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 four 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. Instead of developing biotech policy within individual silos — health, safety, agriculture, economy, science, innovation etc. — we advocate for a broad biotech approach that cuts across directorates. After all, an ecosystem is only as strong as its weakest link: we need to jointly steer in the same direction to achieve the desired success.

To achieve this, 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 bottlenecks - financial, regulatory, implementation or others - 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.

Specific examples that would directly benefit from such an integrated approach include (though are not limited to):

- **Strengthen European food system resilience:** Position food biomanufacturing as a core element of Europe's food security and biosecurity strategy — reducing strategic dependencies and building a more resilient agrifood system.
- **Develop a standing mechanism to ensure that EFSA, ECHA and EMA assess biotech-derived products coherently and consistently.** Currently, these products, including live microorganisms, genetically modified microorganisms (GMMs), organisms derived from new genomic techniques (NGTs), enzymes and biostimulants, frequently fall under more than one regulatory framework at once, spanning food,

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chemicals and medicines. The Biotech Act can close this gap by 1) mandating structured and formal cooperation between EFSA, ECHA and EMA, modelled on the "One Substance, One Assessment" approach and extended to biotech-derived products; by 2) developing joint guidance on data requirements and setting out a single, coherent evidence framework; and 3) by aligning assessment methodologies and enabling data reuse, as currently solely the regulatory entry point can produce divergent outcomes for the same organism or molecule.

- ➜ **Implement a holistic approach to circularity and biomass use**, including 1) the establishment of EU-wide end-of-waste criteria, and 2) EU-level guidance on side streams and CO_2 in food-grade fermentation to ensure consistent treatment of similar feedstocks, as well as 3) the removal of barriers to cross-border movement of residues for efficient use of biomass resources in line with waste and by-product rules, and 4) a more coherent approach for the recognition of circular and CO_2-derived feedstocks in EU-frameworks.
- ➜ **Keep global supply chains open and connected** for innovation, biomanufacturing process & products. Strategic global (trade) partnerships and cooperation are essential for biotech innovation and impact. Given the current geopolitical tensions, this is perhaps more crucial than ever.

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 through for example the next Multiannual Financial Framework and the European Competitiveness Fund, but also by providing simplified applications, stronger follow-on funding and by reducing 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 essential subsidies by adapting the GBER to extend the time limit in which startups are exempted to 15 years and to revise the Undertaking in Difficulty definition so that it does not include deeptech, innovative startups and scaleups.
- ➜ **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.

For Biotech Act II, we specifically call for the following:

- ➜ Opening and/or expanding deployment funding for industrial biotech (e.g., eligibility within major EU instruments) and ensuring access to scale-up finance above TRL 7 to cover both capital expenditure and compliance-related operating costs.

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- Extend the scope of the EU Health Biotechnology Investment Facility and Pilot to all biotech applications, notably food and industrial biotech. Guarantee sufficient and consistent budget, clear evaluation cycles, and extend the time frame of the investment facility to at least 10+ years, in line with to the biotech innovation lifecycle (10-15 years).
- Extend the scope of Biotech Act I strategic projects into biomanufacturing for all sectors, while taking into account the biotech sector's amendments necessary to align the strategic projects with industrial reality.
  - **EU permitting category for biomanufacturing** as an industrial activity, covering food, feed, chemicals, materials and environmental applications
  - **Binding, activity-specific permitting timelines** (9-12 months) calibrated to biomanufacturing processes rather than energy-based metrics, ensuring applicability beyond coverage currently provided via net-zero or decarbonization frameworks.
  - **Standing EU-level FOAK financing instrument** targeting the pilot-demonstration-first commercial transition
  - **European network** of open-access, multi-user biomanufacturing facilities at demonstration and early commercial scale,
  - Shift **EU policy design** from indirect support via climate or energy eligibility criteria to direct, activity-based treatment of biomanufacturing, ensuring that permitting, financing and support frameworks reflect sector-specific technical, economic and time-to-market characteristics.
- **Support replication of commercial plants** (first-of-a-kind to nth-of-a-kind) through blended finance, guarantees, and risksharing tools.
- **Mobilise institutional and private capital at scale** through EU-level initiatives (including the Savings and Investments Union and the EIB Group's TechEU programme)
- **Establish a dedicated biomanufacturing window** within existing venture-scale instruments, with targeted access for SMEs and specialised (next generation) service providers.
- Link new regulatory requirements (such as content quotas or certification obligations) to **dedicated, matched funding** that covers both capital and operating costs over the relevant compliance timeline, ensuring that regulatory demand is accompanied by the financial capacity for implementation.
- **Align EU funding tools** (EIB, InvestEU, STEP) with regulatory pathways to support scale-up in Europe — not relocation abroad.

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.

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- **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.

