Unleashing the full potential of life sciences and biotechnology in Europe

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EuropaBio®

The European Association for Bioindustries

Making our vision a reality: unleashing the potential of life sciences and biotechnology

Introduction

" Life sciences and biotechnology offer opportunities to address many of the global needs relating to health, ageing, food and the environment, and to sustainable development. How can Europe best attract the human, industrial and financial resources to develop and apply these technologies to meet society's needs and increase its competitiveness?"

"A revolution is taking place in the knowledge base of life sciences and biotechnology, opening up new applications in healthcare, agriculture and food production, and environmental protection, as well as new scientific discoveries."

Source: Life Sciences and Biotechnology:
A Strategy for Europe, European Commission, 2002

Nearly twenty years after these observations were first made by the European Commission, the world has changed significantly - with the full globalisation of the economy, the rise of China as a key player, the growing awareness that key world challenges require global solutions and the realisation that innovation in biotechnologies and digital solutions have a transformative societal impact.

To be a part of this ongoing revolution, Europe needs to take significant steps in order to make the "old" continent the global frontrunner in life sciences and biotechnology.

At a critical time of accelerated innovation and convergence of enhanced diagnostic tools, breakthrough biotechnology solutions and transformative digital applications, the life sciences and biotechnology sectors offer many opportunities to contribute to the European Green Deal and its new growth strategy.

This is why EuropaBio, the European Association for BioIndustries, has produced its vision of a comprehensive **European life sciences and biotechnology strategy**. We hope that this will serve as a useful blueprint for policymakers, encouraging them in their efforts to devise and implement a strategy of their own for this flagship sector.

Defining life sciences and biotechnology: time for a fresh look?

Currently, there is no common definition or comprehensive way to characterise the life sciences and biotechnology sector which means that the crucial value the sector brings to Europe is underrepresented and often goes unrecognised. In its 2002 Strategy, the Commission broadly grouped the healthcare, industrial and agricultural sectors as a basis to define the market.

This Vision Document uses the same approach but calls on the Institutions to develop a more complete definition of life sciences and biotechnology, to capture the magnitude of this sector's contribution to people and planet.

About this document

This Vision Document sets out the value the sector brings to Europe: economically, environmentally and societally. Given the already enormous contribution the sector makes to Europe's economic and societal wellbeing, we have outlined several areas of policy which are ripe for reform as well as policy recommendations for inclusion in a future EU industrial strategy to make the most of one of the Union's greatest assets.

Keeping our Manifesto Pledge

Developing and supporting a new EU life sciences and biotechnology strategy was a key pledge in our 2019 Industry Manifesto. EuropaBio and its members will actively support policymakers and stakeholders as they look to make this vision a reality. The moment to act is now.

Europe is currently facing major political and societal challenges. Biotechnologies can help to tackle them:

Addressing the growing burden of disease:

With an ageing population that brings increasing pressures on European health systems through chronic diseases, cancer and a rise in infectious diseases, biotechnology can contribute to a healthier and stronger society by addressing unmet needs through new therapies. A new treatment for cancer or a rare disease is 72% likely to come from an emerging biopharma company. A strong and stable EU IP framework is critical to foster innovative companies to invest in game-changing cures.

Leveraging industrial biotechnology to help tackle climate change and improve resource efficiency:

Industrial biotechnology has led to the creation of new, sustainable products and services from chemicals to plastics, and food to fuel and feed. For example, in 2016, European biorefineries helped to achieve 66% greenhouse gas (GHG) emission savings compared to petrol. A stable, predictable and transparent regulatory framework will stimulate further industry investment in cutting-edge sustainable technologies, cementing the EU as a global market pacesetter, and moving the Union towards its international climate obligations.

European manufacturing policy:

Although efforts are being made to move towards more sustainable practices, heavy industry practices often move Europe away from meeting its global climate obligations. It is important to recognise that a strong and functioning economy for bio-based products contributes to fight climate changes through biofuels, bioplastics and a strong recycling industry - especially for end of life options including mechanical and organic recycling. It also enables biopharmaceutical innovation which creates high skilled manufacturing jobs in the bioindustries of the future and contributes to healthy living.

Doing more with less in agriculture:

Biotechnology (including genetic modification of crops) has increased farmers' yields and incomes while reducing CO_2 emissions, and the need for farmer inputs. However, the regulatory framework has yet to recognise the value of using demonstrably safe GM products for cultivation in the EU and allow them on the market. Meanwhile, a science-based, risk-proportionate and non-discriminatory regulatory framework that allows for gene editing in crops could pave the way for products which offer health and consumer benefits, such as lower carcinogenic potential and biofortification, along with enhanced shelf life and reduced food waste.

Did you know...? Some facts and figures on the sector's economic footprint

- The United States registers around three times as many patents as Europe.[2]
- Biotechnology products are expected to make up 52% of the top 100 healthcare sales by 2024.[3]
- Industrial biotechnology uses renewable raw materials and is one of the most promising, innovative approaches to lowering greenhouse gas emissions. It is estimated that industrial biotechnology and bio-based products could reduce 1 to 2.5 billion tonnes of CO_2 equivalent per year.[4]
- European farmers rely on imports to cover almost 70% of their needed protein-rich crops, the majority of which are gene modified. A lot of it is provided by North and South America.[5]
- The EU biotechnology and life sciences sector contributes almost €40 bn in indirect and induced value to other European sectors, and – for every one job in the lifescience and biotechnology sector – three jobs are created elsewhere in the European economy.[6]

[2] McKinsey, Biotech in Europe: A strong foundation for growth and innovation, Exhibit 4, p. 6
[3] Deloitte 2019 Global life sciences outlook, https://www2.deloitte.com/global/en/pages/life-sciences-and-healthcare/articles/global-life-sciences-sector-outlook.html
[4] https://www.novozymes.com/en/news/news-archive/2009/09/45431
[5] https://www.europabio.org/sites/default/files/infographic_eu_benefits_from_gm_trade.pdf
[6] Wifor study forthecoming

The following pages outline how Europe can make the most of our sector's potential, with policy recommendations in different areas.

