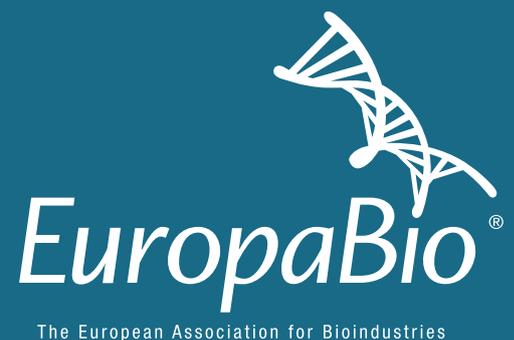


HALF A TERM LEFT TO
**BOOST JOBS, GROWTH
AND COMPETITIVENESS**
THROUGH EU BIOINDUSTRIES

EuropaBio mid-term alert to the EU Commission, Parliament and Council



EuropaBio[®]
The European Association for Bioindustries

1. FOSTERING COMPETITIVE AND BENEFICIAL EU BIOINDUSTRIES

Following months of political turbulence and at a mid-way point in President Juncker's Commission mandate, EuropaBio takes stock of the landscape for the European Union's (EU) Key Enabling Technologies and asks what now needs to be done to provide a smarter, stronger Union for future generations. EuropaBio and its members are also keenly aware of the importance of ongoing Brexit negotiations and remain open to a continuous dialogue with the parties involved to limit potential disruptions to the current business environment and maintain Europe as an attractive destination for business and investments. In this context, EuropaBio and its members stress their commitment to the European project and highlight a number of measures that are now, urgently needed to deliver a strong, healthy, sustainable and inclusive future for its citizens.

European bioindustries have been a pillar of EU competitiveness and innovation for the past twenty years. Our three sectors, spanning healthcare, industrial and agricultural biotechnology, are deeply committed to Europe and the European project. With a presence of over three thousand companies in Europe today, ranging from start-ups of less than ten people to multinational companies present in multiple EU countries, we demonstrate this commitment to Europe's socio-economic development through significant investment in research, innovation and jobs. We believe in a strong, competitive Europe delivering solutions that benefit patients, farmers, other end users and citizens as a whole.

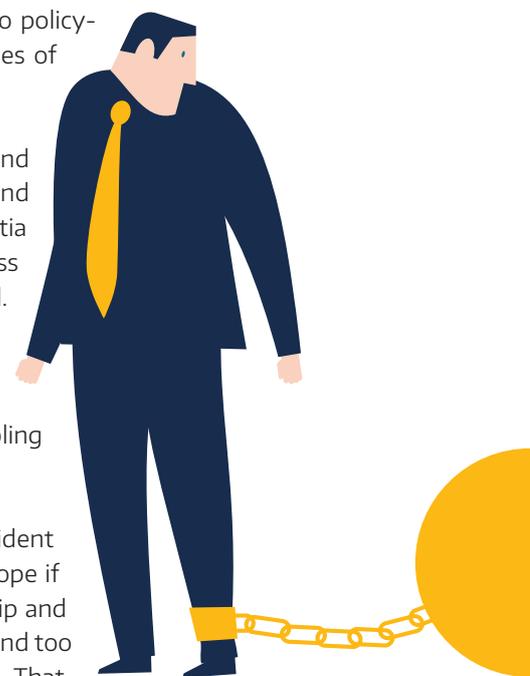
1.1 MORE EU BARRIERS TO INNOVATION IN BIOTECH THAN EVER BEFORE

In our 2014-19 Manifesto "**Time to reap the benefits in Europe**", we emphasised to policy-makers that, in order for Europe to remain competitive for biotech companies, a series of areas needed urgent attention.¹

However, half way through the 2014-19 mandate of the European Commission and Parliament, we are witnessing the existence of more EU barriers to innovation and investment in bioindustries than ever before. This is compounded by a perceived inertia amongst policy makers by the industry and an absence of the supportive, market access measures which currently enable several of the EU's biggest competitors to succeed. As a direct result, despite world leading excellence in science and technology, Europe's bioindustries are faced with significant barriers to their global competitiveness and in providing valuable, much needed solutions to some of Europe's greatest challenges. As a consequence, the EU and its citizens fail to fully reap the benefits of this key enabling technology.

EuropaBio strongly supports the EU agenda on jobs and growth as laid out in President Juncker's 2014 Policy Guidelines: "jobs, growth and investment will only return to Europe if we create the right regulatory environment and promote a climate of entrepreneurship and job creation. We must not stifle innovation and competitiveness with too prescriptive and too detailed regulation". EuropaBio also fully supports the EU's better regulation agenda. That said, our analysis of our sector indicates that, so far, these initiatives have failed to improve the operating environment for biotech companies in Europe in the last two and a half years.

