector-specific literature where coverage is limited.

Industry consultation: designed specifically for this study and disseminated through relevant business associations and direct outreach to firms across Indicative Enclosure I sectors. The consultation questionnaire is reproduced in Annex B. The final usable sample is 13 respondents from medium or large firms⁵⁸. The consultation is not statistically representative of the eligible population: responses are geographically concentrated in Europe and South America, based primarily in animal and plant breeding and biotechnology sectors, and absent entirely for laboratory equipment and information and AI. The findings support the analysis, but they are not considered the main source of evidence. Responses should be interpreted in light of two primary sources of imprecision: the lack of DSI-specific financial tracking systems, which constrains the precise quantification of impacts, and the tendency, common in industry consultations, to report burdens at the upper end of plausible estimates.

No individual respondent is identifiable from any finding reported in this section. Consultation findings are integrated into the pillar analysis in Sections 7.7 to 7.13 at the points where they are most relevant, rather than presented separately.

Submissions to CBD Notification 2024-114: the submissions support the pillar analysis to reflect positions stakeholder positions and to indicate the relative salience of concerns among the Parties and industry stakeholders (rather than as independent evidence of firm behaviour).

External sector sources for competitor geography, market concentration, and market structure indicators are drawn from sector-specific sources including IQVIA for pharmaceuticals, Kleffmann Group data for seeds, and peer-reviewed sector literature elsewhere. Full citations are provided in the relevant sections.

7.4. Evidence on the competitiveness effects of regulatory cost burdens

This section reviews empirical literature on the competitiveness effects of regulatory cost burdens at the scale of the Cali Fund's indicative contribution rates. It establishes the evidence basis for the significance assessments under the competitiveness impacts pillar analysis. The section also provides a baseline read-across of sector-specific evidence, which is taken up in more detail in Sections 7.7 to 7.13.

The first question for the assessment is whether the indicative contribution level is likely to be large enough to generate material competitiveness effects on its own. The most relevant evidence comes from cost burdens imposed by two types of instruments broadly analogous to the Cali Fund: corporate taxes and levies, and environmental levies as a secondary empirical reference.

Competitiveness effects of profit and revenue taxes

Tax literature distinguishes between profit-based and revenue-based burdens, which is directly relevant to the minimum-of-two design introduced above. Revenue-based burdens are generally considered more distortive

⁵⁸ Of 24 responses received, three are excluded: one test entry and two near-identical duplicate submissions from the same industry association. A further seven responses are from micro or small enterprises that do not meet the Decision 16/2 financial thresholds and are therefore not used to draw conclusions about eligible firm behaviour. Of the remaining 14 responses from medium and large firms, two are excluded as the respondents report no DSI use, leaving a working sample of 12 responses. Note that one of the 12 final responses was submitted by an industry association, meaning that it captures sector-level perspective and positions rather than the operational and financial experience of an individual eligible firm.

because liability is based on gross sales, regardless of margin, and can alter production, sourcing, and organisational decisions (Best et al., 2015; Xing et al., 2024). Profit-based burdens are less cost-distortive but often lead to stronger reporting and timing responses. For instance, Coles et. al. (2022) find that two-thirds of firms' responses to a 6-7 percentage point increase in the effective marginal profit tax rate led to accounting transactions such as revenue timing and expense shifting, rather than genuine reductions in investment or employment - a rate change substantially larger than the Cali Fund's indicative one percentage point contribution. The study further finds that large firms are among the least responsive to profit tax changes, which is relevant given that DSI-intensive contributors under are predominantly large firms. This suggests that competitiveness effects operating through genuine reductions in general investment or employment are unlikely at the profit contribution rate modelled here, although R&D investment may represent a more sensitive channel, as discussed below. The minimum-of-two rule further distributes the burden across the eligible entities, where those with profit margins above 10% contribute based on profits, while lower-margin firms are shielded from the more distortive revenue-based contribution payment⁵⁹. This approach limits exposure for more commercially vulnerable firms without requiring changes in behaviour.

The tax literature also identifies an innovation channel through which profit burdens influence competitiveness beyond short-term cost effects. Studies on corporate income taxation show that higher profit taxes reduce R&D, patenting, and related innovation by lowering after-tax returns on risky, intangible investments. Unlike investments in tangible capital, R&D is riskier, harder to redeploy if it fails, and more human-capital intensive. On the contrary, tax cuts increase innovation, with effects emerging over time (Mukherjee, Singh and Žaldokas, 2017; Atanassov and Liu, 2020; Akcigit *et al.*, 2022; Lichter *et al.*, 2025). To contextualise the magnitude, Lichter et al. (2025) find that a one percentage point increase in the effective profit tax burden - broadly comparable to the Cali Fund's indicative rate - reduces R&D expenditure by approximately 6-7% over an eight-year horizon. Effects tend to be greater for financially constrained and those more sensitive to after-tax returns (Atanassov and Liu, 2020; Lichter *et al.*, 2025); large, well-capitalised DSI-intensive contributors are less likely to fall into either category. The existence of widespread R&D tax relief schemes across OECD jurisdictions and beyond provides indirect support of the innovation channel identified above: such schemes are designed explicitly to offset the dampening effect of profit burdens on after-tax returns to R&D, and have been increasingly implemented over the last two decades (OECD, no date b). Empirical estimates confirm that this response is effective. For instance, Dechezleprêtre et. al (2023) find that R&D in the United Kingdom was around 16% higher over 2006-2011 as a result of tax credit policy, with consistent findings reported for Japan and the United States (Kasahara, Shimotsu and Suzuki, 2014; Rao, 2016). For firms operating in jurisdictions with generous relief schemes, the net change in after-tax returns to R&D from a contribution at the Cali Fund's indicative rate is therefore likely to be further attenuated by existing policy design. Evidence on innovation impacts of revenue-based taxes is limited; the distinct mechanisms through which revenue-based obligations affect firm behaviour - primarily production and organisational decisions rather than after-tax returns to innovation - suggest that the innovation channel identified in the profit tax literature does not translate directly to the revenue strand of the contribution.

Competitiveness effects of additional cost burdens from environmental policies

⁵⁹ The minimum rule's protective effect follows standard cost-minimisation theory, that a rational firm chooses the base with the lower liability, so firms with margins below the indifference threshold are automatically protected. This concept is discussed in more detail in Section 4.3.

Empirical research on regulatory cost burdens and competitiveness focuses predominantly on environmental policy, as this area offers the most usable cross-sector evidence for evaluating how extra cost requirements affect firms (Davidson, Kauffmann and Liedekerke, 2021). This is particularly true for environmental literature on carbon pricing, which offers further insight into whether additional cost burdens have significant firm-level effects. The main finding is that often, substantial costs associated with carbon pricing rarely cause significant negative impacts on profits, employment, or investment, especially when some pass-through is possible (Dechezleprêtre, Nachtigall and Venmans, 2018; Joltreau and Sommerfeld, 2019; Venmans, Ellis and Nachtigall, 2020). The established causal analysis in this field (Dechezleprêtre, Nachtigall and Venmans, 2018) reports that regulated firms experienced higher revenues and larger fixed asset bases while also cutting emissions, and it detects no statistically significant adverse effects on profits or employment; the authors explain these results by pointing to cost pass-through, induced investment, and the relatively modest effective compliance burden. For instance, Ganapati et. al. (2020) estimate that US manufacturing firms pass through about 70% of energy cost shocks, with considerable variation across industries – a figure that should be read as indicative rather than directly applicable, given the differences in sector coverage. Like input taxes, revenue levies are proportional to the scale of activity and can in principle be passed through to output prices, making the carbon pricing pass-through literature directly relevant to firms contributing on the revenue base. Firms contributing on the profit base face an even more limited short-run burden, as profit levies do not affect marginal cost structures. This evidence provides a cross-sector reference point suggesting the Cali Fund burden is well below levels at which firm-level competitiveness effects have been detected, though the comparison is indirect given differences in sector coverage and mechanism design. Should firms pass costs through to consumers, any resulting reduction in demand for DSI-derived products would in principle feed back into lower revenue and therefore lower contributions; this second-order effect is not captured in the static revenue model presented here, and would require product-level demand elasticities that are not available for the sectors in scope.

Research shows that when compliance costs reach about 1 percent of turnover in pollution-intensive sectors, or 5-8 percent of material costs under carbon pricing, the impact on trade, employment, and investment location is small and often statistically insignificant. These costs are five to ten times higher than the Cali Fund's revenue-equivalent burden for a typical contributor (Dechezleprêtre and Sato, 2017). Naegele and Zaklan (2019) provide a useful scale anchor: in that study, the average net EU ETS⁶⁰ burden was about 0.10% of material cost, with no systematic effect on trade flows or carbon leakage, which supports a conservative lower bound for the threshold at which environmental cost burdens generate observable firm-level effects. Similarly, Favot et al. (2018) report that extended producer responsibility compliance fees amounting to around 0.36-0.54% of sales were regarded as relatively low in the Italian electrical and electronic equipment industry, although they highlight that such costs may become significant when profit margins are narrow; this offers a useful sales-based reference point that aligns more closely with the revenue contribution approach used here (though still looking at higher effective rates).

This conclusion is cautious; in particular the EU ETS research focuses on energy-intensive industries that typically have slimmer margins and less differentiated products (Dechezleprêtre and Sato, 2017; EC, 2024) than the DSI-using sectors most relevant to the Cali Fund, several of which, including pharmaceutical innovators and premium cosmetics producers, operate in markets with some pricing power and higher margins, as discussed in Sections 7.7 to 7.13.

⁶⁰ European Union Emissions Trading System

When cost burdens are uneven among competitors, the key issue is not the absolute burden but whether uncovered rivals are close substitutes able to capture market share. The EU ETS literature indicates that competitiveness risks arise mainly when uncovered competitors are commercially similar and firms can shift sourcing or production across regulatory boundaries, rather than from the cost burden alone (Fowlie, 2009; Dechezleprêtre and Sato, 2017). Related research on standards shows that regulatory divergence can create fixed market-access costs through duplicated compliance requirements, regardless of price effects (Schmidt and Steingress, 2022). The effective burden may also be higher in practice where a Cali Fund contribution is paid on top of other international benefit-sharing contributions (obligation stacking). For the Cali Fund, this means international competitiveness effects depend more on the commercial proximity of non-participating rivals and any additional fixed compliance costs, rather than the contribution rate. These factors vary by sector and are discussed in Section 7.5.

Sector-specific evidence on payment burdens

The evidence reviewed above suggests that large-firm payment burdens at the indicative Cali Fund rates are unlikely to cause significant competitiveness effects for most firm types. However, this conclusion is based mainly on cross-sectoral environmental literature. This part summarises available sector-specific empirical evidence and highlights where the broad presumption is better or less well supported.

The most robust sector-specific evidence concerns pharmaceuticals and biotech. Key studies examine broad price-regulation and reimbursement regimes that suppress realised revenues and margins over time, rather than discrete contribution payments. Golec et al. (2006) report lower profitability and slower R&D growth among European pharmaceutical firms compared to US firms under stricter European price regulation. Eger and Mahlich (2014) find that large European firms with significant exposure to price-regulated sales have lower R&D intensity once exposure is high. Sood et al. (2008) observe that regulatory revenue reductions accumulate over time, and their incremental introduction has a reduced effect on cost. While these findings are directionally relevant, they address larger and more pervasive revenue restraints than a 1% profit or 0.1% revenue contribution. In contrast, Shaikh et al. (2021), using newer data and accounting for firm-level variation, finds no significant link between price-regulation exposure and R&D intensity, which weakens the inference further. The evidence suggests that large and sustained revenue restraints can affect this sector, but does not support the claim that a modest contribution of the indicative size will have similar effects.

For laboratory equipment and technical services, the medical-device excise tax is the closest sectoral comparison. Lee (2018) finds that a 2.3% excise tax on US medical-device sales reduced R&D investment, sales revenue, gross margins, and profits. Huston et al. (2023) report that firms with greater capacity for income-tax avoidance offset the charge and did not significantly reduce investment or employment, while firms with less avoidance capacity did reduce both. This evidence confirms that a direct sales-based charge can impact the sector, but the 2.3% rate studied is over twenty times higher than the Cali Fund revenue rate, so the findings are not directly transferable.

For digital platforms and information services, Lassmann et al. (2020) find that tax increases in online advertising markets are mostly passed through to prices. However, the study does not show significant reductions in output, employment, or relocation at the firm level. This is consistent with the general assumption of low materiality, but it does not offer direct evidence regarding the Cali Fund's information and technical services contributors.

For nutraceuticals and functional foods, cosmetics and personal care, plant breeding, and animal breeding, the literature search did not identify close payment-burden analogues. For these sectors, the assessment necessarily relies on the broad cross-sectoral evidence as the primary reference, supplemented by the sector-by-sector analysis in Sections 7.7 to 7.13.

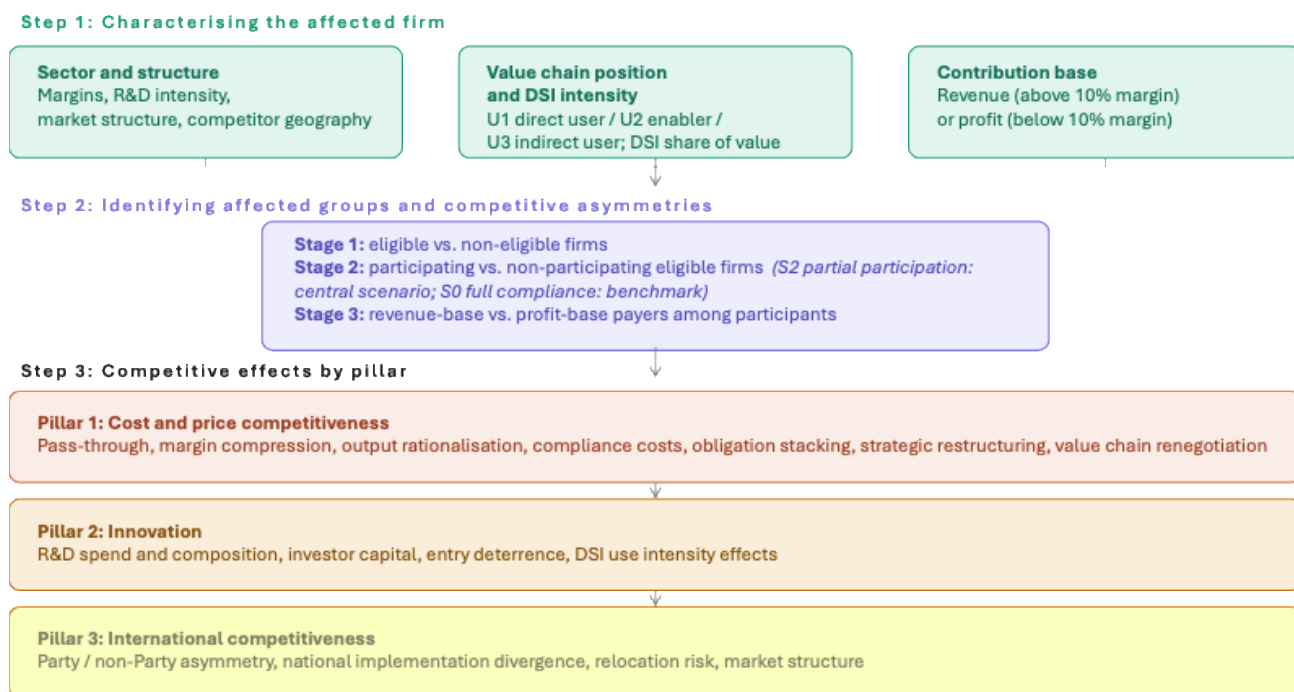
Taken together, these studies suggest that a contribution at the Cali Fund's indicative rate is unlikely to drive significant material changes in employment, pricing or general investment for most affected firms. Based on the tax literature evidence, R&D investment emerges as potentially sensitive to a profit burden of this scale: Lichter et. al (2025) find that a comparable one percentage point tax burden reduces R&D expenditure by approximately 6-8% over an eight-year horizon, however, the most likely firms to face this impact are those financially constrained. The large, well-capitalised firms that account for a large portion of firms in-scope are less likely to fall into that category, and for revenue-based payers the innovation channel may be more indirect. That inference is strongest for diversified, highly profitable firms and weakest where margins are persistently low and where a sector already faces strong product-market revenue restraints. Sections 7.7 to 7.13 examine where these concerns are most material at the sector level. Section 7.14 summarises the competitiveness impact materiality assessment across all sectors.

7.5. Competitiveness assessment framework

Figure 11 presents the three-step assessment framework applied throughout Part III. Step 1 characterises each affected firm across three dimensions: sector and structural features; value chain position and DSI use intensity; and expected contribution base. Step 2 sorts firms into competitive asymmetry groups, since the Cali Fund affects different firms differently. Three asymmetries are relevant, corresponding to the three stages of the participation framework from Section 4: between eligible firms in scope of the assessment and non-eligible competitors operating in the same product markets (Stage 1); within the eligible population, between participating and non-participating firms (Stage 2); and within the participating population, between firms paying on revenue and those paying on profit (Stage 3). Each distinction adds a potential new source of

competitive asymmetry between firms competing in the same market. Step 3 assesses the competitive effects that result from Steps 1 and 2 interacting, organised across the three competitiveness impact pillars introduced in Section 7.3 (“Methodological approach”). Each stage of Step 2 is also conditioned by specific design uncertainties identified in Table 2, which introduce additional sources of asymmetry or ambiguity into the analysis. These links are developed in the relevant stage subsections.

Figure 11 Competitiveness assessment framework



Note: The framework is applied across the seven Indicative Enclosure I sectors. Firm characterisation in Step 1 draws on the eligible population data from Makowska-Curran (2026) (Part II). The three-stage asymmetry groups in Step 2 follow the overarching

analytical framework from Section 4 (participation stages 1-3). Steps 1& 2 findings inform the Pillar analysis in Step 3. The results of the competitiveness analysis are presented in Sections 7.7 to 7.13.

Source: Author's illustration.

A note on how to read the Materiality ratings that follow: they reflect a qualitative judgement about Magnitude and Probability together, rather than a scored or weighted formula. This approach reflects the underlying evidence base, which mixes quantitative estimates (margin data, elasticity studies) with qualitative sources (the industry consultation, CBD submissions) that do not sit on a single numerical scale; a formula would suggest a degree of precision the evidence does not support. As a general rule, a high rating requires both a meaningful magnitude and a reasonable likelihood of occurrence; where either is genuinely uncertain, the impact is rated "Cannot say" rather than assigned a midpoint. Where several impacts bear on a sector's overall competitive position, the cross-sector narrative in Table 45 reflects a judgement of which impacts are most decisive for that sector, rather than an average or index across all of them.

Box 3 illustrates how the framework applies to two firm profiles with different structural characteristics. The following subsections develop each component of the framework in turn.

Box 3: Applying the framework: illustrative classification of two firm profiles

The examples below illustrate how the three-step framework applies to firms with different structural profiles. The firm profiles are drawn from the eligible population characteristics established in Part II and do not refer to any specific firm.

Example 1: Large pharmaceutical innovator with a 20% profit margin

Step 1: operates in markets with moderate to high concentration in the patented drug segment and has high R&D intensity; uses publicly available DSI directly in drug discovery and development; would pay on revenue under the minimum-of-two rule.

Step 2: under partial participation (i.e. with only a share of in-scope firms participating), faces the contribution alongside sub-threshold pharmaceutical firms outside the eligible population (Stage 1) and eligible firms choosing not to participate (Stage 2); paying on revenue can create asymmetries relative to competitors with margins below 10% paying on profit (Stage 3).

Step 3: Pillar 1 examines pricing and margin effects in regulated markets, and potential obligation stacking with the WHO PABS framework as an additional cost channel; Pillar 2 examines R&D investment decisions given pipeline horizons; Pillar 3 examines competitive position relative to non-CBD-Party competitors.

Example 2: Large plant breeding firm with a 5% profit margin

Step 1: operates in markets with high global concentration at the top tier; uses publicly available DSI directly in breeding programmes, though breeding firms typically rely heavily on proprietary genomic databases and germplasm records alongside public sources; would pay on profit under the minimum-of-two rule.

Step 2: under partial participation, faces the contribution alongside sub-threshold breeding firms outside the eligible population (Stage 1) and non-participating eligible competitors within it (Stage 2); paying on profit can create asymmetries relative to competitors with margins above 10% paying on revenue (Stage 3).

Step 3: Pillar 1 examines pass-through capacity to price-sensitive farmer customers and margin implications and potential obligation stacking with the ITPGRFA as an additional cost channel where a firm accesses both physical MLS material and DSI relating to the same genetic resource (see Section Obligation stacking); Pillar 2 examines effects on long-duration breeding programmes; Pillar 3 examines competitive position relative to non-CBD-Party competitors that dominate the global seed market.

Step 1: Characterising the affected firm

Step 1 characterises each affected firm according to three dimensions that influence the competitive effects evaluated in subsequent steps. Each dimension is derived from the analysis in Part II and further developed below.

Sector and structural features

The seven Indicative Enclosure I sectors exhibit significant variation in market structure, profit margins, research and development intensity, value chain position, and the presence of non-CBD-Party competitors.

These structural characteristics shape how a contribution obligation translates into competitive effects. For example, a firm operating in a concentrated market with inelastic demand⁶¹ has different pass-through capacity than a firm in a competitive market with price-sensitive customers. Similarly, a sector with a substantial presence of non-Party competitors faces different international competitiveness pressures than one where eligible firms are primary competitors. Section 7.6 provides a detailed cross-sector characterisation.

Value chain position and DSI use intensity

Firms within the same sector may occupy different positions in the DSI value chain. Some firms are direct users of publicly available DSI in research and product development. Others serve as upstream enablers of sequencing infrastructure without directly using DSI, while some are downstream firms that commercialise DSI-derived products who do not access DSI themselves. The value chain position determines the directness of the relationship between DSI use and commercial activity, which is analytically significant because the contribution is intended to originate from firms that benefit commercially from DSI. The distinction between direct and indirect DSI use is itself unresolved under Decision 16/2 and is discussed in Section 4.1 (“Commercial DSI use”). DSI use intensity, defined as the proportion of a firm's commercial value attributable to DSI use, varies even within value chain positions and influences the proportionality of the contribution to actual DSI dependence. Similarly to the boundary between direct and indirect DSI use, the level of DSI intensity is mostly unobserved and difficult to establish, as explained in the same section.

Expected contribution base

Under the minimum-of-two rule established in Decision 16/2, firms pay the lesser of 0.1% of revenue or 1% of profit. The indifference margin analysis in Part II indicates that firms with profit margins above 10% pay based on revenue, while those with margins below 10% pay based on profit. This distinction determines the economic nature of the payment for each firm at the margin⁶². A revenue-based payer incurs a payment that scales with output and, when treated as a proportional cost in financial planning, operates as an ad valorem output levy. In contrast, a profit-based payer faces a payment that reduces the return on capital without directly affecting marginal costs. As a result, the contribution base shapes the transmission channels through which competitive effects arise. Both bases reduce after-tax returns and, over the medium to long term, influence investment incentives, although the scale of the effect may differ depending on the contribution base.

Table 16 illustrates how Step 1 of the framework classifies firms across the three dimensions described above. Three firm profiles drawn from two Indicative Enclosure I sectors are shown, with indicative structural and economic characteristics. The table is illustrative rather than empirical. The full sector-level characterisation of the eligible population is provided in Section 7.6, with sources cited there.

⁶¹ See Section 7.1 for explanations of key economic terminology used throughout Part III.

⁶² See Section 7.1 for the intuition.

Table 16 Illustration of Step 1 firm classification across selected sectors

Sector	Firm type & example	Market structure and economics	Customer type and demand elasticity	Competitor geography	Value chain position
Pharmaceuticals	U1: Direct DSI user <i>e.g. innovator R&D</i>	Moderately to highly concentrated at the innovator tier; high margins (20-30%); very high R&D intensity (15-20% of revenue)	Public payers and consumers; demand largely inelastic for branded patented drugs, but payer negotiation under reimbursement frameworks constrains price-setting in most CBD Party jurisdictions.	Very high US competitor presence	Core exploiter of DSI; accesses public databases directly
Pharmaceuticals	U2: Downstream indirect user <i>e.g. generic manufacturers commercialising DSI-derived compounds</i>	More fragmented generics segment; lower margins (5-15%); lower R&D intensity (5-8% of revenue, focused on formulation)	Public payers and consumers; demand more elastic within therapeutic class given availability of generic substitutes and price competition	High US and international competitor presence	Downstream of DSI use; does not access DSI databases directly
Laboratory equipment	U3: Upstream enabler <i>e.g. sequencing instrument and consumables producers</i>	Moderately concentrated (sequencing instruments) with broader specialised mid-tier; moderate margins (12-18%); moderate R&D intensity (8-12% of revenue)	Research institutions and commercial labs; demand moderately inelastic for high-quality instruments where switching costs are high	Very high US competitor presence	Upstream of DSI creation; enables sequencing

Note: The figure illustrates Step 1 framework application using selected firm profiles. Structural and economic indicators are sector-level estimates intended as analytical anchors rather than precise measurements. The seven Indicative Enclosure I sectors and their eligible firm populations are characterised in detail in Section 7.6.

The three dimensions together create a taxonomy of firm types for each Indicative Enclosure I sector. These firm types group eligible firms by their DSI value chain position, expected contribution base, and comparable structural features. The taxonomy is used in sector characterisation in Section 7.5 and as the unit of analysis in Step 3 pillar assessments. This approach enables differentiation of competitive effects within sectors where eligible firms are not homogeneous, without requiring analysis at the individual firm level.

Step 2: Identifying affected groups and competitive asymmetries

Step 2 categorises firms into competitive asymmetry groups based on the three stages of the participation framework outlined in Section 4. Each stage generates a distinct competitor benchmark between firms. Design uncertainties identified in Table 2 influence each stage and are highlighted below where they are most significant. Table 17 summarises the three asymmetries before each is examined in detail in the following subsections.

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Table 17 Three-stage competitive asymmetry under Decision 16/2

Stage	Asymmetry type	Firms compared	Mechanism	Addressable by rate revision?
Stage 1 Eligibility	Eligibility asymmetry	Eligible vs. non-eligible firms in the same product market	Threshold design excludes smaller competitors from the contribution eligibility; eligible firms bear a cost that non-eligible competitors in the same product market do not.	No. Requires threshold adjustment
Stage 2 Participation	Participation asymmetry	Participating vs. non-participating eligible firms	Non-legally binding mechanism creates first-mover disadvantage; contributing firms bear a cost that non-contributing eligible competitors do not. This can be offset by the counteracting effect of first-mover advantage, where firms identify reputational and other benefits of early participation.	Partially. Lower rates reduce the magnitude of the first-mover disadvantage but do not eliminate the structural incentive to wait if the perceived first-mover costs outweigh the benefits.
Stage 3 Contribution	Contribution base asymmetry	Revenue-base vs. profit-base payers among participating firms	Minimum-of-two design places firms on different contribution bases depending on margin. The two bases produce different effective rates on revenue and on profit, with competitive significance depending on which dimension is binding.	No. Inherent to the minimum-of-two design; requires a structural change to the rate formula

Note: Stages correspond to the three-stage participation framework introduced in Section 4 and applied in Part II. The asymmetries are cumulative for any participating eligible firm.

Stage 1: Eligibility asymmetry

Eligible firms within the scope of the assessment may incur the contribution while competing with non-eligible firms in the same product markets. Non-eligible firms comprise those below the financial thresholds specified in Decision 16/2, those outside the indicative Enclosure I sector list, and those operating in non-CBD-Party jurisdictions. Effectively, Stage 1 asymmetry involves a comparison between firms included and excluded from the assessment scope.

Stage 1 asymmetry remains structurally permanent under the current threshold design, but it results in a competitive burden only when an eligible firm elects to participate. Non-participating eligible firms incur no contribution costs, despite being formally within the assessment scope. Under full compliance, Stage 1 asymmetry affects the entire eligible population, whereas under the more realistic, partial participation, it applies only to the subset that contributes.

The materiality of the Stage 1 asymmetry depends on the extent to which eligible and non-eligible firms compete directly in the same product markets. In sectors where the eligible population is concentrated in large-firm clusters with limited direct competition from sub-threshold firms, this asymmetry is limited in practice. It is most significant in sectors where eligible and non-eligible firms compete for the same customers.

Two design uncertainties from Table 2 affect this stage. The entity definition uncertainty determines whether eligibility is assessed at the subsidiary level or the consolidated group level, which can include or exclude

entities that would otherwise fall on the opposite side of the eligible population. The direct versus indirect use boundary, discussed in Section 7.5 (value chain), further shapes which firms qualify as eligible in the first place.

Stage 2: Participation asymmetry

Within the eligible population, participating firms incur the contribution, whereas non-participating firms do not. The latter category also captures eligible firms excluded by the profit floor (i.e. making no profit or losses). Firms that report losses do not contribute, no matter their DSI activity or market position, even under the full participation scenario. If any firms near the zero-profit boundary decide to manage earnings downward to avoid contributions, the burden shifts further onto those that do not.

A separate but related asymmetry arises from voluntary (i.e. intentional and not profit-driven) non-participation. Under partial participation, contributing firms must absorb, pass through, or offset the cost, while non-contributing eligible competitors are not subject to this constraint. This asymmetry represents the primary competitive risk under the voluntary mechanism and is most noticeable in the partial participation scenario (S2) described in Part II.

Stage 2 asymmetry can be self-reinforcing. The cost burden discrepancy between participants and non-participants can create a first-mover disadvantage⁶³, which may discourage further participation, as firms often prefer to wait until competitors contribute (Videras and Alberini, 2000; Montiel and Husted, 2009; Delmas and Montes-Sancho, 2010). Evidence from analogous mechanisms in Section 3 demonstrates this dynamic in voluntary benefit-sharing systems with similar structural characteristics.

The first-mover disadvantage can be balanced by a counteracting effect. Some evidence on broader voluntary schemes shows that joining early can boost firms' reputation, in particular for those that are highly visible to consumers or closely watched by investors (Videras and Alberini, 2000; Delmas and Keller, 2005). If these reputational incentives are strong enough, they can make up for the extra costs of being first, which means the first-mover problem does not affect all firms equally. It is most challenging for companies with little to gain in reputation. The pillar assessments explore this difference in more detail.