The policy recommendations are presented by biotechnology sector

AGRICULTURAL BIOTECH

HEALTHCARE BIOTECH

INDUSTRIAL BIOTECH

ALL SECTORS

Building a strong foundation

Capital and financing

BARRIERS

The life sciences and biotechnology sector is, by its very nature, a risky sector for investment. It is R&D-intensive and heavily regulated: the cost of getting a first product to market is significant. However, the rewards both to Europe's society and economy, are enormous.

At the same time, compared to the US, which has a higher appetite for **risk around capital and financing, both in public and private**, Europe certainly has scope to improve. Public funding support for early-stage, private-led R&D is crucial to encourage industry risk taking. In the US, the National Institute of Health invested $26 billion dollars in early innovation in health in 2018 alone. The EU, by contrast, invested only €10 bn ($11 bn) in R&D in all three biotech sectors in 2018.

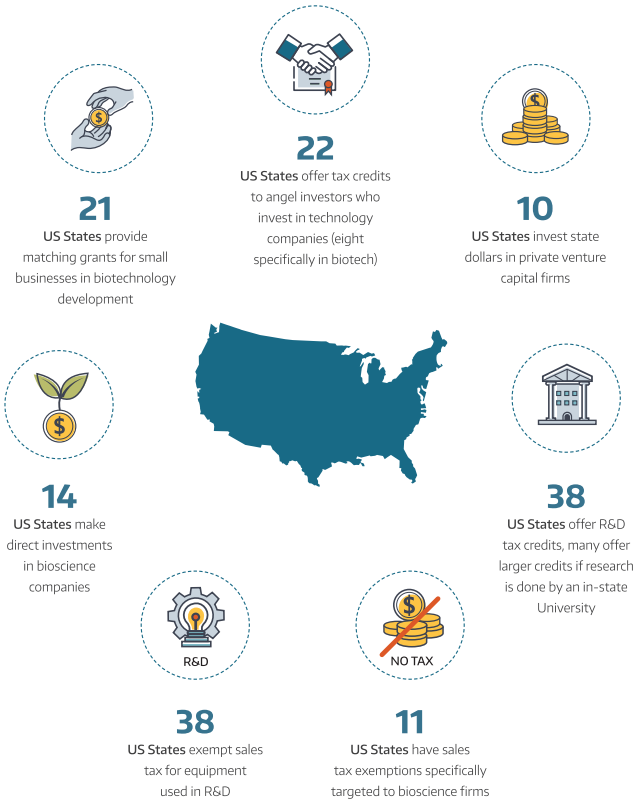
A March 2018 report by the European Investment Bank on **Access-to-Finance** Conditions for Life Sciences R&D (healthcare-specific) found that although venture capital investment has risen, it has not grown sufficiently since the 2008 financial crisis to keep pace with this ballooning sector.

> "We need the European Commission to provide support to health biotechs to thrive and have a positive impact on the health of European Citizens."
>
> Dr. Cindy Serdjebi, Translational Science Manager, Genoscience Pharma

When looking at a comparison between Europe and the US this becomes even more apparent. On the London Stock Exchange, Europe's "biggest stock exchange and a strong bio-region" the median company has a market capitalisation of only £99m. By contrast, the median valuation of NASDAQ biotech companies for mid-2018 sits at $296m.[7] This is particularly detrimental to SMEs, which could benefit most from higher capital investments.

Easier access to capital could allow small companies to diversify their R&D-intensive pipeline, and spread risk in their portfolios, while also offering more, innovative technologies which benefit consumers and society. The problem is particularly acute for projects that require long-term, large-scale infrastructural developments, such as biorefineries – where biomass is sustainably transformed into bio-products such as chemicals, and bioenergy such as biofuels.

In cases where an enterprise can secure capital, one of the largest, but most easily remedied, hurdles at EU-level is **the fragmented environment**: regulatory, scientific, and financial conditions vary greatly across the European Union. Smaller SMEs with limited resources could be deterred from seeking approval in Europe because of cumbersome and lengthy procedures, and risk going bust in the process.[8] This acts as a deterrent to other companies, which may seek investment and product approval in other markets.



[7] https://www.forbes.com/sites/brucebooth/2018/09/21/the-incredible-expanding-universe-of-biotech-stocks/
[8] https://www.eib.org/attachments/pj/access_to_finance_conditions_for_life_sciences_r_d_en.pdf

Source: https://www.bio.org/sites/default/files/BIO_BestPracticesReport2019vF.pdf

OPPORTUNITIES

Europe is **excelling in factoring sustainable and societal considerations into investment decisions,** as is the case with the EU's pioneering sustainable finance taxonomy.[9]

Sustainable development should be at the heart of all financing considerations. Europe should mainstream the UN Sustainable Development Goals (UN SDGs) in all its financing mechanisms, including public procurement and trade agreements. This global best practice will lead other regions to copy and will reinforce Europe's position and that of European industry as champions of sustainable societal ambitions.

The United Nations Sustainable Development Goals:

17 internationally agreed targets to end poverty, protect the planet, and guarantee peace and prosperity by 2030. EuropaBio has published a series of reports on what the industry is doing to help achieve these ambitious targets.