At the same time, in an era of global political and economic uncertainty and fake news, the need to boost economic recovery, access fresh investment, create new markets and cultivate a highly skilled workforce is becoming increasingly critical, if the EU wants to live up to its rhetoric. Bold political leadership which recognises and plays to Europe's competitive and technological strengths rather than stifling them, is needed now more than ever, if the Commission is to create a stronger, smarter Europe delivering the benefits, jobs and growth that its citizens need. **EuropaBio is strongly willing to support this ambition, to engage in the debate and to collaborate wherever appropriate.**



¹ **EuropaBio 2014-2019 Manifesto** "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 less science-based regulatory frameworks and lacks the funding and tailored market pull measures offered by other parts of the world".

² **President Juncker's Policy Guidelines** "A New Start for Europe: My Agenda for Jobs, Growth, Fairness and Democratic Change", July 2014.



2. EUROPEAN COMMISSION MID-TERM SCORECARD: THE FUTURE OF EUROPEAN LEADERSHIP IN BIOTECHNOLOGY AT STAKE

Biotechnology and the bioeconomy are already part of our everyday lives, from the clothes that 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. The choice for the EU is clear: either we address and overcome the barriers to the development of biotech and the bio-based economy in Europe or we will cease to be a technology-driven generator of benefits with a competitive and world-leading industry and become a net importer of those benefits.

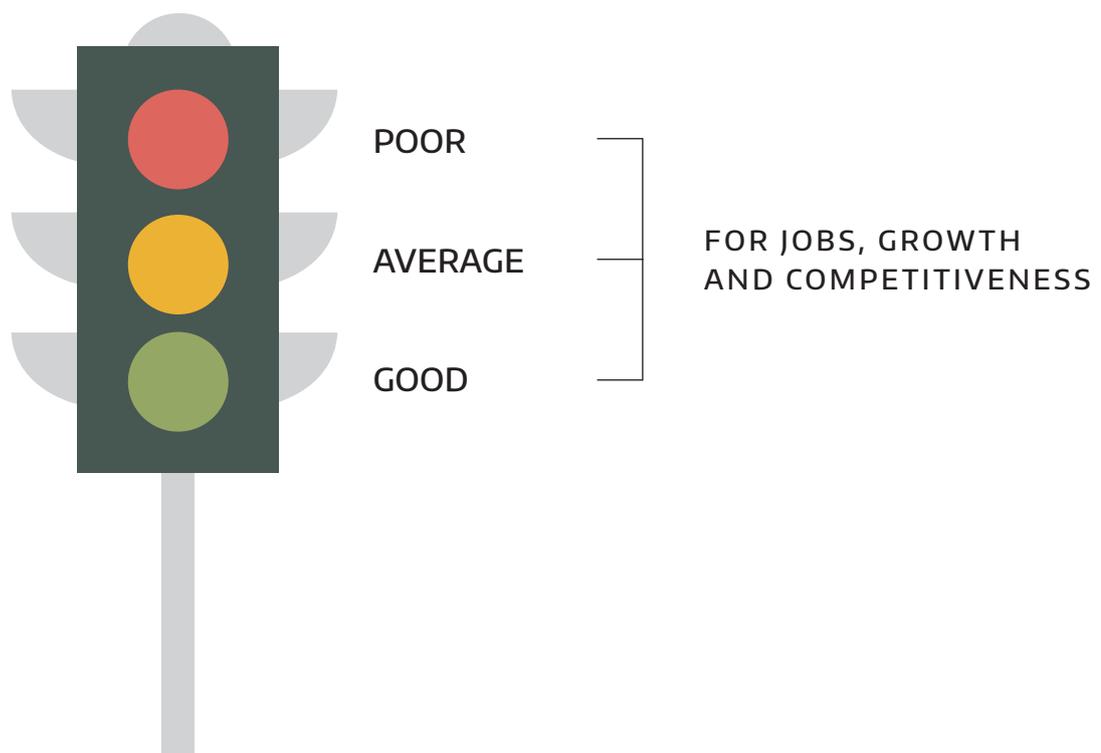
In our 2014-19 Manifesto **“Time to reap the benefits in Europe”**, we called on European decision makers to achieve a number of goals in order to ensure that the EU and its Member States can fully reap the benefits biotechnology has to offer.