Two design uncertainties identified in Table 2 may extend beyond influencing participation decisions and also affect the burden experienced by participating firms. National implementation divergence may result in firms in jurisdictions with stronger reputational or legislative pressures incurring higher effective costs than firms in other regions (Dechezleprêtre and Sato, 2017; Bassford *et al.*, 2024). No CBD Party has yet adopted such measures, so this remains a potential rather than realised source of asymmetry; however, comparable cross-jurisdictional differences are commonly observed in other regulatory areas, including corporate taxation⁶⁴. Similarly, obligation stacking could create cumulative burdens for firms with overlapping benefit-sharing eligibility. Both factors increase the burden differential among participating firms and reinforce the Stage 2 asymmetry.

Finally, it is important to reiterate, that several of the previously identified effects are specific to partial participation and would differ under near-universal adoption. If contributions were to become effectively

⁶³ First-mover disadvantage is the competitive burden on firms that adopt a voluntary commitment before their competitors. When participation is gradual, early participants bear costs that late or non-participants avoid (e.g. reputational costs due to higher visibility). This in turn, may incentivise other firms to delay participation.

⁶⁴ Cross-jurisdictional regulatory variation is the norm rather than the exception in international policy implementation. Corporate income tax rates, environmental compliance requirements, and labour standards all vary across jurisdictions without necessarily constituting prohibitive competitive distortions.

binding e.g. through national legislation the primary competitive concern would shift to the Stage 1 asymmetry between eligible and non-eligible firms.

Stage 3: Contribution base asymmetry

Choosing between the two minimum-of-two bases results in varying effective rates depending on the dimension under consideration.

For the revenue dimension, firms exceeding the threshold pay a uniform 0.1% of revenue, whereas firms below the threshold pay a lower rate (in terms of revenue) that scales with margin. In terms of profit, firms below the threshold pay 1% of profit, while those above the threshold pay a decreasing share as margin increases, such as 0.5% at a 20% margin and 0.33% at a 30% margin. The competitive implications of this asymmetry depend on which contribution base-linked effect is most relevant. For example, the revenue dimension is more significant for pricing and pass-through, where the contribution operates as an ad valorem output levy. On the other hand, the profit dimension is more pertinent to investment and return on capital. Both dimensions are analysed in the pillar analysis.

A key design uncertainty identified in Table 2 is the lack of proportionality to actual DSI use for firms with DSI intensity below 100%. The contribution is calculated based on total firm financials rather than activity specifically attributed to DSI. If two companies in the same industry have the same revenue but rely on DSI to different extents, the all-in approach makes them contribute the same amount. This means that firms with less dependence on DSI end up paying more compared to the value they get from DSI, while firms that rely heavily on DSI pay less per unit of benefit. As a result, there is an uneven playing field within the sector, since companies with limited DSI use face higher costs than their more DSI-focused competitors. The pillar assessments look at how this affects different types of firms.

The three asymmetries in Step 2 influence the magnitude and materiality of the impacts assessed under each of the three competitiveness assessment pillars in Sections 7.7 to 7.13. The eligibility asymmetry determines whether a cost burden leads to a competitive disadvantage compared to direct product-market competitors. Participation asymmetry affects the extent to which this disadvantage occurs under partial uptake. Contribution base asymmetry influences the effective rate and its effects on pricing and investment decisions, depending on which base the firm uses. These effects are reflected in the conditionality dimension of the impact classification in Step 3, with the relevant asymmetry stage identified as the primary driver where applicable.

Step 3: Assessing competitive effects by pillar

The pillar assessment evaluates competitive effects for firms that choose to contribute to the Cali Fund. As established in Step 2, the non-binding design means no firm is legally required to absorb these effects at this moment; eligible firms retain the option of non-participation as a competitive response to the burden. The relevant comparison is therefore between contributing firms and all non-contributing competitors, including both non-Party firms and eligible firms that opt out.

Figure 2. The significance assessments below identify impacts that are structurally plausible for the contributing subset; their magnitude and distribution depend on the participation dynamics in Step 2 and the sector characteristics in 7.5. Impacts associated with the most severe competitive harm, such as restructuring or market exit, are assessed as not likely significant throughout, as firms facing material harm would rationally choose non-participation over exit under a voluntary mechanism (Arora and Cason, 1996; Potoski and Prakash, 2005).

Step 3 integrates the firm characterisation from Step 1 with the asymmetry analysis from Step 2 to provide a structured assessment of competitive effects across the three pillars outlined in Section 7.3 (“Methodological approach:”). This section presents the analytical structure and classification of each potential competitive impact applied in Sections 7.7 to 7.13.

The classification of impacts under each pillar is adopted from the regulatory guidance used and presented in a table format, covering their descriptions, anticipated pathway (whether they affect the contributing firm directly or indirectly via its value chain), time horizon (whether the impact materialises within the contribution period (short-term) or over a longer cycle (medium & long-term), likely significance to eligible firms (Yes / No / Cannot say), together with a short justification. The significance assessment is a preliminary screening method recommended in the guidance. It requires first deciding if the effects are likely to be material (i.e. whether an impact is *plausible*) before conducting a detailed firm-level materiality review. Where impacts are supported by the industry consultation or CBD Notification 2024-114 submissions, this is indicated by the symbol “◆” in the Impact column, with additional footnotes providing more context for more commonly referenced impacts. The role and limitations of both sources are described in Section 7.3. Impacts assessed as not likely significant are not carried forward to the firm-type level assessment; those identified as likely significant or as cannot say are carried forward to the sector-level assessment in Sections 7.7 to 7.13. Note that because the contribution payment imposes costs on firms, its competitive effects across all three pillars are primarily negative. Any positive or ambiguous impacts are explicitly noted below.

The sector-level firm characterisation in Sections 7.7 to 7.13 identifies the relevant firm types within each sector, which serve as the unit of analysis for the pillar assessments for each sector. For each impact carried forward, the pillar assessments evaluate its magnitude relative to the financial and competitive position of the relevant firm type, classified as minor, moderate, or substantial, and the probability that it materialises given sector-specific conditions and the unresolved design parameters in Table 2, classified as low, medium, or high.

Table 18 recalls the key design uncertainties from Table 2 that bear most directly on the findings in this part. This approach follows the assessment methodology recommended in Davidson, Kauffmann and Liedekerke (2021). Given that the mechanism is prospective and voluntary, and that firm-level DSI use intensity remains largely unobserved, quantitative estimation of competitive effects is not feasible at this stage; the assessment therefore relies on qualitative evidence, which the guidance recognises as the appropriate approach where data constraints prevent quantification.

Each impact's materiality is determined by combining magnitude and probability assessments, as shown in the matrix below (Table 19) and in line with standard risk-assessment methodology. The pillar assessment tables present magnitude and probability separately for verification.

Table 18 Design uncertainties relevant for the competitiveness analysis (based on Table 1)

ID	Factor	Mechanism
Stage 1: Who is eligible?		
U3	Entity definition: subsidiary vs. group	Subsidiary branch vs group level affects count and the level of contributions
U4	Direct vs. indirect use boundary	Broader interpretation expands scope; value chain double-counting possible
Stage 2: Who participates?		
U6	Certificate regulatory value	Low regulatory value reduces participation incentive
U7	Obligation stacking	Unresolved overlap with national/international instruments deters participation
U8	National implementation divergence	More implementation increases participation; divergence creates asymmetries
U10	Competitor participation	Low sector uptake deters individual participation; high uptake encourages it
Stage 3: How much do they contribute?		
U12	Partial DSI use and proportionality	Same contribution base regardless of DSI intensity; low-DSI firms face disproportionate burden, reducing participation incentive

Note: This table summarises the design uncertainties relevant to the competitiveness analysis (part of the uncertainties register from Table 2) for ease of reference.

Table 19 Materiality assessment matrix

	Low probability	Medium probability	High probability
Substantial magnitude	Moderate	High	High
Moderate magnitude	Low	Moderate	High
Minor magnitude	Low	Low	Moderate

Note: Materiality is classified as Low, Moderate, or High. Low means the impact is unlikely to affect the competitive position of the relevant firm type. Moderate suggests a plausible competitive effect that should be monitored but is unlikely to be decisive. High indicates a likely material competitive effect that requires design-level attention.

Pillar I: Cost and price competitiveness

Pillar I examines whether the contribution obligation alters the costs for participating firms, with a full list of potential cost burdens outlined in Table 20.

Table 20 Pillar I: Cost and price competitiveness impacts classification

Impact	Description	Pathway	Time horizon	Likely significant?	Justification
Regulatory costs and cost competitiveness					
Administrative burden ♦	Costs of calculating, reporting and documenting the contribution	Direct	Short-term	Cannot say	Low for most firm types under the current revenue/profit design, as both bases rely on indicators already reported for tax and accounting purposes. Significance is highly conditional on resolution of the contribution scope uncertainty: a shift toward product- or use-based attribution would require firms to track and document DSI use at the product level, representing a materially higher information obligation, particularly for firms operating across multiple product lines or jurisdictions. Additional administrative costs may arise for firms subject to overlapping benefit-sharing frameworks, where eligibility and compliance must be assessed and documented across multiple instruments simultaneously.
Substantive compliance costs ♦ ⁶⁵	The contribution payment itself as a direct cost (primary cost channel)	Direct	Short-term	Yes	Contribution falls directly on firm financials; magnitude varies by sector margin and contribution base. 2026-09-30 9:06:00 PM
Factors of production and cost competitiveness					
Cost of land	Effects on cost or availability of land used in production	Direct	Short-term	No	Contribution structure has no land use dimension.
Cost of labour	Indirect effects on staffing costs resulting from the contribution obligation	Indirect	Long-term	No	Contribution structure does not directly affect staffing costs for any eligible firm type. Indirect restructuring-linked labour effects are implausible at indicative rates. See Section 7.4 - no statistically significant employment effects found at EU ETS costs substantially above the Cali Fund's indicative rates (Dechezleprêtre and Sato, 2017). The consultation provided no evidence of anticipated labour cost effects.
Cost of capital	Changes in availability or cost of financing resulting from margin compression or reduced free cash flow	Direct	Short-term / Long-term	Cannot say	Depends on firm-level financial position and whether margin compression is sufficient to affect creditworthiness.

⁶⁵ 8/13 consultation respondents expect to be more negatively affected than competitors.

Impact	Description	Pathway	Time horizon	Likely significant?	Justification
Cost of intermediate consumption ♦ ⁶⁶	Changes in price or availability of upstream inputs where the obligation falls on supplier sectors within indicative Enclosure I	Indirect	Short-term	Cannot say	Materialises only where upstream and downstream eligible firms operate in linked input markets within indicative Enclosure I and where the upstream firm passes the contribution cost forward through input pricing rather than absorbing it; both conditions hold for some sector pairs, e.g. pharmaceuticals and laboratory equipment, but not across the eligible population as a whole.
Cost of entrepreneurship	Effects on incentives for new market entrants and early-stage firms	Direct	Long-term	No	Crossing the eligibility threshold does not automatically trigger a contribution obligation under the voluntary design of the Cali Fund; firms may choose not to participate upon becoming eligible. The threshold deterrence effect documented for mandatory size-based regulatory obligations therefore does not apply in this context.
Distributional and dynamic impacts and cost competitiveness					
Impact on SMEs	Disproportionate incidence of fixed compliance costs on smaller eligible firms relative to larger ones within the same sector	Direct	Short-term	No	Most of the eligible population is predominantly composed of large firms with established legal and compliance teams for whom fixed compliance costs are unlikely to be material relative to operating costs; a marginal disadvantage may arise for threshold-proximate firms but is insufficient to warrant detailed assessment (see Part I discussion on SME thresholds across different jurisdictions).
Restructuring of firms	Market exit, production line closure or reorganisation triggered by the contribution burden	Direct	Long-term	No	Implausible at indicative contribution rates of 0.1% of revenue or 1% of profit, under a non-binding scheme firms would likely opt out from the scheme; no evidence from consultation or submissions of restructuring risk at current indicative rates. See Section 7.4 - no statistically significant profit or employment effects found at EU ETS costs substantially above the Cali Fund's indicative rates (Dechezleprêtre and Sato, 2017).
Cost competitiveness and impacts on consumers					
Pass-through to consumers ♦ ⁶⁷	Extent to which the contribution cost is transferred to customers through output pricing. Positive for the firm where pass-through is feasible, negative where demand elasticity or competitive pressure constrains it.	Direct	Short-term	Cannot say	Direction and magnitude depend on market structure and demand elasticity by sector and firm type (see each sector's own assessment throughout this Part). Error! Reference source not found.

Note: Symbol ♦ indicates impacts supported by the industry consultation or CBD Notification 2024-114 submissions. Impacts without a symbol are assessed on theoretical and structural grounds only.

⁶⁶ 12/13 consultation respondents expect suppliers to pass on DSI-related cost increases.

⁶⁷ 12/13 consultation respondents describe customers as very or moderately price-sensitive, constraining pass-through capacity.

Pillar II: Capacity to innovate

Pillar II assesses whether the contribution obligation affects the capacity of participating firms to innovate, with a full list of potential innovation impacts outlined in Table 21.

Table 21 Pillar II: Capacity to innovate impacts classification

Impact	Description	Pathway	Time horizon	Likely significant?	Justification
Capacity to carry out R&D					
R&D investment capacity ♦ ⁶⁸	Reduction in capital available for research and development activity operating through margin compression or reduced free cash flow due to the contribution	Direct	Long-term	Yes	R&D-intensive sectors face a direct trade-off between contribution payments and investable capital; most significant for firms with long pipeline horizons and high R&D intensity. See Section 7.4 - a comparable one percentage point profit tax burden reduces R&D by approximately 6-7% over eight years, with larger effects for financially constrained firms (Lichter <i>et al.</i> , 2025).
IP protection efficiency	Whether the mechanism affects the ability of firms to appropriate returns from innovation investment through IP protection frameworks	Direct	Long-term	No	Contribution structure does not interact directly with IP protection frameworks; no mechanism by which the payment alters patent, copyright, or trade secret protections for any eligible firm type.
Capacity to market new or improved products					
Product innovation capacity ♦ ⁶⁹	Reduction in capital available for development and commercialisation of new or improved products, operating through the same margin compression channel as R&D investment capacity	Direct	Long-term	Yes	Most significant for sectors with high product development costs and long commercialisation timelines. See Section 7.4 - innovation effects are most pronounced for financially constrained firms; large multinationals accounting for the bulk of contributions are less exposed (Atanasov and Liu, 2020; Lichter <i>et al.</i> , 2025).
Capacity for process innovation					
Process innovation capacity	Reduction in capital available for improvements to production, distribution, marketing, or organisational methods	Direct	Long-term	No	Process innovation investments typically have shorter payback horizons than product R&D and are less likely to be crowded out by a contribution at indicative rates; no sector-specific evidence from the consultation or submissions suggests this impact is material for any eligible firm type.
Access to risk capital					
Access to risk capital	Effect on ability to attract external equity or debt financing for innovation activity where the contribution reduces perceived returns or compresses margins	Direct	Short-term / Long-term	Cannot say	Depends on firm-level financial position and investor sensitivity to margin effects at indicative contribution rates; likely most significant for early-stage biotech and information and AI firms with limited retained earnings. This effect may run in the opposite direction for some firms: visible participation could function as a positive ESG signal to investors, particularly for firms in

⁶⁸ 8/13 consultation respondents report a small likelihood and 1 a medium likelihood of absorbing the contribution via reduced R&D spending (with 4 respondents selecting don't know / not applicable)

⁶⁹ Same impact channel as R&D investment, see the footnote above.

Impact	Description	Pathway	Time horizon	Likely significant?	Justification
					emerging markets with fewer other credible reputational signals available, though this would depend on the certificate achieving genuine visibility and recognition value (see Certificate regulatory value, Section 4.2)
Creative destruction and market entry					
New entrant incentives	Effect on incentives for new firms to enter DSI-using markets	Direct	Long-term	No	Genuine early-stage entrants are likely to fall below the Decision 16/2 financial thresholds and are therefore outside the eligible population entirely. Among eligible firms, loss-making entrants are protected by the profit floor. The residual deterrence effect on firms in early growth phases is narrow. No material impact on new entrant incentives across the eligible population is not supported by the available evidence at indicative contribution rates.
Regulatory environment and innovation incentives					
Certainty and predictability ◆ ⁷⁰	Effect of unresolved Decision 16/2 design parameters on firms' willingness to commit to long-term R&D investment pipelines	Direct	Long-term	Cannot say	The non-binding design means uncertainty primarily deters participation rather than investment; however, for sectors with long R&D horizons, sustained uncertainty about the mechanism's terms (Table 2) may affect pipeline decisions at the margin where DSI access and legal certainty are relevant inputs.
Regulatory stringency effect	Whether the contribution obligation induces compensatory innovation as a behavioural response to cost pressure	Direct	Long-term	No	The Porter hypothesis ⁷¹ channel applies to regulatory constraints that create specific operational pressures to which innovation is a direct response (e.g. green transition). Not applicable to the Cali Fund.

Note: Symbol ◆ indicates impacts supported by the industry consultation or CBD Notification 2024-114 submissions. Impacts without a symbol are assessed on theoretical and structural grounds only.

Pillar III: International competitiveness

Pillar III assesses whether the contribution obligation affects the competitive position of participating firms in international markets relative to non-Party competitors, with a full list of potential international competitiveness impacts outlined in Table 48.

⁷⁰ 5/13 consultation respondents expect no benefits from contributing

⁷¹ The Porter hypothesis holds that well-designed environmental regulation can stimulate innovation sufficient to offset compliance costs (Porter, 1991). Meta-analytic evidence confirms this effect is concentrated in command-and-control regulation; levy-based instruments show no significant relationship with green innovation (Zhang *et al.*, 2024). As the Cali Fund addresses a distributional equity gap rather than a pollution externality, the innovation-offset logic does not apply.

Table 22 Pillar III: International competitiveness impacts classification

Impact	Description	Pathway	Time horizon	Likely significant?	Justification
A. The impact of the contribution on the competitive position of firms internationally and on trade					
Competitive position vs non-Party competitors ◆ ⁷²	Direct cost asymmetry between contributing firms and competitors headquartered in non-CBD-Party jurisdictions, principally the United States, who are not subject to the DSI MLM	Direct	Short-term	Yes	Non-Party competitor presence is significant across multiple indicative Enclosure 1 sectors. See Section 7.4 - competitiveness risks from asymmetric burdens arise primarily where uncovered competitors are close commercial substitutes, rather than from the cost burden alone (Fowlie, 2009; Dechezleprêtre and Sato, 2017).
Export competitiveness ◆ ⁷³	Direct effects on export competitiveness where the contribution increases the cost of doing business and cannot be fully passed through to export customers in non-Party markets	Direct	Short-term	Yes	Materialises where firms compete in export markets with non-Party competitors not subject to equivalent obligations. Contributing firms bear a cost that non-Party export competitors do not; where pass-through to export customers is constrained by competitive pressure, this reduces the contributing firm's margin relative to non-contributing rivals.
Market share effects	Loss of international market share due to sustained cost differences between contributing and non-contributing competitors	Indirect	Long-term	No	A second-order consequence of competitive position and export competitiveness effects above; materialises only where those first-order effects are themselves significant and compound over time.
Regulatory divergence costs ◆ ⁷⁴	Frictions arising from asymmetric national implementation of Decision 16/2 across CBD Party jurisdictions	Direct	Short-term / Long-term	No	No divergence has yet materialised as implementation remains at an early stage across most Parties; significance is highly conditional on how Parties implement Decision 16/2 ahead of and following future COP decisions. Currently not significant.
Conformity assessment costs	Costs of demonstrating compliance with contribution obligations across multiple regulatory frameworks where national assessment procedures differ	Direct	Short-term	No	Under the current design the Cali Fund contribution is non-binding, and participation currently does not provide market access authorisation; no conformity assessment costs arise in the trade sense. This assessment would change if e.g. national implementation established the certificate as a condition of market access for DSI-derived products.
B. Systematic consideration of international regulatory co-operation					
International standards and regulatory dialogues ⁷⁵	Whether divergence between the Cali Fund and other international DSI-related frameworks creates an uneven regulatory environment for	Indirect	Long-term	Cannot say	The Cali Fund operates alongside other international frameworks covering DSI, including the WHO PABS, and BBNJ, none of which are fully aligned in scope, contribution modalities, or coverage; divergence between these frameworks may create asymmetric burdens for firms subject to

⁷² 9/13 consultation respondents cite North America as a competitor location; 8/13 expect to be more negatively affected than competitors.

⁷³ See the footnote above.

⁷⁴ Submissions to CBD Notification 2024-114 from commercial sector representatives raised concerns about divergent national implementation and overlapping framework obligations; see (CBD, 2024b).

⁷⁵ See above.

Impact	Description	Pathway	Time horizon	Likely significant?	Justification
	contributing firms relative to competitors operating under different or overlapping instruments				multiple instruments relative to competitors subject to fewer; the competitive implications could depend on how these overlaps are resolved by the Conference of the Parties.
C. Burdensome regulations and international investment					
FDI and relocation effects ♦ ⁷⁶	Effects on location decisions for R&D and investment activity where the contribution creates jurisdiction-specific cost differentials relative to non-CBD-Party locations.	Indirect	Long-term	Cannot say	Production relocation is implausible at indicative rates given the scale of switching costs. R&D location effects are more plausible at the margin of new investment decisions given lower switching costs; however, Lichter et al. (2025) find that the primary firm response to a comparable profit tax burden is a modest reduction in R&D spending over an eight-year horizon rather than relocation, suggesting deliberate jurisdictional arbitrage is unlikely for most firm types. This finding may not extend to early-stage or emerging-market firms with more limited access to domestic risk capital, for whom relocation costs are lower and the relative burden of the contribution higher (Kreiken and Asveld, 2025).

Note: Symbol ♦ indicates impacts supported by the industry consultation or CBD Notification 2024-114 submissions. Impacts without a symbol are assessed on theoretical and structural grounds only.

⁷⁶ 5/8 consultation respondents answering report medium or large likelihood of shifting R&D abroad (remaining 5: 4 not applicable and 1 don't know). 3/8 responses reporting small likelihood.

7.6. Participation base and contribution burden by sector

Sections 7.6 to 7.14 apply the three-step framework set out in Section 7.5 across the seven indicative Enclosure I sectors. This section summarises the contribution burden by sector under the central scenario, which provides the quantitative anchor for the assessments that follow. Sections 7.7 to 7.13 present the Steps 1–3 analysis for each sector. Section 7.14 draws together the findings across sectors and pillars.

Table 23 summarises the scale of the participating base and estimated contribution burden by Indicative Enclosure I sector under the central scenario (S3)⁷⁷. The central scenario is used as the basis for the competitiveness assessment because it reflects realistic participation conditions calibrated from the literature, rather than the theoretical maximum under full compliance.

Table 23 Contribution burden by sector

Sector	Eligible firms	Participating revenue (USD billion)	Estimated contribution (USD million)	Contribution / revenue (%)
Pharmaceuticals	3,401	712	461	0.065
Biotechnology	3,709	365	178	0.049
Information and AI	5,217	191	103	0.054
Animal and plant breeding	4,256	164	63	0.038
Nutraceuticals	1,513	110	44	0.040
Laboratory equipment	2,846	77	46	0.060
Cosmetics	748	48	34	0.071
Total	21,690	1,668	929	0.056

Note: All figures reflect the central scenario (S3), which applies calibrated sector participation, ownership, and DSI intensity adjustments to the eligible firm population. Participating revenue and contribution estimates are means of 10,000 Monte Carlo draws.
Source: Makowska-Curran (2026), Table 22.

The effective contribution rate across the participating eligible population averages 0.056% of participating revenue, ranging from 0.038% in animal and plant breeding to 0.071% in cosmetics. This variation reflects differences in margin distributions across sectors rather than differences in the underlying rates themselves. Sectors with lower median margins have more profit-based payers, whose revenue-equivalent burden scales with margin under the minimum-of-two rule in Part II. For these firms, the effective rate as a share of revenue is always below the 0.1% headline rate, because the rule caps payment at the lower of the two indicative rates. The headline rates are therefore upper bounds, not typical burdens: a firm with a 5% margin faces a 0.05% revenue-equivalent rate, and firms with even lower margins face proportionally lower burdens. The minimum-

⁷⁷ The S3 estimate of participating revenues (USD 1,668 billion) is broadly consistent with the independent estimate of USD 1,560 billion from an early study for the CBD Secretariat (CBD, 2024d), commissioned to inform the COP16 DSI negotiations (i.e. prior to the implementation of the Decision 16/2). However, the two estimates are not directly comparable. The earlier study's figure covers total revenues across five DSI-using sectors and does not apply the financial thresholds in Decision 16/2 or any participation or ownership adjustments. This study's figure, by contrast, reflects only the total revenues of firms identified after applying the eligibility thresholds, adjusting for participation, and calibrating for DSI intensity. The similarity in totals is therefore partly coincidental: for this study's estimate, the threshold and DSI-intensity adjustments shrink the revenue base in a way that roughly offsets differences in sector coverage and methodology. This comparison thus provides only a coarse external plausibility check on the S3 calibration, not a direct validation. Sector-level differences are discussed in Makowska-Curran (2026).

of-two rule protects profit-base payers from the revenue rate but does not reduce their profit-equivalent burden below the indicative 1% rate.

To put these figures in context, the environmental regulation literature finds no statistically significant firm-level effects at compliance cost burdens five to ten times the revenue-equivalent burden here, though that evidence base draws primarily on energy-intensive sectors with different structural characteristics from DSI-using industries (Dechezleprêtre and Sato, 2017); see Section 7.4 for a full discussion. The contribution also sits well below the ITPGRFA MLS' benefit-sharing rate of approximately 0.77% of sales, the closest operational precedent, under which private sector payments remained negligible across fifteen years of implementation (Section 3).

These comparisons suggest the contribution is unlikely to generate large average competitive effects on average across eligible firms at indicative rates. The extent to which competitive effects materialise depends on the three asymmetries identified in Step 2 and the resolution of the design uncertainties in Table 2, both of which vary across sectors and are examined in the subsections below.

7.7. Pharmaceuticals

Characterisation of affected firms (steps 1 & 2)

The pharmaceutical sector contains 3,401 eligible firms and accounts for 49.6% of estimated contributions, far above its 26.3% share under full compliance (

Table 13 and

Figure 5). This shift reflects the sector's high participation calibration, high DSI intensity, and predominantly revenue-base paying population.

Sector and structural features

The pharmaceuticals sector outperforms all other Indicative Enclosure I sectors across all financial metrics in Part II, including the highest median revenue, assets, and profit margin. It is the only sector where the 25th percentile of profit meets or exceeds the Decision 16/2 profit threshold, indicating a broader distribution of financial capacity to contribute (Figure 3). With a median margin of 10.2% and 51% of eligible firms in the revenue-base group, its contribution profile is more stable and predictable than any other sector (

Table 12).

The pharmaceuticals sector, as defined here, includes firms primarily engaged in developing and manufacturing conventional small-molecule drugs through chemical synthesis, as well as biosimilar producers⁷⁸. For the

⁷⁸ Although biosimilars are produced using biological systems, they are classified here in this group rather than under biotechnology because of how they are positioned commercially: as follow-on products that enter the market once exclusivity has lapsed (e.g. from patents). They primarily compete through lower prices relative to an established reference product (i.e. biologics) rather than through innovation, which makes their competitive behaviour more similar to generics than to originator biologics.

purpose of this analysis, biologics drugs are captured under the biotechnological sector⁷⁹. The sector can be divided further into three groups based on DSI exposure and competitive dynamics: innovative pharmaceuticals, generics, and biosimilars.

Pharmaceuticals innovators, including innovative branded firms and vaccine manufacturers, operate in markets characterised by high R&D intensity and strong regulatory and reimbursement system influence; for innovative branded firms, competition also depends on patent-protected products (Danzon, Pereira and Tejawani, 2005; Golec and Vernon, 2006; Shaikh, Del Giudice and Kourouklis, 2021). These firms retain some pricing power, particularly in the US where price regulation is more limited than in Europe. There are indications that this advantage has weakened in recent years, as manufacturers have moderated list price increases and European regulators have increasingly constrained reimbursement prices (IQVIA, 2020), though the extent of this trend post-2020 across markets remains uncertain. This absorptive capacity is not, however, uniform across research-intensive producers, with vaccine producers presenting a structurally distinct case. Their supply is highly concentrated, and demand is primarily from national immunisation programmes and centralised procurement, rather than private buyers (Danzon, Pereira and Tejawani, 2005; Wilsdon *et al.*, 2020). Tender-driven vaccine markets can compress margins and weaken long-run investment and supplier incentives, which may make vaccine producers especially vulnerable to asymmetric competitive pressures (Wilsdon *et al.*, 2020). Among the top 50 global pharmaceutical companies by prescription sales in 2024, CBD Party-headquartered innovator firms spent approximately 21% of sales on R&D, comparable to the 26% recorded by US-headquartered firms (Pharmaceutical Executive, 2025). Note, however, that for research-intensive pharmaceutical firms contributing on the basis of revenue, the payment does not directly diminish post-tax R&D returns in the same way a profits tax would. The empirical evidence suggests that the link between revenue and R&D expenditure is weaker and more uncertain than is commonly presumed. For example, Dixit and David (2017) found across the ten biggest pharmaceutical companies by R&D spending, research and development outpaced revenue growth between 2005 and 2015. Moreover, when these firms experienced substantial revenue drops, they generally chose either to raise R&D spending or to cut it less aggressively than other types of expenditures. Looking at it from the opposite direction, the recent report of the Joint Committee on Taxation of the US Congress, found that the 2017 corporate tax cuts, which led to an approximately 8 percentage points increase in the industry's net margin, produced no material change in R&D spending. Vogel *et al.* (2024) also illustrate that a revenue loss of up to 4% of global pharmaceutical industry revenues (the harshest scenario under Medicare price negotiation) was not likely to trigger extensive R&D cutbacks.

Generics producers compete after patent expiry and are influenced by procurement conditions, substitution rules, and payer behaviour rather than advanced research. They operate in price-driven markets shaped by high substitution and procurement design which can limit margins and make cost recovery difficult (Magazzini, Pammolli and Riccaboni, 2004; Danzon and Furukawa, 2011). Unbranded generics manufacturers structurally earn slimmer margins than the sector median, with operating margins declining from about 20% to 13% between 2016 and 2019 due to persistent price pressure (KPMG, 2020). Within the broader sector, operating margins vary substantially by firm type: unbranded generics typically operate within a 4-12% range, branded generics within an 18-32% range, and still-on-patent innovator drugs within a 35-55% range (DrugPatentWatch, 2026). This within-sector asymmetry is relevant for the contribution assessment: the profit base is most likely to bind for unbranded generics producers, precisely those for whom the minimum-of-two rule's protective logic

⁷⁹ Note, however, that some biologics producers could be partially captured under the NACE codes used for pharmaceuticals in the contribution modelling.

applies. For generics, the main competitiveness issue is whether they can absorb additional costs in markets with highly elastic demand and in some cases, procurement constraints (Danzon and Furukawa, 2011; Mestre-Ferrandiz, Towse and Berdud, 2016).

