# The Antwerp Declaration for a European Industrial Deal

# Antwerp Dialogue on Biotech

## Brussels, 13 May 2024

*The meeting took place at the invitation of Marco Mensink (Cefic), Olivier de Matos (CropLife Europe), Nathalie Moll (EFPIA) and Claire Skentelbery (EuropaBio), and was chaired by Jacki Davis (Meade Davis Communications).*

This Antwerp Dialogue emphasised the need for a holistic, ecosystem approach to maximise potential of biotechnology. Alongside building public acceptance and attracting young talent, effective communication of the benefits and challenges around biotechnology is crucial for scaling investments, fostering innovation, and meeting regulatory requirements. The conclusions focus on mobilising capital, enhancing public procurement, developing workforce skills, streamlining regulation, ensuring regulatory coherence, and scaling up biotech innovations.

1. Mobilising Capital and Investment: Scaling biotech innovations requires substantial investments backed by a supportive financial ecosystem and enhanced funding mechanisms. Access to capital can be supported by a combination of grants, equity, and blended finance involving both public and private sectors. The European Investment Bank (EIB) and existing innovation funds should be further utilised, alongside exploring new opportunities for co-investment and risk mitigation. Creating a level playing field within the EU, also by completing the Capital Market Union, can incentivise and enable companies to grow capacity within Europe, rather than in other regions with more favourable funding conditions. Specific attention should be given to Intellectual Property rights, as a means to protect innovations and attract investors. Unused recovery and resilience funds could be redirected towards biotech investments, ensuring financial support is available for critical investment decisions. Specific financial support should be provided for building initial production plants, which tend to be more expensive and carry higher risks.

2. EU Measures to Stimulate Market Demand: Promoting the manufacturing of critical products, via biotech, within the EU will reduce strategic dependencies on imports. Strong demand-side measures and strategic public procurement are vital for fostering a robust biotech sector within the EU. Incentives should be introduced to encourage the adoption of biotech solutions and the use of biobased feedstocks in product manufacturing across various sectors, and not solely for their use as fuels or in energy-related applications. Joint procurement initiatives, such as those by the European Commission's DG HERA, could be utilised in very specific cases of health threats to strengthen market capacity, while also being based on multiple bidders and ensure the availability of countermeasures to address health threats. Sufficient R&D funding tools and

capacity should be allocated to DG HERA within the next multiannual financial framework (MFF). Policies that support the use of biobased solutions will also help to stabilise and diversify supply chains.

3. Upskilling and Workforce Development: The biotech sector faces a significant skills gap that hampers its growth and innovation potential. Strategies to attract young talent to the sector will mitigate the challenges of an ageing workforce. Lifelong learning initiatives tailored to the biotech sector should be developed and promoted, ensuring continuous skill development and adaptation to new technologies. Introducing conditionalities in policy instruments, similar to the US Chips Act or Inflation Reduction Act, can incentivise workforce development and skill acquisition. Training and skills criteria should be implemented as prerequisites for accessing support, particularly through public procurement processes.

4. Regulatory Coherence and Predictability: A predictable, future-proof and coherent regulatory framework is essential for the growth and stability of the biotech sector. Biotechnology is applied in many sectors such as agriculture, food, health and environment, and legislation in those areas should consider the support to develop science and its applications. Regulatory pathways also need to be ready to support the integration of cutting-edge technologies, in particular AI, which have enormous capacity to accelerate R&D in biotech. Concerning a potential Biotech Act, several considerations should be made: if comprehensive and ambitious, such an Act could streamline and unify regulations across the EU, providing a stable framework for long-term investments. Yet, caution must be made to avoid adding unnecessary regulation or delay in action, when some pressing challenges must be tackled through non-legislative means in a matter of urgency. Ensuring biotech products are recognised and accessible across all EU Member States requires harmonised regulations to reduce barriers to market entry. Coherence and coordination of regulatory efforts across the EU will reduce bureaucratic hurdles and delays, and foster consistency and predictability. Simplified and agile regulatory processes will enable quicker market access for biotech innovations. Legislating biotechnology within the various sector specific regulatory frameworks would benefit an approach taken in other geographies that moves from a process-based to a product-based approach, to encourage innovation while ensuring safety and public confidence. Furthermore, a set of indicators to measure regulatory efficiency and market access speed, will help monitor and ensure the biotech sector's progress.

5. Scaling Up and Measuring Success: To build Europe’s competitiveness on a global scale, actions must be taken to support the scaling up of startups in Europe similar to initiatives in other regions, like the United States or Asia. A contributing factor preventing the scale-up of biotech innovations in Europe are regulatory bottlenecks. Improving the flexibility of approval processes through regulatory sandboxes can accelerate the introduction of new biotech products while reducing the burden on applicants, particularly SMEs. At the same time, it will be crucial to ensure coherence between biotech-focused initiatives and other EU initiatives, like the EU Green Deal, Critical Raw Materials Act, Farm to Fork Strategy and the Digital Single Market. While innovation success can be difficult to measure, establishing clear industry targets and outcome-based performance indicators, such as the number of marketing authorisations and first launches, will help measure progress and competitiveness. Regular tracking and reporting on key performance indicators will ensure transparency and accountability in the

biotech sector's development. The process to develop these indicators should involve all relevant stakeholders.

In conclusion, participants agreed:

- Biotech is strategic and cross-cutting, and it has the potential to deliver on competitiveness as well as the green agenda.
- The eight actions listed in the Commission Biotech communication are important, but overlook an action for a collective effort involving policymakers and industry in building public trust and acceptance.
- Outcome-based policy making best guarantees bringing innovation to the market, in that all actors would have clear tasks, i.e. policy makers to set targets/outcomes and industry to innovate to deliver on them.
- Policy and regulatory coherence are critical to success.
- Future-proofing and agility of regulatory systems should be the norm.
- A sense of urgency is required to tackle the key bottlenecks to the further development of biotech. The Commission communication mentions the publication of several studies by the end of 2024 / mid-2025. If these studies are sufficiently solution-oriented, they can help solve the challenges during the next Commission mandate.
- All participants were invited to think about indicators to measure progress in terms of speed, agility and scale, and contribute to Commission studies with solutions.

## Endorsing organisations

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