Input from hollandbio - Dutch Biotech Association

# Call for evidence on the EU Biotech Act

**Europe worked hard to become a leader in biotech. But while the rest of the world is taking the next step, we are blocking ourselves. Innovations get stuck in outdated rules and fragmented regulations, talent moves elsewhere, and other continents capitalize on European breakthroughs. If we don't act now, Europe not only loses its frontrunner's position, but also the societal and economic benefits that biotech can deliver: new medicines, smarter and cleaner products and a resilient economy. Hollandbio, the Dutch biotech association, welcomes the EU Biotech Act as a long-awaited opportunity to restore Europe's leadership in biotechnology and strengthen our biotech innovation ecosystem—from invention all the way to uptake.**

The current call for evidence aims to gather evidence and stakeholder input that will inform the European Commission's legislative proposal for the European Biotech Act, expected in Q3 2026. This includes understanding the challenges biotech companies face and assessing the potential impacts of different policy options. The input helps evaluate how best to support the growth, competitiveness, and innovation capacity of the European biotechnology sector through five key objectives: Speed & streamlining, Financing, Scale, Skills and Data and AI. We fully support these ambitions and believe that by embracing an integrated approach, investing in frontrunners, paving the way to market and removing barriers for uptake, the EU can ensure that biotech innovations deliver on their promise—for people, planet, and prosperity.

## 1. Boosting biotech with an integrated approach

On a daily basis, biotech frontrunners face unnecessary hurdles and challenges in their aim to bring products from bench to market in the EU. To unlock biotech's full potential, we believe Europe needs a coordinated, long-term strategy. Therefore, we call for the **establishment of an overarching EU Life Sciences and Biotech Office** to lead strategic direction, implement best practices from Member States, and proactively identify and resolve regulatory bottlenecks before they cause harm. This office would ensure a science-based, predictable, and innovation-friendly environment across the EU, which supports the impact assessment's objective of enhancing speed and streamlining.

The Life Sciences and Biotech offices tasks could include (but not limited to):

- ➜ **Proactively identify and resolve legal or regulatory issues** before they hold back innovation;
- ➜ **Scout for best practices in member states** (regulation, policies and execution) and allow for EU wide implementation;
- ➜ **Seize the 28th regime framework** to simplify regulations and reduce administrative burden, particularly for biotech startups and companies;
- ➜ **Include the expert voice of the biotech ecosystem** when redirecting or setting up initiatives, strategies and/or regulations that concern;
- ➜ **Foster public dialogue and collaboration** to create awareness and to align innovation goals and societal value.

## 2. Investing in progress driven by frontrunners

One of the biggest challenges for start-ups and scale-ups in biotech is obtaining the necessary funding and resources to turn great ideas into valuable products. They face persistent funding gaps—especially in the "Valley of Death" (typically €5M - €50M) between public and private funding. And due to this persistent lack of funding, talent and other facilities many European biotech companies today are forced to move to stronger capital markets, such as the US. Therefore, we call for **sufficient and suitable**

Laan van Nieuw Oost-Indië 133M, 2593 BM Den Haag

**funding and resources** for biotech companies at every stage of development, aligning with the impact assessment's focus on improving biotech financing, scale, skills and use of Data and AI.

To address this, we recommend:
- ➜ **Targeting EU funding for academic tech transfer** and spin-offs to translate science into products;
- ➜ **Providing easily accessible start-up funding** (~€1M) to build a solid foundation for follow-on funding;
- ➜ **Introducing cross-border venture capital incentives** to attract institutional investors;
- ➜ **Creating a competitive IPO market** in Europe that can compete with mature markets like NASDAQ;
- ➜ **Enhancing EIC support** with larger budgets, simplified applications and stronger follow-on funding;
- ➜ **Encouraging national co-funding** for projects with an EU seal of excellence;
- ➜ **Redefine state aid rules** to allow deeptech companies access to essential subsidies;
- ➜ **Accelerate the Unified Patent System** rollout to support SMEs;
- ➜ **Upskilling, reskilling, and attracting global talent** in R&D, engineering, and entrepreneurship;
- ➜ **Expanding access to scale-up infrastructure and digital capabilities** to support biotech growth.

### 3. Paving the way to market entry

In Europe, biotech companies face a complex, fragmented, and inconsistent regulatory framework. This creates delays, high costs, and hampers access to the EU internal market. As biotech is a global effort, companies seek the most attractive route to market to launch first, which is currently rarely the EU. Therefore, we call for efforts to **make the EU the preferred market biotech innovations**, aligning with the impact assessment's goals of speed and streamlining.

To address this, we urge the EU to:
- ➜ **Streamline and harmonize regulatory requirements** to make EU approval routes the fastest and most fit-for-purpose globally;
- ➜ **Adequately resource EU agencies** (EFSA, ECHA, EMA) to improve efficiency and responsiveness;
- ➜ **Introduce regulatory sandboxes** to test innovative biotech solutions in a controlled environment.

### 4. Removing barriers for implementation and uptake

Even after reaching the market, biotech innovations often are held back to deliver their full value in practice. Whether it's a personalized treatment, a future-proof food product, or a carbon-free material — we fail to make the best use of smart solutions, for example due to a lack of demand-side incentives. In healthcare, new diagnostics and curative therapies fail to reach patients because they don't fit into existing national frameworks that were not designed for this time and age. And in the biobased economy, new biobased alternatives must compete with existing fossil-based products that benefit from legacy subsidies, scale advantages, and regulatory familiarity. As a result, patients and consumers are left waiting, and innovators are discouraged from launching in the EU. We therefore call for the **creation of fair and functional market conditions** that give patients, professionals, and consumers access to better, healthier, and affordable options for everyday products and life-saving therapies that work for them.

To address this, we recommend:
- ➜ **Stimulating demand** through public procurement, tax incentives (e.g. VAT reductions), and $CO_2$-based pricing mechanisms;
- ➜ **Mandating minimum shares of biobased materials** in certain product categories;
- ➜ **Supporting labelling and benchmarking** to help consumers make informed, sustainable choices;
- ➜ **Phasing out subsidies** for fossil-based or unsustainable alternatives;
- ➜ **Facilitate discussion and collaboration on national access to health innovation**, for example for rare diseases;
- ➜ **Ensuring sufficient pull incentives to overcome market failure**, such as for rare diseases, antimicrobials and antivirals.

Hollandbio looks forward to continued engagement with the European Commission and stakeholders across the EU to ensure that the EU Biotech Act becomes a catalyst for a thriving, innovation-driven, and globally competitive biotech ecosystem.

Laan van Nieuw Oost-Indië 133M, 2593 BM Den Haag