Half way through the institutional mandate, new and emerging technologies, such as biotech, face a patchy and unpredictable policy landscape. We welcome and support the continuation of some previously established EU support mechanisms, notably in the industrial biotech and bio-based space, which continue to boost innovation. However, these innovation positives face significant headwinds and exist in stark contrast to other actions, such as the current reconsideration of successful incentives supporting innovation to the benefit of patients, in the case of healthcare, and ongoing examples of maladministration, poor access to markets and a lack of commitment to science based decision-making, in the agricultural biotech sector.

Below we provide an analysis of progress to date on the drivers for jobs, growth and competitiveness laid out in our 2014-2019 Manifesto.

MID-MANDATE REPORT, SPRING 2017

Subject: EU | Term: 2014-19



1. RESEARCH AND DEVELOPMENT PHASE

GOALS

EU-funded projects with clear objectives and translation to end products.

EXPLANATION

The Barroso II commission, EP and member states put together a package of over 4 billion euro for bioeconomy-related research and innovation under the Horizon 2020 programme - double the amount that was available under the 7th Framework Programme for Research. This is good progress but work must be continued into FP9 to yield the results that the EU's biobased sector is capable of.

In contradiction with Commission funded research findings (GRACE project) and against EFSA advice, politically imposed requirements such as mandatory 90-day studies remain in place for import authorizations of agricultural GMOs.

Coordination of Member States research to maximise impact.

There are European Reference Networks (ERNs) in place (work driven by the Commission in collaboration with member states), for example for rare diseases, serving as research and knowledge centres. We welcome their rollout and have high hopes that, among their benefits, there will be concrete added value for rare disease research.*

Competitive patent system and data exclusivity to reward innovative European R&D.

The Biopatent Directive appears stabilised, but data exclusivity continues to be challenged.

Funding schemes to support biotech SMEs throughout their capital-intensive pathway to commercialisation.

Progress has been achieved through the InnovFin tool of the EIB although it has not funded as many SMEs as initially hoped for and more efforts are needed to raise awareness of the tool. The H2020 SME Instrument is proving to be an efficacious tool to help individual SMEs with near-to-market products. However, more emphasis should be placed on financing SMEs with innovative projects far from the market that require longer developments (i.e. drug development start-ups).

Support of translational research and proof of concept via Joint Undertakings (e.g. Biobased Industries JU & Innovative Medicines Initiative II).

The BioBased Industries Joint Undertaking (BBI JU) is one area where commitments made in the EU's Bioeconomy strategy and by the Barroso II Commission have been met attracting commitment of €3.7 billion. The EU must keep up the good work to ensure a renewal of the JU beyond 2021 to continue attracting investments and driving bio-based innovation.

IMI-II's €3.3 billion budget for the period 2014-2024 is not exclusively dedicated to biotech healthcare but is a significant boost to develop innovative therapies. In addition, under H2020, the Commission renewed its commitment to the International Rare Disease Research Consortium (IRDiRC) and helped establishing of the International Consortium for Personalised Medicine (ICPerMed) under H2020.

→ **Average combined performance** (Research and Development Phase)

* Topics marked with an asterisk have been marked based on the value of the initiative rather than the outcome. It is too early to evaluate the outcome of said projects/initiatives.



2. ASSESSMENT AND APPROVAL PHASE

GOALS

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 genetically modified crops.

Action plan to eliminate the backlog of pending approvals of genetically modified crops 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.

EXPLANATION

The Competitiveness Council has endorsed the principle, but the Commission and the Parliament have yet to translate it concretely and consider impact of existing and proposed legislation on innovation. This is especially important in the current context where the precautionary principle continues to be misused.

The European Medicines Agency (EMA) plays a crucial and constructive role in the centralized approval system, leading to faster access to innovative therapies via recent initiatives such as 'adaptive pathways' and 'PRIME'.*

In 2016, the EU Ombudsman confirmed that the EU Commission's delays on handling import approvals constituted maladministration. The Commission proposal to change the Comitology procedure tabled on 14.02.2017 risks making authorisations of innovative products even more unpredictable and lengthy.

No such action plan appears to exist. Following a "de facto moratorium" in 2014-15, several products were approved, but since then, new delays and additional uncertainty persist.

Despite the 20-year safety record of genetically modified crops, EFSA timelines continue to lengthen, and politically imposed requirements such as mandatory 90 day studies remain in place against EFSA advice and in contradiction with Commission funded research findings (GRACE project).

While the Commission has communicated about the approval system for genetically modified crops to some extent, neither the Commission nor EFSA clearly stated that there is scientific consensus that genetically modified crops are just as safe as conventionally bred crops. Instead, the Commission continues to provide significant funding to NGOs, which promote unfounded scaremongering.