Biosimilars producers occupy a structurally distinct position within the pharmaceutical sector. Unlike generics, biosimilar entry requires evidence of a high degree of similarity to the reference biologic based on comparability studies, which reflects the molecular complexity of biological products (McCamish, Yoon and McKay, 2016; Leber, 2018). The resulting regulatory track is more demanding and costly than for small-molecule generics, and commercialisation targeting hospitals and specialist prescribers rather than retail pharmacies⁸⁰ (Grabowski, Guha and Salgado, 2014; Mestre-Ferrandiz, Towse and Berdud, 2016; Moorkens *et al.*, 2016). All of these characteristics make competition more similar to branded products than unbranded generics. Biosimilars entry leads to price reductions for reference biologics, but the extent and pace of competition differ widely across markets. These differences are driven by reimbursement frameworks, prescriber behaviour, and supply-side policy design, rather than automatic substitution (Leber, 2018; Song *et al.*, 2025). For biosimilar producers, the main competitive challenge is sustaining investment for regulatory approval and market access, whilst reimbursement-driven price pressure on both originator and biosimilar products.

All firm groups face significant exposure to non-CBD-Party competitors due to the United States dominance in global pharmaceutical markets. US accounted for 53.2% of the global prescription drug market in 2024, with China a distant second at 7.0% (IQVIA, 2025). The sector is fairly concentrated at the top globally, with the ten largest firms accounting for 34.4% of global revenue (Evaluate, 2024). Notably, six of the ten largest firms are headquartered in CBD Party jurisdictions, with the rest based in the US. This suggests that the non-CBD-Party may be of significance for the entire sector, regardless of the firm type. There is a possibility that pharmaceuticals companies also could be subject to potential overlapping obligations through the WHO PIP Framework and the emerging Pandemic Agreement PABS system, especially for vaccine producers (Section 4.2). However, this would depend on the final design of the PABS system once negotiations on the Annex conclude.

Value chain position and DSI use intensity

Pharmaceutical innovators use DSI directly in pharmaceutical research and vaccine development, especially where pathogen sequence data inform health-related innovation (Hiemstra, Brink and Hintum, 2019; Klünker and Richter, 2022). This group is the clearest example of direct DSI use in the sector. Similarly, biosimilars require sequence-based structural characterisation to establish similarity to the reference biologic (Ranjan, 2025). For pharmaceutical innovators, the main competitiveness risk may lie less in the contribution payment itself than whether contributing provides genuine legal certainty over DSI use relative to US competitors who access the same publicly available data with no equivalent obligations (Klünker and Richter, 2022; Michiels *et al.*, 2022). For biosimilar producers, DSI use is more targeted, and the competitiveness concern may materialise primarily through the cost and regulatory burden of the characterisation process.

DSI dependence is weaker among generics. Generics firms are best understood as relatively downstream actors in a pharmaceutical innovation system where DSI is more important at earlier research and discovery stages of

⁸⁰ McGeeney *et. al* (2025) report that manufacturers retained 34-39% of net spending on generic small molecules compared to 60-67% on branded products and 62-68% on biosimilars, consistent with the more competitive pricing dynamics in generic markets.

innovations (Hiemstra, Brink and Hintum, 2019; Klünker and Richter, 2022). There is some evidence that sequence-based analysis is not required in their manufacturing process (Kathpalia H *et al.*, 2025; Ranjan, 2025). Hence, for generics producers, the competitiveness concern operates primarily via the direct cost burden of the contribution.

Expected contribution base

Pharmaceutical innovators pay predominantly on revenue. The contribution functions as an ad valorem levy, stable across earnings cycles. Within the generics, conventional, un-branded generic producers operate in highly competitive markets with margins consistently below 10%, which make them predominantly profit payers. For them the contribution scales directly with earnings and is more sensitive to margin compression. Branded generics face higher margins given stronger pricing power and brand-adjacent competitive dynamics; this places them in the revenue-base group. Biosimilar producers face higher entry costs and stricter regulation than unbranded generics and keep some pricing power versus reference biologics, implying margins above generic levels; however, reimbursement-driven price pressure and heterogeneous markets make margins hard to define, and contribution likely varies widely by firm size and portfolio.

The three asymmetries identified in Step 2 are reflected in the pillar assessments below: eligibility asymmetry is most significant given US market dominance across all firm types; participation asymmetry operates through first-mover dynamics given the non-binding design; and contribution base asymmetry is most relevant for unbranded generics, which pay on profit in markets with limited pass-through capacity.

Pillar assessment (step 3)

Table 24, Table 25, and Table 26 present the materiality assessment for Pillars I, II and III respectively, drawing on the sector characterisation in Section 0, the broader empirical literature findings in Section 7.4 and the analytical framework in Section 7.5.

The pharmaceutical sector presents a varied materiality profile, with most direct cost channels assessed as Low at indicative contribution rates. The principal risks are concentrated in three areas: structural competitive asymmetry with US-headquartered rivals, which generates High materiality for innovators on competitive position versus non-Party competitors; unresolved WHO PABS dual-framework obligations, which generate a second High materiality finding for innovators on international standards; and regulatory certainty for research-intensive producers given long pipeline horizons, which generates Moderate materiality on certainty and predictability. Within the sector, unbranded generics are the most directly cost-exposed firm type, given thin margins, limited pass-through capacity in procurement-driven markets, and a proportionality concern from the all-in contribution base despite weaker DSI dependence relative to innovators. Pharmaceuticals innovators benefit from high margins and some pricing power in patent-protected markets that limit direct cost burden exposure across Pillar I but face Moderate materiality in Pillar II driven by pipeline horizon sensitivity and vaccine producer exposure, and High materiality in Pillar III from structural competitive asymmetry with US rivals. Innovators retain moderate pass-through capacity in patent-protected markets, constrained by HTA and reference pricing across most European CBD Party markets. Biosimilar producers face moderate competitive position risk given the growing US biosimilar market, though brand-adjacent competition partially insulates.

Vaccine producers occupy a distinct position within the innovator group, facing compressed margins in tender-driven procurement and unresolved dual-framework obligations under WHO PABS⁸¹.

Where competitive impacts do materialise, their downstream effects are likely to differ by firm type. For research-intensive innovators, the main theoretical concern is that tighter margins could, at the margin, dampen pipeline investment, with potential consequences for the speed of drug development over long time periods; however, the evidence reviewed here indicates that large, well-capitalised companies do not scale back R&D in direct proportion to revenue shifts at burden levels of this size. For unbranded generics in procurement-driven markets with little scope to pass through costs, absorbing the additional cost is the more probable reaction, which may squeeze supplier margins. However, the non-binding nature of the scheme offers an important safeguard for this and other detrimental impacts. It also remains possible that some share of the contribution could be reflected in drug pricing for innovators with sufficient pricing power, particularly in less regulated markets such as the United States (where many of the firms in-scope also sell their products), although at the indicative rates considered this effect would be negligible relative to existing price-setting dynamics.

⁸¹ This would consider only pathogen with pandemic potential, not all vaccines produced.

Table 24 Pillar I: costs and price competitiveness impacts materiality assessment - Pharmaceuticals

Impact	Firm type	Magnitude	Probability	Key conditions	Materiality
Administrative burden Costs of calculating, reporting, and documenting the contribution. Low under current revenue/profit design as both bases use indicators already reported for tax and accounting. Significance rises substantially if scope shifts to product- or use-based attribution, requiring DSI tracking at product level.	Pharmaceuticals innovators	Minor	Low	Potential obligation stacking with WHO PABS (U7) may add administrative complexity for vaccine producers; contribution base definition (U12). For innovators, compliance burden uncertainty also operates through access to open sequence data and related compliance obligations, may raise competitiveness concerns beyond the contribution payment itself (Klünker and Richter, 2022; Michiels <i>et al.</i> , 2022).	Low
	Generics producers	Minor	Low	Contribution base definition (U12); lower multi-framework exposure than innovators	Low
	Biosimilars producers	Minor	Low	Sequence data is used in the biosimilar regulatory approval process; if this counts as DSI use under the Cali Fund, biosimilar producers face additional documentation obligations on top of an already demanding approval pathway. Contribution base definition (U12)	Low
Substantive compliance costs The contribution payment itself as a direct cost burden. Wide within-sector margin dispersion: innovator margins 35-55%, branded generics 18-32%, unbranded generics 4-12% (DrugPatentWatch, 2026) means the effective burden varies substantially. At indicative rates the absolute burden is small relative to sector revenues (0.065% of participating revenue, Table 20), but its competitive significance depends less on magnitude than on the asymmetry with non-contributing rivals and on pass-through capacity, both of which vary by firm type and are assessed below.	Pharmaceuticals innovators	Minor	Medium	For research-intensive producers paying on revenue, the contribution functions as a small ad valorem levy; at margins of 35-55%, the 0.1% revenue rate translates to well under 0.3% of profit, well below the cost burden thresholds at which firm-level competitiveness effects are typically detected (see Section 7.4). Rate revision; potential obligation stacking with WHO PABS (U7) elevates effective burden particularly for vaccine producers in tender-driven markets with compressed margins (Wilsdon <i>et al.</i> , 2020); US non-Party competitor presence (U10); entity definition for group structures (U3); subsidiary-level assessment enables contribution base minimisation through group restructuring for large multinationals.	Low
	Generics producers	Moderate	Medium	Unbranded generics: profit-base payers with margins 4-12%, making burden proportionally higher and more sensitive to margin compression (KPMG, 2020); limited pass-through capacity in procurement-driven markets (Danzon and Furukawa, 2011). Proportionality concern amplified by all-in contribution base: generics contribute on the same financial base as innovators despite weaker DSI dependence (U12). Branded generics: revenue-base payers with stronger pricing power; lower exposure. Other conditions: rate revision; US non-Party competitor presence (U10); entity definition (U3).	Moderate
	Biosimilars producers	Minor/Moderate	Medium	Biosimilar producers span a wide margin range: larger producers with stronger pricing power relative to reference biologics pay on revenue and face a minor burden comparable to innovators; smaller developers with thinner margins pay on profit and face proportionally higher exposure, though voluntary opt-out constrains severe outcomes for this group. Reimbursement-driven price pressure and heterogeneous	Low /Moderate

Impact	Firm type	Magnitude	Probability	Key conditions	Materiality
				market conditions across jurisdictions make the contribution base difficult to characterise at the sector level. Rate revision; potential obligation stacking (U7). Low for larger producers, moderate for thin-margin producers.	
Cost of capital Changes in cost or availability of financing from margin compression or reduced free cash flow. Large well-capitalised firms are least responsive to profit-burden changes of higher magnitude (see Section 7.4). Voluntary opt-out constrains severe outcomes.	Pharmaceuticals innovators	Minor	Low	Large well-capitalised firms least sensitive (Coles <i>et al.</i> , 2022); high margins (35-55%) provide buffer	Low
	Generics producers	Minor	Low	Unbranded generics more constrained given thin margins; branded generics less exposed.	Low
	Biosimilars producers	Minor	Low	Smaller biosimilar developers with high fixed development costs and limited retained earnings face somewhat higher exposure within this Low assessment.	Low
Cost of intermediate consumption Indirect cost increase if laboratory equipment firms pass Cali Fund contributions forward via input pricing. Materialises only where upstream firms participate and do not absorb the contribution.	Pharmaceuticals innovators	Minor	Low	Dependent on laboratory equipment sector participation and pass-on behaviour; direct vs indirect use boundary (U4) affecting laboratory equipment eligibility.	Low
	Generics producers	Minor	Low	Weaker supply chain link to sequencing and laboratory equipment given downstream position in innovation system (Hiemstra, Brink and Hintum, 2019); direct vs indirect use boundary (U4).	Low
	Biosimilars producers	Minor	Low	Sequence-based structural characterisation creates some laboratory equipment dependency; direct vs indirect use boundary (U4).	Low
Pass-through to consumers Extent to which contribution cost is transferred to customers via output pricing. 12/13 consultation respondents described customers as price-sensitive, constraining pass-through capacity. Feasibility depends on market structure, demand elasticity, and procurement design, which differ substantially across firm types.	Pharmaceuticals innovators	Moderate	Medium	Innovators: some pricing power in patent-protected markets and US market (more limited price regulation); constrained by HTA and reference pricing in European CBD Party markets (IQVIA, 2020). Vaccine producers: constrained pass-through in tender-driven centralised procurement (Wilsdon <i>et al.</i> , 2020). Many companies in this category also operate in the US which provides a potential pass-through channel. National implementation divergence (U8).	Moderate
	Generics producers	Minor	Low	Unbranded generics: structural barriers to cost recovery from procurement frameworks and substitution rules (Danzon and Furukawa, 2011; Mestre-Ferrandiz, Towse and Berdud, 2016). Branded generics: higher margins and pricing power provide more capacity. National implementation divergence (U8).	Low
	Biosimilars producers	Minor	Low	Reimbursement-driven price pressure on both originator and biosimilar products constrains pass-through; markets vary widely across jurisdictions (Leber, 2018; Song <i>et al.</i> , 2025). National implementation divergence (U8).	Low

Table 25 Pillar II: capacity to innovate impacts materiality assessment - Pharmaceuticals

Impact	Firm type	Magnitude	Probability	Key conditions	Materiality
R&D investment capacity Reduction in capital available for R&D through margin compression or reduced free cash flow. A comparable 1pp profit tax burden reduces R&D by ~6–7% over eight years (Lichter <i>et al.</i> , 2025); effects concentrated in financially constrained firms. Research-intensive producers pay predominantly on revenue, making the profit channel indirect; high margins provide additional buffer. Among top 50 global pharma firms, CBD Party-headquartered innovators spent ~21% of sales on R&D vs 26% for US firms (Pharmaceutical Executive, 2025).	Pharmaceuticals innovators	Moderate	Medium	Research-intensive producers direct approximately 21% of sales to R&D, creating meaningful sensitivity to any mechanism that affects free cash flow available for pipeline investment, even where the direct revenue-to-R&D link is weak. Long development horizons of 10-15 years mean marginal cost increases compound over time and may affect pipeline commitment decisions at the margin. Potential obligation stacking with WHO PABS raises effective burden for vaccine producers in tender-driven markets (U7); rate revision. Large well-capitalised firms are nonetheless least financially constrained at indicative rates (Coles <i>et al.</i> , 2022); and R&D spending among large pharmaceutical firms does not respond proportionally to revenue changes - revenue reductions substantially larger than the Cali Fund's indicative rates are not expected to result in large-scale R&D defunding (Dixit and David, 2017; Vogel <i>et al.</i> , 2024). Moderate magnitude reflects pipeline horizon sensitivity and vaccine producer exposure rather than a direct revenue-to-R&D transmission.	Moderate
	Generics producers	Minor	Low	Minimal R&D intensity for unbranded generics (compete on price after patent expiry); branded generics have some product development activity but shorter pipelines. Rate revision.	Low
	Biosimilars producers	Minor	Medium	Complex development requirements raise exposure relative to conventional generics; financially constrained biosimilar developers more at risk. Overall lower R&D intensity than innovators limits magnitude. Rate revision.	Low
Product innovation capacity Reduction in capital for development and commercialisation of new products via the same margin compression channel as R&D investment. Most significant for firms with long pipelines and high commercialisation costs. Innovation effects most pronounced for financially constrained firms (Atanassov and Liu, 2020; Lichter <i>et al.</i> , 2025)	Pharmaceuticals innovators	Moderate	Medium	Same channel as R&D investment capacity; additionally encompasses commercialisation costs across the full development pipeline from clinical trials through regulatory approval and market access, broadening the capital sensitivity beyond R&D spending alone. Long pipeline horizons of 10-15 years mean marginal capital constraints may affect product development commitments at the planning stage. Potential obligation stacking with WHO PABS (U7); rate revision. Innovation responses concentrated among financially constrained firms, with well-capitalised firms showing substantially smaller effects (Coles <i>et al.</i> , 2022; Lichter <i>et al.</i> , 2025). Moderate magnitude reflects full pipeline breadth and long horizon sensitivity rather than an expected direct reduction in product development spending.	Moderate
	Generics producers	Minor	Low	Conventional generics have no product innovation in the relevant sense. Branded generics have some formulation development activity but limited pipeline depth. Rate revision.	Low

Impact	Firm type	Magnitude	Probability	Key conditions	Materiality
	Biosimilars producers	Minor	Low	Biosimilar development affected at the margin; complex regulatory pathway for each new biosimilar creates some pipeline exposure. Rate revision.	Low
Access to risk capital Effect on ability to attract external financing for innovation where margin compression reduces perceived returns. Large well-capitalised firms are least exposed (Coles <i>et al.</i> , 2022). Voluntary opt-out constrains severe outcomes for firms facing material financing constraints.	Pharmaceuticals innovators	Minor	Low	Large well-capitalised innovators least exposed; high margins provide buffer. Rate revision.	Low
	Generics producers	Minor	Low	Limited innovation financing needs for unbranded generics; branded generics have some innovation financing needs; stronger margins than unbranded reduce exposure. Rate revision.	Low
	Biosimilars producers	Minor	Low	Smaller biosimilar developers reliant on external financing face somewhat higher exposure; voluntary opt-out limits' severe outcomes. Rate revision.	Low
Certainty and predictability Effect of unresolved Decision 16/2 design parameters on willingness to commit to long-term R&D investment pipelines. Non-binding design means uncertainty primarily deters participation rather than investment, but long pipeline horizons increase conditional sensitivity.	Pharmaceuticals innovators	Moderate	Medium	Long R&D horizons (10-15+ years) requiring regulatory certainty; certificate of contribution legal value (U6); potential WHO PABS overlap creating unresolved dual-framework uncertainty for vaccine producers (U7); Potential rate revision trajectory ahead of COP17.	Moderate
	Generics producers	Minor	Low	Shorter development horizons reduce sensitivity to long-run regulatory uncertainty; certificate legal value less central (U6). Rate revision.	Low
	Biosimilars producers	Minor	Low	Moderate pipeline horizons; uncertainty about how characterisation process obligations interact with contribution scope creates additional regulatory uncertainty for biosimilar developers beyond innovator exposure. Certificate legal value (U6); rate revision.	Low

Table 26 Pillar III: international competitiveness impacts materiality assessment - Pharmaceuticals

Impact	Firm type	Magnitude	Probability	Key conditions	Materiality
Competitive position vs non-Party competitors Direct cost asymmetry with competitors headquartered in non-CBD-Party jurisdictions, principally the US, which accounts for 53.2% of the global prescription drug market (IQVIA, 2025). Six of the ten largest pharma firms are CBD Party-headquartered; four are US-based (Evaluate, 2024) Competitiveness	Pharmaceuticals innovators	Moderate	High	US accounts for approx. 53.2% of global prescription market (IQVIA, 2025); non-Party firms not subject to equivalent obligations; national implementation divergence affecting competitive pressure (U8); participation asymmetry: competitive significance depends on the rate of participation among CBD Party-headquartered peers.	High
	Generics producers	Moderate	Medium	US generic market presence significant; procurement-driven markets partially limit commercial proximity of non-Party rivals; unbranded generics more exposed than branded given thinner margins and weaker capacity to absorb cost differentials. National implementation divergence (U8).	Moderate

Impact	Firm type	Magnitude	Probability	Key conditions	Materiality
risks arise primarily where non-Party rivals are close commercial substitutes (Fowlie, 2009; Dechezleprêtre and Sato, 2017).	Biosimilars producers	Moderate	Medium	US biosimilar market growing rapidly; contribution creates cost asymmetry with US-headquartered biosimilar producers not subject to equivalent obligations; reimbursement framework differences across markets create variable exposure. Brand-adjacent competition partially limits commercial proximity relative to innovators. National implementation divergence (U8).	Moderate
Export competitiveness Effects on export competitiveness where contribution cost cannot be fully passed through to export customers facing non-Party competition. Research-intensive producers have some pass-through capacity via price negotiation in regulated markets; generics and biosimilars face more constrained conditions in procurement-driven tender markets.	Pharmaceuticals innovators	Minor	Medium	Some pass-through capacity in export markets via regulated price negotiation; constrained in European CBD Party markets by HTA and reference pricing; vaccine producers most exposed in tender-driven export markets. National implementation divergence (U8); rate revision.	Low
	Generics producers	Moderate	Medium	Limited pass-through in price-driven export tender markets (Danzon and Furukawa, 2011); procurement design in destination countries constrains cost recovery; unbranded generics most exposed given thin margins and high price sensitivity of procurement buyers. National implementation divergence (U8); rate revision.	Moderate
	Biosimilars producers	Minor	Medium	Reimbursement-driven price pressure constrains export pass-through; market heterogeneity across jurisdictions creates variable exposure (Song <i>et al.</i> , 2025). National implementation divergence (U8).	Low
International standards and regulatory dialogues Divergence between the Cali Fund and other DSI-related instruments creates potential conflicting compliance requirements. Most significant for research-intensive producers and vaccine producers given WHO PABS overlap (Section 0).	Pharmaceuticals innovators	Moderate	Moderate	Potential WHO PABS overlap creates unresolved dual-framework obligations for vaccine producers and potentially biopharmaceutical innovators (U7); certificate of contribution recognition across frameworks (U6); national implementation divergence (U8).	Moderate
	Generics producers	Minor	Low	Limited multi-framework exposure; national implementation divergence (U8).	Low
	Biosimilars producers	Minor	Low	Uncertainty about how characterisation process obligations interact with contribution scope under any future product-attribution approach; some sensitivity to PABS framework if pathogen-adjacent biologics in portfolio. National implementation divergence (U8).	Low
FDI and relocation effects Effects on R&D and investment location decisions. Primary firm response to a comparable profit burden is spending reduction rather than relocation (Lichter <i>et al.</i> , 2025). Manufacturing relocation implausible given fixed infrastructure costs. R&D location effects plausible only at the margin of new investment decisions.	Pharmaceuticals innovators	Minor	Low	R&D location decisions at margin of new investment for globally distributed discovery operations; primary response is spending reduction not relocation (Lichter <i>et al.</i> , 2025); manufacturing relocation implausible. Rate revision.	Low
	Generics producers	Minor	Low	Manufacturing relocation implausible given fixed infrastructure costs; limited R&D base to relocate. Rate revision.	Low
	Biosimilars producers	Minor	Low	Manufacturing relocation implausible; some R&D location sensitivity for smaller developers with globally distributed operations. Rate revision.	Low

7.8. Biotechnology

Characterisation of affected firms (steps 1 & 2)

The biotechnology sector contains 3,709 eligible firms and accounts for 19.2% of the central estimate contributions (USD 179 million), the second largest sector share (

Table 13 and

Figure 5). With a median margin of 7%, most eligible firms pay on profit (Figure 4). The sector has greater variation in financial performance than pharmaceuticals with many loss-making or near-zero-margin firms alongside established producers with higher margins. Although firm-level data do not directly indicate development stage, the financial profiles of loss-making firms align with early-stage or pre-commercial ventures, which typically rely on external equity rather than internal cash flow - a pattern widely documented in the biotechnology literature (Golec and Vernon, 2006; DiMasi and Grabowski, 2007; Bruneo *et al.*, 2023).

The sectoral scope, as defined here, includes firms whose main business is applying biological systems, living organisms, or their derivatives to develop products, processes, or services. However, biotechnology is best viewed as a set of interconnected product and value-chain positions rather than a single market. Its sub-sectors differ significantly in product type, development costs, commercialisation timelines, regulatory requirements, and vertical specialisation (Craig Shimasaki, 2014; Wydra, 2019a). The sector as defined here includes four firm types: biopharmaceutical innovators, molecular diagnostics and clinical laboratory services, industrial biotechnology and biomanufacturing, and R&D service and platform organisations⁸² (Craig Shimasaki, 2014; Wydra, 2019b). Firms operating at the biotechnology interface whose primary activity is the development of computational tools, AI platforms, or data infrastructure for biological applications, including bioinformatics software providers and AI-driven sequence analysis platforms, are captured under the information and AI sector. Agricultural biotechnology is covered separately under animal and plant breeding.

Sector and structural features

Biopharmaceutical innovators, or originator biologics, operate in the most research-intensive segment of biotechnology, with high development costs comparable to those of pharmaceutical innovators, long development cycles, high project failure risk, and strong reliance on outsourcing (Cockburn, 2004; DiMasi and Grabowski, 2007; Enzing and Valk, 2010; Balconi and Lorenzi, 2017a). The market is mixed: with larger integrated firms remaining central to commercialisation of products, while smaller, financially constrained firms play a major role in upstream innovation through alliances (e.g. with universities or larger firms) and outsourcing (Cockburn, 2004; Balconi and Lorenzi, 2017a). According to the study by Popa *et al.* (2018a), the biopharmaceutical industry is R&D-intensive among the top-performing firms⁸³, with approximately 16% of sales being reinvested into R&D. The study further finds that this sub-industry exhibits a wide dispersion of net

⁸² The classification used in the contribution modelling presented in Part II use the NACE-based firm-level extraction from Makowska-Curran (2026), which broadly matches this scope but may (i) classify some conventional chemical manufacturers as industrial biotechnology and (ii) assign firms active in both pharmaceuticals and biotechnology to the pharmaceuticals sector according to their primary registered activity.

⁸³ The study looked at top 25 firms in the sector.

profit margins, which reflects the presence of early-stage innovators making losses, and highly profitable established firms. The median net profit margins were estimated at almost 17% from 2004 to 2016 (Popa *et al.*, 2018a). Biopharmaceuticals is now a leading and expanding segment of the wider pharmaceutical market. By 2022, the annual FDA approval rate for biologics exceeded that of small-molecule entities, and in 2021, 4 out of 10 of the highest-selling drugs globally were biologics (Urquhart, 2022; Senior, 2023). After patent expiry, biologics face strong competition from biosimilars, rather than generics (Lyman *et al.*, 2018; Carl *et al.*, 2022; Song *et al.*, 2025). Biosimilars entry has led to significant reductions in prices and expenditures in high-income countries. However, the level of competitive pressure varies widely across markets due to differences in regulatory frameworks, reimbursement mechanisms, and prescriber behaviour (Song *et al.*, 2025). Originator biologics face similar competition from the US rivals as pharmaceuticals, with the US capturing 48% of the global biologics market (Grand View Research, 2024).

Molecular diagnostics and clinical laboratory services operate in a large, fragmented market, with North America holding the largest regional share⁸⁴ (Fortune Business Insights, 2026b). Market position depends as much on coverage decisions, reimbursement pathways, and laboratory oversight frameworks as on the underlying test performance (Miller *et al.*, 2011; Klein, 2020; Sireci *et al.*, 2020). Firms in this sub-group may face prolonged price pressure on reimbursement resulting from regulatory changes to fee schedules. This dynamic is exemplified by the experience in the United States after the implementation of the Protecting Access to Medicare Act (PAMA), under which reimbursement rates were cut for 75% of clinical laboratory tests (Sireci *et al.*, 2020). Competition from non-CBD-Party firms is limited because diagnostics and laboratory services are mainly delivered domestically. However, detailed firm-level information needed to conduct a more granular competitiveness analysis for this sub-group is largely absent from publicly accessible data sources.

Industrial biotechnology and biomanufacturing compete primarily on process economics, engineering capability, and the ability to scale production (Clarke and Kitney, 2020; Biggs *et al.*, 2021). They manufacture chemicals, materials, biofuels, and other industrial inputs (Philp, Ritchie and Allan, 2013; Craig Shimasaki, 2014), and must compete against more mature petrochemicals (Philp, Ritchie and Allan, 2013; Kim *et al.*, 2026). Commodity chemicals produced through mature petrochemical pathways generally sell for less than USD 5 per kg, which makes it inherently difficult for bio-based alternatives to compete on price (Kim *et al.*, 2026). Additional investment in new bio-based manufacturing capacity is hindered by uncertain demand growth and exposure to fluctuating oil prices, both of which undermine reliable long-term financial planning (Kim *et al.*, 2026). The transition from research to large-scale commercial production is also problematic: downstream processing alone can represent 15-90% of total production costs, and scale-up continues to be a major economic constraint, especially for smaller companies (Clarke and Kitney, 2020; Biggs *et al.*, 2021; Asin-Garcia *et al.*, 2025). Industrial applications also differ substantially in volume and price, making market conditions highly product-specific (Wydra, 2019b).

R&D service and platform organisations, such as contract research organisations and other specialised service providers, contribute to biotechnology innovation mainly by offering research and technical capabilities, rather than by focusing on the commercialisation of end products (Dimachkie Masri *et al.*, 2012; Balconi and Lorenzi, 2017b). These companies benefit from outsourcing arrangements and vertical specialisation within biopharmaceutical and wider biotechnology innovation networks (Dimachkie Masri *et al.*, 2012). Their

⁸⁴ Commercial market size estimates for molecular diagnostics may encompass both laboratory equipment as well as clinical laboratory service providers. The distinction between these segments is not consistently clear in market research sources and could not be fully determined from the available data.

competitive advantage relies predominantly on their accumulated expertise and bargaining strength in contracts, rather than on conventional final-product price competition (Billette de Villemeur, Scannell and Versaevael, 2022). Contract research organisations and related service providers operate with structurally low margins because they function as cost-cutting intermediaries within the pharmaceutical value chain, in which individual service steps capture only a small share of the overall product value (Huang, 2019a).

Value chain position and DSI use intensity

DSI use is direct across all four biotechnology sub-groups, though its competitive significance differs by firm type. The biological sequence data are extensively used in commercial biotechnology innovation, as documented through patent citation analyses (Oldham, Hall and Forero, 2013; Bousfield *et al.*, 2016a). For industrial biotechnology firms, DSI is used directly in strain engineering and process characterisation (Abbate *et al.*, 2023). For molecular diagnostics companies, DSI is used mainly during assay design and validation, rather than in routine commercial manufacturing (Sireci *et al.*, 2020). In the case of R&D service and platform providers, these organisations both use and generate sequence data directly, but given they are upstream providers for biopharma and biotech clients, they can pass any contribution costs onto them (Huang, 2019b).

Expected contribution base

The sector's contribution base reflects its financial heterogeneity. With a median margin of 7%, most eligible firms pay on profit, with contributions scaling directly with earnings. Early-stage and pre-commercial firms are unlikely to meet the minimum-of-two threshold criteria and fall largely outside the eligible population. Established biopharmaceutical firms, with median net profit margins of approximately 17% (Popa *et al.*, 2018b), are revenue payers. For industrial biotechnology, margins vary substantially by product market, making a characterisation of the contribution base difficult. For molecular diagnostics and R&D service providers, available data are insufficient to determine the likely contribution base with confidence.

