## 10 priorities for the EU Biotech and Biomanufacturing Initiative







Att.: European Commission; Cabinet to President Ursula von der Leyen and DG GROW

## Appeal to the European Commission to develop conducive framework conditions to allow the strong EU biosolutions sector to become a key driving force of the green transition: Priorities for the EU Biotech and Biomanufacturing Initiative

The Alliance for Biosolutions, Food Fermentation Europe, Bio Base Europe Pilot Plant, VTT and Atova Regulatory Consulting, welcome President of the European Commission Ursula van der Leyen's announcement of an 'EU Biotech and Biomanufacturing Initiative' as a priority in her Letter of Intent at the State of the Union on 13 September 2023.

Biosolutions are products and solutions that are produced with the use of living microorganisms and fermentation technology. Today, the sector already delivers innovative, sustainable solutions that enable the EU green transition in a wide range of other sectors, such as industry, agri-food and transport. Innovative biosolutions have the potential to become an even bigger driving force of the green transition, help the EU economy grow and provide new jobs while supporting the EU's strategic autonomy.

The European biotechnology sector employs around 223,000 people<sup>1</sup> directly and supports 710,500 jobs along the value chain, mainly created by the suppliers of goods and services to the biotechnology industry. For each position in the biotechnology industry there are 3.2 additional jobs in the overall economy.

A recent study conducted for the Alliance for Biosolutions estimated that the global market potential for biosolutions in other industries such as, transport and the agri-food sectors could surge from EUR 240 billion in 2020 to EUR 640 billion in 2030, if optimal framework conditions are created.<sup>2</sup>

The same study found the achievable global emission reduction potential of mature, ready-to-deploy biosolutions to amount to roughly 4,300 million tons of CO2 equivalents towards 2030, corresponding to around 8 pct. of current global emissions.

This growth potential and an accelerated green transition can become a reality and evolve even further if full and faster market access for biosolutions is prioritized within the EU.

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<sup>&</sup>lt;sup>1</sup> EuropaBio (2021). Measuring the economic footprint of the Biotechnology Industry in Europe (WifOR Study)

<sup>&</sup>lt;sup>2</sup> Copenhagen Economics (2022). The Potential of Biosolutions



For example, biological plant protection products and bio-fertilizers can complement synthetic products thereby reducing the use and the risk of hazardous (chemical) pesticides and fertilizers.

Fermentation technology can enable a more efficient and healthier food production, including through the development of new protein sources and the reduction of food loss and waste.

New sustainable protein sources for food and feed production can help reduce the environmental impact, enable more efficient land use and improve biodiversity. Bio-based materials can help replace synthetic, fossil-based plastics.

Finally, biosolutions can ensure carbon capture, replace fossil fuels and contribute overall towards a shift to a biobased, sustainable economy. Unlocking the access to sustainable biosolutions will thus have a positive impact on the environment, human and planetary health including a resilient food system.

However, to unleash the full potential of biosolutions, to scale up production capacity and to stimulate further innovation and investments in the sector, it is crucial to improve the framework conditions in the EU on several levels. Critically important in this respect is the adoption and implementation of a tailored regulatory system and faster approval processes that enable biologicals' swift entry to the market, thereby creating incentives for investments in jobs and opportunities to drive the global green transition and improve human health.

The increasing investments in government funds from countries like the US and China coupled with efficient regulatory frameworks for biosolutions, pose a real challenge for Europe's competitiveness. Europe remains world class in research and innovation but does not excel in turning research into commercial products and, therefore, societal solutions.

The EU should provide predictable and stable conditions to incentivize investments, attract talents and to deliver on the EU objectives. This could help strengthening European autonomy and reduce dependency on third countries.

## The need for a significant shift in the EU paradigm

The undersigned urge the EU Commission to make the upcoming *EU Biotech and Biomanu-facturing Initiative* the point of departure for a significant paradigm shift towards regulation and legislative framework conditions that prioritize bio-innovation and sustainable solutions based on biotechnology, acknowledging these as fundamental drivers of industrial competitiveness and green transition. Therefore, we call on the EU institutions to:

1. **Recognize biobased solutions as a separate**, **enabling sector:**The EU should recognize biosolutions, biotech and biomanufacturing as a separate industry, differentiated from chemical solutions, and in need of a tailored regulatory



- and policy framework, including update of EU NACE codes to include biosolutions as a sector in its own right.
- 2. **European autonomy:** Strengthen European autonomy and reduce dependency on third countries by increasing the availability and accessibility on the EU market of innovative biosolutions through more efficient regulatory procedures, and by stimulating the demand-side of sustainable biosolutions.
- 3. Research, innovation, and development investments: Prioritize substantial investments in research and development to foster innovation in biosolutions. This includes funding for cutting-edge biotechnologies, such as gene editing and synthetic biology, to advance the field. Moreover, harmonization between research and industrial policy should be ensured.
- 4. Mainstream sustainability in EU law and policy and address regulatory uncertainty by fully implementing the innovation principle: Truly mainstream sustainability in all union policies by fully implementing the innovation principle in EU law and policy, to drive change toward innovative, sustainable solutions. To ensure the level of innovation and technological progress needed to ensure the green transition, EU legislation should be responsive to innovation, while also providing regulatory predictability. To this end, the innovation and precautionary principles should go hand in hand and the better regulation principles should be strictly applied.
- 5. **Adopt risk-benefit assessment of biotech and biosolutions:** Adopt risk-benefit assessment of new biosolutions, adopting an explicit mandate for the EU risk assessor to evaluate both risk and benefit in a broad sense to help inform the risk-manager of the broader real-world impacts of innovations.
- Talent development and education: Invest in educational programs and workforce development to ensure a skilled and knowledgeable workforce in biotech and biomanufacturing as well as regulatory sciences and cross-disciplinarity.
- 7. **Access to funding and capital:** Facilitate access to venture capital, grants, and other forms of financial support for startups and established biotech companies. Encourage collaboration between public and private sectors to accelerate innovation and growth in the biotech industry.
- 8. **Infrastructure, scaling, and capacity building:** Direct investments or economic incentives towards development of infrastructure and capacity required for scaling and accelerated adoption of biosolutions. This also includes rapid expansion of fermentation capacity at regional and local levels where start-ups can test their innovative production on a much bigger scale.



- 9. **Trade agreements and international standards:** EU should lead negotiations towards mutual recognition and common standards for biosolutions to allow for rapid and non-bureaucratic placement on markets of recognized goods and services that enable green transition.
- 10. **Criteria for enabling solutions:** Development of EU Green Taxonomy criteria for economic activities based on sustainability enabling biosolutions, i.e., nature-based solutions that can support the green transition of other sectors.