→ **Poor combined performance** (Assessment & Approval Phase)



3. MARKET ACCESS PHASE

GOALS

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.

Revision of the Renewable Energy Directive II.

EXPLANATION

Since 2015, Member States are allowed to ban the cultivation of EU-approved genetically modified crops nationally, and the Commission has proposed to extend this bad precedent to the "use" of imported genetically modified crops, which would put an end to the single market.

For healthcare, EuropaBio welcomes the progress achieved so far on EU cooperation on Health Technology Assessment (HTA) via EUnetHTA Joint Action 1 and 2. However, the joint work has not been used to the extent that it should have. Joint Action 3 now needs to set the grounds for the future by establishing a sustainable permanent EU HTA model.*

For industrial biotechnology, the majority of the Lead Market Initiative recommendations for biobased products, developed with the support of DG GROW to help stimulate markets for renewable alternatives to fossil carbon products, remain unimplemented. The Commission has not followed through on its 2011 Industrial policy communication, which pledged to support Industrial Biotech both as a Key Enabling Technology and as one of the EU's 6 sectors with the potential to tackle the Eurozone economic crisis. See Public Procurement below for further details.

There is a successful framework of rewards via Intellectual Property (IP) rights and Incentives in place, such as market exclusivity and Supplementary Protection Certificates for Orphan Medicinal Products via the regulation. However, the current public debate initiated by the Dutch Council conclusions and EP Report on Access to Medicines (2016) is calling for a review of incentives which could jeopardize healthcare biotech Research & Development throughout the EU.

Despite strong leadership from DG RTD, support has failed to materialise from other parts of the Commission for implementing the Bioeconomy Strategy. Support for enabling the creation of new markets has not been provided and sufficient leadership and resources have not been made available by the Commission despite the potential to create jobs, growth and value for the 18 million people working within the EU circular bioeconomy. Furthermore, the necessary cross-policy coherence has been lacking to enable new market stimulation measures to be put in place.

An unfortunate example of 'worst in class' in the case of the European Commission's proposed phase-out of conventional biofuels by 2030. This represents an 'own goal' for European jobs and growth, undermining many promising industries who had been encouraged to make investments within the EU bioethanol sector and threatening to remove one of the EU's best options for reducing greenhouse gases and decarbonising transport. The only glimmer of green light here is the incentivisation of advanced biofuels where a minimum target has been proposed. However, as conventional and advanced biofuels are interlinked a phasing out of conventional biofuels can only have the knock-on effect of discouraging investment in advanced biofuels. Good news for big oil – bad news for a decarbonized transport system. Users competing for the same raw material should be placed on the same level playing field regardless of usage. Hence, EU policies should promote a level-playing field between the different sustainable uses of biomass.



Public procurement programmes and supportive measures.

An example of 'paralysis by analysis'. Whilst the US shows top-down leadership helping to create a market of almost \$400 billion of biobased products and 4 million jobs, the Commission's lack of commitment and support for EU biobased industries helps prolong the fossil-carbon dominated status quo. The Commission must acknowledge the dependence of the circular economy on a dynamic, competitive and sustainable Bioeconomy if either is to succeed and provide the resource efficient solutions needed.

For healthcare, the revised EU directive on public procurement (directive 2014/24/EU) focuses on implementing the EU's growth strategy – Europe 2020 – which aims to ensure that the European economy is based on sustainable growth, fostering innovation and social inclusion. EuropaBio members welcome the new EU public procurement directive as regards the promotion of innovation-friendly public procurement.

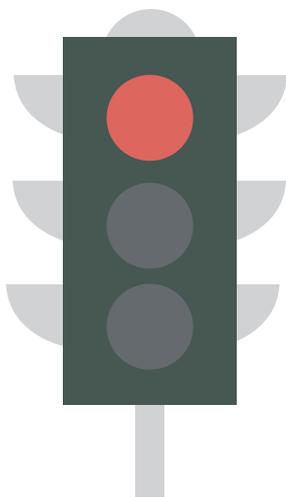
Revision of the Bioeconomy Strategy and commitment to communication of the benefits of bioindustries and the bioeconomy with society.

