Comments on the EU Biotech Act

aimed at transforming our economy into a bioeconomy

Biotechnology is nature's toolbox and gives humankind vital room to manoeuvre. It has the potential to provide transformational solutions for the challenges of today and tomorrow.

Biotechnology thus serves as a bridge between biological discoveries and real-world innovations and is playing an increasingly important role in many areas, such as medicine (diabetes, cancer and rheumatoid arthritis drugs), the environment (sewage treatment plants, detergents), climate change (CO_2-neutral production), raw materials (degradable bioplastics) and energy (biokerosene). The technology's sustainability is contingent on the use of biological production processes and on the CO_2-neutral extraction and conversion of renewable raw materials.

In order to leverage the power of biotechnology, the EU Biotech Act must strengthen Europe's global position in the development of this strategic technology through an ambitious, cross-sectoral approach. In doing so, the EU Biotech Act should further bolster the effectiveness and impact of EU initiatives such as the Life Sciences and Biotechnology Strategy, the Bioeconomy Strategy, and the Clean Industrial Deal.

In particular, the EU Biotech Act provides a pathway to:

- Strengthen value chains, from R&D to end users, so that groundbreaking advances from European research benefit Europe's economy and its citizens.
- Create coherent regulatory pathways so that Europe is a priority destination for both domestic and global innovation.
- Build an innovation ecosystem that features high-quality, skilled jobs and resilient global value chains in all Member States.

The EU Biotech Act should address four pillars that reflect European ambitions in terms of competitiveness, sustainability, health and strategic autonomy:

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1. Improving the financing environment

- Establishing a Biotech for Europe Initiative in order to accelerate R&D and commercialisation in the biotechnology sector.
- Creating an Important Project of Common European Interest (IPCEI) that promotes pilot projects and commercial bioproduction facilities in the EU.
- Setting up European capital-collecting institutions that facilitate investment in venture capital.
- Enabling self-disclosure by companies with regard to compliance with blending quotas and material specifications in order to ease the entry of bio-based products onto the market.
- Linking up EU funding programmes with the UN Sustainable Development Goals in order to support the aims of the European Green Deal.

2. Simplifying rules and procedures

- Mapping and evaluating all existing laws and directives at EU level that are relevant for biotechnological manufacturing processes and bio-based products (including therapeutics, diagnostics, enzymes and biomaterials) in order to reduce regulatory hurdles. Continuous monitoring so that regulatory adjustments can be made quickly as soon as new technologies and markets emerge.
- Creating a clear legal environment for biotechnology and biomanufacturing and for the protection of IP rights and biotechnological innovations.
- Introducing the use of fictional consent and opt-out solutions in order to speed up processes.
- Adopting special approval regulations for production organisms that focus on the safety of the end product rather than on the techniques involved or the respective technology categories (e.g. "genetic engineering").

3. Intensifying cooperation

- Establishing an EU Biotech Office under the leadership of a Chief Biotech Officer to ensure policy coherence and accelerate the market entry of biotech products, as well as setting up an advisory body comprised of representatives from industry and academia to guide policy decisions.
- Launching an EU-wide network of national and regional biotech hubs and developing a European-wide exchange programme for researchers and innovators in order to support start-ups and SMEs in the biotechnology sector.
- Creating a European Biotech Forum to promote dialogue between EU institutions, Member States, industry and academia.
- Strengthening expertise by assessing the need for skilled workers in the biotechnology sector and attracting and retaining global talent, as well as creating an EU-wide educational programme in collaboration with universities for training the next generation of biotech experts.

4. Broadening acceptance of biotechnology

- Promoting public relations efforts, dialogue with society, and a clear commitment to communicating innovative technologies and products transparently.