

Asks for a bold biotech act

The EU Biotech Act is Europe's opportunity to lead in biotech — not just for health and sustainability, but also for strategic autonomy and economic resilience. Biotech offers smart solutions for a healthier, greener, and more competitive future. But if Europe wants to remain a global player, we must ensure that these innovations can be developed, scaled, and implemented on European soil. The coming years are crucial: Europe must dare to boost biotech with an integrated approach, invest in progress driven by frontrunners, pave the way to market entry, and remove barriers for implementation and uptake. Only then can we make Europe the most attractive region for biotech innovation, strengthen our strategic autonomy, drive economic growth, and deliver societal impact. In a world of growing geopolitical tensions and supply chain dependencies, Europe cannot afford to be a picky buyer of biotech developed elsewhere. We must invest in the jobs, infrastructure, and innovation capacity that will allow us to shape the future from within. Representing the vibrant biotech sector in the Netherlands, hollandbio calls on the EU to take bold action and deliver on these essential asks.

1. Boosting biotech with an integrated approach

To unlock biotech's full potential, we believe Europe needs a coordinated, long-term strategy. On a daily basis, biotech frontrunners face unnecessary hurdles and challenges in their aim to bring products from bench to market in the EU. 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. Key tasks for this office include (but are not limited to):

- **Proactively spotting and solving legal and regulatory challenges** before they hinder progress.
- **Identifying and implementing best practices** from across Member States at EU level.
- **Seizing the 28th regime framework** to simplify regulations and reduce administrative burden.
- **Ensuring alignment and proportionality across EU legislation** (e.g. Biotech Act, AI Act, MDR/IVDR) to guarantee legal certainty, workable implementation and reduced administrative burden.
- **Guaranteeing biotech experts have a seat at the table** when new initiatives, strategies, or regulations are developed.
- **Promoting an integrated EU-wide cluster strategy** that encourages knowledge sharing, benchmarking, and collaboration between support organizations, focusing on quality and regional expertise.
- **Fostering public dialogue and collaboration** to build awareness and align innovation with societal needs.

2. Investing in progress driven by frontrunners

Unlocking biotech's full potential means giving entrepreneurs the resources they need to turn breakthrough ideas into real-world impact. Yet, start-ups and scale-ups in Europe face persistent funding gaps, especially in the "Valley of Death" between public and private investment. Too often, promising companies are forced to relocate to stronger capital markets abroad. Therefore, we call for **sufficient and suitable funding and resources** for biotech companies at every stage of development. To address this, we recommend:

- **Targeting EU funding for academic technology transfer and spin-offs**, ensuring Europe's leading scientific leadership translates into products and commercialization.
- **Providing easily accessible start-up grants** (~€1M) to lay a solid foundation for follow-up funding.
- **Introducing cross-border venture capital incentives** to attract institutional investors.
- **Building a competitive IPO market** in Europe that can compete with mature markets like NASDAQ.



- **Accelerate and simplify EU funding programmes** (e.g. EIC) by providing larger budgets, simplified applications, stonger follow-on funding and reduces time-to-grant and administrative requirements to better serve biotech start-ups and scale-ups.
- **Encouraging national co-funding** for projects with an EU seal of excellence.
- **Redefine state aid rules** to allow innovative deep tech companies access to essential subsidies.
- **Accelerate the rollout of the Unified Patent System** to support SMEs.
- **Investing in upskilling, reskilling, and attracting global talent** in R&D, engineering, and entrepreneurship, so available skills align better with industry needs.
- **Expanding and simplifying access to scale-up infrastructure and digital capabilities** to fuel biotech growth, such as (permitting for) pilot and demonstrator facilities, biomanufacturing sites and (standardized) data sharing platforms.
- **Securing critical resources such as energy and raw materials** for biotech manufacturing within Europe to boost capacity and competitiveness.
- **Harmonising and standardising rules for intellectual property protection, licensing, and spin-off** to facilitate smooth technology transfer across the EU, in a way that enables businesses to grow and operate freely in pursuit of their ambitions, while ensuring that control over innovation transfer does not concentrate disproportionately within academic institutions.

3. Paving the way to market entry

European biotech companies face a maze of complex, fragmented, and inconsistent regulations. 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 go-to market for biotech innovations** again. To address this, we recommend:

- **Streamlining and harmonizing regulatory requirements** so that European routes to product approval become the most efficient, fit-for-purpose, and fastest in the world.
- **Regularly updating regulatory frameworks** (“fitness checks”) to ensure they remain science-based, flexible, and adaptive to technological advances.
- **Benchmarking EU procedures against international best practices** to reduce unnecessary duplication, lower compliance costs, and accelerate market access.
- **Transitioning from a precautionary to a pro-innovation regulatory mindset**, allowing products with a positive (safety) risk/(societal) benefit profile to reach the market faster.
- **Assessing products based on their end characteristics**, not the technology used to create them (e.g. GM-derived products that do not contain viable organisms should not fall under food/feed regulation).
- **Equipping regulatory agencies** (EFSA, ECHA, EMA) with the resources and capacity they need to operate efficiently, responsively and collaboratively, to avoid duplications and delays.
- **Introducing regulatory sandboxes** to allow innovative biotech solutions to be tested in a controlled environment.
- **Supporting conditional approvals and early access routes** that enable faster market access, especially for products addressing unmet medical needs or urgent societal challenges
- **Streamlining ongoing compliance and renewal procedures**, ensuring that authorization duration and mandatory (follow-up) studies are proportionate and based on a proven safety track record.
- **Harmonising and accelerating EU-wide administrative and fiscal requirements**, including permitting procedures, procurement frameworks, taxation (e.g. tax credits and VAT rules), and customs regulations, to stimulate rapid, cross-border deployment of biotech innovation, especially in crises situations.

4. Removing barriers for implementation and uptake

Even after reaching the market, biotech innovations often struggle to prove their value in practice. Whether it’s a personalized treatment, a future-proof food product, or a carbon-free biomaterial — smart solutions are held back by 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 are based on standard care. 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 the better, healthier, and affordable options for everyday products and life-saving therapies that they want and need. To address this, we recommend:

- **Ensuring broad recognition of biotech as a key enabling technology** for health, sustainability, defense and economic growth, and actively promoting its positive role to policymakers, consumers, and future generations.
- **Enabling key transitions that create systemic change** for a better future, such as moving towards a circular rather than linear economy, biobased rather than fossil-based industry, plant-based rather than animal-based proteins, and personalised rather than generic medicine.
- **Empowering consumers to choose better** through clear labelling and benchmarking of future-proof alternatives.
- **Stimulating demand** through public procurement, tax incentives (e.g. VAT reductions), and CO₂-based pricing mechanisms, especially in areas where the market is not yet existing or where rapid uptake of biotech solutions is required to deliver necessary societal benefits.
- **Mandating minimum shares of biobased materials** in selected product categories to accelerate market uptake.
- **Phasing out subsidies** for fossil-based or unsustainable alternatives to level the playing field.
- **Facilitate national dialogue** on access to health innovation, including for rare diseases.
- **Ensuring sufficient pull incentives** to overcome market failure in areas such as rare diseases and antimicrobials.