The perception of inertia creates doubt over whether the Commission will abandon the bioeconomy or will they instead build on the extensive and increasingly embraced efforts of Member States, regions, sectors and industries who have made commitments to developing competitive and sustainable jobs and economic growth across a broad range of struggling sectors, particularly in the EU's rural, coastal and de-industrialised zones. The signals are not promising, a sense of inaction creates doubt and suspicions of a withdrawal of support and resources. Therefore, now is the time for the Commission's leadership and college to voice their commitment to the Bioeconomy. It is important that the EU shows the long-term support needed not to undermine their member's earlier efforts which means ensuring a full revision of the existing strategy, co-owned by all the relevant DGs. In addition, in the future it will be important to emphasise the synergies and complementarities of developing both the circular economy and the bioeconomy.

→ **Poor combined performance** (Market Access Phase)

Poor overall performance (Mid-mandate Report, spring 2017)

* Topics marked with an asterisk have been marked based on the value of the initiative rather than the outcome. It is too early to evaluate the outcome of said projects/initiatives.



Half way through the institutional mandate, much innovation remains stuck at the red lights. The EU biotech industry continues to demonstrate its outstanding track record of producing new and innovative products and processes which meet societal needs, add value and create jobs and growth. Global competition is growing as is recognition of these benefits emerging from the biotech and bio-based industry. Bill Gates recently commented that if he was to go back to university today, one of his top three subjects of choice would be biosciences for its enormous potential. However, with a lack of similar vision from the EU's decision makers how many EU students will make a similar choice?

European bioindustries call on the European Institutions to address the above-mentioned significant barriers to innovation and operation in research and development, assessment and approval and market access in order to enable Europe to become a more attractive continent for investment in the growth and development of one of its core strengths, its innovative biotech industry. We provide our recommendations to do so in the next chapter.



3. WORKING TOGETHER TO CAPTURE THE FULL POTENTIAL OF EU BIOINDUSTRIES



3.1 SECTOR SPECIFIC RECOMMENDATIONS

Healthcare biotech-specific recommendations

- Keep stimulating innovation in healthcare by maintaining the existing successful IP/Incentives frameworks.
- Ensuring that EMA can keep playing their crucial and constructive role in the centralized approval system and that (faster) patient access to innovative therapies will continue without delays.
- Beyond EUnetHTA (Health Technology Assessment) Joint Action 3, set the conditions for an integrated system delivering an EU-wide view of the clinical part of HTA and tackle any barriers that currently prevent Member States to use the outcomes of joint assessments in their national processes.
- Carefully monitor the use of public procurement and tendering of biological medicines by Member States to ensure that this is aimed at: securing access for patients to innovative therapies, guaranteeing high standards of quality, safety and efficacy of products purchased, and incentivising companies to compete in a free and dynamic internal market.
- Continue supporting, through coordination and funding, initiatives focussing on research and development of innovative therapies, such as, the Innovative Medicines Initiative (IMI), the International Rare Diseases Research Consortium (IRDiRC), the International Consortium for Personalised Medicine (ICPerMed). Allocate adequate resources to unlock the potential of the recently launched European Reference Networks in the field of research.

Agricultural biotech-specific recommendations

- Implement the existing GMO authorization system efficiently and avoid undue delays in the risk assessment and in the 'comitology' process.
- Withdraw the 'comitology' and 'import opt-out' proposals.
- Increase communication to defend scientific consensus on GMOs.

Industrial biotech-specific recommendations

- Ensure full revision of the EU Bioeconomy Strategy with cross sectoral policy support and the development of a dialogue to develop policy in a smart, sustainable and inclusive way.
- Introduce supportive measures acknowledging the role of sustainable conventional biofuels such as ethanol in creating a low carbon economy to decarbonise transport while promoting the deployment of advanced biofuels through a specific mandate.



- Implement concrete measures to help bring innovative, bio-based products to the EU market, including through public procurement and via the EU Circular Economy Package.
- Secure a second mandate for the ground-breaking Bio-Based Industries Joint Undertaking.
- Place a stronger emphasis on supporting circular bioeconomy development through EFSI, CAP, FP9, Climate, energy and transport and industrial policy and put in place a distinct European BioEconomy Strategic Investment Fund (EBESIF).

3.2 OVERALL RECOMMENDATIONS

- Reduce barriers to bring innovative biotech, including bio-based products to the market, and instead focus on stimulating innovation.
- Enable innovation by providing leadership and legal clarity on the status of new, targeted methods such as genome editing.
- Ensure timely, efficient and science-based product authorization systems and risk assessment.
- Increase trust in the risk assessment agencies.
- Expanding, speeding up, simplifying and adapting access to European and national funding instruments for biotech SMEs, as well as coordinating between funding mechanisms at European level and at national level.



Based on these recommendations, EuropaBio is eager to engage and collaborate with the European Institutions as appropriate and required, and together remove existing barriers to the development of European Bioindustries for the benefit of all Europeans.

