



BIOTECHNOLOGY

INDUSTRY MANIFESTO 2019

Resetting the ambition
for biotechnology
in the EU

BIOTECHNOLOGY INDUSTRY MANIFESTO 2019



INNOVATIVE BIOTECHNOLOGY BENEFITTING PEOPLE AND PLANET

EuropaBio, the European Association for Bioindustries, is the recognised voice of the EU biotech community, championing world-class solutions for society's challenges. EuropaBio and its members are committed to the responsible use of biotechnology to improve quality of life, to prevent, diagnose, treat and cure diseases, to improve the quality and quantity of food and feedstuffs and to move towards a bio-based and zero-waste economy.

Very few other sectors enhance quality of life, knowledge, innovation, productivity and environmental protection like biotechnology. From new drugs that can address unmet medical needs and fight epidemics and rare diseases, to industrial processes that use renewable feedstocks instead of crude oil, to drought-resistant crops that allow farmers around the world to feed more people under ever-harsher climatic conditions, promoting and investing in biotech pays economic, societal and environmental dividends.



INDUSTRIAL BIOTECH

CO₂ mitigation potential of industrial biotech and bio-based products between **1-2.5 billion tonnes** of CO₂ equivalent per year by 2030



Close to 500,000 jobs in the IB value chain and **€ 31.6 billion** added value



1:4 job multiplier: for every job created in industrial biotech there are 4 jobs created elsewhere



Greener transport thanks to sustainable biofuels, rubber, tyres and bioplastic parts



Sustainable alternatives to fossil-based products: bio-chemicals, plastics, seed inoculants and pest control, etc.



Solutions to improve **resource efficiency** of industrial processes



HEALTHCARE BIOTECH

A new treatment of cancer or a rare disease is **72%** likely to come from an **emerging biopharma company**



EuropaBio Healthcare Members spend **€ 62 billion a year on R&D** = 16% revenue



EuropaBio SMEs invest close to **150% of revenue in R&D**



> 160 drugs for rare diseases **approved** in the EU



> 3.4 million Europeans are diagnosed with cancer every year and **30 million** Europeans suffer from rare diseases



AGRICULTURAL BIOTECH

17 million farmers globally grow GM/biotech crops on **189.8 million hectares**



Built-in **protection against insects**



Less fuel and CO₂ emissions - Equivalent to saving **27.1 million tonnes** of CO₂ each year



Reduced soil erosion - **Saving land from plowing and cultivation**



6% to 30% more yield



Less toxins in food



Helping alleviate poverty and hunger - Uplifting the lives of 16-17 million small farmers and their families totaling **> 65 million people**

Resetting the ambition for biotechnology in the EU

INTRODUCTION

Over the coming decades, it will be essential to innovate towards delivering sustainable solutions to the broad range of challenges that Europe is facing. The biotech industry can help tackle several of these significantly, contributing to a more resource efficient, climate neutral and innovation driven knowledge-based economy that improves the health and well-being of people and planet.

Biotechnology is one of the key enabling technologies driving the fourth industrial revolution. It has delivered huge advances in many sectors, including healthcare, industrial processes and agriculture. To help achieve the UN Sustainable Development Goals by 2030, a proportionate, fit-for-purpose and science-based approach to modern technologies, such as innovative biotechnology, is essential.



The EU's biotech industry is led by a highly-skilled community of large, medium and small (SMEs) research and development intensive businesses, start-ups, scientists and academics. Going forward, the key will be to retain and grow talent, encourage collaboration across countries, secure increased investment and faster uptake of innovations.



With its own specific biotech ecosystem, Europe can take the global lead by sustainably developing its economy, to protect the environment, secure jobs, improve the health, life expectancy and well-being of European citizens.

Biotechnology is part of our everyday lives and offers citizens concrete solutions. However, regulatory roadblocks such as slow and politicised authorisation systems for some biotech applications are blunting Europe's competitive edge and are already limiting the availability of and access to demonstrably safe biotech products and processes in Europe. While Europe holds a leading position in some areas of biotech research, the last decade has seen an exodus of R&D expertise and decline in investment in the EU .

Europe is lagging behind, especially in the field of agricultural biotechnology, partly due to an excessive emphasis on precautionary policies. Precious years to innovate, invest, create jobs and bring new solutions to patients, consumers and farmers have been lost.

TIME TO ENGAGE IN A NEW DIALOGUE AND EMBRACE THE POTENTIAL OF BIOTECHNOLOGY IN EUROPE

The complexity of the technology, combined with misinformation and a backlash against science, academia and expertise have created misunderstandings and unfounded concerns about biotech. To be successful, Europe's core values of progress and solidarity need to be applied. An open and transparent dialogue is critical to reinstating trust in sound science and policy making.