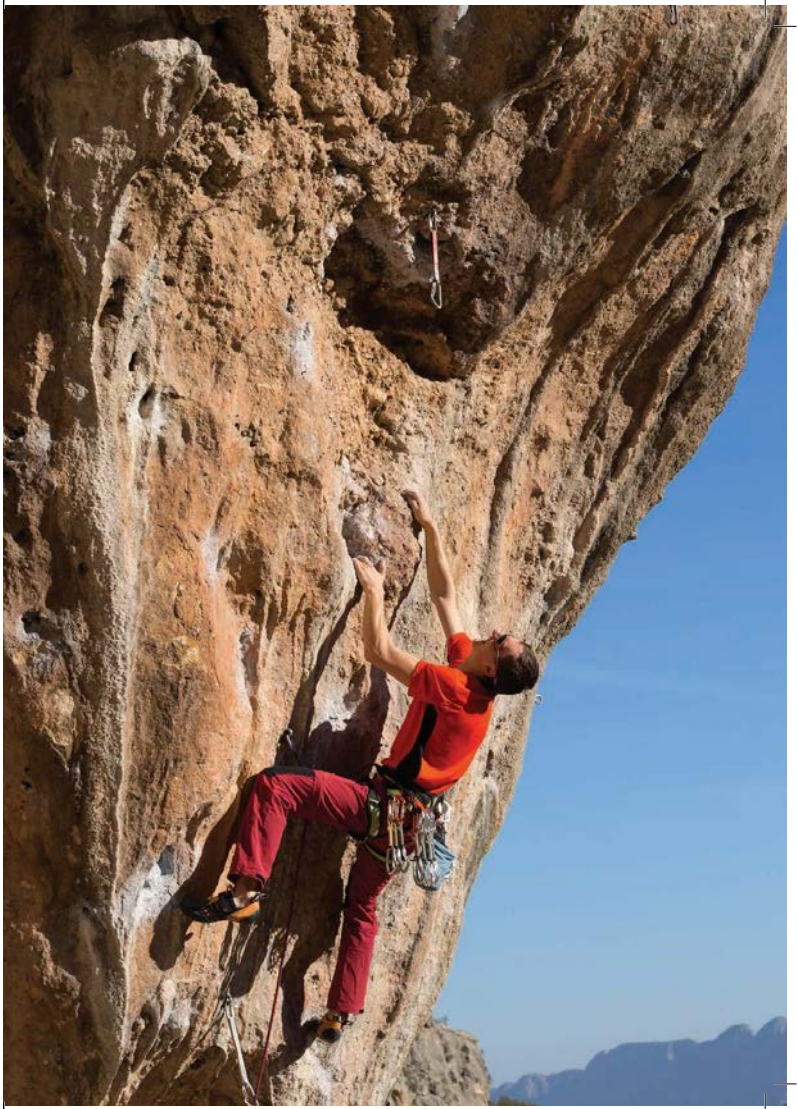
Europe's pioneering sustainable finance taxonomy:

This paradigm shift will create a common European classification for "sustainable" economic activities and provide more clarity for investors to help bring in a new green economy.

POLICY RECOMMENDATIONS

- Launch a multi-sectoral forum of EU and US actors (public and private) to understand and share best practices on risk mitigation in financing. This could be developed within the EU-US Financial Regulatory Forum.
- Reassess how the EU is attracting investment and developing policies to attract and grow it.
- Implement the European Investment Bank (EIB)'s recommendation to include a more unified and better capitalised public market for life sciences R&D.
- Leverage the newly formed European Innovation Council to de-risk early-phase private Research & Development & Innovation (R&D&I), to ensure the commercialisation of truly innovative life sciences and biotechnology.
- Pilot a "one stop shop" at EU level for biotech SMEs seeking support from funding to regulatory and beyond, with a more patient investment model to support their long development cycles. Implement EuropaBio's call for a dedicated European BioEconomy Strategic Investment Fund (EBESIF) to pool resources from different financing mechanisms.
- Mainstream the UN SDGs in all EU finance mechanisms: including public procurement and all Free Trade Agreements.
- Increase funding and improve coherence of financing mechanisms for the circular bioeconomy, to encourage a move towards a carbon-neutral economy.

[9] Output from the European Commission's Technical Expert Group on sustainable finance to establish a classification system for sustainable activities that can make a substantial contribution to climate change mitigation



Skills and labour

BARRIERS

Historically, Europe has offered world-leading education systems, creating the workforce and skills base needed to enable innovation. Europe still has an array of high-ranking universities but international rankings show that the US is coming out at the top for academic leadership (according to the Times World University Rankings 2019, seven of the top ten and 14 of the top 20 universities for sciences are in the US). Excellent universities incubate life sciences and biotechnology ecosystems too, with SMEs and start-ups flocking to where the world class R&D and graduates are being produced. The high concentration of scientific hotspots in the US is drawing potential graduates, R&D, and business away from Europe.

Another challenge is that science, technology, engineering and mathematics (STEM) graduates may be tempted to emigrate **for better employment and better working conditions elsewhere**. In comparison to Europe, the US offers more attractive salaries, better research opportunities, more innovative hubs, and greater likelihood of regulatory systems that will allow research results to yield tangible societal and economic benefits. It is crucial to look at Science, Technology, Engineering, Mathematics (STEM) not only from an education perspective, but also as a recruitment ground for graduates entering the workforce. This exodus is already seen in agricultural biotechnology. Since the 1980s, flagship European crop protection companies have been relocating to the United States, building a presence in the Research Triangle Park (RTP) hub in North Carolina, where there is a particularly strong link between local government and local universities. This has helped create an ecosystem to attract businesses and their future employees[10], some of whom may otherwise have brought their skills and knowledge to Europe.

