

Biotechnology Industry 2014-2019

Manifesto

for the new European Parliament
and new Commissioners



Time to reap
the benefits in Europe



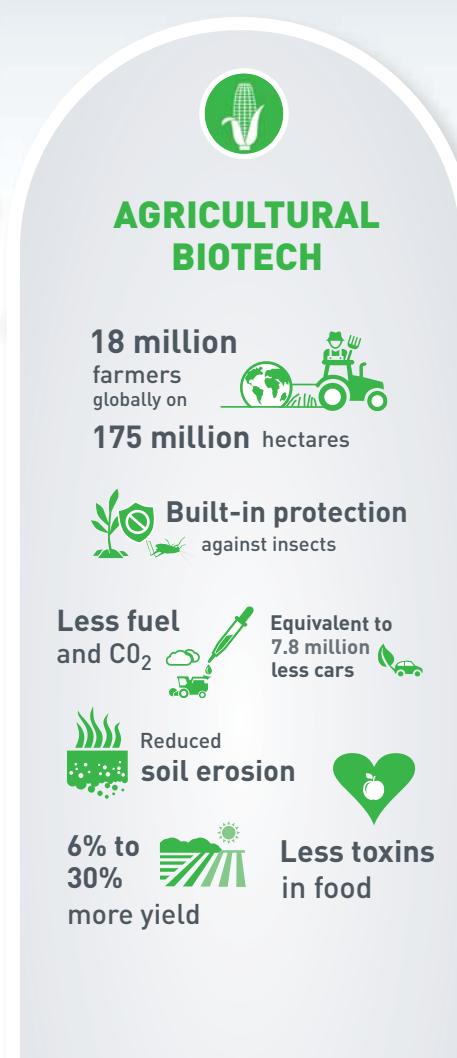
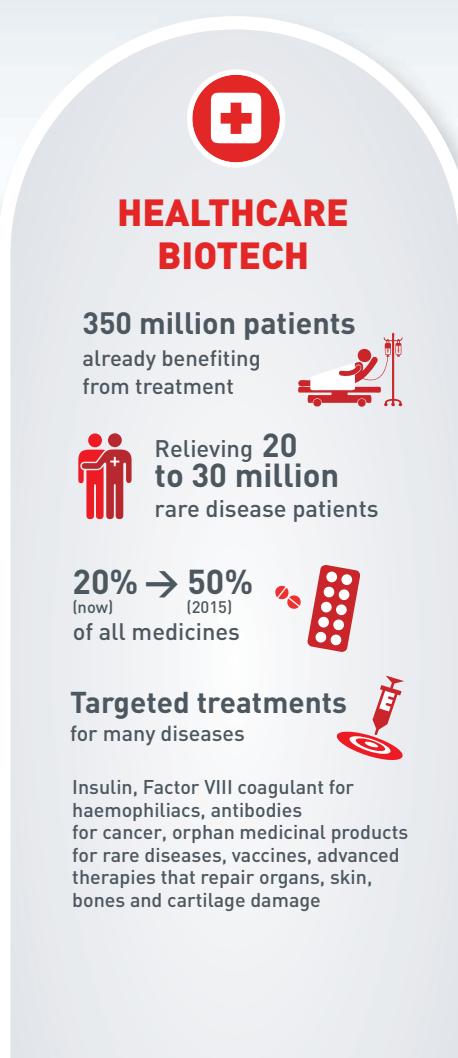
Time to reap the benefits of biotechnology in Europe

Biotechnology is geared at enhancing our quality of life and responding to society's grand challenges such as an ageing and ever increasing population, healthcare choice and affordability, resource efficiency, food security, climate change, energy shortages and economic growth.

Biotechnology can be found in the clothes we wear, the products we use to wash them sustainably, the food we eat and the sources it comes from, the medicines we use to keep us healthy and even the fuel we use to take us where we need to go.

Until now, biotechnology has also been a cornerstone of Europe's competitiveness in terms of research and innovation as well as in terms of industrial growth, number of jobs and new companies created in Member States.

