

Positions

**BIO DEUTSCHLAND**

Biotechnologie-Industrie-Organisation Deutschland e. V.

Promoting the Biotechnology Industry in Germany

Germany's biotechnology industry ranks among the most sustainable and forward looking of today's cutting-edge technologies. Biotechnology is about developing new therapies and drugs, breeding improved crop plants and producing industrial raw materials. And the biotechnology industry is mainly driven by small and medium-sized businesses.

Germany's biotechnology industry in numbers:

- Some 756 companies, employing a total of 45,020 people, use biotechnologies to manufacture innovative products or to provide specialised services.
- The medical biotechnology sector alone has nearly doubled its gross value added over the past ten years, to 8.8 billion euros.

Topic: Industrial Bioeconomy



Industrial biotechnology is a main pillar of the bio-based economy, the so-called bioeconomy. Biotech entrepreneurs are developing innovative technologies, processes and products that, for example, reduce greenhouse gas emissions.

They need:

- an investment-friendly environment that facilitates the market entry of sustainable products and processes
- a commitment from policymakers to the bioeconomy and the importance of biotechnology
- a mandatory target for advanced biofuels
- a fact-based and open-ended dialogue on new research methods and breeding technologies

Topic: Intellectual Property Rights



Protecting intellectual property rights is essential for promoting cutting-edge technologies. Research-based SMEs are making amazing technological leaps. This innovative potential must be fostered.

We call for:

- the introduction of a grace period in German and European patent law
- the reduction of patent costs for SMEs in Europe
- effective harmonised legal protection in all EU member states through vigorous enforcement of the directive on biotechnological inventions
- a shortening of the patent examination process only upon request (by a third party or the applicant)

Topic: Regulatory Matters



German biotechnology firms are among Europe's leaders in pharmaceutical research. Simple and clear procedures are necessary to facilitate the ability of businesses, especially SMEs, to develop innovative products.

We therefore call for:

- improvements in the development and approval processes for advanced therapy medicinal products in order to accelerate patients' access to state-of-the-art medicine
- greater planning security by establishing stable framework conditions for R&D
- an optimisation of the conditions for clinical research in Germany

Topic: Technology Transfer



Germany is a high-tech country whose economic strength is derived primarily from its innovative strength. Effective technology transfer is therefore vital.

We call for:

- greater support for technological advancement and validation
- the creation of incentive systems to increase cooperation between all parties
- enhanced action on improving entrepreneurial dynamics and conditions
- a renewal of the guiding principles for technology transfer

Topic: Innovation, Entrepreneurship and Jobs



Entrepreneurs in the biotechnology industry want to make a sustainable contribution to the future viability of our economy and to the well-being and prosperity of our society. As a key technology, biotechnology is improving patients' prospects for recovery through effective therapies and increasing people's quality of life through, for example, more healthily produced food and bio-based daily products.

We need:

- an innovation-friendly climate for the equity financing of cutting-edge start-ups
- an entrepreneurial and high-achieving culture (an ethos of courage, curiosity and risk-taking)

Topic: Bio IT and Big Data



The laws and regulations in Germany make data sharing between patients, clinics and researchers difficult.

To fully realise the potential of health data in research, it is necessary to:

- guarantee patients a right to access for medical and biotech research purposes
- enact German framework legislation on health data
- establish a committee of experts with biotech expertise that defines uniform standards and develops these further
- require uniform cross-sectoral communication processes (interoperability)

Topic: Health Policy



In the field of medicine, biotechnology companies are opening up new possibilities for treating previously untreatable diseases. Prevention, early detection, therapy and aftercare are today being transformed by advances in biology.

- The planned medical information system should inform physicians without restricting therapeutic freedom.
- The turnover ceiling for reimbursement sends the wrong signal to entrepreneurs developing drugs for previously untreatable diseases.
- A reimbursement system is needed that rewards innovations benefitting patients.

Topic: Diagnostics



From high-performance sequence analysis to genetic diagnostics and in vitro diagnostics, conditions in the diagnostics sector need to be right so as to ensure that patients benefit from the new methods developed by biotech companies.

In particular, it is necessary to:

- promote companion diagnostics for patients as an important complement to personalised therapy
- reimburse innovative tests taking into account their innovative character and their positive impact on healthcare quality
- create competitive conditions for in vitro diagnostics (by implementing the EU's IVD Regulation effectively)

Topic: Finance and Taxation



Sustainable financing is indispensable for biotech entrepreneurs. Current policies must be strengthened in a lasting way, in particular when it comes to growth financing.

This includes:

- providing a withholding tax exemption for investment in research-intensive companies
- establishing an IDEE Fund: offsetting a portion of the investment against income tax liability and granting a tax exemption in the case of a successful outcome
- introducing – in addition to project funding – an R&D tax incentive of 10% with a higher incentive for SMEs (30%)



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