While innovations from STEM fields have brought countless benefits for Europe and the world, there are strong imbalances when it comes to diversity. For instance, Eurostat found that 83% of scientists and engineers in high and medium-high technology manufacturing were male. For the skills of Europeans this means that there is a loss of talent and an enormous **under-representation of women in science**.

OPPORTUNITIES

To integrate the full spectrum of the population in STEM fields, more education and career opportunities should be created to make fields like science more attractive to under-represented groups. We can make a start on this during early school years so that **life sciences and biotechnology are seen as inclusive and achievable sectors for all**. Europe should ensure that no one is left behind and that access to the STEM fields is equal. Fostering champions is important but elevating the possibility for a wide range of the population to access education and career opportunities is crucial and would elevate the level of biotechnology and life sciences in Europe.

Europe should strive to **create an "Ivy League" of centres of excellence in life sciences**. An integral first step would be creating a heatmap. This could assess where there is current academic excellence. One could then determine what a cluster is offering, what skills the life sciences and biotechnology industry needs, and how the clusters deliver this to industry. The results of this could be used as a "blueprint" to create more centres of excellence across Europe. In addition, EuropaBio recommends creating a ranking table of higher-level education centres to foster healthy competition and striving for excellence.

In order to bridge the diversity gap in STEM education, to further enhance the skills of the European population and create a solid workforce, tailored education for specialist skills in the life science industry are needed. The European Union should assist national education systems more through soft tools. A good example is assessments on where gaps are. Member States should also leverage programmes like Erasmus+ to the best extent possible. A good example is building on the 2018 Bioeconomy Strategy which sets out a series of measures to "Promote education, training and skills across the bioeconomy".[11]

To help new entrepreneurs entering the market, the Erasmus programme could be extended to young professionals, especially in sectors where Europe needs to foster innovation, such as life sciences and biotechnology. This would provide young entrepreneurs with opportunities to gain all the benefits of Erasmus in a professional setting, and would diffuse best-in-class approaches to boost the competitiveness of the sector throughout Europe.

The Bioeconomy strategy

Action 2.4 of the strategy aims to build up local bioeconomies rapidly across Europe by promoting education, training and skills across the bioeconomy. EuropaBio calls for this approach to be expanded to the health and agriculture sector.

POLICY RECOMMENDATIONS

- Create EU-wide indicators to identify best practices for integrating and promoting STEM subjects in national and regional early years education curricula.
- Map at EU-level academic excellence in biotechnology clusters. Profile each cluster and create a blueprint for best practices.
- Encourage Member States to offer tailored educational programmes to equip tomorrow's workforce with the necessary skills for a thriving European life sciences and biotechnology sector.
- Implement Action 2.4 of the 2018 **Bioeconomy Strategy** more widely, across the health, agriculture and industrial sectors.
- Extend the Erasmus programme to include young entrepreneurs, to help share best practices and boost the competitiveness of the sector.

[10] https://croplife-r9qnrxt3qxgjra4.netdna-ssl.com/wp-content/uploads/2018/09/Challenges-Facing-Farmers-and-the-Plant-Science-Industry-in-the-EU-report.pdf

[11] https://ec.europa.eu/research/bioeconomy/pdf/ec_bioeconomy_strategy_2018.pdf#view=fit&pagemode=none – pg 86

A forward-looking approach to life sciences and biotechnology

R&D and innovation

BARRIERS

Like many of its international and national partners, Europe is grappling with a small, but vocal, minority – often described as an **"anti-science movement"**. Admirably, the EU has sought to tackle this, including appointing a Commission Vice President responsible for "strengthening [the Commission's] culture of evidence-based policymaking".[12] However, regrettably, this has not always led to positive changes in behaviour. An example is decreasing vaccination rates in European populations. In some cases, the anti-science movement has even led to regulatory barriers that can seem to contradict the EU's evidence-based policymaking process – such as the current discussions around genome editing. Politicians in some EU Member States remain reluctant to promote these technologies, based on fears about pre-existing GMO technology, despite the fact that over 3 trillion GMO meals have been safely eaten, and the scientific consensus that GMOs are as safe as conventionally bred crops, as confirmed by 280+ scientific institutions.[13] This fact is supported by over 140 Nobel laureates.[14]

As a result, the R&D barriers to life sciences and biotechnology are twofold: a growing **public distrust**, **facilitated by low levels of public understanding**; and **a spill-over of this distrust into EU policymaking** and legislation, undermining the EU's core principle of evidence-based policymaking.

OPPORTUNITIES

Many of the current and future challenges the EU faces today can be addressed, at least in part, through the life sciences and biotechnology sector. Whether ageing populations, Key Enabling Technologies, diminishing energy sources and climate change, or food and feed sustainability, tomorrow's solutions will be built on today's R&D and innovation. Much of the sector's innovation comes from SMEs, so it is crucial that they are able to access the financial support to bring their products to market (see section on Financing and Capital), but also that regulatory barriers do not prevent genuinely innovative solutions from contributing to tackling society's challenges.

Innovation and precaution need to work hand in hand to complement each other. With a new European Parliament and European Commission, there is an opportunity for fresh thinking about how to strike the right balance on risk, and to deliver the benefits of safe and beneficial solutions to EU citizens.

Horizon 2020 offers ample opportunity to promote R&D and innovation in European biotechnology related projects. The same counts for the Innovative Medicines Initiative, which earmarked €3.3 billion for pharmaceutical R&D between 2014 - 2020. It is a strong indicator that Horizon Europe will aim to tackle key societal challenges, such as the rise of chronic diseases, increased environmental pollution and competitiveness with global players. There is a chance to be even more ambitious and to ensure that more funding is invested in the European biotech industry, particularly SMEs.