Today however, we risk turning Europe into the world's biotech research hub and not reaping the benefits of the products and services provided by this key enabling technology.





Call to action for a smart, successful and performing European biotech industry

The operating environment for biotech companies in Europe is becoming less attractive than that in other geographic areas. In addition to high energy costs, Europe has less predictable and science-based regulatory frameworks than those of other geographies, lacks the funding and tailored market pull measures offered by other parts of the world and needs to ensure faster and more equitable access to biotech products and processes for patients, farmers and consumers.

With the right environment, Europe's biotech industry can continue to play a leading role in tackling major European problems in energy, environment, food security, health, international competitiveness, local job creation and security. It can be at the forefront and contribute to Europe's industrial renaissance.

The next five years will be critical for Europe – and they will also determine the success of Europe's biotech industry. We call on MEPs and Commissioners to actualise the following goals to ensure Europe and Member States can fully reap the benefits this technology has to offer.

1. Research and development phase

- EU-funded projects with clear objectives and translation to end products.
- Coordination of Member States research programmes to maximise impact.
- Competitive patent system and data exclusivity to reward innovative European R&D.
- Funding schemes to support biotech SMEs throughout their capital-intensive pathway to commercialisation.
- Support of translational research and proof of concept via Joint Undertakings (e.g. Biobased Industries JU & Innovative Medicines Initiative II).

RESULTS
Jobs + Innovation + Intellectual capital

2. Assessment and approval phase

- Innovation Principle adopted in EU decision making to avoid innovation being held up by unfounded concerns.
- Adaptive assessment and access frameworks for innovative biological products in the fields of Personalised Medicine, Orphan Medicinal Products and Advanced Therapy Medicinal Products.
- Respect for legislative timelines in the approval process for agricultural biotech products (GMOs).
- Action plan to eliminate the backlog of pending approvals of agbiotech products (GMOs) and deal with legal uncertainty.
- Science-based assessment criteria with sufficient implementation time and no retroactivity.
- Increased rapid risk communication by competent public authorities to counter unfounded concerns.

3. Market access phase

- Fast and equitable citizen access to innovative biotech products & processes in all Member States.
- Fair and sustainable reward systems supporting research and development of biotechnology-derived therapies in Europe.
- Implementation of the European Commission's Bioeconomy strategy and its action plan.
- Public procurement programmes and supportive measures to stimulate the biobased economy.
- Communication of the benefits of biotechnology and the bio-economy with society including consumers, investors, industry, and policy makers via dedicated communication programmes.

RESULTS
Product & processes with societal benefit + Economic value for Europe

Sources:

OECD, Key Biotechnology Indicators, June 2013: <http://www.oecd.org/innovation/inno/keybiotechnologyindicators.htm>
Beyond Borders, EY: [http://www.ey.com/Publication/vwLUAssets/Beyond_borders/\\$FILE/Beyond_boundaries.pdf](http://www.ey.com/Publication/vwLUAssets/Beyond_borders/$FILE/Beyond_boundaries.pdf)



Biotechnology applications and benefits

Personalised treatments, often involving biotechnology via the use of predictive biomarkers, support the identification of the safest and most effective treatment for patients, often preventing illnesses from occurring

Orphan Medicinal Products (OMPs) provide often the only treatment for diseases that are rare, chronic and life-threatening

Biotechnology enzymes speed up fermentation in beer

Modern biotech medicines help Multiple Sclerosis patients recover a high level of mobility

Insulin is a life saving biotech medicine for patients with diabetes. By combining a medical device and a therapeutic product, new healthcare technologies increase the convenience of treatment for diabetes

Biotechnology enzymes can help reduce the amount of bleaching needed for paper production and also remove inks from paper to be recycled

EuropaBio is the European Association of BioIndustries. Our members are involved in research, development, testing, manufacturing and commercialisation of biotech products and processes in human and animal healthcare, diagnostics, bioinformatics, chemicals, crop protection, agriculture, food and environmental products and services. EuropaBio also counts a number of National Biotech Associations in its membership who in turn represent more than 1800 biotech SMEs.