

COVINGTON

Inside EU Life Sciences

Updates on Legal Developments in the EU Life Sciences Industry

The Cali Fund and Why Legal Certainty Matters for Life Sciences R&D

By Bart Van Vooren on March 3, 2025



On February 26, 2025, the Cali Fund was officially **launched**. Established by the 196 parties to the Convention on Biological Diversity (“CBD”), the Cali Fund invites pharma, cosmetics, food, AI, plant breeding, animal breeding, biotech, and other companies to “share monetary benefits” from uses of digital sequence information on genetic resources

(“DSI”). Large companies in these sectors are **expected** to contribute 1% of their global profit, or 0.1% of their global revenue for biodiversity conservation.

Legal certainty is a top priority for stakeholders exploring the new Cali Fund, yet non-lawyers often struggle to grasp exactly what it entails, why it matters, or how to achieve it. This short explainer aims to clarify these issues for stakeholders who already know the basics of DSI and the Cali Fund. To illustrate the points in a practical, plain-English way, we present fictitious (but realistic, based on our legal practice) scenarios reflecting real-world R&D decision-making. By showing where uncertainties crop up for companies, we hope to shed light on how clearer rules can foster both innovation and fair benefit-sharing.

A Clear Definition of “DSI” and “Use”

What:

- Companies need to know what counts as “digital sequence information” on genetic resources and which activities count as “using” that DSI.
- Decision 16/2 for the Cali Fund references “direct or indirect benefit from use” but does not define these concepts.

Why it matters for R&D:

- **Example:** Suppose a company wants to investigate the anti-inflammatory properties of a plant from the Amazon rainforest. Instead of physically collecting samples, they download published genomic data of that plant from a public database. They run computational screening to see which genetic sequences might produce the anti-inflammatory compound found in that plant.
- **Impact of unclear definitions:** The company does not know if merely downloading these sequences—or using them in AI-driven product development—counts as “use” that triggers payment. They could spend months in legal consultations, delaying the project and driving up costs. Because R&D budgets are finite, a firm may skip the entire project if there is a risk of future compliance headaches.

Relevance to investment decisions:

- Business leaders typically need clarity at an early stage in R&D. If they cannot pin down whether the sequences they work with will subject them to year-by-year payments and reporting (with unclear penalties), they may stop development or switch to alternative approaches.
- This uncertainty can stifle innovation: potentially beneficial products (e.g., new skin formulations or nutraceuticals) never reach consumers.

Certainty About the Payment Formula

What:

- The Cali Fund text suggests “indicative rates” (e.g., 0.1% of revenue or 1% of profit). But it is unclear if these rates will apply to just the part of a company’s business that uses DSI or to all activities. It is also not certain whether a company needs to exactly match the percentages, or if those percentages are merely “indicative”.

Why it matters for R&D:

- **Example:** Imagine a company invests in developing a novel enzyme derived from mushroom genome data. The R&D project might cost millions of dollars over five years. The company does a 10-year revenue forecast for the resulting product.
- **Impact of fuzzy calculation formulas:** If the CFO cannot reliably project how the Cali Fund payment would affect product profit margins (is it 1% of total company profit, or only that product line?), the project’s financial viability is uncertain. This directly influences go/no-go decisions. If the rate is ambiguous or might increase later, the risk factor rises. That risk can tip the scales against investing in uncertain biotech ventures.

Relevance to investment decisions:

- Companies plan product pipelines years in advance. They rely on stable projections to convince boards or investors that an R&D project is worthwhile. If the final “tax-

like” burden could suddenly double, or if they might owe back payments once they commercialize the product, decision-makers might opt for simpler, less uncertain projects.

Proof That Payment Equals Compliance

What it means:

- Many companies want a single, globally recognized “certificate” or document stating that once they pay the Cali Fund, they have legally satisfied benefit-sharing requirements.
- Right now, a country can still demand separate benefit-sharing under national ABS laws.

Why it matters for R&D:

- **Example:** A biotech firm identifies a new probiotic strain from a particular region’s soils. After analyzing the strain’s DSI from a public database, they decide to commercialize a dietary supplement. They dutifully pay into the Cali Fund.
- **Impact of no guaranteed “freedom to operate”:** The country of origin’s national authorities might still demand additional negotiations or fees under their own ABS regime—even though the company already contributed to the global fund. This puts companies in a bind: do they risk going to market and face possible fines or reputational damage later?

Relevance to investment decisions:

- Legal unpredictability undermines business confidence. If a company’s IP or product can be challenged after it has invested tens of millions of dollars, that risk is often unacceptable to shareholders.
- Many firms will simply not begin R&D if they suspect a second (or third) wave of demands or legal trouble.