[12] https://ec.europa.eu/commission/sites/beta-political/files/mission-letter-maros-sefcovic-2019_en.pdf
[13] https://www.isaaa.org/resources/publications/pocketk/56/default.asp
[14] https://www.supportprecisionagriculture.org/nobel-laureate-gmo-letter_rjr.html

The European Partnership for Innovative Health, which aims to provide a collaborative platform for precompetitive research and innovation for biotech and digital companies to speed up the development of innovation in public health, and the new Circular Biobased Europe partnership (the successor to the Bio-Based Industries Joint Undertaking, the BBI JU) are good steps towards ensuring access to R&D. To attract SMEs, high administrative burdens cannot be a barrier to participation.

POLICY RECOMMENDATIONS

Communicating R&D and Innovation

The Commission and national authorities should put consumers at the heart of their communications policy and produce and implement a robust 'general plan for risk communication', particularly around food safety. All institutions and authorities should publicly push back against misinformation around GMOs, vaccines, chemicals and other innovations scientifically proven to be safe.

- The EU should put forward strategies to empower researchers and scientists to raise their voice more often and more efficiently in the innovation/risk debate. Additionally, Europe should create reference points to substantiate scientific information, including novel ways to communicate science to the general public.
- Publish EFSA and Commission risk assessments of GM crops in an efficient, transparent, meaningful and contextualised manner, to help build public trust in the safety of gene editing.

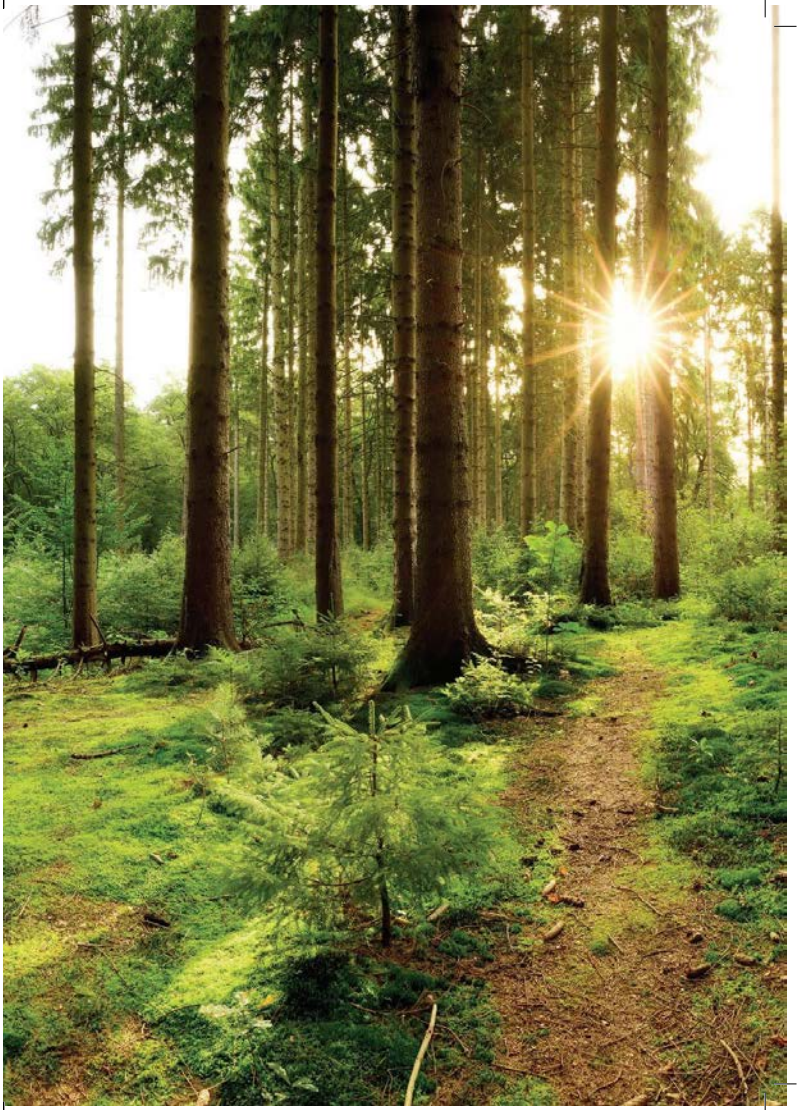
- Promote the responsible research and innovation approach in order to work towards outcomes to benefit society.
- In a time of growing scepticism, politicians should commit to re-endorsing the innovation principle, as was the case in the May 2016 Council Conclusions on research and innovation-friendly regulation,[15] and the May 2016 Council Conclusions on better regulation to strengthen competitiveness.[16]
- Regulatory and scientific requirements should remain focused on products and their benefit for society, rather than processes.

Addressing regulatory barriers to R&D and innovation

- Mainstream **the innovation principle** and other EU best practices in science-based policymaking across all areas. The Commission should propose a science-based approach to non-transgenic crops developed using genome editing. Such crops should not be classified or regulated as GMOs.
- Remove scientifically unjustified regulatory requirements. For example, around GM crops.

The Innovation Principle

Endorsed by most EU Institutions, the Innovation Principle is a framework to make sure that policy decisions allow innovation to flourish, and that any new policies are innovation-friendly.