The new mandate of the European Parliament and Commission for 2019-2024 will represent an opportunity to reset the ambition for biotechnology in Europe. We encourage all decision makers at European and national level to consider our call to action.



Now is the time for the EU to move forward decisively, improving its competitiveness on the world stage, investing in sustainable growth, and tackling the global challenges facing people and planet.

5 guiding principles for a competitive EU biotechnology industry

- 1 Sound science-based policy making** applying the precautionary principle as intended, fully implementing the innovation principle, and ensuring efficient product authorisation systems.
- 2 Fast and equitable access** to innovative biotechnology products and processes to the benefit of patients, consumers and farmers, reflecting a fully functioning single market.
- 3 Fair and sustainable Intellectual Property systems**, supporting research and development of biotechnology-derived products and processes.
- 4 A supportive and predictable funding framework** which includes a focus on building a stronger SME and start-up biotech ecosystem and facilitating access to finance for SMEs.
- 5 A highly-skilled workforce in all Member States** to increase competitiveness and meet the evolving needs of a fast-moving, innovative biotechnology sector.



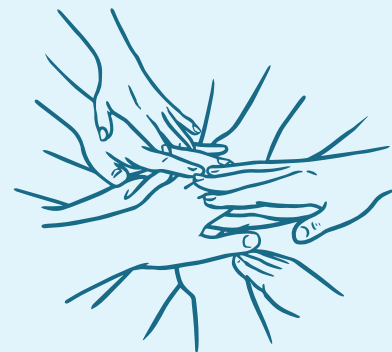
CALL TO ACTION

1 Foster innovation-enabling supportive measures and regulation

- Urgently take measures to ensure a science-based, predictable and fair approach to genome editing, that reflects technological progress and is based on the principle of proportionality. Enable utilisation of genome editing for product development and ensure that organisms developed with precise, modern mutagenesis techniques are not subjected to disproportionate regulatory requirements.
- Ensure efficient risk assessment, especially for products with decades of safe use, such as transgenic crops.
- Remove scientifically unjustified regulatory requirements, especially when they contradict the EU's policy to reduce animal testing.
- Make science-based decisions: Member States and Members of the European Parliament should support the approval of safe products.
- Confirm renewed commitment to the EU bioeconomy and recognise the central role of biotechnology as an enabling technology for a more competitive, sustainable bioeconomy.
- Boost market uptake of innovative bio-based products and adopt measures to support their deployment, such as the rolling out of public procurement initiatives and measures to raise awareness of their benefits.

2 Build trust

- a. Make a step change in risk communication: the Commission and other authorities should prioritise delivering the forthcoming 'general plan for risk communication' on food safety.
- b. Combat the spread and sources of misinformation.
- c. Engage in active discussions on ethical aspects of innovation by fostering a dialogue with industry, consumers, patients, farmers, media, investors, purchasers and policy makers.



3 Protect intellectual property

- a. Maintain the biotech patents directive in its current form, which is already fit for purpose.
- b. Strive to offer the most internationally competitive suite of IP incentives in order to attract investment and stimulate future innovation in the context of lengthy product authorisation processes. This should include Supplementary Protection Certificates as well as other intellectual property rights and incentives for products such as pharmaceuticals (e.g. Orphan Medicinal Products and Paediatric indications), biosimilars and crop protection products.
- c. Continue to protect confidential business information and trade secrets, also in regulatory systems.

4 Establish a supportive and predictable funding framework

- a. Prioritise easy access to funding to build a stronger SME and start-up biotech ecosystem, favouring the development of small enterprises.
- b. Ensure an appropriate level of funding for the bioeconomy and biotechnology under Horizon Europe to enable the development of new biotech solutions.
- c. Support translational research projects, and Joint Undertakings, in particular ensure continuation of the Bio-based Industries Joint Undertaking and the Innovative Medicines Initiative II.
- d. Establish a new life science financing mechanism addressing both financing and therapeutic gaps.
- e. Improve coherence of different financing mechanisms.



5 Develop a strategy for biotechnology-focused industrial innovation

- a. Foster strong European knowledge-based bioindustries.
- b. Develop and support a new EU life sciences and biotechnology strategy to make the EU a world leader in cutting edge, coherent and integrated innovation to create new jobs in modern bioindustries through technological progress.
- c. Prioritise life sciences and biotechnology amongst the Key Enabling Technologies for the future in the EU Industrial Policy Strategy: a vision for 2030.
- d. Create the conditions for a progressive EU innovation ecosystem, addressing full value chain creation, ranging from fundamental discovery and to business creation right through to the consumer.

EuropaBio, the European Association for Bioindustries

Avenue de l'Armée 6, 1040 Brussels, Belgium

t. +32 2 735 03 13 | **f.** +32 2 735 49 60

www.europabio.org