A Single, Global Approach to ABS (Instead of a Patchwork of National Laws)

What:

- Ideally, the Cali Fund would give users a one-stop shop for compliance. But because each country might implement it differently—or not implement it at all—companies could still face a mosaic of national rules on top of the global mechanism.

Why it matters for R&D:

- **Example:** A pharmaceutical company has R&D labs in six different countries. It sources DSI for anti-malaria drug candidates from multiple public databases.
- **Impact of a patchwork:** Each lab's legal department must figure out how local ABS rules layer onto global commitments. They could face a swirl of inconsistent guidelines, deadlines, or even contradictory obligations. If the overhead in hiring lawyers and compliance staff becomes too great, the entire project's cost skyrockets and may become cost prohibitive.

Relevance to investment decisions:

- Large multinationals do routine “risk mapping” for new product lines. Where complexity or the risk of non-compliance is high, projects get downgraded or cancelled.
- A single, predictable mechanism would reduce compliance costs, speeding up R&D decisions.

Clarity on “Direct” vs. “Indirect” Benefit

What it means:

- Decision 16/2 states that anyone who “directly or indirectly benefits from DSI” should pay, but does not specify the cutoff point.

- Does “indirect” mean a company that uses an ingredient from a supplier, where the supplier did the DSI-based R&D?

Why it matters for R&D:

- **Example:** A consumer-facing food brand buys a novel botanical extract from a specialized ingredient supplier. That supplier used DSI-based methods (e.g., gene sequencing to identify potent plant compounds). The brand itself never looked at a single base-pair of data; they just buy the ingredient.
- **Impact of confusion:** Do they owe the Cali Fund money “indirectly” since they benefit from the supplier’s DSI-based breakthroughs? If so, are they double-paying if the supplier already contributed? This leads to chain-of-custody headaches. Companies often have complex supply chains with multiple tiers of suppliers.

Relevance to investment decisions:

- Without bright-line rules, brand owners might fear being labelled non-compliant or unethical if any upstream partner used DSI. This can chill investment—firms might avoid certain novel ingredients or technologies just to be “safe” legally.

No Conflict or Double Payments with Other Systems

What it means:

- Beyond the CBD, other treaties (e.g., the Plant Treaty, the new High Seas Treaty, or WHO’s Pandemic Influenza framework) may require separate benefit-sharing.
- The Cali Fund does not automatically replace these.

Why it matters for R&D:

- **Example:** A seed company develops a new drought-resistant rice variety. They use genomic data from a global seed bank that falls under the Plant Treaty.
- **Impact of overlap:** If the data also qualifies as “DSI” under the Cali Fund, do they owe two separate fees—one to the Plant Treaty’s benefit-sharing fund and another

to the Cali Fund? Paying multiple times (and possibly negotiating separate contracts) might push the company to work with simpler or synthetic alternatives that bypass these laws altogether.

Relevance to investment decisions:

- Double payments cut profit margins and slow time-to-market.
- If the rules remain overlapping, some companies might shift focus away from biodiversity-based R&D, undermining both innovation and conservation goals.

Balanced Coverage That Exempts Smaller Players

What it means:

- Current text suggests the Cali Fund applies mainly to larger enterprises (e.g., above certain turnover or asset thresholds).
- But there is discussion about expanding obligations to medium and small businesses in the future.

Why it matters for R&D:

- **Example:** An innovative startup in biotech using CRISPR-based editing of microbial sequences wants to pioneer a “green” pesticide. They are still small, with limited revenue, so under the current guidelines they might be exempt.
- **Impact of possible expansion:** If tomorrow they cross a threshold—or if rules change—they could suddenly owe a significant chunk of their still-unstable revenue or profit. This might deter them from even scaling up. That unpredictability harms early-stage companies, which typically need clarity to pitch investors.

Relevance to investment decisions:

- Startups already face high failure rates. Uncertain or unexpected regulatory costs could be the tipping point that makes their R&D unviable.

- A stable, clearly articulated cutoff (with widely recognized definitions of SME vs. large enterprise) ensures that only companies with the means to contribute must do so.

Concluding Thoughts

Each of these elements ties directly into whether a company decides to pursue an R&D project involving genetic sequences. R&D pipelines often span years and cost millions—or even billions—of dollars. Company decision-makers do a complex cost–benefit analysis, factoring in technical feasibility, consumer demand, and legal/regulatory risks. If the Cali Fund’s infrastructure remain vague or if companies worry about legal snares (such as paying more than once, or paying without receiving genuine legal certainty), many promising research avenues may be delayed or abandoned.

By clarifying definitions, harmonizing rules worldwide, ensuring that paying into the fund pre-empts extra claims, and offering a stable payment formula, the Cali Fund can provide the legal certainty essential for robust, biodiversity-based R&D. That would help secure both business innovation and tangible support for biodiversity conservation.

Inside EU Life Sciences