[15] http://data.consilium.europa.eu/doc/document/ST-9510-2016-INIT/en/pdf
[16] https://www.consilium.europa.eu/en/press/press-releases/2016/05/26/conclusions-better-regulation/

Intellectual Property and incentives

BARRIERS

Intellectual Property (IP) rewards and incentives are the oxygen that allows the fragile ecosystem of biotechnology development in Europe to thrive. At the heart of the European biotechnology industry's success has been Europe's IP reward and incentive framework that attracts funding and encourages high-risk, complex and long-term research and product development. Many of the innovative medicines that benefit patients today would never have been developed without the right framework.

Europe's IP system is essential for the biotechnology sector. It attracts the necessary funding for SMEs to conduct R&D efforts, for companies to recoup their investments and funding for the next generation of discoveries. Without incentives no company would approach rare diseases areas and patients would not receive much-needed medicines, for which there otherwise would be no treatment.
SMEs are also particularly likely to struggle with high costs for **patenting innovations**, especially in such a fragmented market as the EU. The risks can be significant and lead to bankruptcy or filings elsewhere, while the benefits can be immense for companies and society. A survey of 190 venture capital-seeking biotech companies showed that having at least one patent application filed reduced the time period to the first VC investment by 76%.[17]

OPPORTUNITIES

Results at EU level have been mixed. In agricultural policy the so-called Biotechnology Directive (Directive 98/44/EC) in its current form, provides much-needed certainty and predictability to industry, and should be maintained as it is. In the healthcare sector, the recently adopted manufacturing waiver for the export of medicinal products protected by Supplementary Protection Certificates was a significant cause of concern. EuropaBio hopes any future amendments to IP law governing biotechnology, will aim for a high level of patent and intellectual property right protection.

Stronger intellectual property rights and a more streamlined patenting process will also help Europe boost rates of research and innovation. There are several ongoing or upcoming files where the EU has the chance to send clear signals to industry that it values intellectual property and the contribution it makes to Research & Innovation and tries to ensure a dynamic environment, especially in the healthcare sector.

Clearing the patent cost hurdle not only creates growth; it also brings to market truly innovative products for European citizens. The more harmonised the European patenting framework is, the easier it will be for businesses – especially SMEs – to get their products to market. The decision to adopt a Unitary Patent is a step in the right direction, but much will depend on its timely, stable and uniform application, and whether all EU Member States ultimately sign up to it and use it.

POLICY RECOMMENDATIONS

- Ensure the pharmaceutical legislation (e.g. the review of the Orphan Medicinal Products Regulation) continues to provide strong incentives and ensures a dynamic market environment for start-ups, SMEs and companies in general.
- Support biotech SMEs by ensuring a timely and uniform application of the Unitary Patent when it is launched in the first half of 2020. Encourage all EU Member States to become signatories.

[17] Discussion Paper No. 09-003, To Be Financed or Not... The Role of Patents for Venture Capital Financing, Carolin Haeussler, Dietmar Harhoff, and Elisabeth Mueller

Manufacturing

BARRIERS

The main barrier facing European manufacturing today is one of perception: for many, **Europe is still viewed as a bastion of heavy industry alone**. This undermines the future potential of smart manufacturing, and the pivotal roles digital and Artificial Intelligence (AI) will play in the future. Such an approach to manufacturing also tends to neglect the potential Key Enabling Technologies (KETs)[18] and other emerging technologies can offer for people and planet – putting the emphasis instead on less clean, less efficient processes. A mindset shift in how Europe sees manufacturing would lay the foundations for fundamental economic and societal change.

OPPORTUNITIES

Europe and the rest of the world is facing unprecedented challenges: growing populations in emerging markets and ageing populations in Europe, combined with a depletion of natural resources, and the impact of climate change means the EU – and other regions – will have to produce more with less.

Europe has correctly identified that **Key Enabling Technologies (KETs)** such as industrial biotechnology and advanced manufacturing procedures can help tackle these economic and societal challenges, while also providing Europe with a competitive advantage and boosting manufacturing in Europe. Regrettably, KETs have slipped down the political agenda. However, the recent Council Conclusions on *An EU Industrial Policy Strategy: a Vision for 2030*[19] have rightfully stressed the importance of these technologies. With this renewed political impetus, policymakers should do more to ensure KETs reclaim their place at the centre of an EU industrial policy fit for the future.

The European Commission has also launched its **Strategic Forum for Important Projects of Common European Interest (IPCEI)**. The Forum aims to shape a common vision on key value chains for the EU. It also seeks to boost investment in sectors, which include smart health and low carbon technologies. The EU is right to prioritise strategic sectors in the KETs and IPCEI, and should broaden the scope to include healthcare, industrial, and agricultural biotechnologies.

There is great regional, societal, and economic potential also for European manufacturing. **Creating regional "manufacturing hubs"** for advanced biotechnology manufacturing can go some way in mitigating the economic disparities within and between European countries (See regional policy section for more information).

POLICY RECOMMENDATIONS

- Rejuvenate the European strategy for KETs in manufacturing, integrating them into any future EU manufacturing or industrial strategy.
- Increase the funding allocated to KETs under the new Horizon Europe programme, and offer reduced submission requirements for applicants to encourage more SMEs to invest in KET R&D.
- Recognise the central role of industrial biotechnology as an enabling technology for a more competitive, sustainable and circular bioeconomy, and encourage the use of bio-based alternatives in relevant sectors such as packaging, chemicals, energy, coatings, fertilisers, automotive, and cosmetics.
- Mainstream life sciences and biotechnology throughout the KETs and IPCEI, acknowledging their potential in boosting domestic economic growth, fostering global competitiveness, and addressing the societal challenge of producing more with less.
- Leverage the European Commission's Smart Specialisation approach to regional development to construct smart manufacturing biotech hubs in economically-depressed regions, supporting more industrial modernisation, bio-energy and agri-food thematic projects at the EU's periphery.