The three asymmetries identified in Step 2 are reflected in the pillar assessments below: eligibility asymmetry is most significant for biopharmaceutical innovators given US dominance of the global biologics market, and for industrial biotech firms competing against petrochemicals; participation asymmetry operates through first-mover dynamics given the non-binding design, with R&D service firms least exposed due to their ability to pass costs upstream to clients; and contribution base asymmetry is most relevant for industrial biotech and molecular diagnostics firms, which pay predominantly on profit in markets with limited pass-through capacity relative to the biopharmaceutical innovators paying on revenue.

Pillar assessment (step 3)

Table 27, Table 28, and Table 29 present the materiality assessment for Pillars I, II and III respectively, drawing on the sector characterisation in Section 7.8, the broader empirical literature findings in Section 7.4 and the analytical framework in Section 7.5.

The biotechnology sector's principal competitive risk lies in the structural asymmetry with US-headquartered rivals, which generates a high materiality finding for biopharmaceutical innovators on competitive position versus non-Party competitors given US dominance of the global biologics market. Most direct financial channels across Pillar I are assessed as Low for biopharmaceutical innovators, with the exception of pass-through capacity which is Moderate given some pricing power through reimbursement negotiations; Moderate materiality also arises for certainty and predictability given long development pipeline horizons and unresolved WHO PABS dual-framework uncertainty, and for R&D investment and product innovation capacity given high

R&D intensity and long development cycles. Industrial biotechnology and biomanufacturing firms are the most exposed firm type in Pillar I, where thin margins and competition against petrochemical benchmarks mean even small cost differentials are competitively significant. R&D service and platform organisations are the least exposed throughout, given their ability to pass contribution costs upstream to biopharma and biotech clients. Molecular diagnostics firms face limited competitiveness risk overall, given predominantly domestic service delivery and reimbursement-constrained markets where non-Party competitor exposure is low.

Where competitive effects do materialise, their downstream implications would vary by firm type. For biopharmaceutical innovators, the primary theoretical concern is that margin compression could affect biologics development pipelines at the margin, with potential implications for the pace of innovation in biological medicines over long time horizons; as with pharmaceutical innovators, however, large well-capitalised firms do not reduce R&D proportionally to revenue changes at burden levels of this magnitude, and early-stage innovators most sensitive to financing constraints fall largely outside the eligible population under the profit floor. For industrial biotechnology and biomanufacturing firms, the more immediate concern is competitive viability in commodity-adjacent markets where margins are already thin and bio-based alternatives compete against established petrochemicals; cost absorption rather than pass-through is the likely response, with the non-binding design providing a safeguard for the most exposed firms. The possibility that biopharmaceutical innovators pass some portion of the contribution into output pricing through reimbursement negotiations cannot be excluded, though at indicative rates this effect would be negligible relative to the scale of existing pricing dynamics in regulated biopharmaceutical markets.

Table 27 Pillar I: costs and price competitiveness impacts materiality assessment - Biotechnology

Impact	Firm type	Magnitude	Probability	Key conditions	Materiality
Administrative burden Costs of calculating, reporting, and documenting the contribution. Low under current revenue/profit design as both bases use indicators already reported for tax and accounting. Significance rises substantially if scope shifts to product- or use-based attribution, requiring DSI tracking at product level. All four biotech firm types use DSI directly, documented through patent citation analyses (Oldham, Hall and Forero, 2013; Bousfield et al., 2016b).	Biopharmaceutical innovators	Minor	Low	Potential obligation stacking with WHO PABS (U7) for pathogen-adjacent activities; contribution base definition (U12).	Low
	Molecular diagnostics and clinical laboratory services	Minor	Low	DSI use concentrated in assay design and validation rather than routine manufacturing (Sireci et al., 2020), limiting documentation burden; contribution base definition (U12).	Low
	Industrial biotechnology and biomanufacturing	Minor	Low	DSI used directly in strain engineering and process characterisation (Abbate et al., 2023); broad scope interpretation could require product-level DSI tracking; contribution base definition (U12).	Low
	R&D service and platform organisations	Minor	Low	These firms both use and generate sequence data directly; documentation burden may be lower given DSI is central to their core activity. Contribution base definition (U12).	Low
Substantive compliance costs The contribution payment itself as a direct cost burden. The sector median margin is 7% (Table 10), with most eligible firms paying on profit. Established biopharmaceutical firms with median net profit margins of approximately 17% (Popa et al., 2018b) are revenue-base payers facing a minor burden. Industrial biotech and R&D service firms with structurally lower margins face a proportionally higher profit-base burden. Early-stage and pre-commercial firms fall largely outside the eligible population under the two-of-three threshold rule.	Biopharmaceutical innovators	Minor	Medium	Established biopharmaceutical firms with median margins ~17% pay on revenue; burden minor as a share of revenue. Smaller financially constrained innovators more exposed but typically below the eligibility threshold. Rate revision; potential WHO PABS obligation stacking (U7); entity definition (U3).	Low
	Molecular diagnostics and clinical laboratory services	Minor	Medium	Reimbursement fee schedule pressure (e.g. PAMA cuts affecting 75% of US clinical laboratory tests, Sireci et al., 2020) already compresses margins; contribution adds to a constrained cost structure. Limited firm-level margin data available. Rate revision; entity definition (U3).	Low
	Industrial biotechnology and biomanufacturing	Moderate	Medium	Competing against mature petrochemical routes where commodity chemicals sell below USD 5/kg (Kim et al., 2026); even small cost differentials affect competitiveness. Downstream processing represents 15-90% of production costs, limiting margin headroom (Clarke and Kitney, 2020). Rate revision; entity definition (U3).	Moderate
	R&D service and platform organisations	Minor	Low	Structurally low margins as cost-cutting intermediaries in the pharma value chain (Huang, 2019a); upstream position enables pass-forward of contribution costs to biopharma and biotech clients (Huang, 2019b), limiting net burden. Rate revision; entity definition (U3).	Low
Cost of capital Changes in cost or availability of financing from margin compression or reduced free cash flow. Large well-capitalised firms are least responsive to profit-burden changes of higher magnitude (see Section 7.4). Voluntary	Biopharmaceutical innovators	Minor	Low	Established large biopharmaceutical firms least exposed; smaller innovators with limited retained earnings face somewhat higher exposure within this Low assessment. Rate revision.	Low
	Molecular diagnostics and clinical laboratory services	Minor	Low	Reimbursement-constrained margins increase sensitivity; voluntary opt-out limits severe outcomes. Rate revision.	Low

opt-out constrains severe outcomes. Early-stage loss-making firms are largely outside the eligible population under the profit floor.	Industrial biotechnology and biomanufacturing	Minor	Low	Scale-up financing needs are significant, but contribution burden is too small to materially affect creditworthiness at indicative rates. Voluntary opt-out limits severe outcomes. Rate revision.	Low
	R&D service and platform organisations	Minor	Low	Structurally low margins but reliance on contracted client relationships rather than capital-intensive innovation limits exposure. Rate revision.	Low
Cost of intermediate consumption Indirect cost increase if laboratory equipment firms pass Cali Fund contributions forward via input pricing. Biotechnology firms are among the primary users of sequencing and analytical equipment, making this channel more relevant here than in most other sectors. Materialises only where upstream firms participate and do not absorb the contribution.	Biopharmaceutical innovators	Minor	Medium	Strong supply chain dependence on sequencing and laboratory equipment; direct vs indirect use boundary (U4) affecting laboratory equipment eligibility.	Low
	Molecular diagnostics and clinical laboratory services	Minor	Medium	DSI use concentrated in assay design using laboratory equipment; direct vs indirect use boundary (U4).	Low
	Industrial biotechnology and biomanufacturing	Minor	Low	DSI use in strain engineering via sequencing tools; weaker ongoing dependence than biopharmaceutical innovators; direct vs indirect use boundary (U4).	Low
	R&D service and platform organisations	Minor	Low	These firms generate as well as use sequence data; partly within the laboratory equipment supply chain themselves. Direct vs indirect use boundary (U4).	Low
Pass-through to consumers Extent to which contribution cost is transferred to customers via output pricing. Pass-through capacity varies substantially across biotech firm types. Biopharmaceutical innovators have some capacity through reimbursement systems. Industrial biotech firms face price-sensitive industrial customers benchmarking against petrochemical routes, where pass-through is structurally constrained. R&D service firms can pass costs upstream to biopharma and biotech clients given their upstream value chain position (Huang, 2019b).	Biopharmaceutical innovators	Moderate	Medium	Moderate pass-through capacity through reimbursement and pricing negotiations; constrained in European CBD Party markets by HTA frameworks. National implementation divergence (U8).	Moderate
	Molecular diagnostics and clinical laboratory services	Minor	Low	Reimbursement fee schedules constrain pricing flexibility; competition from non-Party firms limited given predominantly domestic service delivery. National implementation divergence (U8).	Low
	Industrial biotechnology and biomanufacturing	Minor	Low	Price-sensitive industrial customers benchmarking against petrochemical routes (Kim et al., 2026) create structural barriers to pass-through; even small cost differentials affect procurement decisions. National implementation divergence (U8).	Low
	R&D service and platform organisations	Minor	Low	Upstream position enables pass-forward of contribution costs to biopharma and biotech clients (Huang, 2019b); overall pass-through capacity dependent on the degree of specialisation (e.g. stronger for specialist CROs); National implementation divergence (U8).	Low

Table 28 Pillar II: capacity to innovate impacts materiality assessment - Biotechnology

Impact	Firm type	Magnitude	Probability	Key conditions	Materiality
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R&D investment capacity Reduction in capital available for R&D through margin compression or reduced free cash flow. A comparable 1pp profit tax burden reduces R&D by ~6-7% over eight years, with effects concentrated in financially constrained firms (Lichter et al., 2025). Established biopharmaceutical innovators with median margins of ~17% are relatively insulated; industrial biotech and R&D service firms with thinner margins face higher exposure per unit of contribution.	Biopharmaceutical innovators	Moderate	Medium	High R&D intensity (~16% of sales, Popa et al., 2018a); long development cycles with high project failure risk (DiMasi and Grabowski, 2007); mix of large well-capitalised integrated firms (least exposed) and smaller financially constrained innovators (more at risk, Lichter et al., 2025); potential WHO PABS overlap (U7); rate revision.	Moderate
	Molecular diagnostics and clinical laboratory services	Minor	Low	Moderate R&D intensity; shorter development cycles than biopharmaceutical innovators; reimbursement constraints already compress margins available for R&D. Rate revision.	Low
	Industrial biotechnology and biomanufacturing	Minor	Low	Scale-up and process engineering R&D is significant but shorter-cycle than drug development; already constrained by uncertain demand growth and oil price exposure (Kim et al., 2026). Rate revision.	Low
	R&D service and platform organisations	Minor	Low	R&D is primarily contracted client work rather than proprietary pipeline investment; contribution burden limited given pass-forward capacity to clients (Huang, 2019b). Rate revision.	Low
Product innovation capacity Reduction in capital for development and commercialisation of new products via the same margin compression channel as R&D investment. Most significant for firms with long pipelines and high development costs. Innovation effects most pronounced for financially constrained firms.	Biopharmaceutical innovators	Moderate	Medium	Long development cycles and high project failure risk (DiMasi and Grabowski, 2007); mix of large integrated firms and financially constrained smaller innovators; rate revision; potential obligation stacking (U7).	Moderate
	Molecular diagnostics and clinical laboratory services	Minor	Low	Test development cycles shorter than drug development; reimbursement pathway uncertainty already a primary constraint on product commercialisation. Rate revision.	Low
	Industrial biotechnology and biomanufacturing	Minor	Low	Scale-up from research to large-scale production is a major independent constraint; contribution burden too small to materially add to existing commercialisation challenges at indicative rates (Clarke and Kitney, 2020). Rate revision.	Low
	R&D service and platform organisations	Minor	Low	Product innovation not the primary competitive model; services-based rather than product pipeline. Rate revision.	Low
Access to risk capital Effect on ability to attract external financing for innovation where margin compression reduces perceived returns. Most relevant for early-stage biopharmaceutical innovators reliant on external equity. Early-stage and loss-making firms are typically exempt under	Biopharmaceutical innovators	Minor	Low	Early-stage loss-making innovators are exempt under the profit floor; established firms with retained earnings least exposed; investor perception of regulatory environment may be affected at the margin. Rate revision.	Low
	Molecular diagnostics and clinical laboratory services	Minor	Low	Reimbursement-constrained financing environment already challenging; contribution burden minor relative to existing constraints. Rate revision.	Low

the profit floor and outside the eligible population, but the mechanism may affect investor perception of the sector's regulatory environment.	Industrial biotechnology and biomanufacturing	Minor	Low	Scale-up financing needs significant but contribution burden too small to materially affect investor decisions at indicative rates. Voluntary opt-out limits severe outcomes. Rate revision.	Low
	R&D service and platform organisations	Minor	Low	Contract-based business model reduces reliance on risk capital for innovation; limited exposure. Rate revision.	Low
Certainty and predictability Effect of unresolved Decision 16/2 design parameters on willingness to commit to long-term R&D investment pipelines. Non-binding design means uncertainty primarily deters participation rather than investment. Significant for biopharmaceutical innovators with long pipelines comparable to pharmaceutical innovators; low for industrial biotech and R&D service firms with shorter development cycles.	Biopharmaceutical innovators	Moderate	Medium	Long development pipelines where DSI access uncertainty and legal certainty around contribution obligations affect pipeline commitments; certificate of contribution legal value (U6); potential WHO PABS overlap (U7); potential rate revision trajectory ahead of COP17.	Moderate
	Molecular diagnostics and clinical laboratory services	Minor	Low	Shorter development horizons reduce sensitivity to long-run regulatory uncertainty; certificate legal value (U6); rate revision.	Low
	Industrial biotechnology and biomanufacturing	Minor	Low	Investment uncertainty already driven by oil price exposure and demand growth uncertainty (Kim et al., 2026); contribution regulatory uncertainty a secondary factor. Certificate legal value (U6); rate revision.	Low
	R&D service and platform organisations	Minor	Low	Contract-based model with shorter project horizons; regulatory uncertainty around mechanism design has limited impact on business pipeline. Certificate legal value (U6); rate revision.	Low

Table 29 Pillar III: international competitiveness impacts materiality assessment - Biotechnology

Impact	Firm type	Magnitude	Probability	Key conditions	Materiality
Competitive position vs non-Party competitors Direct cost asymmetry with competitors in non-CBD-Party jurisdictions. The US captures 48% of the global biologics market and dominates biopharmaceutical innovation globally (Grand View Research, 2024). Industrial biotech firms face non-Party competitors in petrochemical-route incumbents, many headquartered outside CBD Party jurisdictions. Competition from non-Party firms is limited for molecular diagnostics given predominantly domestic service	Biopharmaceutical innovators	Moderate	High	US captures 48% of global biologics market (Grand View Research, 2024); direct product-market competition with US-headquartered biopharmaceutical firms not subject to equivalent obligations; asymmetry permanent under current mechanism design; national implementation divergence (U8); participation rate among sector peers.	High
	Molecular diagnostics and clinical laboratory services	Minor	Low	Competition from non-Party firms limited given predominantly domestic service delivery and reimbursement-linked market access; national implementation divergence (U8).	Low
	Industrial biotechnology and biomanufacturing	Moderate	Medium	Competing against petrochemical-route incumbents where many major producers are headquartered outside CBD Party jurisdictions; even	Moderate

delivery; R&D service firms compete primarily on specialist expertise rather than price.				small cost differentials affect competitiveness in commodity-adjacent markets (Kim et al., 2026). National implementation divergence (U8).	
	R&D service and platform organisations	Minor	Low	Competitive advantage based on specialist expertise and contractual relationships rather than price; non-Party competitor presence less commercially significant. National implementation divergence (U8).	Low
Export competitiveness Effects on export competitiveness where contribution cost cannot be fully passed through to export customers facing non-Party competition. Most relevant for biopharmaceutical innovators and industrial biotech firms with significant cross-border activity; less relevant for molecular diagnostics and R&D service firms with more locally contracted business.	Biopharmaceutical innovators	Minor	Medium	Some pass-through capacity in regulated export markets; constrained by HTA and reference pricing in European CBD Party markets; US biologics market dominance limits pricing flexibility. National implementation divergence (U8); rate revision.	Low
	Molecular diagnostics and clinical laboratory services	Minor	Low	Predominantly domestic service delivery limits export competitiveness exposure. National implementation divergence (U8).	Low
	Industrial biotechnology and biomanufacturing	Moderate	Medium	Price-sensitive industrial buyers benchmarking against petrochemical alternatives in export markets; limited pass-through capacity (Kim et al., 2026); significant cross-border trade in bio-based chemicals and materials. National implementation divergence (U8); rate revision.	Moderate
	R&D service and platform organisations	Minor	Low	Contract-based cross-border services; competitive advantage based on expertise limits price-driven export competitiveness concerns. National implementation divergence (U8).	Low
International standards and regulatory dialogues Divergence between the Cali Fund and other DSI-related instruments. Most significant for biopharmaceutical innovators given potential WHO PABS overlap for pathogen-adjacent activities. Industrial biotechnology, molecular diagnostics, and R&D service firms have lower multi-framework exposure.	Biopharmaceutical innovators	Moderate	Medium	Potential WHO PABS overlap for pathogen-adjacent biopharmaceutical activities (U7); certificate of contribution recognition across frameworks (U6); national implementation divergence (U8).	Moderate
	Molecular diagnostics and clinical laboratory services	Minor	Low	Limited multi-framework exposure; national implementation divergence (U8).	Low
	Industrial biotechnology and biomanufacturing	Minor	Low	Limited multi-framework exposure; national implementation divergence (U8).	Low
	R&D service and platform organisations	Minor	Low	Limited multi-framework exposure; national implementation divergence (U8).	Low
FDI and relocation effects Effects on R&D and investment location decisions. Primary firm response to a comparable profit burden is spending	Biopharmaceutical innovators	Minor	Low	R&D location effects plausible at margin of new facility investment for innovators with globally distributed discovery operations; primary response is spending reduction not relocation (Lichter et al., 2025). Rate revision.	Low

reduction rather than relocation (Lichter et al., 2025). Manufacturing relocation implausible for industrial biotech given scale-up infrastructure requirements. R&D location effects plausible only at the margin of new investment decisions for biopharmaceutical innovators.	Molecular diagnostics and clinical laboratory services	Minor	Low	Predominantly domestic service delivery limits relocation incentives. Rate revision.	Low
	Industrial biotechnology and biomanufacturing	Minor	Low	Manufacturing relocation implausible given scale-up infrastructure requirements (Clarke and Kitney, 2020); R&D location effects limited. Rate revision.	Low
	R&D service and platform organisations	Minor	Low	Contract-based model with locally embedded client relationships limits relocation incentives. Rate revision.	Low

7.9. Animal and plant breeding

Characterisation of affected firms (steps 1 & 2)

The animal and plant breeding sector contains 4,256 eligible firms and accounts for 6.8% of estimated contributions, below its 10.7% share under full compliance (

Table 13 and

Figure 5). This decline reflects the sector's lower participation calibration and DSI intensity adjustment, which together reduce the participating revenue base substantially relative to the full eligible population. With a median margin of 7% and the widest interquartile range (IQR) (0.5% to 17.8%), the sector shows the greatest within-sector financial heterogeneity of any Indicative Enclosure I sector, which means that aggregate figures are less representative of individual firm experience here than elsewhere.

Sector and structural features

The sector divides naturally into two top-level groups, plant breeders and animal breeders, each with internal distinctions that matter for the competitiveness assessment.

Plant breeders, particularly those focused on broad-acre and field crops, operate in markets that are highly concentrated, shaped by large-scale private R&D investment, strong intellectual property protection, and extensive trait licensing⁸⁵ (Fuglie *et al.*, 2011; Howard, 2015; Bonny, 2017; Clancy and Moschini, 2017). Recent evidence from the US seed industry confirms that royalties for genetically engineered traits contribute materially to firm markups, with licensing between competitors a significant feature of market structure in this sector (Moschini and Perry, 2026). Plant breeders working with crops and forages listed in Annex I of the ITPGRFA face a narrower version of this risk: potential obligation stacking arises specifically where a firm accesses both physical material under the ITPGRFA's Multilateral System and DSI relating to the same genetic resource under the Cali Fund, rather than as a general feature of operating in this sector (see Obligation stacking, Section 4.2). The level of concentration in seed markets varies substantially by crop and country, while markets for biotech traits tend to be even more concentrated due to their high fixed R&D costs and the complementarities among seeds, traits, and crop-protection technologies (OECD, 2018; Deconinck, 2020). A small number of multinational firms accounts for the bulk of private R&D and controls most of the global proprietary seed market, with concentration having increased markedly in recent decades (Fuglie *et al.*, 2011; Howard, 2015; Bonny, 2017). The latest estimates from 2025 place the top five plant breeding companies as capturing 42.5% of the entire global market, with the United States being the dominating market (Global Market Insights, 2026b). This concentration extends beyond the largest firms: an independent analysis prepared for the ITPGRFA's Working Group to Enhance the Functioning of the Multilateral System found that the top 40 or so companies, classified as Tier 1 (over USD 500 million in sales) and Tier 2 (USD 100-500 million), together account for around 85% of the total seed market (IHS Markit Agribusiness Consulting, 2019). Recent evidence

⁸⁵ Trait licensing is the arrangement in which seed companies grant other firms the right to use particular genetic traits e.g. herbicide tolerance or insect resistance, in return for royalty payments. This system enables the trait developer to capture value through intellectual property rather than relying solely on selling seed directly.

suggests that private breeding remains focused primarily on widely cultivated, high-value crops, which helps clarify why commercial breeding efforts are most intensive in the major field-crop sectors rather than being spread evenly across plant breeding overall (Burris *et al.*, 2025). By contrast, vegetable and horticultural seed markets are more segmented by crop, trait, and end use, and depend more heavily on local adaptation and consumer preferences; it is inferred that they are also often poorly served by regulatory frameworks originally designed for cereals or other field crops rather than vegetables (Dias, 2014; Schreinemachers *et al.*, 2021; Kuhlmann *et al.*, 2023).

Animal breeders use a different appropriation model from plant breeders. In poultry and, to a lesser extent, other intensive livestock sectors, a few companies run tightly structured breeding pyramids⁸⁶ and distribute genetics via vertically managed multiplication chains⁸⁷, rather than relying primarily on formal intellectual property rights (Narrod and Fuglie, 2000; Neeteson *et al.*, 2023b). Their competitive strength comes from ownership of elite lines, control over multiplication, contractual marketing channels, and large stores of performance and genomic data (Narrod and Fuglie, 2000; Neeteson *et al.*, 2023b). By contrast, cattle AI and genomic systems follow a different commercial logic: they are characterised by a consolidated but less vertically integrated industry that revolves around semen collection and processing, cooperator herds, national genetic evaluation schemes, and export networks, with competitive advantage depending strongly on the size of reference populations and the associated evaluation datasets (Funk, 2006; Fugerey-Scarbel *et al.*, 2021; Van Eenennaam, 2025). The global animal genetics market shows moderate concentration, with several multinational corporations dominating the global breeding stock supply across cattle, poultry and swine (Grand View Research, 2026). Because trade in elite livestock genetics is highly internationalised and North America accounts for the largest share of global supply, contributing firms are likely to face material competition from US-headquartered rivals not subject to equivalent obligations. This inference follows from the structure of global genetics trade rather than from direct empirical evidence (Funk, 2006; Martyniuk and Haska, 2021; Grand View Research, 2026).

Value chain position and DSI use intensity

Plant and animal breeders are intensive, primary users of DSI. In plant breeding, sequence-derived data support genomic selection, genome-wide association studies, management of germplasm collections, and pre-breeding efforts in both field crops and horticulture (Aubry, 2019; Fugerey-Scarbel *et al.*, 2021). More specifically, DSI is combined with phenotypic data to identify genetic markers associated with traits of interest, which improves the precision of genomic selection and informs the choice of parent lines in developing new varieties (FAO, 2024). In major commercial animal breeding systems, genomic selection is embedded in routine selection programmes and increases the value of large genotyped and phenotyped reference populations, especially in poultry and cattle breeding (Fugerey-Scarbel *et al.*, 2021; Neeteson *et al.*, 2023b; Van Eenennaam, 2025).

Expected contribution base

With a sector median margin of 7% and a wide margin distribution, the contribution base varies considerably within the sector. Large seed multinationals and concentrated livestock breeding firms with margins above 10% pay on revenue; the majority of smaller breeders pay on profit. The wide profit margin range means the profit

⁸⁶ Breeding pyramid = a hierarchical system where a small number of elite animals at the top generate genetics distributed through multiplier tiers to commercial producers below (Neeteson *et al.*, 2023a).

⁸⁷ Multiplication chain = A network of licensed farms that produce and distribute commercial breeding stock from elite lines under contractual arrangements with the breeding firm (Neeteson *et al.*, 2023a).

floor applies to a meaningful tail of firms with very thin margins, where the minimum-of-two rule provides partial protection.

The three asymmetries identified in Step 2 are reflected in the pillar assessments below: eligibility asymmetry is most significant for large seed multinationals given US dominance of the global seed market, where the top five companies capture 42.5% of global sales, and for animal breeders given North America's dominant share of global animal genetics supply; participation asymmetry operates through first-mover dynamics given the non-binding design, with large seed multinationals facing the strongest reputational incentives to participate early; and contribution base asymmetry is most relevant for vegetable and horticultural breeders and smaller animal breeders, which pay predominantly on profit given margins below the 10% indifference threshold, in markets with limited pass-through capacity relative to large seed multinationals paying on revenue.

Pillar assessment (step 3)

Table 30,

Table 31, and

Table 32 present the materiality assessment for Pillars I, II and III respectively, drawing on the sector characterisation in Section 7.9, the broader empirical literature findings in Section 7.4 and the analytical framework in Section 7.5.

The animal and plant breeding sector presents a concentrated materiality profile, with most competitive impact categories assessed as Low and the principal risks focused on large seed multinationals facing structural asymmetry with US-headquartered rivals and multi-framework compliance uncertainty from potential ITPGRFA MLS obligation stacking. The High materiality finding for large seed multinationals on competitive position versus non-Party competitors reflects US dominance in the global seed market and the absence of equivalent obligations for US-headquartered competitors. Large seed multinationals face the most significant risks across Pillars II and III; vegetable and horticultural breeders and animal breeders are less exposed given more fragmented or locally oriented market structures, though animal breeders face Moderate competitive position risk given North American dominance of global animal genetics supply. The ABS literature identifies upstream governance effects, such as the fragmented germplasm access rules and traceability obligations, as a potentially more significant competitiveness concern for plant breeders than the contribution payment itself (Aubry, 2019; Ebert et al., 2023). The same difference in regulatory experience may cut the other way once any duplication risk with the ITPGRFA is resolved: plant breeders' familiarity with SMTA-style reporting and benefit-sharing procedures may make compliance under the Cali Fund smoother and faster, while animal breeders, who have no comparable ABS experience, may face a steeper learning curve regardless of their lower current exposure to stacking risk.

Where competitive effects do materialise, their downstream implications would be most significant for plant breeders. For large seed multinationals, the primary theoretical concern is that margin compression and regulatory uncertainty could affect long-horizon development programmes at the margin; however, large seed multinationals are among the most well-capitalised firms in the eligible population and are least financially constrained at indicative contribution rates. A more distinctive concern for this sector is the potential interaction between the Cali Fund and ITPGRFA MLS obligations, particularly in the genomics-assisted management of germplasm collections, which could affect access to germplasm and DSI used in breeding programmes independently of the contribution payment itself. This effect would fall disproportionately on CBD Party-headquartered breeders relative to US competitors not subject to the Cali Fund contributions. The same potential interaction applies to vegetable and horticultural breeders where their crops are covered by ITPGRFA Annex I, or where genebanks voluntarily share material through the SMTA regardless of formal Annex I status, which is a widespread practice for vegetable germplasm; this risk is not confined to field-crop breeders. For animal breeders and vegetable and horticultural breeders, cost absorption is the most likely firm-level response given limited pass-through capacity in price-sensitive agricultural markets; the non-binding design provides an important safeguard for the most margin-constrained firms in this sector.