For Biotech Act II, we specifically call for the following:

- Setting up a fit-for-purpose framework to unlock and scale the **broad use of micro-organisms**. Smart use of micro-organisms is one of the driving forces of biotech's potential. However, the current regulatory framework was never designed with the extensive opportunity of micro-organisms in mind. Therefore, to fully unlock the potential of micro-organisms, we call for a dedicated horizontal EU regulation on micro-organisms that 1) applies across sectors (including food, feed and environmental applications, but excludes health); 2) covers conditions (contained use and deliberate release) and 3) applies to all types of micro-organisms (category 0, 1 and 2). The new framework facilitates at least the:
  - Exclusion of micro-organisms from the GMO frameworks (2009/41/EC and2001/18/EC)
  - Exemption of microbial food cultures from the scope of article 3(2)(a) of Regulation 1333/2008 on Food Additives.
- Implement structural improvements to the **Novel Food Framework**
  - Introduce a more centralised and science-based EU approach, with earlier EFSA involvement where appropriate, to support consistent interpretation of novel food status across Member States
  - Improve and modernise the Novel Food Catalogue through clearer criteria, and a more transparent, user-friendly and regularly updated format to reduce the need for repeated case-by-case assessments and double-checking by applicants and authorities, together with a standardised, detailed template for Member State report.
  - Increase capacity and staffing of EFSA to process dossiers
  - Urgently include Novel Foods in regulatory sandboxes through Biotech Act I to ensure timely market access for safe and innovative solutions.
- Implement structural improvements to the **Food and Feed framework** (including GM)
  - Ensure legal clarity and harmonisation for **food and feed** across Member States by providing targeted legislative clarification to address persistent divergences:
    - Reintroduce a definition and provisions for feed additives intended for export only in Regulation (EC) No 1831/2003 on additives for use in animal nutrition.
    - Explicitly exclude food cultures from Regulation (EC) No 1333/2008 on food additives by adding them to the list of exemptions.
  - Remove the renewal requirements for GM import authorisations under the GM Food and Feed Regulation (EC1829/2003), as they have already been assessed as safe by EFSA and robust post-market monitoring already requires developers to report any safety concerns of GMOs.
  - Streamline the risk assessment of GM stacked events. Currently, stacked events are currently regulated in the EU (EC 2001/18 and 1829/2003) as essentially new products, requiring a separate and near-comprehensive risk assessment. The Commission should ensure that EFSA implements simplification measures in the GM sector, including reviewing data requirements for established technologies with a history of safe use, such as GM stacks, specifically by changing the Implementing Regulation.
  - Shifting from the current mandatory requirement to a case-by-case approach to animal feeding studies, under Implementing Regulation (EU) No 503/2013 on applications for authorisation of genetically modified food and feed. This shift is not only scientifically justified but also a legal obligation under the 3R Directive.
- Improve **EFSA authorisation procedures**
  - Harmonising the use of "stop-the-clock" by defining clear criteria, limiting iterative requests, and setting reasonable timelines.
  - Ensuring adequate resourcing and capacity within EFSA to deliver timely and efficient risk assessments.
  - Establish an earlier, structured and formal pre-submission consultation process between innovators and regulators, including pre-submission guidance and joint scientific advice, with

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EFSA to clarify data requirements and prevent delays. To maintain scientific independence, a dedicated 'front desk', separate from scientific evaluators, should oversee these consultations.

⟶ Develop qualified presumption of safety (QPS)-type publicly available lists for cell-based foods, including cell-types, media, or equipment components that are safe to use, as well as substances of concern (in processes or products, based on dialogues and results of safety reviews.

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, climate, 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, including biotech into the EU Taxonomy Regulation, tax incentives (e.g. VAT reductions), and CO_2-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.

For Biotech Act II, we specifically call for the following:

- **Remove market implementation barriers & increase consumer understanding**

⟶ Amend labelling provisions to explicitly allow the use of non-technical or common microorganism or product names (including Latin names where appropriate), unless more precise naming is strictly necessary for safety reasons, to align with consumer understanding and market practice.

⟶ Updated EU definition of bio-based to include advanced biotechnologies.

⟶ Harmonised communication standards for biotech-derived products.

⟶ Creation of meaningful, aligned and scientifically robust communication language for consumers (for both biotech and conventional products).

⟶ Avoid disproportionate or misleading labelling requirements that hinder innovation without improving consumer understanding. Don't give in to innovation blocking lobby arguments that hide their true agendas pretending to protect citizens, saying things like "the consumer has a right to know" or "these names will confuse consumers" to ban common-sense product naming, or to push for senseless labelling requirements of f.e. the technique used to make products, patents, etc.

- **Create lead markets and a level playing field** with fossil-based products

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- **Create a toolbox of market-pull measures**, tailored by value chain. Provide a coherent set of demand-side instruments — content targets, labelling, public procurement, VAT and other tax measures, certificate and credit systems, and Contracts for Difference — and apply the right combination to each value chain (food and feed; chemicals, home and personal care; materials and plastics), rather than a one-size-fits-all approach.
- **Make content targets technology neutral**. Where product-level content targets are used, define them at end-product or product-group level, and allow both bio-based and bio-attributed (mass-balance) content to count towards compliance.
- **Recognise bio-attributed** (mass-balance) products as contributing equally to EU goals. Treat bio-attributed products as delivering the same benefits as physically bio-based products and as counting fully toward EU climate and circularity objectives.
- **Scale public procurement** to create early demand. Expand sustainable and green public procurement to build early markets for bio-based products beyond healthcare.
- **Use fiscal incentives and buyer commitments** to accelerate uptake. Deploy reduced VAT, targeted tax relief and aggregated buyer commitments to help close the cost gap and bring volumes to scale.
- **Review taxonomy criteria** for sustainability finance, either within the current technical screening criteria revision, or by committing the next review cycle and related delegated acts including revisiting criteria for bio-based products
  - Distinguish between biotech and conventional processes in the EU Taxonomy framework
  - Removal of eligibility criteria for bio-based plastics which sets a precedent for other non-food applications).
- **Ensure science-based and technology-neutral sustainability criteria** that are predictable, proportionate and workable in practice. This includes aligning carbon accounting methodologies, leveraging existing certification schemes and infrastructures, and building on tools such as the Digital Product Passport, rather than introducing fragmented or overlapping systems.

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