[18] Key Enabling Technologies are technologies that can be applied across industries, identified by the EU as crucial to creating advanced and sustainable economies. The six KETs include industrial biotechnology and advanced manufacturing technologies.

[19] https://www.consilium.europa.eu/media/39507/st09706-en19.pdf

Digitalisation

BARRIERS

For Europe to be a global competitor in biotech and life sciences, digitalisation must be fully embraced. **Fragmented national systems**, especially for data collection and data access, prevent progress towards digitalisation and impact advances in fields where more data is needed. An example of this is AI, which advances not only medicines development, but also biotech and pharmaceutical companies, contributing to faster and less invasive methods of diagnosis and treatment of diseases. However, it requires large volumes of data that need to be collected, stored and transformed. In the field of rare diseases, the potential of European Reference Networks to collect quality data in registries and Real-World Evidence settings should be fully leveraged.

An underlying problem is **the lack of access to data for scientific research**. While it is crucial to protect personal data, there are many restrictions on the (re)use of data and contradictions within the EU body of law which make it incredibly difficult for researchers to access-much needed data. This prevents Europe from creating truly innovative products and services. Removing regulatory barriers to voluntary sharing of data could be a step towards integrating digitalisation more into life sciences.

Consistent implementation at national level is also crucial. The EU can support by providing more guidance and feedback on how the General Data Protection Regulation (GDPR) interacts with sector-specific legislation (e.g. the Clinical Trials Regulation) and dissuading "gold-plating" by Member States.

This would provide business with more certainty and encourage further investment in Europe.

OPPORTUNITIES

Europe can do more to encourage digitalisation by **pooling data** across the EU. This would have positive societal impacts, for example by using data to better inform prevention policies in healthcare, to more accurately identify hotspots for industrial greenhouse gas emissions, or better drought management and more resource-efficient precision farming practices in agriculture.

Digitalisation and better use of available data can also bring into scope more efficient R&D. For instance, duplication of research can be avoided by sharing data, and more innovative life sciences and biotech products can be developed on the basis of more integrated digitalisation. **More available data in common formats** could change the way we diagnose, understand and treat illnesses.

POLICY RECOMMENDATIONS

- Use the Commission's review of the GDPR in 2020 to address three things: the lack of data available for (re-) use in scientific research which benefits society, fragmented national systems for data collection, and ensuring legislation is implemented uniformly across the EU Member States.
- Draw up common standards for data collection and pooling and streamlining processes.

- Address the challenges a lack of access to data for research creates for science, by removing the regulatory barriers to the voluntary sharing and reuse of citizens' data. Build trust with EU citizens by explicitly stating this data will be used only for scientific purposes and inform them how this research will benefit them and society.
- Enable companies to make the voluntary sharing of non-regulatory data subject to intellectual property, confidentiality, contract law and other rights.

Making Europe a global competitor

Creating clusters (regional development)

BARRIERS

Europe is a leader in Research & Development & Innovation (R&D&I) and is home to some of the most advanced industrial and manufacturing processes and practices in the world. However, many of these are heavily concentrated in more-developed regions, which attract the skilled workforces away from other areas, reinforcing geographic disparities.

Regional development has increasingly become an EU policy powerhouse and is a building block for Europe to become globally competitive. Between 2014 – 2020, 34% of the EU's budget was allocated to "Economic, social and territorial cohesion". Today, the European Regional Development Fund (ERDF) has a budget of €278 billion for the period 2014 – 2020. Of this, €62 billion is dedicated to research and innovation and €50 billion to the competitiveness of SMEs. This does much to address the dual need of investing in depressed regions, while simultaneously looking at which will offer the highest return on investment. As negotiations draw to a close on the 2021 – 2027 budget, it will be important to ensure that **funding continues to be allocated to fields which stimulate growth and create the opportunities to maintain regional development** - such as R&D&I, competitiveness, the bioeconomy and biorefineries, and SMEs. Furthermore, the ability to innovate should be coupled with maintaining a strong R&D&I network.

Smart Specialisation Platform

An EU platform to help regions flourish economically by leveraging local specificities to set priorities and targets for development and growth.

S3 SMART SPECIALISATION PLATFORM

OPPORTUNITIES

Leveraging the EU's Smart Specialisation Platform is vital in addressing regional inequalities. The EU must continue to support Member States and regions in developing specialisation strategies in sectors that can help create jobs and growth. Special attention should be paid to how the bioeconomy can improve specialisation in rural and de-industrialised zones, which often lag economically. Here, the contribution of biorefineries – located close to rural feedstock sources – plays a crucial role in creating jobs, growth, and regional specialisation. Building more regional clusters of life sciences and biotechnology excellence will go a long way in achieving the overarching objective of EU regional policy.

As a leading employer of highly skilled, future-proof jobs, the life sciences and biotechnology sector should be included in discussions on the specificities of smart specialisations, as they will be the organisations creating the products, and responding to the needs of tomorrow. Bio-entrepreneurs should be encouraged (e.g. through tax breaks, finance) to invest and set up facilities in areas identified for smart specialisation.

POLICY RECOMMENDATIONS

- Prioritise regional funding in areas that have the highest return on investment (R&D&I, competitiveness, SMEs)
- As a highly skilled, future-proof job creating sector, put life sciences and biotechnology at the heart of the Smart Specialisation Platform, consulting with industry on how the platform can support future requirements.
- Provide incentives for the sector to invest in less-developed regions, helping to address geographic disparities in the longer term.
- Create geographic dashboards, comparing which developing regions have/are creating the right environment to attract life science and biotechnology investment, encouraging best practice sharing between authorities.