Table 30 Pillar I: costs and price competitiveness impacts materiality assessment – Animal and plant breeding

Impact	Firm type	Magnitude	Probability	Key conditions	Materiality
Administrative burden Costs of calculating, reporting, and documenting the contribution. Low under current revenue/profit design. Significance rises substantially if scope shifts to product- or use-based attribution. Germplasm collection managers, already subject to the ITPGRFA MLS, could face an additional complexity in their use of DSI	Plant breeders (large seed multinationals)	Minor	Low	Potential obligation stacking with ITPGRFA MLS (U7): While the ITPGRFA MLS covers physical accessions, the now-routine use of genetic-based tools to manage germplasm collections could create some potential overlap for them in complying with the Multilateral Mechanism as well as the International Treaty. (Section 4.2) Potential obligation stacking with the MLS of the ITPGRFA can also occur for Non-Annex-I crops including vegetables, which are included in the MLS, e.g. materials from Article-15 collections (CGIAR and others); contribution base definition (U12). Upstream governance effects from fragmented access rules may raise transaction costs independent of the contribution (Aubry, 2019; Ebert et al., 2023).	Low
	Plant breeders (vegetable and horticultural)	Minor	Low	Contribution base definition (U12); ITPGRFA MLS overlap less material for horticultural varieties not covered by Annex I; lower multi-framework exposure than field crop breeders.	Low
	Animal breeders	Minor	Low	Lower multi-framework exposure than plant breeders; no ITPGRFA MLS overlap; contribution base definition (U12).	Low
Substantive compliance costs The contribution payment itself as a direct cost burden. The sector has a median margin of 7% and the widest interquartile range of any sector (0.5% to 17.8%), meaning aggregate figures are less representative of individual firm experience than elsewhere. Large seed multinationals with margins above 10% pay on revenue; the majority of smaller breeders pay on profit. The effective contribution rate is 0.038% of participating revenue, the lowest of any Indicative Enclosure I sector (Table 20).	Plant breeders (large seed multinationals)	Minor	Medium	Large seed multinationals with higher margins pay on revenue; burden modest relative to revenues. Potential obligation stacking with ITPGRFA MLS (U7) elevates effective burden; US non-Party dominance in seed market (top five companies: 42.5% global market share, Global Market Insights, 2026b) creates eligibility asymmetry; rate revision; entity definition (U3).	Low
	Plant breeders (vegetable and horticultural)	Minor	Medium	Potential ITPGRFA MLS obligation stacking (U7); more fragmented, lower-margin market with price-sensitive customers; profit-base payers more common; proportionality concern from all-in contribution base given variable DSI intensity across crop types (U12). Rate revision.	Low
	Animal breeders	Minor	Medium	Wide margin range across poultry, swine, and cattle breeding; large multinationals dominating genetics supply better placed to absorb burden; smaller breeders more exposed. North America accounts for largest share of global animal genetics supply (Grand View Research, 2026). Rate revision; entity definition (U3).	Low
Cost of capital Changes in cost or availability of financing from margin compression. Large well-capitalised firms are least responsive to profit-burden changes of higher magnitude (see Section 7.4). Voluntary	Plant breeders (large seed multinationals)	Minor	Low	Large seed multinationals with strong IP portfolios and licensing revenues least exposed. Rate revision.	Low
	Plant breeders (vegetable and horticultural)	Minor	Low	Smaller breeders and firms with constrained access to capital face somewhat higher exposure within this Low assessment; voluntary opt-out limits severe outcomes. Rate revision.	Low

opt-out constrains severe outcomes. The P25 margin of 0.5% indicates a meaningful tail of firms with very thin margins.	Animal breeders	Minor	Low	Smaller aquaculture and cattle AI firms with more constrained access to capital face somewhat higher conditional exposure. Rate revision.	Low
Cost of intermediate consumption Indirect cost increase if laboratory equipment firms pass Cali Fund contributions forward via input pricing. Plant and animal breeders use sequencing services and reagents extensively in genomic selection programmes, making this channel relevant.	Plant breeders (large seed multinationals)	Minor	Medium	Plant breeders using sequencing services and reagents in genomic selection face indirect cost exposure if laboratory equipment firms participate and pass costs forward; direct vs indirect use boundary (U4).	Low
	Plant breeders (vegetable and horticultural)	Minor	Low	Lower genomic intensity than large field crop breeders limits exposure; direct vs indirect use boundary (U4).	Low
	Animal breeders	Minor	Medium	Genomic selection embedded in routine selection programmes (Van Eenennaam, 2025) creates dependence on sequencing services; direct vs indirect use boundary (U4).	Low
Pass-through to consumers Extent to which contribution cost is transferred to customers via output pricing. Agricultural producer customers are price-sensitive; procurement design limits pass-through for both plant and animal breeders. Seed and genetics markets involve some degree of pricing power for major trait licensors, but farmer price sensitivity constrains the extent of pass-through.	Plant breeders (large seed multinationals)	Minor	Medium	Some pricing power through trait licensing and IP protection in concentrated seed markets (Moschini and Perry, 2026), but farmer price sensitivity constrains pass-through; royalty structures provide partial insulation. National implementation divergence (U8).	Low
	Plant breeders (vegetable and horticultural)	Minor	Low	More competitive, fragmented markets with price-sensitive customers; limited pass-through capacity. National implementation divergence (U8).	Low
	Animal breeders	Minor	Low	Genetics supplied through vertically managed multiplication chains (Neeteson et al., 2023b) with price-sensitive downstream customers; limited pass-through capacity. National implementation divergence (U8).	Low

Table 31 Pillar II: capacity to innovate impacts materiality assessment - Animal and plant breeding

Impact	Firm type	Magnitude	Probability	Key conditions	Materiality
R&D investment capacity Reduction in capital available for R&D through margin compression or reduced free cash flow. A comparable 1pp profit tax burden reduces R&D by ~6-7% over eight years, with effects concentrated in financially constrained firms (Lichter et al., 2025). Plant breeding has long programme horizons and high genomic R&D intensity; animal breeders have shorter selection cycles.	Plant breeders (large seed multinationals)	Moderate	Medium	Long variety development timelines (often 10+ years for field crops); high genomic R&D intensity; potential ITPGRFA MLS obligation stacking raises effective burden (U7); large seed multinationals least financially constrained but long pipeline commitments increase sensitivity; rate revision.	Moderate
	Plant breeders (vegetable and horticultural)	Minor	Low	Shorter development cycles for vegetable varieties; lower R&D intensity than field crop majors; financially constrained smaller breeders more at risk but often below eligibility threshold. Rate revision; potential ITPGRFA obligation stacking (U7).	Low
	Animal breeders	Minor	Low	Shorter selection cycles than plant breeding; genomic selection embedded in routine programmes rather than long-horizon R&D pipelines; large multinationals least financially constrained. Rate revision.	Low
Product innovation capacity Reduction in capital for development and commercialisation of new varieties and genetics. Most significant for firms with long breeding programme commitments and high genomic investment. Innovation effects most pronounced for financially constrained firms (Atanassov and Liu, 2020; Lichter et al., 2025).	Plant breeders (large seed multinationals)	Moderate	Medium	Long variety development timelines and high commercialisation costs; large seed multinationals least financially constrained; potential ITPGRFA MLS obligation stacking (U7); rate revision.	Moderate
	Plant breeders (vegetable and horticultural)	Minor	Low	Shorter development cycles; product innovation more locally driven and less capital-intensive than field crop breeding. Rate revision; potential ITPGRFA MLS obligation stacking (U7)	Low
	Animal breeders	Minor	Low	Genetic improvement cycles shorter than plant variety development; competitive advantage based more on data and elite line ownership than long-horizon product pipelines. Rate revision.	Low
Access to risk capital Effect on ability to attract external financing for innovation where margin compression reduces perceived returns. Large well-capitalised firms are least exposed (Coles et al., 2022). Voluntary opt-out constrains severe outcomes.	Plant breeders (large seed multinationals)	Minor	Low	Large seed multinationals with strong IP portfolios and licensing revenues least exposed. Rate revision.	Low
	Plant breeders (vegetable and horticultural)	Minor	Low	Smaller breeders with constrained access to capital face somewhat higher exposure within this Low assessment; voluntary opt-out limits severe outcomes. Rate revision.	Low
	Animal breeders	Minor	Low	Smaller aquaculture and cattle AI firms with constrained capital access face somewhat higher conditional exposure. Rate revision.	Low
Certainty and predictability Effect of unresolved Decision 16/2 design parameters on willingness to commit to long-term breeding programme	Plant breeders (large seed multinationals)	Moderate	Medium	Long breeding programme commitments where DSI access uncertainty and ITPGRFA MLS stacking resolution (U7) affect pipeline decisions; certificate of contribution legal value (U6); potential rate revision trajectory ahead of COP17.	Moderate

investments. Non-binding design means uncertainty primarily deters participation rather than investment. Significant for large seed multinationals with long programme commitments and ITPGRFA stacking uncertainty.	Plant breeders (vegetable and horticultural)	Minor	Low	Shorter development horizons reduce sensitivity to long-run regulatory uncertainty; ITPGRFA MLS stacking exposure. Certificate legal value (U6); rate revision.	Low
	Animal breeders	Minor	Low	Shorter selection cycles limit sensitivity to long-run regulatory uncertainty; no ITPGRFA stacking exposure. Certificate legal value (U6); rate revision.	Low

Table 32 Pillar III: international competitiveness impacts materiality assessment - Animal and plant breeding

Impact	Firm type	Magnitude	Probability	Key conditions	Materiality
Competitive position vs non-Party competitors Direct cost asymmetry with competitors headquartered in non-CBD-Party jurisdictions. The US dominates the global seed market, with the top five companies capturing 42.5% of global sales (Global Market Insights, 2026b). North America accounts for the largest share of global animal genetics supply (Grand View Research, 2026). Competitiveness risks arise primarily where non-Party rivals are close commercial substitutes (Fowlie, 2009; Dechezlepretre and Sato, 2017).	Plant breeders (large seed multinationals)	Moderate	High	US dominance in global seed market (42.5% top five market share, Global Market Insights, 2026b); direct competition with US-headquartered seed multinationals not subject to equivalent Cali Fund obligations; asymmetry permanent under current mechanism design; national implementation divergence (U8).	High
	Plant breeders (vegetable and horticultural)	Minor	Medium	More fragmented market with higher proportion of CBD Party-based competitors; US dominance less pronounced than in field crops; non-Party exposure varies by crop and market. National implementation divergence (U8).	Low
	Animal breeders	Moderate	Medium	North America's dominant share of global animal genetics supply creates material non-Party asymmetry (Grand View Research, 2026); inference from global genetics trade structure rather than direct empirical evidence (Martyniuk and Haska, 2021). National implementation divergence (U8).	Moderate
Export competitiveness Effects on export competitiveness where contribution cost cannot be fully passed through to export customers facing non-Party competition. Seed and genetics trade is global; both plant and animal breeders have significant export activity with price-sensitive agricultural customers.	Plant breeders (large seed multinationals)	Minor	Medium	Global seed trade with price-sensitive agricultural producer customers; limited pass-through capacity constrains export cost recovery; potential ITPGRFA MLS stacking may compound export burden for crops covered by both instruments (U7). National implementation divergence (U8); rate revision.	Low
	Plant breeders (vegetable and horticultural)	Minor	Medium	Export activity significant for major vegetable seed suppliers; price-sensitive export markets; limited pass-through capacity. National implementation divergence (U8); rate revision; Potential ITPGRFA MLS obligation stacking also applies to vegetable and horticultural crops covered by Annex I or shared voluntarily through the SMTA, though exposure varies by crop and by genebank practice	Low
	Animal breeders	Minor	Medium	Elite livestock genetics trade highly internationalised; export competitiveness depends on reference population size and genomic data advantage rather than price alone, partially insulating from cost asymmetry; North America supply dominance limits pass-through in destination markets. National implementation divergence (U8); rate revision.	Low
International standards and regulatory dialogues Divergence between the Cali Fund and other DSI-related instruments. Most significant for plant breeders given multi-framework environment navigating	Plant breeders (large seed multinationals)	Moderate	Medium	Multi-framework environment with ITPGRFA covering physical material under the ITPGRFA's Multilateral System (listed in Annex I (U7); certificate of contribution recognition across frameworks (U6); national implementation divergence (U8); US non-Party competitors not subject to equivalent multi-framework obligations, compounding asymmetry.	Moderate

potential DSI-based ITPGRFA obligations for crops covered by both instruments in the future.	Plant breeders (vegetable and horticultural)	Minor	Low	Multi-framework environment with ITPGRFA covering physical material under the ITPGRFA's Multilateral System (listed in Annex I (U7); national implementation divergence (U8).	Moderate
	Animal breeders	Minor	Low	No ITPGRFA overlap; limited multi-framework exposure; national implementation divergence (U8).	Low
FDI and relocation effects Effects on R&D and investment location decisions. Primary firm response to a comparable profit burden is spending reduction rather than relocation (Lichter et al., 2025). R&D location effects possible for large seed multinationals with distributed plant breeding research operations, though low probability at indicative rates.	Plant breeders (large seed multinationals)	Minor	Low	R&D location effects possible for large seed multinationals with distributed plant breeding research operations; primary response is spending reduction not relocation (Lichter et al., 2025). Rate revision.	Low
	Plant breeders (vegetable and horticultural)	Minor	Low	Limited R&D base to relocate; local adaptation requirements constrain relocation. Rate revision.	Low
	Animal breeders	Minor	Low	Elite line ownership and reference population data are geographically embedded; relocation implausible. Rate revision.	Low

7.10. Nutraceuticals

Characterisation of affected firms (steps 1 & 2)

The nutraceuticals sector contains 1,513 eligible firms and accounts for 4.7% of estimated contributions, below its 6.5% share under full compliance (

Table 13 and

Figure 5). With the lowest median margin of any sector at 4%, virtually all eligible firms pay on profit. The sector's thin margin profile means the profit-base burden is proportionally higher relative to earnings than in most other sectors, despite the low absolute contribution rate.

Sector and structural features

The sector is wide-ranging and diverse, covering vitamins and minerals, herbal supplements, functional foods, and probiotic products. For the purpose of this analysis, it is treated as one competitiveness group for the pillar assessments, with two internal distinctions flagged where they are analytically material (botanical supplement producers and probiotic and microbial supplement producers).

Across jurisdictions, nutraceutical products may be categorised as foods, natural health products, or therapeutic goods under different regulatory regimes, which makes the regulatory classification a key source of competitive advantage (Hobbs, Malla and Sogah, 2014; Dwyer, Coates and Smith, 2018; Djaoudene *et al.*, 2023). The United States is a major market for the sector (Djaoudene *et al.*, 2023; Wallace and Koturbash, 2025). It also serves as a key reference market for potential international competitiveness impacts: under DSHEA⁸⁸, dietary supplements are not subject to premarket efficacy approval, enabling a large and commercially accommodating sector that contrasts significantly with the more restrictive regulatory approaches in Europe (Bailey, 2020; Wallace and Koturbash, 2025). In addition to regulation, nutraceutical markets appear to be shaped more by product credibility and quality signalling than by pure price competition (Hobbs, 2002a; Hobbs, Malla and Sogah, 2014).

Value chain position and DSI use intensity

Nutraceutical firms are largely downstream consumer-facing producers. DSI dependence seems to vary within the sector and is presumably lower on average than in pharmaceuticals or biotechnology. With credible information missing for the broader functional foods and supplements, two clearly DSI-reliant sub-groups can be identified: botanical supplements and probiotic and microbial supplement producers. The former group may be more DSI-dependent than the sector average because cross-border sourcing of variable plant materials makes species identification, authentication, and quality assurance commercially important (Franz *et al.*, 2011; Shipkowski *et al.*, 2018). The latter group emerges as the most evident direct users of DSI, because strain

⁸⁸ The Dietary Supplement Health and Education Act of 1994 (DSHEA).

identification, taxonomy, and label verification commonly use targeted PCR⁸⁹ and high-throughput sequencing (Morovic *et al.*, 2016; Shehata and Newmaster, 2020).

Expected contribution base

With a median margin of 4% and virtually all eligible firms in the profit-base group, the contribution scales directly with earnings across the sector. Thin margins mean the sector has the highest profit-equivalent burden of any Indicative Enclosure I sector outside cosmetics. The proportionality concern is particularly relevant for supplement producers with low or no direct DSI use.

The three asymmetries identified in Step 2 are reflected in the pillar assessments below: eligibility asymmetry is most significant given the presence of a large US-based non-Party competitor base operating under DSHEA's accommodating regulatory environment, which creates a cost asymmetry across all firm types; participation asymmetry operates through first-mover dynamics given the non-binding design, with firms facing thin margins most likely to opt out rather than absorb the burden; and contribution base asymmetry is less differentiated within this sector than elsewhere, as most eligible firms pay on profit given the sector median margin of 4%, making the burden uniformly sensitive to earnings fluctuations across firm types.

Pillar assessment (step 3)

Table 33,

⁸⁹ Polymerase Chain Reaction.

Table 34, and

Table 35 present the materiality assessment for Pillars I, II and III respectively, drawing on the sector characterisation in Section 7.10, the broader empirical literature findings in Section 7.4 and the analytical framework in Section 7.5.

The nutraceuticals sector faces Moderate materiality primarily on Pillar I substantive compliance costs, driven by the sector's thin median margins (4%, the lowest of any Indicative Enclosure I sector) and the proportionality concern arising from the all-in contribution base. Most eligible firms pay on profit, and the contribution imposes the same financial base on firms with limited DSI use as on those for whom DSI is central to product development - a structural feature that distinguishes this sector from more research-intensive Indicative Enclosure I sectors. The two DSI-intensive sub-groups, botanical supplement producers and probiotic and microbial supplement producers, face lower proportionality concerns but remain exposed through thin margins. Competitive position versus non-Party competitors is assessed as Low, reflecting the significant presence of European CBD Party-based competitors in the sector and the quality-signalling rather than price-based nature of competition in differentiated segments, which partially insulates from cost-based asymmetry. Across all pillars, the voluntary opt-out constrains severe outcomes: firms facing material cost pressure would likely choose non-participation over absorption.

Where competitive effects do materialise, their principal downstream consequence would be cost absorption rather than pass-through, given the limited pricing power of most nutraceuticals producers in consumer-facing markets. For firms with the thinnest margins, sustained cost pressure could affect market participation decisions over time, though the voluntary design means that firms facing material cost pressure would rationally choose non-participation rather than absorb unviable contributions. The proportionality concern is the most policy-relevant downstream risk: firms with limited or no direct DSI use contributing on the same financial base as DSI-intensive sub-groups face a burden that is not commensurate with their benefit from the DSI commons, which may affect participation decisions and the representativeness of the contributing population. Pass-through to consumers is constrained across most market segments given price sensitivity, with partial exceptions for premium and authenticated products where quality signalling supports some pricing flexibility.

Table 33 Pillar I: costs and price competitiveness impacts materiality assessment – Nutraceuticals

Impact	Firm type	Magnitude	Probability	Key conditions	Materiality
Administrative burden Costs of calculating, reporting, and documenting the contribution. Low under current revenue/profit design as both bases use indicators already reported for tax and accounting. Significance rises if scope shifts to product- or use-based attribution. DSI dependence varies within the sector: most producers have limited direct DSI use, while botanical supplement and probiotic sub-groups use DSI more intensively in authentication and strain characterisation.	Nutraceuticals producers	Minor	Low	Contribution base definition (U12). Proportionality concern most acute for firms with no direct product-level DSI reliance contributing on the same financial base as DSI-intensive sub-groups. Botanical supplement producers: species identification and quality assurance using sequence data (Franz et al., 2011; Shipkowski et al., 2018). Probiotic and microbial supplement producers: strain identification and label verification using targeted PCR and high-throughput sequencing (Morovic et al., 2016; Shehata and Newmaster, 2020).	Low
Substantive compliance costs The contribution payment itself as a direct cost burden. With a median margin of 4%, the lowest of any Indicative Enclosure I sector, virtually all eligible firms pay on profit. The profit-base burden is proportionally higher relative to earnings than in most other sectors, despite the low absolute contribution rate. Proportionality concern particularly relevant for firms with limited or no direct DSI use contributing on the same total financial base as DSI-intensive sub-groups (U12).	Nutraceuticals producers	Moderate	Medium	Thin margins (sector median 4%) mean profit-base contribution scales directly with earnings and is sensitive to margin compression; proportionality concern most acute for general producers with limited DSI dependence (U12). Consumer-facing markets shaped more by product credibility than price competition (Hobbs, Malla and Sogah, 2014), providing limited but partial pass-through capacity for premium segments. Botanical and probiotic sub-groups: lower proportionality concern given higher DSI intensity, but thin margins still mean a proportionally high profit-base burden. Rate revision.	Moderate
Cost of capital Changes in cost or availability of financing from margin compression or reduced free cash flow. Thin margins (4% sector median) create the most plausible cost of capital exposure of any Indicative Enclosure I sector. Voluntary opt-out constrains severe outcomes: firms facing material financing constraints would rationally choose non-participation.	Nutraceuticals producers	Minor	Low	Thin margins create most plausible cost of capital exposure within this Low assessment; voluntary opt-out means firms facing material constraints would choose non-participation over absorption. Rate revision.	Low
Cost of intermediate consumption Indirect cost increase if laboratory equipment firms pass Cali Fund contributions forward via input pricing. Relevant primarily for botanical and	Nutraceuticals producers	Minor	Low	Botanical supplement producers: some sequencing equipment use in species authentication. Probiotic and microbial supplement producers: PCR and sequencing equipment used in strain identification. General producers: limited laboratory equipment dependence. Direct vs indirect use boundary (U4).	Low

probiotic sub-groups that use sequencing equipment in authentication or strain characterisation; limited for most general nutraceuticals producers.					
Pass-through to consumers Extent to which contribution cost is transferred to customers via output pricing. Consumer-facing markets with moderate price sensitivity. Some pass-through plausible for premium or differentiated products; limited for commodity segments. Markets shaped more by product credibility and quality signalling than pure price competition (Hobbs, 2002a; Hobbs, Malla and Sogah, 2014).	Nutraceuticals producers	Minor	Low	Commodity segments face price-sensitive consumers with limited pass-through capacity; premium and authenticated products have more flexibility. National implementation divergence (U8).	Low

Table 34 Pillar II: capacity to innovate impacts materiality assessment – Nutraceuticals

Impact	Firm type	Magnitude	Probability	Key conditions	Materiality
R&D investment capacity Reduction in capital available for R&D through margin compression or reduced free cash flow. The nutraceuticals sector has limited R&D intensity relative to pharmaceuticals or biotechnology. No close payment-burden analogues identified in the sector-specific literature; assessment relies on broad cross-sectoral evidence (Section 7.4).	Nutraceuticals producers	Minor	Low	Limited R&D intensity across the sector; short product development cycles; thin margins increase conditional sensitivity but voluntary opt-out constrains severe outcomes. Probiotic sub-group: moderate R&D intensity in strain development relative to sector average; still limited compared to pharmaceuticals. Rate revision.	Low
Product innovation capacity Reduction in capital for development and commercialisation of new products via the same margin compression channel as R&D investment. Innovation cycles are shorter than in pharmaceuticals or biotechnology. Innovation effects most pronounced for financially constrained firms (Atanassov and Liu, 2020; Lichter et al., 2025).	Nutraceuticals producers	Minor	Low	Short product development cycles; limited capital intensity of product innovation relative to pharmaceuticals; thin margins increase conditional sensitivity but voluntary opt-out constrains severe outcomes. Rate revision.	Low
Access to risk capital Effect on ability to attract external financing for innovation where margin compression reduces perceived returns. Thin margins (4% sector median) create the highest conditional exposure of any sector within the Low assessment. Voluntary opt-out constrains severe outcomes.	Nutraceuticals producers	Minor	Low	Thin margins create most plausible risk within the Low assessment; voluntary opt-out means firms facing material constraints would choose non-participation. Rate revision.	Low
Certainty and predictability Effect of unresolved Decision 16/2 design parameters on willingness to commit to product development investments. Non-binding design means uncertainty primarily deters participation rather than investment. Limited sensitivity given short product development cycles.	Nutraceuticals producers	Minor	Low	Short product cycles reduce sensitivity to long-run regulatory uncertainty; certificate of contribution legal value (U6); rate revision.	Low

Table 35 Pillar III: international competitiveness impacts materiality assessment - Nutraceuticals

Impact	Firm type	Magnitude	Probability	Key conditions	Materiality
Competitive position vs non-Party competitors Direct cost asymmetry with competitors headquartered in non-CBD-Party jurisdictions. The United States is a major market under DSHEA's accommodating regulatory environment (Wallace and Koturbash, 2025), enabling a large commercially active non-Party competitor base. Competitiveness risks arise primarily where non-Party rivals are close commercial substitutes (Fowlie, 2009; Dechezlepretre and Sato, 2017).	Nutraceuticals producers	Minor	Medium	US DSHEA regulatory environment supports a large non-Party competitor base; nutraceutical markets shaped more by product credibility and quality signalling than price (Hobbs, Malla and Sogah, 2014), partially insulating from cost-based asymmetry. European CBD Party-based competitors form a significant part of the competitive landscape, limiting the non-Party asymmetry relative to sectors dominated by US firms. National implementation divergence (U8).	Low
Export competitiveness Effects on export competitiveness where contribution cost cannot be fully passed through to export customers facing non-Party competition. Consumer-facing markets with moderate price sensitivity; some pass-through plausible for premium differentiated products.	Nutraceuticals producers	Minor	Low	Consumer-facing export markets with moderate price sensitivity; limited pass-through capacity for commodity segments; premium and authenticated products more insulated. National implementation divergence (U8).	Low
International standards and regulatory dialogues Divergence between the Cali Fund and other DSI-related instruments. Limited multi-framework DSI exposure for nutraceuticals; no potential ITPGRFA or WHO PABS overlap. The primary regulatory divergence risk is asymmetric national classification of nutraceutical products across jurisdictions, which is a pre-existing competitive factor.	Nutraceuticals producers	Minor	Low	Limited multi-framework DSI exposure; national implementation divergence (U8); regulatory classification divergence across jurisdictions a pre-existing competitive factor independent of the Cali Fund.	Low
FDI and relocation effects Effects on R&D and investment location decisions. Limited R&D base to relocate; manufacturing relocation implausible given consumer-facing product nature and regulatory classification requirements across jurisdictions.	Nutraceuticals producers	Minor	Low	Manufacturing relocation implausible; limited R&D base to relocate; regulatory classification requirements in destination markets constrain location flexibility. Rate revision.	Low

7.11. Information and AI

Characterisation of affected firms (steps 1 & 2)

The information and AI sector contains 5,217 eligible firms, the largest eligible population of any sector, but accounts for only 11.1% of estimated contributions, down sharply from 25.2% under full compliance (

Table 13 and

Figure 5). This is the largest absolute decline in contribution share between full compliance and the central scenario of any sector, reflecting the sector's low participation calibration and DSI intensity adjustment. With a median margin of 6%, most eligible firms pay on profit, and the sector has the highest zero-contributor share across all Indicative Enclosure I sectors.

Sector and structural features

The sector is best conceptualised as a technical services layer rather than a traditional product market. Firms operating in this space deliver data access, computing resources, workflows, curation, and interpretive services that support downstream life-science research and product development across pharmaceuticals, biotechnology, diagnostics, and adjacent fields (Grossman, 2019; Harrow *et al.*, 2021).

Market structure is difficult to characterise precisely given the sector's breadth. The upper segment is dominated by large, US-based cloud and platform providers. The three main cloud and platform companies, namely AWS, Google Cloud, and Microsoft Azure, which are widely used for genomics and life-science data workflows⁹⁰, capture 63% of the global market (Richter, 2026). Moreover, they are all headquartered in the United States and hence, are not covered by the mechanism. Non-CBD-Party competitor exposure is the highest of any Indicative Enclosure I sector as a result. Public archives for raw sequencing data have been doubling in size every 18 months, creating growing demand for scalable cloud infrastructure and associated services (Langmead and Nellore, 2018).

Four within-sector sub-groups matter here, although the lines between them are blurry. Bioinformatics and analysis services provide reproducible sequence-data pipelines on cloud or hosted infrastructure, and compete on usability, scalability, and how well their workflows integrate (Lau *et al.*, 2017; Ahalt *et al.*, 2023). Cloud genomics platforms and data commons bring data, compute resources, software and access control together in managed environments (Grossman, 2023; Brady *et al.*, 2024). Recent large-scale genomics initiatives such as All of Us and the UK Biobank research analysis platform show that the field is moving toward secure cloud platforms where researchers analyse data in place rather than downloading it (Deflaux *et al.*, 2023; Grossman, 2023; Brady *et al.*, 2024). Knowledgebase, curation, and interpretation services convert raw sequence data into curated, searchable, and clinically usable information, where the main competitive bottlenecks are the effort required for curation and the fragmentation of user interfaces (Borchert *et al.*, 2021). Public and hybrid infrastructure brokers manage and allocate shared resources across institutions, and many private-sector

⁹⁰ For example, see the AWS website dedicated to genomics research at <https://aws.amazon.com/health/genomics/> Accessed 4th June 2026.

companies treat these as direct commercial inputs (Garcia, Smith and Blomberg, 2018; Harrow *et al.*, 2021). AI is considered here as a built-in capability across these sub-groups, rather than being treated as a standalone category (Ahalt *et al.*, 2023; Brady *et al.*, 2024).

Value chain position and DSI use intensity

The key feature of this sector is its reliance on open and reusable DSI infrastructures. For many companies, normal business operations would be severely constrained, or even impossible, without access to publicly available sequence databases and shared data commons (Garcia, Smith and Blomberg, 2018; Harrow *et al.*, 2021). Firms in this sector sit upstream of the other Indicative Enclosure I sectors: they provide the data access, compute, workflow, and interpretation services through which pharmaceutical, biotechnology, and breeding firms process and apply sequence data, rather than selling DSI-derived products themselves.

Within the sector, companies vary widely in how intensively they use DSI and in whether they access it directly or mainly through intermediaries. DSI use is more direct for the bioinformatics workflow and cloud platform sub-groups, and more indirect for the curation and infrastructure broker sub-groups. AlphaFold, developed by Google DeepMind, illustrates the direct upstream end of this spectrum: it processes amino acid sequences derived from genomic DSI to predict protein structures, functioning as an upstream service input for pharmaceutical and biotechnology research rather than as a downstream commercial product (Jumper *et al.*, 2021).

Expected contribution base

With a median margin of 6%, most eligible firms pay on profit. The high zero-contributor share reflects the prevalence of loss-making or early-stage firms. Among contributing firms, large cloud platform providers with higher margins may pay on revenue. The proportionality concern is particularly acute given the wide range of DSI intensity within the eligible population. Even though the sector is treated as one competitiveness group for the pillar assessments, two internal distinctions are retained where analytically material: direct and indirect DSI services providers.

Pillar assessment (step 3)

Table 36,

Table 37, and

Table 38 present the materiality assessment for Pillars I, II and III respectively, drawing on the sector characterisation in Section 7.11, the broader empirical literature findings in Section 7.4 and the analytical framework in Section 7.5.

The information and AI sector faces the highest non-Party competitor exposure of any Indicative Enclosure I sector, with a high materiality finding for direct DSI service providers on competitive position versus non-Party competitors, driven by US-headquartered cloud giants capturing 63% of the global market without equivalent contribution obligations (Richter, 2026). The proportionality concern is also particularly acute: general cloud and platform providers contribute on the same financial base as computational biology specialists despite DSI being relevant to only a portion of their operations, generating a Moderate materiality finding for indirect DSI service providers on substantive compliance costs. Indirect DSI service providers are less exposed throughout, given lower commercial proximity to US-headquartered rivals and more locally embedded service models. Across Pillar II, both firm types are consistently Low given short development horizons. The direct vs indirect use boundary uncertainty (U4) is the most sector-specific design parameter, affecting both eligibility determination and the administrative burden of demonstrating compliance.

Where competitive effects do materialise, their downstream implications would be concentrated among direct DSI service providers facing structural cost asymmetry with US-headquartered cloud giants. For CBD Party-headquartered bioinformatics and genomics platform providers, the primary concern is not the direct cost burden (which is modest relative to the scale of the US market dominance already shaping competitive dynamics) but the cumulative effect of contributing on a full financial base while competing against non-contributing rivals with substantially greater market scale and no equivalent obligations. Cost absorption rather than pass-through is the most likely response given competitive constraints from US platforms, with potential implications for the pricing and availability of genomics compute services in CBD Party markets over time. For indirect DSI service providers, the proportionality concern is the most significant downstream risk: firms contributing on the same financial base despite DSI being peripheral to their operations face a burden misaligned with their DSI benefit, which may affect participation decisions and create a selection effect in the contributing population. The voluntary design mitigates the most severe outcomes across both firm types.

Table 36 Pillar I: costs and price competitiveness impacts materiality assessment – Information and AI

Impact	Firm type	Magnitude	Probability	Key conditions	Materiality
Administrative burden Costs of calculating, reporting, and documenting the contribution. Low under current revenue/profit design. The sector's breadth creates a distinctive challenge: the direct vs indirect use boundary (U4) is unresolved, and many firms cannot readily determine whether they fall within scope. For indirect providers in particular, demonstrating DSI use to the satisfaction of national implementing authorities may itself be burdensome.	Direct DSI service providers (bioinformatics, cloud genomics platforms)	Minor	Low	DSI use direct and central to business operations (Garcia, Smith and Blomberg, 2018; Harrow et al., 2021); eligibility clearer but scope of DSI-generating activity vs DSI-using activity may create attribution uncertainty. Contribution base definition (U12); direct vs indirect use boundary (U4).	Low
	Indirect DSI service providers (curation, infrastructure brokers)	Minor	Low	Eligibility itself is contested given indirect DSI use; documenting DSI reliance for contribution purposes requires demonstrating a commercial benefit from DSI that may not be straightforwardly attributable. Direct vs indirect use boundary (U4); contribution base definition (U12).	Low
Substantive compliance costs The contribution payment itself as a direct cost burden. With a median margin of 6%, most eligible firms pay on profit; contributions scale directly with earnings. The sector has the highest zero-contributor share of any Indicative Enclosure I sector, reflecting the prevalence of loss-making or early-stage firms. Among contributing firms, large cloud platform providers with higher margins may pay on revenue. The proportionality concern is particularly acute: general cloud and platform providers contribute on the same financial base as computational biology specialists despite DSI being relevant only to a portion of their total operations (U12).	Direct DSI service providers (bioinformatics, cloud genomics platforms)	Minor	Medium	DSI central to operations; proportionality concern lower than for indirect providers. AWS, Google Cloud, and Microsoft Azure (all US-headquartered) capture 63% of global market (Richter, 2026) and are not subject to equivalent obligations, creating significant cost asymmetry. Service pricing more flexible in some segments. Rate revision; entity definition (U3).	Low
	Indirect DSI service providers (curation, infrastructure brokers)	Moderate	Medium	Proportionality concern most acute: general cloud and platform providers with DSI relevant to only a portion of operations contribute on the same full financial base as direct providers (U12); indirect use boundary uncertainty may cause some firms to contribute unnecessarily or to face compliance uncertainty. Rate revision; direct vs indirect use boundary (U4); entity definition (U3).	Moderate
Cost of capital Changes in cost or availability of financing from margin compression or reduced free cash flow. Large well-capitalised firms are least responsive to profit-burden changes of higher magnitude. Voluntary opt-out constrains severe outcomes. Loss-making early-stage firms are outside the eligible population under the profit floor.	Direct DSI service providers (bioinformatics, cloud genomics platforms)	Minor	Low	Large cloud platform providers with higher margins least exposed; smaller bioinformatics and genomics platform firms more constrained. Rate revision.	Low
	Indirect DSI service providers (curation, infrastructure brokers)	Minor	Low	Structurally lower DSI intensity limits contribution exposure; voluntary opt-out constrains severe outcomes. Rate revision.	Low

Cost of intermediate consumption Indirect cost increase if laboratory equipment firms pass Cali Fund contributions forward via input pricing. Direct DSI service providers depend on sequencing infrastructure and data storage hardware; indirect providers depend less on DSI-specific laboratory inputs.	Direct DSI service providers (bioinformatics, cloud genomics platforms)	Minor	Medium	Bioinformatics and cloud genomics platform providers depend on sequencing infrastructure and compute hardware from laboratory equipment firms; direct vs indirect use boundary (U4).	Low
	Indirect DSI service providers (curation, infrastructure brokers)	Minor	Low	Lower dependence on DSI-specific laboratory inputs; direct vs indirect use boundary (U4).	Low
Pass-through to consumers Extent to which contribution cost is transferred to customers via output pricing. Service pricing is more flexible in some segments; competitive cloud markets limit full pass-through for platform providers. Lassmann et al. (2020) find that tax increases in online advertising markets are mostly passed through to prices but without significant reductions in output or employment, providing suggestive evidence of pass-through capacity in digital services markets.	Direct DSI service providers (bioinformatics, cloud genomics platforms)	Minor	Medium	Service pricing more flexible than product markets; however, highly competitive cloud infrastructure markets dominated by US-headquartered non-Party providers constrain pass-through for commodity genomics compute services. National implementation divergence (U8).	Low
	Indirect DSI service providers (curation, infrastructure brokers)	Minor	Low	Curation and infrastructure brokerage services face competitive markets; limited pass-through capacity where US-headquartered platforms provide equivalent services. National implementation divergence (U8).	Low

Table 37 Pillar II: capacity to innovate impacts materiality assessment – Information and AI

Impact	Firm type	Magnitude	Probability	Key conditions	Materiality
R&D investment capacity Reduction in capital available for R&D through margin compression or reduced free cash flow. Information and AI platforms iterate rapidly with shorter development cycles than pharmaceuticals or biotechnology. A comparable 1pp profit tax burden reduces R&D by ~6-7% over eight years, with effects concentrated in financially constrained firms (Lichter et al., 2025).	Direct DSI service providers (bioinformatics, cloud genomics platforms)	Minor	Low	Rapid iteration cycles; R&D investment in platform development; financially constrained smaller firms more at risk but often below eligibility threshold under two-of-three rule. Rate revision.	Low
	Indirect DSI service providers (curation, infrastructure brokers)	Minor	Low	Limited R&D intensity relative to direct providers; short development cycles. Rate revision.	Low
Product innovation capacity Reduction in capital for development and commercialisation of new services and capabilities. Rapid iteration cycles characterise this sector; innovation effects most pronounced for financially constrained firms (Atanassov and Liu, 2020; Lichter et al., 2025).	Direct DSI service providers (bioinformatics, cloud genomics platforms)	Minor	Low	Rapid platform iteration cycles; contribution burden too small to materially constrain service development at indicative rates. Rate revision.	Low
	Indirect DSI service providers (curation, infrastructure brokers)	Minor	Low	Short development cycles; limited capital intensity of service innovation. Rate revision.	Low
Access to risk capital Effect on ability to attract external financing for innovation where margin compression reduces perceived returns. Loss-making early-stage firms are outside the eligible population under the profit floor. Voluntary opt-out constrains severe outcomes.	Direct DSI service providers (bioinformatics, cloud genomics platforms)	Minor	Low	Early-stage loss-making firms outside eligible population under profit floor; established firms with higher margins least exposed; investor perception of regulatory environment may be affected at the margin given novelty of mechanism for this sector. Rate revision.	Low
	Indirect DSI service providers (curation, infrastructure brokers)	Minor	Low	Lower capital intensity; voluntary opt-out limits severe outcomes. Rate revision.	Low
Certainty and predictability Effect of unresolved Decision 16/2 design parameters on willingness to commit to platform development investments. The direct vs indirect use boundary (U4) creates particular uncertainty for this sector: firms cannot determine whether their activities fall within scope, which	Direct DSI service providers (bioinformatics, cloud genomics platforms)	Minor	Low	Short iteration cycles reduce long-run investment sensitivity; direct vs indirect use boundary uncertainty (U4) creates participation uncertainty; certificate of contribution legal value (U6); rate revision.	Low
	Indirect DSI service providers (curation,	Minor	Low	Boundary uncertainty (U4) is most significant for indirect providers, affecting participation rather than investment decisions; short platform development cycles. Certificate legal value (U6); rate revision.	Low

Table 38 Pillar III: international competitiveness impacts materiality assessment – Information and AI

Impact	Firm type	Magnitude	Probability	Key conditions	Materiality
Competitive position vs non-Party competitors Direct cost asymmetry with competitors headquartered in non-CBD-Party jurisdictions. Non-CBD-Party competitor exposure is the highest of any Indicative Enclosure I sector: AWS, Google Cloud, and Microsoft Azure, all US-headquartered, capture 63% of the global cloud market (Richter, 2026) and are not subject to equivalent obligations. Competitiveness risks arise primarily where non-Party rivals are close commercial substitutes (Fowlie, 2009; Dechezlepretre and Sato, 2017).	Direct DSI service providers (bioinformatics, cloud genomics platforms)	Moderate	High	US-headquartered cloud providers (AWS, Google Cloud, Microsoft Azure) capture 63% of global market (Richter, 2026) and face no equivalent obligations; direct competition for genomics workflow and bioinformatics services; asymmetry permanent under current mechanism design; national implementation divergence (U8); participation rate among peers.	High
	Indirect DSI service providers (curation, infrastructure brokers)	Minor	Medium	Lower commercial proximity to US-headquartered cloud giants for curation and infrastructure brokerage services; competitive advantage based on specialised knowledge partially insulates. National implementation divergence (U8).	Low
Export competitiveness Effects on export competitiveness where contribution cost cannot be fully passed through to export customers facing non-Party competition. Direct DSI service providers with significant cross-border service delivery face US-headquartered rivals not subject to equivalent obligations.	Direct DSI service providers (bioinformatics, cloud genomics platforms)	Minor	Medium	Cross-border digital services face direct competition from US-headquartered platforms without equivalent obligations; service pricing more flexible than physical goods but commodity genomics compute constrained. National implementation divergence (U8); rate revision.	Low
	Indirect DSI service providers (curation, infrastructure brokers)	Minor	Low	More locally embedded curation and infrastructure services; limited cross-border export exposure relative to direct providers. National implementation divergence (U8).	Low
International standards and regulatory dialogues Divergence between the Cali Fund and other DSI-related instruments. Interoperability standards and open data frameworks create regulatory co-ordination needs for direct DSI service providers. The direct vs indirect use boundary (U4) and certificate of contribution recognition (U6) are particularly unresolved for this sector given the breadth of activities captured.	Direct DSI service providers (bioinformatics, cloud genomics platforms)	Moderate	Medium	Interoperability standards and open data frameworks create regulatory co-ordination needs (U6, U8); direct vs indirect use boundary uncertainty affects how competing service standards are interpreted across jurisdictions; national implementation divergence (U8).	Moderate
	Indirect DSI service providers (curation, infrastructure brokers)	Minor	Low	Limited multi-framework DSI exposure; national implementation divergence (U8).	Low
FDI and relocation effects Effects on R&D and investment location decisions. Digital services are theoretically portable, but cloud and platform infrastructure has	Direct DSI service providers (bioinformatics,	Minor	Low	Digital services theoretically portable but cloud infrastructure switching costs constrain relocation; primary response is spending reduction not relocation (Lichter et al., 2025); most plausible sector for location effects though still Low at indicative rates. Rate revision.	Low

meaningful switching costs in practice. Primary firm response to a comparable profit burden is spending reduction rather than relocation (Lichter et al., 2025). Most plausible sector for operational location effects given digital service portability, though still Low at indicative rates.	cloud genomics platforms)				
	Indirect DSI service providers (curation, infrastructure brokers)	Minor	Low	Curation and infrastructure brokerage services locally embedded in institutional relationships; relocation implausible. Rate revision.	Low

7.12. Cosmetics

Characterisation of affected firms (steps 1 & 2)

The cosmetics sector contains 748 eligible firms, the smallest Indicative Enclosure I sector⁹¹, and accounts for 3.7% of estimated contributions, broadly in line with its 4.2% share under full compliance (

Table 13 and

Figure 5). Despite its small estimated size, cosmetics has the highest effective contribution rate of any sector. With a median margin of 6%, most eligible firms pay on profit, and the sector's combination of moderate margins and contested DSI use intensity makes the proportionality concern particularly acute relative to other sectors.

Sector and structural features

Cosmetics sector competitiveness is best seen as a connected value chain rather than a single homogeneous market, comprising two analytically distinct segments⁹² that encounter different competitive constraints (Ferreira *et al.*, 2022; Morel *et al.*, 2023; Bourgaud, Twyman and Oksman-Caldentey, 2025).

Downstream branded cosmetics firms compete through branding, product portfolios, regulatory compliance, and channel access rather than through direct control of sequence-based innovation (Sedita *et al.*, 2021; Ferreira *et al.*, 2022; Morel *et al.*, 2023). For this segment, competitive advantage depends heavily on navigating regulatory regimes across jurisdictions where harmonisation is still partial: the same formulation may be treated as a cosmetic, a medicinal product, a quasi-drug, or a higher-risk category depending on the country. In consequence, branded firms must manage ongoing compliance tasks such as maintaining Product Information Files⁹³, conducting safety assessments, and reformulating products when ingredients are restricted or reassessed (Ferreira *et al.*, 2022; Morel *et al.*, 2023; Vieira *et al.*, 2024). The production of cosmetics and beauty products is heavily concentrated and controlled by several multinational corporations (Statista, 2026). Nonetheless, competition in the market continues to intensify, as beauty industry leaders point to heightened consumer scrutiny of value and unpredictable spending as key threats to growth. Those are further compounded by increasing pressure from independent brands and emerging rivals (McKinsey, 2025).

Upstream active ingredient developers compete through scientific validation, scalable production, and regulatory acceptance of novel actives derived from plant, marine, microbial, or precision fermentation systems (Rotter *et al.*, 2024; Bourgaud, Twyman and Oksman-Caldentey, 2025; Silva *et al.*, 2025a). Plant genetic

⁹¹ Note that this smaller number compared to other sectors may be the consequence of the data limitations (see Makowska-Curran (2026)).

⁹² The eligible population under the Decision 16/2 classification may also include contract manufacturers, formulation specialists, and distribution-focused firms whose competitive position does not fit neatly into either category. For these firms, the contribution operates primarily as a downstream commercial cost with limited DSI-specific implications, and they are assessed under the downstream branded firms group for the purposes of the pillar assessments.

⁹³ Product Information File (PIF) is a mandatory document required by the European Union and the United Kingdom for new cosmetics products registration. It compiles information and data regarding product safety and quality measures (Product Information File (PIF), 2026).

resources, marine bioresources, and engineered microorganisms are among the primary sources of cosmetic active ingredients, with precision fermentation increasingly used to produce ingredients such as collagen or hyaluronic acid in scalable and standardised forms (Silva *et al.*, 2025b). This group faces material bottlenecks in ingredient approval, efficacy validation, scale-up, and ABS-sensitive innovation pathways (Klünker and Richter, 2022; Michiels *et al.*, 2022; Bourgaud, Twyman and Oksman-Caldentey, 2025). At the point of research and ingredient development, legal fragmentation and uncertainty pose a more immediate commercial constraint than downstream benefit-sharing payments (Klünker and Richter, 2022; Michiels *et al.*, 2022). The active ingredients market is significantly concentrated, with top five suppliers holding approximately 49% of the global market in 2025 (Global Market Insights, 2026a).

Non-CBD-Party competitor exposure is moderate across the sector. The US market is significant for branded cosmetics and the global ingredient supply chain (North America recorded 28% share in 2025), though the competitive set includes a higher proportion of European and CBD Party-based firms compared to other Indicative Enclosure I sectors, like pharmaceuticals or biotechnology (L'Oréal, 2026). For active ingredients specifically, North America is the largest regional market (Global Market Insights, 2026a).

Value chain position and DSI use intensity

DSI use is concentrated upstream and likely mixed downstream. Many branded firms may be developing capabilities related to DSI mainly via acquisitions and external innovation alliances rather than through internal R&D (Sedita *et al.*, 2021). Evidence from cosmetics patents also indicates that leading beauty companies pursue biodiversity-related innovation and, in some instances, may depend on DSI or on synthetic alternatives instead of obtaining direct physical access to natural source materials (Jefferson and Robinson, 2025). On that basis, their DSI exposure is often better understood as indirect or varied. Their downstream value chain position means that any contribution costs borne by active ingredients upstream developers may be passed forward via ingredient pricing; this would in turn increase the cost burden of downstream producers beyond their own contribution. For upstream active ingredient developers, DSI is central to their product development (via plant & marine genetic resources and sequence-based fermentation systems) (Hiemstra, Brink and Hintum, 2019; Rotter *et al.*, 2024; Bourgaud, Twyman and Oksman-Caldentey, 2025). Depending on their cost-pass through ability, they might be able to reduce their cost burden from contributions.

Expected contribution base

Contribution base varies within each group, with the overall industry profit margins perceived as high (McKinsey, 2023). Among downstream branded cosmetics firms, premium multinationals brands have stronger pricing power and brand positioning, achieving higher margins and thus falling into the revenue-base group. Mass beauty brands operate under tougher competition and lower margins, with some likely falling into the profit-base group. Among active ingredient developers, large consolidated suppliers with niche positions may earn high margins which would place them in the revenue-base group. The proportionality concern is greatest for downstream branded firms with limited DSI dependence.

Pillar assessment (step 3)

Table 39,

Table 40, and Table 41 present the materiality assessment for Pillars I, II and III respectively, drawing on the sector characterisation in Section 7.12, the broader empirical literature findings in Section 7.4 and the analytical framework in Section 7.5.

The cosmetics sector faces Moderate materiality on substantive compliance costs for downstream branded firms, driven by the highest effective contribution rate of any Indicative Enclosure I sector and the proportionality concern that is most critical for firms with limited direct DSI dependence contributing on the same financial base as DSI-intensive ingredient developers. Upstream active ingredient developers face Moderate materiality in Pillar II on R&D investment and product innovation capacity, given long development pipelines for biotechnology-derived actives where ABS governance fragmentation is already the primary constraint on innovation investment. Pillar III is assessed as Low across both firm types, reflecting the significant presence of European CBD Party-based competitors in both branded cosmetics and active ingredient markets, which limits non-Party asymmetry relative to more US-dominated sectors. The intra-sector pass-through channel, where ingredient developers pass contribution costs forward via ingredient pricing, is distinctive and increases the effective burden on downstream branded firms beyond their own contribution obligation.

Where competitive effects do materialise, their downstream implications would differ substantially between firm types. For downstream branded firms, cost absorption is the most likely response given limited pass-through capacity in consumer-facing markets, particularly in mass beauty segments facing intensifying competition from independent brands; at indicative rates, the effect on product pricing would be negligible relative to the cost differentials already shaping competitive dynamics. For upstream active ingredient developers, the more significant concern is that margin compression could affect long-horizon development programmes for biotechnology-derived actives, where ABS governance fragmentation is already a primary constraint on innovation investment; the Cali Fund adds a further layer of regulatory uncertainty without resolving the underlying fragmentation. The intra-sector pass-forward channel is the most distinctive downstream consequence in this sector, as it concentrates the effective burden on downstream firms regardless of their own DSI intensity.

Table 39 Pillar I: costs and price competitiveness impacts materiality assessment – Cosmetics

Impact	Firm type	Magnitude	Probability	Key conditions	Materiality
Administrative burden Costs of calculating, reporting, and documenting the contribution. Low under current revenue/profit design. The proportionality concern is distinctive for downstream branded firms given contested DSI use intensity: documenting DSI use for contribution purposes is more complex where DSI dependence is indirect or varies across the product portfolio.	Downstream branded cosmetics firms	Minor	Low	DSI exposure often indirect or acquired through external alliances (Sedita et al., 2021; Jefferson and Robinson, 2025); documenting DSI use for contribution purposes may be challenging where DSI dependence is contested or portfolio-level; contribution base definition (U12).	Low
	Upstream active ingredient developers	Minor	Low	DSI central to product development via plant, marine, and fermentation systems (Rotter et al., 2024; Bourgaud, Twyman and Oksman-Caldentey, 2025); documentation burden lower relative to downstream firms given clearer DSI use; ABS governance fragmentation and traceability obligations are the primary constraint (Klunker and Richter, 2022; Michiels et al., 2022). Contribution base definition (U12).	Low
Substantive compliance costs The contribution payment itself as a direct cost burden. The sector has the highest effective contribution rate of any Indicative Enclosure I sector (0.071% of participating revenue, Table 20) due to its margin distribution. Contribution base varies significantly: premium branded multinationals with higher margins pay on revenue; mass beauty brands and some ingredient developers pay on profit. The proportionality concern is greatest for downstream branded firms with limited DSI dependence contributing on the same financial base as DSI-intensive ingredient developers (U12).	Downstream branded cosmetics firms	Moderate	Medium	Premium multinationals with higher margins pay on revenue; mass beauty brands pay on profit with the burden more sensitive to margin compression. Proportionality concern most acute for firms with limited direct DSI dependence (U12); intensifying competition from independent brands and emerging rivals (McKinsey, 2025) constrains pass-through. Rate revision; entity definition (U3).	Moderate
	Upstream active ingredient developers	Minor	Medium	Large consolidated suppliers with niche positions pay on revenue; smaller ingredient developers pay on profit. ABS governance fragmentation is a more immediate commercial constraint than the contribution payment (Klunker and Richter, 2022; Michiels et al., 2022). Upstream position enables some pass-forward of contribution costs via ingredient pricing. Rate revision; entity definition (U3).	Low
Cost of capital Changes in cost or availability of financing from margin compression or reduced free cash flow. Large well-capitalised firms are least responsive to profit-burden changes of higher magnitude (see Section 7.4). Voluntary opt-out constrains severe outcomes.	Downstream branded cosmetics firms	Minor	Low	Large premium multinationals with high margins least exposed; mass beauty brands more constrained given margin pressure from intensifying competition (McKinsey, 2025). Voluntary opt-out limits severe outcomes. Rate revision.	Low
	Upstream active ingredient developers	Minor	Low	Smaller ingredient developers with high fixed development costs face somewhat higher exposure within this Low assessment; larger consolidated suppliers with niche positions least exposed. Rate revision.	Low
Cost of intermediate consumption Indirect cost increase from upstream contribution pass-through. The distinctive feature of cosmetics is the intra-sector	Downstream branded cosmetics firms	Minor	Medium	Intra-sector pass-forward channel: if upstream active ingredient developers contribute and pass costs forward via ingredient pricing, downstream branded firms face indirect cost increase beyond their own contribution; conditional on upstream firm participation and pass-	Low

channel: if upstream active ingredient developers pass Cali Fund contributions forward via ingredient pricing, downstream branded firms face an additional cost burden beyond their own contribution obligation.				through decision (Hiemstra, Brink and Hintune, 2019). Direct vs indirect use boundary (U4).	
	Upstream active ingredient developers	Minor	Low	Laboratory equipment dependence for precision fermentation and sequencing-based ingredient development; direct vs indirect use boundary (U4). If contribution costs can be passed forward to downstream branded clients, net burden is reduced.	Low
Pass-through to consumers Extent to which contribution cost is transferred to customers via output pricing. Consumer-facing markets with moderate price sensitivity. Some pass-through plausible for premium or differentiated products; limited for mass beauty segments facing intensifying competition from independent brands (McKinsey, 2025).	Downstream branded cosmetics firms	Minor	Medium	Premium branded multinationals with stronger brand positioning have some pass-through capacity; mass beauty brands face more price-sensitive consumers and intensifying competition constraining pass-through (McKinsey, 2025). National implementation divergence (U8).	Low
	Upstream active ingredient developers	Moderate	Medium	Upstream position enables pass-forward of contribution costs via ingredient pricing to downstream clients; competitive concentration in active ingredients market (top five suppliers: 49% global market share, Global Market Insights, 2026a) supports some pricing power. National implementation divergence (U8).	Moderate

Table 40 Pillar II: capacity to innovate impacts materiality assessment – Cosmetics

Impact	Firm type	Magnitude	Probability	Key conditions	Materiality
R&D investment capacity Reduction in capital available for R&D through margin compression or reduced free cash flow. A comparable 1pp profit tax burden reduces R&D by ~6-7% over eight years, with effects concentrated in financially constrained firms (Lichter et al., 2025). R&D investment capacity is more significant for upstream active ingredient developers with long pipelines for biotechnology-derived actives; low for downstream branded firms that acquire innovation externally.	Downstream branded cosmetics firms	Minor	Low	Downstream branded firms acquire innovation externally via acquisitions and alliances (Sedita et al., 2021); limited internal R&D pipeline; innovation effects concentrated in financially constrained firms not representative of premium multinationals. Rate revision.	Low
	Upstream active ingredient developers	Moderate	Medium	Long pipelines for biotechnology-derived active ingredients; high development costs for efficacy validation and regulatory acceptance (Bourgaud, Twyman and Oksman-Caldentey, 2025); ABS governance fragmentation is a primary constraint on innovation investment beyond contribution (Klunker and Richter, 2022; Michiels et al., 2022). Rate revision; potential obligation stacking uncertainty (U7).	Moderate
Product innovation capacity Reduction in capital for development and commercialisation of new products and actives. Most significant for upstream active ingredient developers with long pipelines and high development costs. Innovation effects most pronounced for financially constrained firms (Atanassov and Liu, 2020; Lichter et al., 2025).	Downstream branded cosmetics firms	Minor	Low	Product innovation primarily through external acquisition and formulation adaptation rather than internal R&D pipelines; limited long-horizon investment exposure. Rate revision.	Low
	Upstream active ingredient developers	Moderate	Medium	Long development pipelines for novel active ingredients; ingredient approval, efficacy validation, and scale-up bottlenecks create high commercialisation costs (Bourgaud, Twyman and Oksman-Caldentey, 2025). Rate revision; ABS governance fragmentation (U7).	Moderate
Access to risk capital Effect on ability to attract external financing for innovation where margin compression reduces perceived returns. Large well-capitalised firms are least exposed (Coles et al., 2022). Voluntary opt-out constrains severe outcomes.	Downstream branded cosmetics firms	Minor	Low	Large premium multinationals least exposed; voluntary opt-out constrains severe outcomes for mass beauty brands facing margin pressure. Rate revision.	Low
	Upstream active ingredient developers	Minor	Low	Smaller ingredient developers with constrained access to capital face somewhat higher exposure within this Low assessment; voluntary opt-out limits severe outcomes. Rate revision.	Low
Certainty and predictability Effect of unresolved Decision 16/2 design parameters on willingness to commit to long-term R&D investments. Non-binding design means uncertainty primarily deters participation rather than investment. More significant for upstream active ingredient developers where ABS governance fragmentation is already the primary constraint on innovation.	Downstream branded cosmetics firms	Minor	Low	Downstream branded firms acquire innovation externally; limited long-run R&D pipeline sensitivity. Certificate of contribution legal value (U6); rate revision.	Low
	Upstream active ingredient developers	Minor	Medium	Unresolved DSI scope and certificate legal value (U6) compound existing uncertainty; long development pipelines increase sensitivity to regulatory clarity. Rate revision.	Low

Table 41 Pillar III: international competitiveness impacts materiality assessment - Cosmetics

Impact	Firm type	Magnitude	Probability	Key conditions	Materiality
Competitive position vs non-Party competitors Direct cost asymmetry with competitors headquartered in non-CBD-Party jurisdictions. Non-CBD-Party competitor exposure is moderate across the sector: North America accounts for 28% of the global cosmetics market (L'Oreal, 2026) and is the largest regional market for active ingredients (Global Market Insights, 2026a), but the competitive set includes a higher proportion of European and CBD Party-based firms than in pharmaceuticals or biotechnology. Competitiveness risks arise primarily where non-Party rivals are close commercial substitutes (Fowlie, 2009; Dechezlepretre and Sato, 2017).	Downstream branded cosmetics firms	Minor	Medium	North America holds 28% of global cosmetics market (L'Oreal, 2026) with US-based brands not subject to equivalent obligations; however European and CBD Party-based brands form a significant part of the competitive landscape, limiting asymmetry relative to pharmaceuticals. Intensifying competition from independent brands and emerging rivals (McKinsey, 2025) amplifies sensitivity to cost differentials. National implementation divergence (U8).	Low
	Upstream active ingredient developers	Minor	Medium	North America largest regional market for active ingredients (Global Market Insights, 2026a); US-headquartered ingredient suppliers not subject to equivalent obligations; top five suppliers capture 49% of global market (Global Market Insights, 2026a), but significant European CBD Party-based suppliers limit asymmetry. National implementation divergence (U8).	Low
Export competitiveness Effects on export competitiveness where contribution cost cannot be fully passed through to export customers facing non-Party competition. Both firm types have significant export activity; premium branded firms have more pass-through capacity than mass beauty brands.	Downstream branded cosmetics firms	Minor	Medium	Export markets with moderate consumer price sensitivity; premium brands have more pass-through capacity than mass beauty brands; intensifying competition from non-Party independent brands constrains pass-through in export markets (McKinsey, 2025). National implementation divergence (U8); rate revision.	Low
	Upstream active ingredient developers	Minor	Medium	Export activity significant for active ingredient suppliers; some pricing power through niche concentration (49% top five market share) may support pass-through; pass-forward to downstream clients partially offsets export burden. National implementation divergence (U8); rate revision.	Low
International standards and regulatory dialogues Divergence between the Cali Fund and other DSI-related instruments. Limited multi-framework DSI exposure for cosmetics; no potential ITPGRFA or WHO PABS overlap. The primary regulatory divergence risk is ABS governance fragmentation affecting upstream ingredient developers, which is a pre-existing constraint amplified by the Cali Fund.	Downstream branded cosmetics firms	Minor	Low	Limited multi-framework DSI exposure; regulatory classification divergence across jurisdictions is a pre-existing competitive factor; national implementation divergence (U8).	Low
	Upstream active ingredient developers	Minor	Low	ABS governance fragmentation is already a primary constraint (Klunker and Richter, 2022; Michiels et al., 2022); Cali Fund adds a further layer but does not resolve underlying fragmentation. National implementation divergence (U8).	Low

FDI and relocation effects Effects on R&D and investment location decisions. Manufacturing relocation implausible given consumer-facing product nature, regulatory classification requirements, and established supply chains. Limited R&D base to relocate for downstream branded firms; more plausible at the margin for upstream ingredient developers.	Downstream branded cosmetics firms	Minor	Low	Manufacturing relocation implausible given regulatory classification requirements and established distribution channels; limited internal R&D base to relocate. Rate revision.	Low
	Upstream active ingredient developers	Minor	Low	R&D location effects plausible at the margin for ingredient developers with distributed precision fermentation or bioactive research operations; primary response is spending reduction not relocation (Lichter et al., 2025). Rate revision.	Low

7.13. Laboratory equipment

Characterisation of affected firms (steps 1 & 2)

The laboratory equipment sector contains 2,846 eligible firms and accounts for 5.0% of estimated contributions, broadly in line with its 11.5% share under full compliance (

Table 13 and

Figure 5). The decline between full compliance and the central scenario reflects the sector's lower participation calibration and DSI intensity adjustment, consistent with its indirect use rationale. With a median margin of 7.9%, most eligible firms pay on profit, though the sector sits closest to the 10% indifference threshold of any profit-base sector, meaning a meaningful share of firms may pay on revenue.