Global competitiveness

BARRIERS

Europe's ability to compete on the global stage is hindered by its **internal fragmentation**. With so many different national markets, divergent legislation, and varying approaches to building a life sciences and biotechnology sector, it is difficult for Europe to speak globally with one voice, or to project the attractive image of a truly single market. This sets the EU a disadvantage in comparison to the US or China. SMEs are particularly exposed to the drawbacks of a fragmented Single Market. The Commission should consider a more "bottom-up" legislative and regulatory approach to reducing cross-border fragmentation by drawing on the experience of industry (especially SMEs), regional authorities, and other local agencies to reduce the burdens that matter most to them.

Brexit also poses a threat for competitiveness. The UK represents 25-30% of EU expertise in biotechnology and life sciences. It is also the most attractive EU destination for talent, according to the World Economic Forum (WEF). Therefore, although links to the EU will surely remain even post-Brexit, the UK's departure will have an impact on the skills, workforce, manufacturing and innovation of the industry. This must be offset by making the EU 27 more appealing for Foreign Direct Investment and talent: both from a policy and communications perspective.

OPPORTUNITIES

There is no "quick fix" for making Europe globally competitive. Attracting investment and boosting competitiveness will be the result of systematically **putting in place the right policy and regulatory framework**. This ranges from building a strong foundation (capital and financing, skills and labour), to delivering a forward-looking approach to life sciences and biotechnology (R&D and innovation, regulation, manufacturing, digitalisation). Once this framework is constructed, investment and competitiveness will follow.

Europe rightly prides itself on being a pioneer in **addressing global issues in the international arena** and setting the pace of global reform (for example, achieving the United Nations Sustainable Development Goals). The life sciences and biotechnology industry will provide some of the answers to some of the pressing questions raised in trying to achieve the UN SDGs. Across the healthcare, industrial, and agricultural sectors, the life sciences and biotechnology industry is working hard to create products and services that benefit people and planet.

EuropaBio also welcomes Commission President von der Leyen's call for a **European Green Deal**, and encourages the Commission to make sure Green Deal measures support companies promoting a greener tomorrow. To quote President von der Leyen's remarks on the Green deal at the 2019 United Nations Climate Change Conference (COP25), EuropaBio eagerly awaits a Deal that can serve as "Europe's new growth strategy... cut[ting] emissions while also creating jobs and improving our quality of life."[20]

Sending signals to international markets that Europe is open to do business. This sector will attract investment into the EU. This will create new jobs and products for EU citizens and add to the EU's arsenal of responses to the most critical global and societal challenges. A coherent, far-reaching EU life sciences and biotechnology industrial policy, which attracts these investments and innovations, would be a major step in being able to respond to these challenges. Public Private Partnerships (PPPs) such as the BBI JU and IHI, also provide excellent signals to industry of the EU's commitment to innovation and should be continued.

Recent media reports of Commission proposal for a European Future Fund of €100bn to build champions in strategic sectors, is a good first step. This could be complemented with a Biotech Leadership Package (like the Digital Leadership Package in the European Commission's proposal). This leadership package could define strategic priorities and value chains, investment opportunities, and high impact projects to offer a signpost for where investors should allocate resources to make Europe a global leader and ensure its strategic autonomy. Arable produce – where the EU is not self-sufficient – is a sector which demands particular attention. Refocusing the European agricultural products approval systems away from hazard, towards science and innovation, could lead to a burgeoning EU agricultural sector, reducing the dependence on imports, and potentially boosting exports.[21]

POLICY RECOMMENDATIONS

- Address fragmentation of the EU single market, beginning with cross-sectoral impact assessment to identify and analyse how fragmentation impacts life sciences and biotechnology competitiveness.
- Integrate existing cross-cutting initiatives, such as the bioeconomy, into sectoral policies to help ensure its uptake.

[20] https://ec.europa.eu/commission/presscorner/detail/en/speech_19_6651

[21] https://croplife.org/wp-content/uploads/2018/09/Challenges-Facing-Farmers-and-the-Plant-Science-Industry-in-the-EU-report.pdf - pp 18 - 22

- Work with Member States and stakeholders to ensure global competitiveness is increased.
- Create a "bottom-up" Single Market Strategy, inviting SMEs, regional and local authorities to share their experience of internal fragmentation. Create a pilot programme at border regions to test possible solutions to these problems in a "regulatory sandbox".
- Revise the regulatory framework in the Single Market to include more science-based policy and decision-making.
- Set up a cross-DG European Commission Task Force to scale up successful pilots, and implement large-scale harmonisation measures in collaboration with industry, SMEs, and local and regional authorities.
- Implement the Commission's planned European Future Fund in the strategic sector of life sciences and biotechnology, to attract investment and to build European champions in the field. Complement this with a focus on protecting strategic value chains.
- Ensure an ambitious PPP on bio-based industries building on the BBI JU's successes and future IHI.
- Put in place policies and communication strategies to send clear signals to industry that the impact of Brexit will be offset in the EU27, to continue to attract the most promising talent.
- Leverage the potential for the EU to fight global challenges at an international level by devising an implementing and EU life sciences and biotechnology industrial policy based on the key elements outlined in this document.

Concluding remarks from Joanna Dupont-Inglis, Secretary General, EuropaBio

"Capturing the full potential of life sciences and biotechnology is fundamental to finding new solutions to the challenges that Europe is facing. These include health and ageing, climate change mitigation, healthy food and soils and sustainable economic, environmental and societal development. Life sciences and biotechnology are transforming our lives and Europe needs to be at the forefront of this revolution."

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