Sector and structural features

The sector is considered a single competitiveness group, unified by a common business model. Firms compete through platform solutions that integrate hardware, proprietary consumables, automation software, maintenance, and recurring service contracts (Meder *et al.*, 2016; Raja, Frandsen and Mouritsen, 2017; Holland and Davies, 2020). As a result, competitiveness relied on ongoing instrument improvement, rather than one-time hardware sales (Raja, Frandsen and Mouritsen, 2017; Holland and Davies, 2020). Innovation is also demand-driven, with research institutions and advanced users prompting suppliers to develop new products - for instance, by creating technical bottlenecks and performance requirements (Bianchini, Llerena and Patsali, 2019).

One internal distinction is particularly important. Within laboratory equipment, sequencing systems and related molecular technologies are the most clearly identifiable direct DSI enablers. Their competition extends beyond the instrument itself to include throughput, cost, compatibility with existing workflows, informatics capabilities, and ongoing consumables (Niedringhaus *et al.*, 2011; Watson, 2014; Holland and Davies, 2020; Schwarze *et al.*, 2020). In sequencing and molecular platforms, R&D is closely linked with bioinformatics⁹⁴, sample preparation, interpretation, and clinical or reimbursement constraints (see Section 7.7 on pharmaceuticals). Consequently, these businesses are more workflow- and systems-intensive than typical equipment markets (Curnutte *et al.*, 2014; Deverka, Kaufman and McGuire, 2014a; Schwarze *et al.*, 2020). In clinical environments, reimbursement structures, demonstrated clinical utility, and regulatory requirements introduce an additional competitive dimension (Curnutte *et al.*, 2014; Deverka, Kaufman and McGuire, 2014b).

The sector is highly concentrated, with high entry costs associated with development of specialist equipment, regulatory compliance costs and technical maintenance support (Fortune Business Insights, 2026a). This in turn corresponds to higher competition for the remaining companies, competing through pricing strategies, and

⁹⁴ In practice, the distinction between laboratory equipment and the information, scientific, and technical services sector is often blurred. Companies that deliver integrated sequencing platforms may simultaneously offer bioinformatics software, cloud-based data processing, and AI-driven interpretation services, which fall under the information and AI sector as specified in Enclosure I. When such companies satisfy the eligibility criteria for both sector categories, Makowska-Curran (2026) classifies them according to the primary NACE code reported in Orbis.

effectively putting downward pressure on their margins. North America holds the largest regional share at 38% (Grand View Research, 2025), which indicates a significant exposure to non-CBD-Party competitors. Pharmaceutical and biotechnology industries drive demand, positioning laboratory equipment firms as upstream suppliers to other Indicative Enclosure I sectors and creating a cost of intermediate consumption channel discussed in the pillar assessments.

Value chain position and DSI use intensity

DSI use emerges as indirect across most of the sector and direct primarily in the sequencing sub-group, which itself generates sequence data. For the rest of the sector, instruments are used in DSI-intensive laboratories, but the equipment manufacturer is not a direct DSI user in the same sense as pharmaceutical or biotechnology firms. These companies are more accurately described as DSI enablers: their products and services underpin the research and diagnostic workflows through which sequence data are produced, processed, and used; this creates a commercial reliance on DSI-intensive activities. Effectively, they constitute upstream providers who, if contributing to the Fund, could pass on those costs onto downstream buyers of their products and services, many of which are also listed under Enclosure I.

Expected contribution base

With a median margin of 7.9%, most eligible laboratory equipment firms pay on profit. A meaningful share sits close to the 10% indifference threshold, particularly among larger integrated platform suppliers with stronger margins, some of whom may pay on revenue. The proportionality concern is present here, with the all-in contribution base treating sequencing platform providers and generic consumable suppliers identically, despite the potential substantial difference in their DSI dependence. For the sector as a whole, the contribution operates more as a downstream commercial cost than as a direct charge on DSI-derived value.

Pillar assessment (step 3)

Table 42,

Table 43, and

Table 44 present the materiality assessment for Pillars I, II and III respectively, drawing on the sector characterisation in Section 0, the broader empirical literature findings in Section 7.4 and the analytical framework in Section 7.5.

The laboratory equipment sector faces a high materiality finding for integrated platform suppliers on competitive position versus non-Party competitors, driven by North America's 38% market share and direct competition from major US-headquartered sequencing platform providers not subject to equivalent obligations. Substantive compliance costs and pass-through capacity are Moderate for integrated platform suppliers (given platform lock-in supporting some pricing power) and Low for general supplies firms where commodity competition constrains both cost absorption and cost recovery. Across Pillar II, both firm types are consistently Low given demand-driven short innovation cycles. The sector's inclusion in Enclosure I based on indirect DSI benefit rather than direct DSI use for most firms creates a distinctive eligibility and documentation challenge, with the direct vs indirect use boundary (U4) the most relevant unresolved design parameter. The upstream position of the sector means that contribution costs can be partially passed forward to downstream pharmaceutical, biotechnology, breeding, and cosmetics clients, which is a mitigating factor that distinguishes this sector from most other Indicative Enclosure I sectors.

Where competitive effects do materialise, their downstream implications would differ between firm types. For integrated platform suppliers, the primary concern is competitive position, namely the structural asymmetry with US-headquartered sequencing platform providers creates a permanent cost differential in markets where switching costs partially but do not fully insulate from new instrument procurement competition. The ability to pass contribution costs forward to downstream clients partially offsets the direct burden, though pass-through capacity depends on the degree of platform lock-in and the availability of competing instruments from non-contributing US rivals. For general supplies firms, cost absorption is the more likely response given commodity-like competitive conditions and limited pricing power; the proportionality concern is the most significant downstream risk, as these firms contribute on the same financial base as sequencing platform providers despite substantially more indirect DSI benefit. The upstream position of the sector means that the laboratory equipment contribution has downstream cost implications for pharmaceutical, biotechnology, animal and plant breeding, and cosmetics firms that rely on sequencing infrastructure - an indirect cost channel assessed separately in those sector assessments.

Table 42 Pillar I: costs and price competitiveness impacts materiality assessment – Laboratory equipment

Impact	Firm type	Magnitude	Probability	Key conditions	Materiality
Administrative burden Costs of calculating, reporting, and documenting the contribution. Low under current revenue/profit design. The sector's inclusion in Enclosure I is based on indirect DSI benefit for most firms rather than direct use, creating a distinctive documentation challenge: demonstrating eligibility requires establishing commercial benefit from DSI without necessarily using DSI directly.	Laboratory equipment firms	Minor	Low	Contribution base definition (U12) and direct vs indirect use boundary (U4) are the most relevant uncertainties. Integrated platform suppliers: eligibility clearer given direct DSI generation and use in sequencing. General supplies firms: eligibility contested given indirect benefit; documenting DSI reliance challenging where commercial benefit is mediated through instrument sales to DSI-intensive customers.	Low
Substantive compliance costs the contribution payment itself as a direct cost burden. With a median margin of 7.9%, the sector sits closest to the 10% indifference threshold of any profit-base sector; a meaningful share of integrated platform suppliers may pay on revenue. The all-in contribution base treats sequencing platform providers and generic consumable suppliers identically despite substantially different DSI dependence, with the proportionality concern most acute for general supplies firms (U12). The contribution operates more as a downstream commercial cost than a direct charge on DSI-derived value. The sector-specific analogue, the US medical-device excise tax of 2.3%, reduced R&D and margins (Lee, 2018), but that rate is over twenty times higher than the Cali Fund revenue rate and is not directly transferable.	Laboratory equipment firms	Moderate	Medium	Integrated platform suppliers: higher margins may place some of them in the revenue-base group; lower proportionality concern given stronger DSI dependence; upstream position enables pass-forward of contribution costs to downstream pharma, biotech, and breeding clients. General supplies firms: profit-base payers with margin pressure from price competition (Fortune Business Insights, 2026a); proportionality concern more acute given indirect DSI benefit (U12). North America's 38% market share (Grand View Research, 2025) creates non-Party asymmetry for both sub-groups. Rate revision; direct vs indirect use boundary (U4); entity definition (U3).	Moderate
Cost of capital Changes in cost or availability of financing from margin compression or reduced free cash flow. Large well-capitalised firms are least responsive to profit-burden changes of higher magnitude (see Section 7.4). Voluntary opt-out constrains severe outcomes.	Laboratory equipment firms	Minor	Low	Integrated platform suppliers with higher margins and stronger market positions least exposed. General supplies firms face somewhat higher conditional exposure given margin pressure from price competition; voluntary opt-out limits severe outcomes. Rate revision.	Low

Cost of intermediate consumption For laboratory equipment, this channel operates in reverse relative to most other Indicative Enclosure I sectors: laboratory equipment firms are themselves upstream suppliers whose contribution costs may be passed forward to pharmaceutical, biotechnology, breeding, and cosmetics firms downstream. This is assessed from the perspective of the laboratory equipment firm's own cost structure.	Laboratory equipment firms	Minor	Low	Laboratory equipment firms do not face significant upstream contribution pass-through from their own suppliers in this context; their contribution costs are primarily passed forward to downstream clients. The magnitude of their own cost of intermediate consumption impact is minor. Rate revision.	Low
Pass-through to consumers Extent to which contribution cost is transferred to customers via output pricing. Integrated platform suppliers have some pricing power through platform lock-in and ecosystem switching costs; general laboratory and consumable supplies firms face more commodity-like market constraints.	Laboratory equipment firms	Moderate	Medium	Integrated platform suppliers: platform lock-in and high switching costs for integrated sequencing systems provide some pricing power (Holland and Davies, 2020; Schwarze et al., 2020). Clinical and reimbursement constraints limit pass-through in some markets (Curnutte et al., 2014). General supplies firms: commodity-like competition limits pricing flexibility. National implementation divergence (U8).	Moderate

Table 43 Pillar II: capacity to innovate impacts materiality assessment – Laboratory equipment

Impact	Firm type	Magnitude	Probability	Key conditions	Materiality
R&D investment capacity Reduction in capital available for R&D through margin compression or reduced free cash flow. Laboratory equipment innovation is demand-driven, with research institutions and advanced users prompting product development (Bianchini, Llerena and Patsali, 2019). A comparable 1pp profit tax burden reduces R&D by ~6-7% over eight years, with effects concentrated in financially constrained firms (Lichter et al., 2025).	Laboratory equipment firms	Minor	Low	Demand-driven innovation with shorter cycles than pharmaceuticals or biotechnology; integrated platform suppliers more R&D intensive than general supplies but still shorter-horizon than drug development; large well-capitalised firms least financially constrained (Coles et al., 2022). Rate revision.	Low
Product innovation capacity Reduction in capital for development and commercialisation of new instruments and consumables. Innovation is demand-driven with shorter cycles than pharmaceuticals. Innovation effects most pronounced for financially constrained firms (Atanasov and Liu, 2020; Lichter et al., 2025).	Laboratory equipment firms	Minor	Low	Ongoing instrument improvement is core to competitiveness (Raja, Frandsen and Mouritsen, 2017; Holland and Davies, 2020) but contribution burden too small to materially constrain product development at indicative rates. General supplies firms: limited product innovation relative to integrated platform suppliers. Rate revision.	Low
Access to risk capital Effect on ability to attract external financing for innovation where margin compression reduces perceived returns. Large well-capitalised firms are least exposed. Voluntary opt-out constrains severe outcomes.	Laboratory equipment firms	Minor	Low	Integrated platform suppliers with stronger margins and market positions least exposed. General supplies firms face somewhat higher conditional exposure from margin pressure; voluntary opt-out limits severe outcomes. Rate revision.	Low
Certainty and predictability Effect of unresolved Decision 16/2 design parameters on willingness to commit to product development investments. Non-binding design means uncertainty primarily deters participation rather than investment. The direct vs indirect use boundary (U4) creates eligibility uncertainty that may affect participation decisions more than investment decisions.	Laboratory equipment firms	Minor	Low	Short innovation cycles reduce long-run regulatory sensitivity; direct vs indirect use boundary (U4) most relevant for general supplies firms whose eligibility is less clear; certificate of contribution legal value (U6); rate revision.	Low

Table 44 Pillar III: international competitiveness impacts materiality assessment – Laboratory equipment

Impact	Firm type	Magnitude	Probability	Key conditions	Materiality
Competitive position vs non-Party competitors Direct cost asymmetry with competitors headquartered in non-CBD-Party jurisdictions. North America holds the largest regional share at 38% (Grand View Research, 2025), with major US-headquartered sequencing and molecular technology firms not subject to equivalent obligations. Competitiveness risks arise primarily where non-Party rivals are close commercial substitutes (Fowle, 2009; Dechezlepretre and Sato, 2017).	Laboratory equipment firms	Moderate	High	Integrated platform suppliers: North America's 38% market share (Grand View Research, 2025) with major US-headquartered sequencing platform providers not subject to equivalent obligations; direct commercial competition in global sequencing and molecular diagnostics markets; platform lock-in partially insulates but does not eliminate asymmetry for new instrument procurement. General supplies firms: non-Party competitor presence significant but more fragmented, with higher proportion of CBD Party-based suppliers limiting asymmetry. Asymmetry permanent under current mechanism design. National implementation divergence (U8).	High
Export competitiveness Effects on export competitiveness where contribution cost cannot be fully passed through to export customers facing non-Party competition. Integrated platform suppliers have significant cross-border instrument sales with direct US competition; general supplies firms trade internationally in more fragmented markets.	Laboratory equipment firms	Minor	Medium	Integrated platform suppliers: global instrument markets with direct competition from US-headquartered sequencing platform providers in export markets; platform lock-in partially supports pricing in installed base. General supplies firms: more commoditised export markets with broader mix of CBD Party and non-Party suppliers. National implementation divergence (U8); rate revision.	Low
International standards and regulatory dialogues Divergence between the Cali Fund and other DSI-related instruments. Limited multi-framework DSI exposure. The primary regulatory complexity is the unresolved direct vs indirect use boundary (U4), which affects how the sector's upstream position relative to DSI use is interpreted across national implementations.	Laboratory equipment firms	Minor	Low	Limited multi-framework DSI exposure; direct vs indirect use boundary (U4) most relevant for general supplies firms whose eligibility rests on indirect benefit; certificate of contribution recognition (U6); national implementation divergence (U8).	Low
FDI and relocation effects Effects on R&D and investment location decisions. Manufacturing relocation implausible given high capital intensity of specialist equipment manufacturing and established supply chains. Primary firm response to a comparable profit burden is spending reduction rather than relocation (Lichter et al., 2025).	Laboratory equipment firms	Minor	Low	Manufacturing relocation implausible given capital intensity and regulatory compliance requirements for specialist instruments; R&D location effects limited at indicative rates; primary response is spending reduction not relocation (Lichter et al., 2025). Rate revision.	Low

7.14. Summary materiality assessment across Indicative Enclosure I sectors

Table 45 presents the materiality findings for all carried-forward impacts across all seven Indicative Enclosure I sectors and three pillars. For each impact, the Low, Moderate, and High columns list the sectors and firm types recording that materiality level; where no distinction exists within a sector, all firm types are listed collectively. The final column provides a cross-sector narrative drawing on the findings of Sections 7.7 to 7.13. Impacts screened out at the classification stage are excluded. Sector abbreviations: PH = Pharmaceuticals; BT = Biotechnology; APB = Animal and plant breeding; NU = Nutraceuticals; IA = Information and AI; CO = Cosmetics; LE = Laboratory equipment.

Table 45 Materiality assessment – summary across sectors (Enclosure I)

Impact	Low	Moderate	High	Cross-sector narrative
Pillar I: Cost and price competitiveness				
Administrative burden	All sectors & all firm types			Low across all sectors and firm types. The current revenue- and profit-based design uses indicators already reported for tax and accounting, so most firms face minimal additional reporting requirements. The main condition is a potential shift toward product- or use-based attribution, which would substantially increase tracking and documentation requirements. This is conditional on the contribution base definition (U12). PH/BT: potential obligation stacking with WHO PABS adds administrative complexity for vaccine producers and biopharmaceutical innovators (U7). APB: Germplasm collection managers may face additional burden from their use of DSI in managing those physical collections (U7). LE: eligibility documentation may be challenging given indirect use rationale, conditional on the introduction of a product- or use-based contributions.

Substantive compliance costs	PH: pharmaceuticals innovators, biosimilars BT: innovators, molecular diagnostics and R&D service and platform APB: all IA: direct DSI services providers LE: integrated platform suppliers CO: upstream active ingredient developers	PH: generics producers, (some) biosimilars producers BT: industrial biotech NU: all firm types IA: indirect DSI service providers LE: general supplies firms CO: downstream branded cosmetics		Moderate for firms with thin margins and proportionality concerns, reflecting medium probability of materialisation rather than large absolute magnitude. For most innovative, research-intensive producers contributing on revenue at high margins, the burden is Low at indicative rates. Competitive significance derives primarily from asymmetry with non-Party competitors rather than from direct cost burden. Conditional on rate revision and contribution base definition (U12). PH: generics most exposed given thin margins and all-in contribution base despite weaker DSI dependence. BT: most significant for industrial biotech competing against petrochemical benchmarks. NU: thin margins (4% median) mean proportionally higher profit-base burden. IA: proportionality concern most acute for indirect providers whose DSI use is limited relative to their full financial base. CO: downstream branded firms face highest effective rate (0.071%) despite limited direct DSI dependence. LE: both sub-groups face proportionality concern given indirect DSI benefit underpinning eligibility.
	All sectors & all firm types			
	All sectors & all firm types			
Cost of capital				Low across all sectors and firm types. Research-intensive producers are among the largest and most well-capitalised firms in the eligible population, and large firms are least responsive to profit tax changes at comparable rates (Coles et al., 2022). The voluntary design further limits this risk, as firms for whom the contribution would materially affect creditworthiness retain the option of non-participation. PH: most plausible for unbranded generic producers where margins are thin. BT: early-stage firms exempt under profit floor; smaller biopharmaceutical innovators with limited retained earnings most exposed within sector. APB: P25 margin of 0.5% indicates a meaningful tail of very thin-margin firms. NU: thin margins (4% median) create most plausible cost of capital exposure of any sector.
Cost of intermediate consumption				Low across all sectors and firm types, but with medium probability for research-intensive producers linked to eligible laboratory equipment firms in their supply chains: PH innovators, BT innovators, APB plant breeders using sequencing services, and downstream CO producers. If laboratory equipment firms pass their contribution costs forward through input pricing, downstream sectors face an indirect cost increase. This is conditional on laboratory equipment firm participation and pass-on behaviour. The magnitude remains minor because laboratory equipment firms contribute on the same small effective rate as other sectors under the non-binding design. CO: distinctive intra-sector channel where upstream active ingredient developers may pass costs forward to downstream branded firms.

Pass-through to consumers	PH: generics producers, biosimilars producers; BT: molecular diagnostics, industrial biotechnology, R&D service and platform organisations; APB: vegetable/horticultural breeders, animal breeders; NU: all firm types; IA: direct and indirect DSI service providers; CO: downstream branded cosmetics firms; LE: all firm types.	PH: innovators; BT: biopharmaceutical innovators; APB: large seed multinationals; CO: upstream active ingredient developers.		Moderate for firms with meaningful pricing power in reimbursement-linked or IP-protected markets; Low for firms with price-sensitive customers or procurement-driven market structures. PH: Moderate for innovators given some pricing power in patent-protected markets and US market exposure; Low for generics given structural barriers in procurement frameworks. BT: Moderate for biopharmaceutical innovators through reimbursement negotiations; Low for industrial biotech given petrochemical benchmarking and R&D service firms which pass costs upstream. APB: Moderate for large seed multinationals via trait licensing in concentrated seed markets; Low for vegetable/horticultural and animal breeders given farmer price sensitivity. CO: Moderate for upstream active ingredient developers via ingredient pricing to downstream clients; Low for downstream branded firms. IA/NU: consumer-facing and competitive markets constrain pass-through; some flexibility for premium segments. LE: Moderate pricing power for integrated platform suppliers through lock-in, but assessed as Low overall given commodity competition across the sector
Pillar II: Capacity to innovate				
R&D investment capacity	PH: generics producers, biosimilars producers; BT: molecular diagnostics, industrial biotechnology, R&D service and platform organisations; APB: vegetable/horticultural breeders, animal breeders; NU: all firm types; IA: all firm types; CO: downstream branded cosmetics firms; LE: all firm types.	PH: innovators; BT: innovators; APB: large seed multinationals; CO: upstream active ingredient developers		Moderate for R&D-intensive sectors with long development pipelines; Low for sectors with shorter development cycles or lower R&D intensity. The primary channel is margin compression reducing capital available for innovation investment. A comparable 1pp profit tax burden reduces R&D by ~6-7% over eight years, with effects concentrated in financially constrained firms (Lichter et al., 2025); large well-capitalised firms are least responsive (Coles et al., 2022). Conditional on rate revision and obligation stacking (U7). PH: Moderate for research-intensive producers given long pipeline horizons; Low for generics. BT: Moderate for biopharmaceutical innovators (~16% of sales in R&D); Low for shorter-cycle sub-sectors. APB: Moderate for large seed multinationals with long breeding programme horizons. CO: Moderate for upstream active ingredient developers with long pipelines for biotechnology-derived actives. All other sectors Low.

Product innovation capacity	PH: generics producers, biosimilars producers; BT: molecular diagnostics, industrial biotechnology, R&D service and platform organisations; APB: vegetable/horticultural breeders, animal breeders; NU: all firm types; IA: all firm types; CO: downstream branded cosmetics firms; LE: all firm types.	PH: innovators; BT: biopharmaceutical innovators; APB: large seed multinationals; CO: upstream active ingredient developers		Moderate for R&D-intensive sectors with long development pipelines; Low for sectors with shorter development cycles or lower R&D intensity. Follows the same capital constraint channel as R&D investment capacity. Innovation effects most pronounced for financially constrained firms (Atanassov and Liu, 2020; Lichter et al., 2025). PH: Moderate for research-intensive producers; Low for generics (no product innovation in the relevant sense) and biosimilars (affected only at the margin). BT: Moderate for biopharmaceutical innovators; Low for other sub-sectors. APB: Moderate for large seed multinationals; Low for animal breeders. CO: Moderate for upstream active ingredient developers; Low for downstream branded firms that acquire innovation externally. All other sectors Low.
Access to risk capital	All sectors & all firm types			Low materiality across all sectors and firm types. Large well-capitalised firms are unlikely to face investor sensitivity to margin effects at indicative contribution rates. The non-binding design further limits the risk, as firms facing material financing constraints would rationally choose non-participation. Conditional on rate revision. PH: smaller biosimilar developers with high fixed development costs face somewhat higher exposure. BT: most relevant for early-stage biopharmaceutical innovators, but typically loss-making and therefore exempt under the profit floor. APB: smaller breeders and aquaculture firms with constrained capital access most exposed within Low. NU: thin margins create the most plausible risk within the Low assessment.
Certainty and predictability	PH: generics producers, biosimilars producers; BT: molecular diagnostics, industrial biotechnology, R&D service and platform organisations; APB: vegetable/horticultural breeders, animal breeders; NU: all firm types; IA: all firm types; CO: downstream branded cosmetics firms; LE: all firm types.	PH: innovators; BT: biopharmaceutical innovators; APB: large seed multinationals; CO: upstream active ingredient developers		Low to Moderate depending on R&D horizon length and DSI access dependency. The non-binding design means uncertainty primarily deters participation rather than investment. For sectors with long R&D horizons, unresolved design parameters create background regulatory uncertainty that may delay participation decisions. Conditional on certificate of contribution legal value (U6), rate revision, and potential obligation stacking (U7). PH: Moderate for research-intensive producers given long pipeline horizons and potential WHO PABS overlap. BT: Moderate for biopharmaceutical innovators; Low for shorter-cycle sub-sectors. APB: Moderate for large seed multinationals given ITPGRFA stacking uncertainty and long programme commitments. CO: Moderate for upstream ingredient developers where ABS governance fragmentation is already the primary constraint on long-term innovation investment IA: direct vs indirect use boundary creates participation uncertainty but investment not materially affected at indicative rates.

Pillar III: International competitiveness				
Competitive position vs non-Party competitors	BT: molecular diagnostics, R&D service and platform organisations; APB: vegetable/horticultural breeders; NU: all firm types; CO: all firm types; IA: indirect DSI service providers.	PH: generics producers, biosimilars producers; BT: industrial biotechnology; APB: animal breeders; IA: indirect DSI service providers.	PH: innovators; BT: biopharmaceutical innovators; APB: large seed multinationals; IA: direct DSI service providers; LE: all firm types.	High to Moderate depending on non-CBD-Party competitor presence. The US accounts for a dominant share of several key markets and is not a CBD Party. This structural asymmetry is permanent under the current mechanism design and is the single most significant cross-cutting competitive risk in this assessment. Conditional on national implementation divergence (U8) and participation rate among sector peers. PH: High for innovators (US 53.2% of global prescription market); Moderate for generics and biosimilars given US generic and biosimilar market presence. BT: High for biopharmaceutical innovators (US 48% of global biologics market); Moderate for industrial biotech (petrochemical competitor dominance). APB: High for large seed multinationals (US 42.5% top five seed market share); Moderate for animal breeders (North America dominant in animal genetics supply). IA: High for direct DSI service providers (AWS, Google Cloud, Azure capture 63% of global cloud market). LE: High for all firm types (North America 38% market share). NU/CO: Low, with higher proportion of CBD Party-based competitors limiting non-Party asymmetry
	PH: innovators, biosimilars producers; BT: biopharmaceutical innovators, molecular diagnostics, R&D service and platform organisations; APB: all firm types; NU: all firm types; IA: all firm types; CO: all firm types; LE: all firm types	PH: generics BT: industrial biotech;		Moderate for sectors with significant export activity where pass-through to export customers is structurally constrained by non-Party competition. Low where market positions are more nationally concentrated or where pass-through capacity exists. PH: Moderate for generics producers in price-driven export tender markets; Low for innovators and biosimilars. BT: Moderate for industrial biotech competing against petrochemical alternatives in export markets; Low for biopharmaceutical innovators given some regulated market pass-through capacity. APB: Low for all firm types given price-sensitive agricultural export markets and limited pass-through. IA: Low for all firm types. CO: Low for both firm types. NU: Low given nationally concentrated market positions. LE: Low for all firm types.

International standards and regulatory dialogues	PH: generics producers, biosimilars producers; BT: molecular diagnostics, industrial biotechnology, R&D service and platform organisations; APB: vegetable/horticultural breeders, animal breeders; NU: all firm types; CO: all firm types; IA: indirect DSI service providers; LE: all firm types.	PH: innovators; BT: biopharmaceutical innovators; APB: large seed multinationals; IA: direct DSI service providers.		Low across most sectors; Moderate for sectors subject to overlapping international frameworks. PH: Moderate for innovators given WHO PABS dual-framework obligations for vaccine producers and biopharmaceutical innovators. BT: Moderate for biopharmaceutical innovators with pathogen-adjacent activities. APB: Moderate for large seed multinationals navigating ITPGRFA obligations for crops covered by both instruments. IA: Moderate for direct DSI service providers given interoperability standards and open data framework co-ordination needs. All other sectors and firm types Low.
FDI and relocation effects	All sectors & all firm types			Low materiality across all sectors and firm types. The non-binding design means non-participation is available as a less costly alternative to relocation, which constrains plausibility at indicative rates. R&D spending reduction is a more plausible firm response than relocation at a comparable burden level (Lichter et al., 2025). Conditional on rate by the Conference of the Parties. PH: R&D location effects most plausible at the margin for research-intensive producers with globally distributed discovery operations; manufacturing relocation implausible. BT: R&D location effects plausible for biopharmaceutical innovators at the margin; industrial biotech manufacturing relocation implausible given scale-up requirements. APB: possible for large seed multinationals with distributed breeding operations; Low probability at indicative rates. IA: most plausible sector for location effects given digital service portability, but still Low at indicative rates.

Note: Each row lists the sector–firm type combinations recording Low, Moderate, or High materiality respectively. Grey cells indicate that no combination recorded that level for the impact in question. Sector abbreviations: PH = Pharmaceuticals; BT = Biotechnology; APB = Animal and plant breeding; NU = Nutraceuticals; IA = Information and AI; CO = Cosmetics; LE = Laboratory equipment

7.15. Discussion and implications

The findings in Sections 7.7 to 7.13 point to five key implications for the design decisions open for the Conference of the Parties. They are presented here not as recommendations but as analytical observations about the consequences of the choices before Parties.

- **The principal competitive risk is structural, not cost-driven, and cannot be resolved through rate adjustment:** across all seven Indicative Enclosure I sectors, the most significant competitive finding is the asymmetry between CBD Party-headquartered firms and US-headquartered rivals that face no equivalent contribution expectation. This asymmetry generates High materiality findings for the most globally active firm types in five of seven sectors and is permanent under the current mechanism design. Revising rates downward would reduce the cost differential but would not eliminate the asymmetry; revising rates upward would widen it. The competitive risk from non-Party presence is therefore a function of scope, not rate, and can only be addressed through mechanisms that either broaden non-Party engagement or compensate contributing firms through the certificate of contribution system in ways that create commercially meaningful differentiation.
- **The proportionality concern is the most material design-level competitive risk for several sectors:** the all-in contribution base, which treats firms identically regardless of DSI use intensity, generates disproportionate burdens for firm types with indirect or limited DSI dependence: unbranded generics producers, indirect DSI service providers, general laboratory supplies firms, and nutraceuticals producers. For these groups, the contribution functions effectively as a levy on commercial activity rather than a benefit-sharing obligation linked to DSI use. This is not resolved by rate adjustment and would require either a scope revision that narrows eligibility to firms with demonstrable direct DSI benefit, or a proportionality mechanism within the contribution base. Narrowing the definition of indirect use, or fixing a single point of contribution liability within the value chain, would reduce the risk of the same DSI use being captured at more than one stage.
- **Unresolved design parameters generate regulatory uncertainty that is analytically distinct from, and in some cases larger than, the direct cost burden:** for research-intensive producers with long development pipelines, the certainty and predictability channel generates Moderate materiality not because the contribution is large but because unresolved parameters, including the certificate of contribution's legal value, the rate revision trajectory, and the potential WHO PABS overlap for vaccine producers, make it difficult to model the contribution's long-run cost implications. A firm committing to a 10–15-year development programme cannot reliably assess what it will owe over that period. This uncertainty effect is most acute for pharmaceutical and biopharmaceutical innovators and large seed multinationals, and could be reduced by the establishment of a clear rate trajectory and resolve the multi-framework stacking question for sectors subject to both the Cali Fund and WHO PABS or ITPGRFA MLS obligations.
- **The voluntary design constrains severe competitive outcomes but creates a participation asymmetry among CBD Party-headquartered peers:** the option of non-participation means that firms for whom the contribution would generate material cost pressure can exit rather than absorb an unviable burden. This limits the most severe Pillar I outcomes across all sectors. However, it simultaneously creates a participation asymmetry within the CBD Party-headquartered population:

firms that participate face costs that non-participating peers do not. This dynamic is self-limiting, since widespread non-participation by CBD Party firms would undermine both fund revenue and the legitimacy of the mechanism. Design features that increase the commercial value of participation, particularly a certificate of contribution that provides meaningful legal certainty over DSI access and is recognised across regulatory frameworks, are likely to be the most effective lever for aligning the competitive and participation incentives of eligible firms.

- **Sector-specific competitive exposure varies substantially and has implications for engagement strategy:** the competitiveness assessment reveals significant variation across sectors that is not visible in aggregate revenue projections. Sectors with the highest non-Party competitive asymmetry, principally information and AI and laboratory equipment, are also among those with potentially the highest eligibility uncertainty. Sectors with the most stable and significant revenue contribution, principally pharmaceuticals, also face the multi-framework compliance uncertainty through the potential WHO PABS overlap. Sectors with the thinnest margins and strongest proportionality concerns, nutraceuticals and unbranded generics, are those where voluntary non-participation is most likely to be the firm response. These patterns suggest that decisions on certificate value, contribution scope, and obligation stacking resolution will affect sectors differently, and that engagement with the private sector could benefit from a sector-specific approach.

Conclusion

This report has examined the Cali Fund established under CBD Decision 16/2 across three dimensions: the eligibility and threshold design, the revenue potential under alternative participation and design scenarios, and the competitiveness implications for eligible firms across all seven Indicative Enclosure I sectors. The analysis draws on the contribution rate modelling across 21,690 eligible firms, scenario-based revenue projections under four participation assumptions, and structured, expert-judged qualitative competitiveness assessment applied sector by sector, reflecting a prospective, model-based outlook given that the Fund is not yet operational and no contribution behaviour can be directly observed. These findings on contribution rates and competitiveness should be read alongside the broader context set out earlier: the mechanism reflects a negotiated balance between open DSI access and fair benefit-sharing, and depends on conservation work carried out largely by megadiverse countries.

On eligibility and threshold design, the analysis benchmarks the Decision 16/2 thresholds against six international SME frameworks and synthesises submissions received under CBD Notification 2024-116. The current thresholds broadly align with criteria for large enterprises across most reference frameworks, though the assets threshold falls below the EU medium-enterprise balance sheet ceiling and some medium-sized firms under Indian and Chinese classifications would fall within scope. The analysis identifies six design gaps of potential relevance for the Conference of the Parties: the absence of an explicit SME exemption or reduced-contribution tier, despite broad support for such protection in Party submissions; the use of absolute profit rather than a profit margin as a contribution criterion, which has no direct parallel in the frameworks reviewed; the absence of affiliation conditions comparable to those in EU and US frameworks, which leaves the entity-level design potentially vulnerable to corporate restructuring; the tension between a uniform threshold structure and the significant structural differences in financial characteristics across Indicative Enclosure I sectors, which are most pronounced for pharmaceuticals relative to the remaining six sectors; the absence of an employee count criterion, which diverges from almost all international frameworks reviewed, though Party submissions consistently viewed financial metrics as more relevant than employee numbers for determining contribution capacity; and the absence of a mechanism to periodically revise the thresholds for inflation or exchange rate movements, given they are currently fixed in nominal USD terms.

On revenue potential, the central finding is that the fund's scale is highly sensitive to participation rather than to rate calibration. The uncertainty-adjusted range spans from approximately USD 5 million to USD 929 million per year at the same indicative rates, with the width of that range determined by unresolved structural features rather than by the rate level itself. These estimates are illustrative analytical scenarios, not forecasts; actual revenue will depend on COP17's decisions on thresholds and rates, subsequent national implementation, and how participation and corporate behaviour evolve in practice. The analysis suggests that participation is the binding constraint: the certificate of contribution's operational value, the clarity of contribution scope, and the resolution of obligation stacking determine how many firms contribute at all, while the rate level only determines how much each participating firm pays. Threshold design has important governance implications while also influencing participation, administrative efficiency and fund revenue. Under the scenarios analysed, doubling all thresholds removes 43.5% of eligible firms while reducing contributions by only 7.4%, because contributions are heavily concentrated among the largest firms regardless of where the cutoff is set. Pharmaceutical sector participation is the single most significant determinant of fund revenue under realistic participation scenarios, reflecting both the sector's above-threshold margin distribution and the stability of

revenue-base contributions relative to profit-base contributors in other sectors. This concentration reflects current patterns of DSI use across the seven Enclosure I sectors and the assumptions and data underlying this analysis; it is not a predetermined or permanent feature of the mechanism. As DSI use expands in emerging fields such as artificial intelligence and synthetic biology, and as national implementation measures and participation evolve following COP17's decisions, the sectoral composition of Cali Fund contributions may shift over time.

On competitiveness, the direct cost burden on eligible firms is modest relative to sector margins at indicative rates and is unlikely to generate material cost and price competitiveness effects for most firm types. The dominant competitive risk is the structural asymmetry with US-headquartered rivals operating outside the mechanism's scope, which is permanent under the current design and most acute for the globally active, research-intensive firm types that also account for the largest share of fund revenue. For research-intensive producers with long development pipelines, regulatory uncertainty around unresolved design parameters generates a Moderate competitiveness concern that is analytically distinct from, and in several sectors larger than, the direct cost burden. The proportionality concern, where firms contribute on the same financial base regardless of DSI use intensity, is the most acute design-level competitive risk for sectors with indirect or limited DSI dependence. The non-binding design is both the mechanism's most important protective feature and its most significant constraint: it limits severe outcomes for financially marginal firms while simultaneously creating the participation dynamics that determine whether the fund achieves meaningful scale.

Several design parameters remain open ahead of COP17 and will materially shape both the revenue potential and the competitive implications of the mechanism: the rate revision trajectory, the legal value of the certificate of contribution, the resolution of potential obligation stacking with WHO PABS and ITPGRFA MLS, and the direct versus indirect use boundary for sectors whose eligibility rests on indirect DSI benefit. Since participation is the binding constraint on revenue, how these parameters are resolved will determine not only how much the Cali Fund raises, but whether the incentives for private entities to participate are strong enough to raise it in a way that is perceived as equitable and predictable.

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Annex A: Methodological Notes

A.1 Geographical scope (Part II)

Table 46 CBD Parties not included in the revenue modelling

Category	N	Parties
In-scope firms present but none meet eligibility thresholds	15 Parties	Congo (Democratic Republic of the), Ethiopia, Ghana, Iraq, Kyrgyzstan, Lao People's Democratic Republic, Lebanon, Liechtenstein, Malawi, Mongolia, Montenegro, Papua New Guinea, Paraguay, Syrian Arab Republic, Tanzania (United Republic of)
In the database but no in-scope firms identified (9 Parties)	9 Parties	Azerbaijan, Barbados, Benin, Costa Rica, Guyana, Marshall Islands, Rwanda, Saint Kitts and Nevis, Venezuela (Bolivarian Republic of)
No database coverage	71 Parties	Afghanistan, Andorra, Angola, Belize, Bhutan, Brunei Darussalam, Burkina Faso, Burundi, Cabo Verde, Cambodia, Cameroon, Central African Republic, Chad, Comoros, Cook Islands, Cuba, Djibouti, Dominica, Dominican Republic, El Salvador, Equatorial Guinea, Eritrea, Gabon, Gambia, Grenada, Guatemala, Guinea, Guinea-Bissau, Haiti, Honduras, Kiribati, Korea (Democratic People's Republic of), Lesotho, Liberia, Libya, Madagascar, Maldives, Mali, Mauritania, Micronesia (Federated States of), Monaco, Mozambique, Myanmar, Nauru, Nicaragua, Niger, Niue, Palau, Saint Lucia, Saint Vincent and the Grenadines, Samoa, San Marino, Sao Tome and Principe, Senegal, Seychelles, Sierra Leone, Solomon Islands, Somalia, South Sudan, Sudan, Suriname, Tajikistan, Timor-Leste, Togo, Tokelau, Tonga, Turkmenistan, Tuvalu, Vanuatu, Wallis and Futuna, Yemen

Notes: Coverage status based on Orbis (Moody's Analytics) data as used in Makowska-Curran (2026). In-scope firms are those operating in at least one Indicative Enclosure I sector. Eligibility thresholds applied as two-of-three rule: total assets exceeding USD 20 million, annual sales exceeding USD 50 million, and profit exceeding USD 5 million, averaged over 2021-2023. The United States is excluded as a non-Party to the CBD.

Source: Adapted from Makowska-Curran (2026).

A.2 Monte Carlo calibration parameters (Part II)

Table 47 Sector-level participation rate assumptions (scenarios S1-S3)

Sector	Rate	Justification	Key sources
Cosmetics	0.60	The cosmetics sector is characterised by direct consumer engagement and heightened brand sensitivity regarding natural ingredients and biodiversity sourcing. Reputational incentives are driven by consumer purchasing behaviour, which increases the value of public commitments for firms in this industry.	(Haddock-Fraser and Fraser, 2008; Escobedo and Lojenga, 2013)
Pharmaceuticals	0.50	Large pharmaceutical firms are accustomed to scrutiny related to access and benefit-sharing (ABS) and operate within established sustainability reporting frameworks. Although reputational pressure is significant, it is primarily addressed through investor and regulatory channels rather than direct consumer engagement. This dynamic results in a moderate participation rate.	(Demir and Min, 2019; Michiels <i>et al.</i> , 2022)
Nutraceuticals	0.40	Consumer interest in natural origin and product provenance generates reputational incentives for participation. However, fragmented regulations across jurisdictions and complex ingredient supply chains contribute to uneven engagement across the sector.	(Hobbs, 2002b; Stamboulakis and Sanderson, 2020)
Biotechnology	0.35	Exposure to DSI and awareness of ABS differ significantly across biotechnology sub-sectors. Reputational and regulatory	(Kang, Jung and Ryu, 2015; Karabin,

Sector	Rate	Justification	Key sources
		pressures are substantial for firms adjacent to the biopharmaceutical industry but are considerably weaker for upstream research companies. This variation supports an intermediate participation rate.	Mansfield and Frow, 2021)
Laboratory equipment	0.20	Laboratory equipment and reagent suppliers occupy an upstream position in the DSI value chain and do not typically face direct consumer or biodiversity-related reputational pressure. Their indirect connection to DSI use limits both the visibility and the perceived relevance of voluntary benefit-sharing commitments.	(Haddock-Fraser and Fraser, 2008)
Animal and plant breeding	0.20	Despite substantial use of plant genetic resources and related sequence data, the sector has historically shown limited engagement with monetary benefit-sharing under comparable multilateral frameworks, including the ITPGRFA. Traceability challenges and high transaction costs further constrain participation incentives.	(Rabitz, 2017; Wynberg <i>et al.</i> , 2021)
Information and AI	0.15	DSI use in this sector is diffuse and technically complex, and is not typically linked to biodiversity-facing products or supply chains visible to consumers. The lack of established ABS engagement and weak reputational connections to biodiversity outcomes contribute to a low baseline participation rate.	(Nawaz, Satterfield and Hagerman, 2021; Lawson, Englezos and Rourke, 2025)

Notes: Rate values are calibrated from the empirical literature on voluntary environmental scheme membership, including engagement with existing ABS, and represent central estimates rather than observed participation rates. Full literature justifications are provided in Makowska-Curran (2026). The author also provides sensitivity analysis results for varying parameter ranges.

Source: Adapted from Makowska-Curran (2026).

Table 48 Ownership-based participation multipliers (scenarios S1-S2)

Firm category	Rate	Justification	Key sources
Listed	1.30	Publicly listed firms experience heightened investor scrutiny, more frequent sustainability disclosure requirements, and greater reputational exposure than unlisted firms of similar size. Empirical literature associates these factors with higher rates of voluntary participation in environmental schemes.	(Lee, 2009; Rasche <i>et al.</i> , 2022)
Unlisted	0.85	Unlisted firms encounter weaker external disclosure pressures and reduced exposure to investor-driven sustainability expectations. Although customer and supply chain pressures can incentivise participation in certain instances, average participation rates remain lower than those observed for listed firms.	(Lee, 2009; Rasche <i>et al.</i> , 2022)

Notes: Rate values are calibrated from the empirical literature on voluntary environmental scheme membership, and reputational pressure across company types. Full literature justifications are provided in Makowska-Curran (2026). The author also provides sensitivity analysis results for varying parameter ranges.

Source: Adapted from Makowska-Curran (2026).

Table 49 DSI intensity multipliers (scenario S3 only)

Sector	Rate	Justification	Key sources
Biotechnology	1.00	Patent citation studies and analyses of database usage demonstrate that publicly deposited sequence data is essential to commercial innovation in biotechnology, thereby supporting a maximum DSI intensity value.	(Oldham, Hall and Forero, 2013; Bousfield <i>et al.</i> , 2016b)

Sector	Rate	Justification	Key sources
Pharmaceuticals	1.00	Public sequence databases play a significant role in pharmaceutical research and drug discovery, with substantial evidence indicating a connection between DSI access and subsequent patenting activity. The sector is primarily composed of innovative firms and large generic manufacturers with extensive biosimilar portfolios, both of which depend on sequence-based analysis.	(Jefferson <i>et al.</i> , 2015; Bousfield <i>et al.</i> , 2016b)
Animal and plant breeding	0.80	Substantial use of DSI is well documented in the plant segment of this sector, as evidenced by research on crop genomics and plant genetic resource databases. In contrast, evidence for DSI use in animal breeding is less comprehensive, supporting a high, but not maximum, multiplier.	(von Wettberg and Khoury, 2020; Brink and van Hintum, 2022)
Information and AI	0.75	Bioinformatics and data-intensive life science services make significant use of public sequence data; however, commercial DSI utilisation in this sector is often indirect and not adequately reflected in standard sector-level metrics, justifying a high but sub-maximum multiplier.	(Lawson, Englezos and Rourke, 2025)
Laboratory equipment	0.55	Suppliers of sequencing equipment and consumables benefit from DSI primarily through increased demand for sequencing capacity, rather than through direct application of sequence data in their products or processes. Consumables account for a significant portion of sequencing costs, supporting a moderate multiplier.	(Schwarze <i>et al.</i> , 2020)
Nutraceuticals	0.45	Commercial activity in this sector is primarily extract-based, with minimal evidence of systematic use of genetic sequence data in product development. Patent activity is limited in scope and focused on specific compounds rather than genomic innovations, supporting a below-midpoint multiplier.	(Oldham, Hall and Forero, 2013)
Cosmetics	0.35	The primary cosmetics pipeline relies on plant and botanical extracts rather than sequence-based research. Although an emerging subsector utilises fermentation and synthetic biology, which may involve DSI use, this constitutes only a small portion of the eligible population, supporting a low multiplier.	(Oldham, Hall and Forero, 2013)

Notes: Values are expert-informed estimates based on indirect evidence of sectoral DSI use intensity. Direct observation of firm-level DSI use is not currently possible. Because Decision 16/2 defines the contribution base as total financials rather than DSI-attributed activity, S3 represents a conceptual lower bound rather than an alternative central estimate. Full literature justifications are provided in Makowska-Curran (2026). The author also provides sensitivity analysis results for varying parameter ranges.

Source: Adapted from Makowska-Curran (2026).

Annex B: Industry Consultation Questionnaire

Cali Fund's revenue stability and competitiveness impacts study

This study aims to obtain firm-level information required for modelling contribution rates to **the Cali Fund**, the new **multilateral mechanism for benefit-sharing from the use of Digital Sequence Information on genetic resources (DSI)**. The requested data will support quantitative analysis of global industry participation, revenue projections across multiple contribution scenarios, and the design of equitable and proportionate contribution models for sectors that use DSI.

To support the implementation of Decision 16/2 establishing the Cali Fund, the CBD Secretariat has been requested to produce an evidence-based assessment of contribution rates for the Fund, including implications for revenue generation and economic competitiveness across DSI-dependent sectors. Delivering this analysis requires reliable information on the number, size, financial characteristics, use of DSI and other attributes of firms that fall within the Decision's definition of potential contributors (see 'Cali Fund Contributors' below). Because no global dataset currently provides consistent firm-level information across all these dimensions, targeted data collection is necessary to construct a robust sample of global firms required for the analysis.

This Data Request is intended to address this evidence gap by collecting the information required to model Cali Fund contribution rates and assess their potential impacts on affected businesses. By providing the requested data, your organization will directly support the quality and credibility of the underlying analysis, helping ensure that future reviews and revisions of the Fund are informed by realistic estimates of sector dynamics.

8. We thank you in advance for your assistance and contribution to this work.

USE OF DATA DISCLAIMER All data and information provided will be used exclusively for analytical modelling to assess potential contribution options for the Cali Fund. No firm-level information will be disclosed at any stage. Results will be presented only in aggregated, non-disclosive form, ensuring that individual firms or identifiable attributes cannot be inferred. Any analysis derived from the data will comply with confidentiality requirements and will be included solely as part of the accompanying Policy and Technical Reports. For a full data privacy notice, please see 'GDPR Privacy Notice' attached to the invitation email.

. Scope of DSI, Cali Fund contributors and contribution rates

The following information is provided as support on the notions of **Digital Sequence Information (DSI)**, the **entities and sectors identified as potential contributors**, and the **indicative contribution rates** to the Cali Fund.

A. DSI DEFINITION AND SCOPE

There is no CBD-agreed definition of digital sequence information on genetic resources at this point. An Ad Hoc Technical Expert Group was mandated in 2018 to provide clarity on digital sequence information on genetic resources, considering concept, scope and use. In 2022, the COP at its fifteenth meeting:

- Recognized "the different understandings of the concept and scope of digital sequence information on genetic resources, and the range of views regarding the need to define such concept and scope"
- Agreed "on the continuing use of the term "digital sequence information" for further discussions"
- Also agreed "that the benefits from the use of digital sequence information on genetic resources should be shared fairly and equitably"

At the last COP meeting in 2024, decision 16/2 decided on the scope of DSI under the multilateral mechanism and its Cali Fund: Annex para. 1: The multilateral mechanism for the fair and equitable sharing of benefits from the use of digital sequence information on genetic resources covers, without prejudice to national legislation, digital sequence information on genetic resources:

- (a) That is made publicly available, in compliance with national legislation, where applicable;
- (b) That is not subject to mutually agreed terms established at the time of access to the genetic resources from which the digital sequence information is derived, unless those terms allow for the making of the digital sequence information on genetic resources freely available;
- (c) For which the fair and equitable sharing of benefits from the use of digital sequence information on genetic resources is not provided for under other international instruments on access and benefit-sharing, unless the multilateral mechanism is chosen for that purpose under those instruments.

For this survey, DSI refers to DSI under the scope of the Multilateral Mechanism for the Fair and Equitable Sharing of Benefits from the Use of Digital Sequence Information on Genetic Resources, including the Cali Fund.

Scope of DSI, Cali Fund contributors and contribution rates

The following information is provided as support on the notions of **Digital Sequence Information (DSI)**, the **entities and sectors identified as potential contributors**, and the **indicative contribution rates** to the Cali Fund.

B. CALI FUND CONTRIBUTORS

Company size: [Decision 16/2 Annex para. 3] *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 United States dollars, and profit: 5 million United States dollars) averaged over the preceding three years.*

DSI-dependent sectors: [Decision 16/2 Enclosure I para. 1] *Sectors that may benefit directly or indirectly from the use of digital sequence information on genetic resources include: (a) Pharmaceuticals; (b) Nutraceuticals (food and health supplements); (c) Cosmetics; (d) Animal and plant breeding; (e) Biotechnology; (f) Laboratory equipment associated with the sequencing and use of digital sequence information on genetic resources, including reagents and supplies; (g) Information, scientific and technical services related to digital sequence information on genetic resources, including artificial intelligence*

C. CONTRIBUTION RATES [Decision 16/2 Annex para. 3] (...) *should contribute to the global fund **1 per cent of their profits** or **0.1 per cent of their revenue**, as an indicative rate*

1. Have you heard about the **Cali Fund** before?

☐ Yes

☐ No

Basic Information

This section collects essential details about your organization to help us understand how corporate structure may affect Cali Fund obligations.

2. Please provide your **full name**

3. Please provide your **position**

4. Please provide your **e-mail**

Please enter an email

5. Please provide your company's **legal name** *

6. Please provide your company's **legal entity number (LEI)**

An LEI number is a 20-character code based on the ISO 17442 standard developed by the International Organization for Standardisation (ISO).

7. Please provide your company's **country of registration** *

8. Which sector best describes your organisation's **primary activity**? (Select one) *

☐ Pharmaceuticals

☐ Nutraceuticals (food and health supplements) ☐

Cosmetics

☐ Animal and plant breeding ☐

Biotechnology

☐ Laboratory equipment associated with the sequencing and use of digital sequence information on genetic resources, including reagents and supplies

☐ Information, scientific and technical services related to digital sequence information on genetic resources, including artificial intelligence

☐ Other

9. Which sector(s) best describe your organisation's **secondary activities**? (Select all that apply) *

☐ Pharmaceuticals

☐ Nutraceuticals (food and health supplements) ☐

Cosmetics

☐ Animal and plant breeding ☐

Biotechnology

☐ Laboratory equipment associated with the sequencing and use of digital sequence information on genetic resources, including reagents and supplies

☐ Information, scientific and technical services related to digital sequence information on genetic resources, including artificial intelligence

☐ None of the above

☐ Other

10. What's your company's size? *

☐ Micro (1-9 employees)

☐ Small (10-49 employees)

☐ Medium (50 to 249 employees)

☐ Large (250+ employees)

11. Which best describes your organisation **within its corporate group**? (Select one) *

☐ Independent company (not part of a group)

☐ Parent company / headquarters of a domestically controlled group ☐

Parent company / headquarters of a foreign-controlled group



Subsidiary of a domestic parent



Subsidiary of a foreign parent ☐

Joint venture



Other

DSI Use and Exposure

These questions assess how your organization uses digital sequence information and how central DSI is to your operations, helping us identify which firms would be most affected by the Cali Fund mechanism.

12. Does your organisation use DSI **directly** and/or **indirectly**?

☐ Yes

☐ No

☐ Don't know

13. In the previous question, you answered that your organisation uses DSI directly and/or indirectly.

How critical is DSI to your organisation's operations? *

- **Essential:** DSI is central to our core activities and products/services.
- **High importance:** DSI is frequently used and important, but not central to all core activities.
- **Moderate importance:** DSI is used regularly in specific activities (e.g. R&D, product development) but is not core to most operations.
- **Limited importance:** DSI is used occasionally or indirectly.
- **Not important:** Our organisation does not use DSI for this category
- Don't know

Essential High importance Moderate importance Limited importance Not important Don't know

Direct DSI use	☐	☐	☐	☐	☐	☐
Indirect DSI use (used in products/service- es purchased)	☐	☐	☐	☐	☐	☐

14. Which of the following roles and activities does your organisation perform in the DSI value chain?

Select your primary activity. *

- ☐ Generating DSI (sequencing)
- ☐ Analytics / bioinformatics ☐
- Storage / distribution
- ☐ Using DSI in research & development
- ☒ Using DSI in product development / manufacturing
- ☐ Providing downstream services based on DSI
- Other

15. Which of the following roles and activities does your organisation perform in the DSI value chain?

Select all your secondary activities. *

- ☐ Generating DSI (sequencing)
- ☐ Analytics / bioinformatics ☐
- Storage / distribution
- ☐ Using DSI in research & development
- ☐ Using DSI in product development / manufacturing ☐
- Providing downstream services based on DSI
- ☐ Other

16. How difficult would it be to substitute DSI with alternative approaches or technologies? *

- ☐ Impossible
- ☐ Very difficult
- ☐ Moderately difficult
- ☐ Relatively easy
- ☐ Don't know

17. How do you expect your organisation's use of DSI to change over the next 5–10 years? *

- ☐ Increase significantly
- ☐ Increase moderately

- ☐ Stay the same
- ☐ Decrease moderately
- ☐ Decrease significantly
- ☐ Don't know

Economic significance of DSI Use

This section quantifies the **financial importance of DSI to your business** and explores **how your organisation might respond to potential cost increases** from Cali Fund contributions.

18. Please indicate the approximate share corresponding to each of the following indicators that is associated **with the use of DSI**, either **directly or indirectly**.

	0%	0-5%	6-20%	21-50%	>50%	Don't know	Prefer not to say
Share of total revenue	☐	☐	☐	☐	☐	☐	☐
Share of total profit	☐	☐	☐	☐	☐	☐	☐
Share of R&D expenditure	☐	☐	☐	☐	☐	☐	☐
Share of product/service portfolio	☐	☐	☐	☐	☐	☐	☐

19. How many patents or IP linked to DSI has your company filed or been granted? *

For 'Don't know' or 'Prefer not to say' type 99999

The value must be a number

20. Approximately what share of your organisation's **total operating costs as % of revenue is directly related to DSI** (e.g. sequencing, data storage, analytics, licences)? *

- ☐ 0%
- ☐ 0-1%
- ☐ 1-5%
- ☐ 5-10%
- ☐ 10% or more
- ☐ Don't know
- ☐ Prefer not to say

21. If DSI-related costs increase through contributions to the Cali Fund, **how easily could your**

organisation switch to DSI alternatives? *

- ☐ Very easily
- ☐ Easily
- ☐ With some difficulty
- ☐ Impossible
- ☐ Don't know

22. Do you expect your suppliers to pass on DSI-related cost increases to you? *

- ☐ Yes, likely
- ☐ Possibly
- ☐ Unlikely
- ☐ Don't know

23. How would your organisation respond to a potential increase in DSI-related operational costs? For each row, select the lowest DSI-related cost increase which would trigger a given response. Select one column for each row, incl. 'Not applicable' if you do not expect a given response to a DSI-related cost increase. *

Small (1%-5%)	Medium (5-15)	Large (15%+)	Don't know	Prefer not to	Not applicable
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Increase product or service prices	☐	☐	☐	☐	☐	☐
Reduce DSI use	☐	☐	☐	☐	☐	☐
Cease DSI use	☐	☐	☐	☐	☐	☐
Absorb the cost by reducing R&D spending	☐	☐	☐	☐	☐	☐
Absorb the cost by reduced hiring	☐	☐	☐	☐	☐	☐
Delay capital investments	☐	☐	☐	☐	☐	☐
Shift production or activities abroad	☐	☐	☐	☐	☐	☐
Shift R&D abroad	☐	☐	☐	☐	☐	☐
Reduce shareholder dividends	☐	☐	☐	☐	☐	☐
Seek exemptions / alternative models	☐	☐	☐	☐	☐	☐
Exit the market	☐	☐	☐	☐	☐	☐

24. What benefits, if any, would your organisation expect from contributing to the Cali Fund? (Select all that apply) *

☐ Commercial benefits (e.g. price premiums, revenue opportunities) ☐

Reputational or branding benefits

☐ Improved access to markets, tenders or partnerships ☐

Reduced regulatory or policy risk

☐ Improved ESG performance or access to finance

☐ Improved access to knowledge, data, or technical networks ☐

Internal or strategic benefits (e.g. learning, staff engagement) ☐ No

expected benefits

☐ Other

Market Competition & Consumers

These questions examine your competitive environment and customer base to understand whether firms can pass Cali Fund costs to customers or must absorb them, affecting competitiveness.

25. Where are your organisation's **main competitors** located (Select all that apply) *

- ☐ Domestic market
- ☐ Europe
- ☐ North America
- ☐ South America
- ☐ Asia
- ☐ Africa
- ☐ Australia

26. To what extent does your organisation face competition from the following types of companies?

*

	Not at all	To a small extent	To a moderate extent	To a large extent	Don't know
Domestic companies	☐	☐	☐	☐	☐
Foreign companies	☐	☐	☐	☐	☐

27. To the best of your knowledge, **to what extent do your main competitors depend on DSI?** *

- ☐ Not at all
- ☐ To a small extent
- ☐ To a moderate extent
- ☐ To a large extent
- ☐ Don't know

28. How many **significant competitors** does your main product/service face? *

- ☐ None (monopoly)
- ☐ 1 competitor (duopoly)
- ☐ 2-5 competitors
- ☐ More than 5 competitors ☐

Don't know

29. Would potential Cali Fund contributions affect your organisation **differently from your competitors?** *

- ☐ We'd be more negatively affected (competitive disadvantage) ☐

About the same impact

- ☐ We'd be less negatively affected (competitive advantage) ☐

Don't know

30. Who are the typical buyers of your organisation's products and/or services? (Select all that apply) *

☐ Private consumers ☐

Public sector entities ☐

Other companies

☐ Other

31. Do you consider your **customers price-sensitive?** *

Consumers are price-sensitive when their purchasing decisions change noticeably in response to price changes, meaning even small price increases or discounts can strongly affect how much they buy or whether they buy at all.

- ☐ Very price sensitive
- ☐ Moderately price sensitive
- ☐ Not very sensitive
- ☐ Don't know
- ☐ Other

Financial Information

This section requests financial data to help model aggregate industry impacts and potential Cali Fund contribution flows. We recognize this information is commercially sensitive.

Please provide financial data at the appropriate level (consolidated for group-level assessment or unconsolidated accounts figures for subsidiaries/individual companies).

32. What was your organisation's **average profit (net income)** over the **past 3 years**? *

☐ Less than \$5 million USD ☐

\$5 million USD or more

☐ Loss-making (negative profit) ☐

Don't know

☐ Prefer not to say

33. What was your organisation's **average revenue (sales/net turnover)** over the **past 3 years**? *

☐ Less than \$50 million USD

☐ \$50 million USD or more

☐ Don't know

☐ Prefer not to say

34. What was your organisation's **average total assets** over the **past 3 years**? *

☐ Less than \$20 million USD

☐ \$20 million USD or more

☐ Don't know

☐ Prefer not to say

35. Please use the space below to share any additional comments, clarifications, or information that you consider relevant to this study

36. Before you finish the survey, please select ONE option: *

- Authorize us to link your survey responses to publicly and/or privately available financial databases (e.g. Companies House).
Recommended - minimal effort.
- Submit simplified financial data using the Excel template attached to the invitation email. Please address it to [contact details removed]
- Skip this section if you prefer not to provide your financial data.