BBIA

CHAMPIONING THE INDUSTRIAL BIOECONOMY

Biotech Act II (EU): Addressing cross-cutting challenges and establishing an enabling regulatory framework for industrial biotechnology and biomanufacturing

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1. Executive Summary

Europe is at a decisive point in its industrial transition. Industrial biotechnology and biomanufacturing can become core pillars of a competitive, resilient, and defossilised European economy, enabling the production of chemicals, materials, fuels, food ingredients, and consumer goods from renewable biological resources, captured carbon, and circular feedstocks. However, despite world-class scientific capacity and strong sustainability ambitions, Europe is not yet scaling these technologies at the pace required due to fragmented regulation, weak demand signals, and insufficient investment certainty. The key challenge is now commercial deployment and systems integration, not proving the biology.

The proposed Biotech Act II is a critical opportunity to address these barriers. To succeed, it must go beyond an enabling framework and function as a coherent, market-shaping industrial strategy that aligns demand creation, investment conditions, sustainability governance, and regulatory simplification. To be effective, measures must be proportionate, implementable, and reflect feedstock constraints and the practical realities of complex value chains.

This response addresses the five priority pillars for action:

1. Creating Lead Markets and Predictable Demand

A central requirement is the creation of stable lead markets to drive industrial uptake of bio-based and biomanufactured products. Without predictable demand signals, private investment will not scale. The Act should therefore introduce long-term policy certainty, strengthen green public procurement, and establish clear, technology-neutral targets for bio-based, recycled, and carbon-captured content in products. These measures should be designed to be lifecycle-based, enforceable, and applied consistently across domestic and imported goods. A single biomass-derived content target per product group can improve simplicity, flexibility, and investment confidence while reducing administrative burden.

2. Improving Predictability for Investment

Europe must strengthen investment conditions across the innovation and deployment lifecycle. This includes improving demand certainty, scaling blended finance instruments, and aligning EU funding programmes to reduce fragmentation and complexity. Greater support is needed for first-of-a-kind and next-of-a-kind facilities, including expanded access to pilot and demonstration infrastructure and patient capital. Sustainable finance frameworks should avoid unintentionally excluding bio-based pathways and must be aligned with lifecycle-based sustainability principles. Extending innovation support beyond R&D to cover scale-up and commercial deployment is essential to close the “valley of death”.

3. Establishing Coherent Sustainability Criteria

Sustainability frameworks must be harmonised, science-based, and consistently applied across fossil-based, bio-based, recycled, and emerging materials to ensure a level playing field. Lifecycle

assessment should underpin all product-level sustainability claims, supported by harmonised carbon accounting and improved recognition of biogenic carbon flows, circularity benefits, and avoided emissions. Biomass governance should prioritise high-value applications while maintaining flexibility through cascading use principles rather than rigid hierarchies. Sustainability criteria should be performance-based and technology-neutral to avoid excluding innovative feedstocks and production pathways.

Existing and emerging frameworks (e.g. PPWR, SUPD, RED, PEF) must be aligned to reduce fragmentation and avoid conflicting requirements. Any expansion of impact categories (e.g. biodiversity, persistence, microplastics) should be phased, proportionate, and based on robust data availability.

4. Simplifying and Enabling Regulation

Regulatory simplification is essential to enabling industrial scale-up. Biotech Act II should reduce fragmentation across EU, national, and international frameworks and strengthen coordination between regulatory agencies such as ECHA, EFSA, and EMA. A risk-based, product-focused regulatory approach should replace process-based classification, with faster and more proportionate pathways for approval of biotech products and microorganisms.

Key measures include expanded regulatory sandboxes, development of NAMS suitable for biotechnology, faster permitting for R&D, pilot, and industrial facilities, and improved GMO and biotechnology frameworks that reduce cost, delay, and uncertainty. A clearer, harmonised, science-based lexicon across bio-based, biodegradable, and compostable materials is also needed to improve regulatory coherence and public understanding.

5. Strengthening Non-Legislative Ecosystem Support

Non-legislative measures are essential to complement regulatory reform. These should include improved coordination across EU, national, and regional funding instruments, stronger biotech innovation networks, and better access to scale-up infrastructure. Enhanced visibility and simplification of funding mechanisms will be critical for SMEs and scale-ups. Cross-border collaboration in biomanufacturing ecosystems should be strengthened to accelerate knowledge transfer and industrial deployment.

Conclusion

Industrial biotechnology is a strategic industrial priority for Europe's future competitiveness, resilience, and climate neutrality. Biotech Act II must therefore function as a market-shaping framework that creates demand, unlocks investment, ensures coherent sustainability governance, and enables rapid scale-up through simplified regulation.

If designed effectively, it can position Europe as a global leader in circular, bio-based manufacturing while strengthening strategic autonomy, industrial competitiveness, and sustainable growth.

2. About the BBIA

The Bio-based and Biodegradable Industries Association (BBIA) is the UK's leading trade association for the bioeconomy, representing organisations engaged in the development, manufacture, and promotion of bio-based chemicals, materials, and products. Founded in 2015, BBIA works to accelerate the growth of the industrial bioeconomy through advocacy, collaboration, and education—supporting the shift away from fossil-based resources and towards a more sustainable, circular economy.

BBIA's membership spans the full bio-based value chain, from early-stage innovators and SMEs to established multinational manufacturers and technology providers. Members operate across diverse sectors including packaging, chemicals, agriculture, consumer goods, and advanced materials.

Collectively, this network reflects a truly global footprint, with operations, supply chains, and markets extending across the UK, Europe, North America, and beyond. A significant proportion of manufacturing members are based in Europe, where advanced industrial capacity enables large-scale production of bio-based solutions.

This breadth and diversity underscores the international nature of the bioeconomy and reinforces BBIA's role as a connector of innovation, policy, and industry across borders—helping to build a competitive, circular bioeconomy at global scale.

3. Introduction

Europe stands at a critical turning point in its transition towards a competitive, resilient, and defossilised industrial economy. Industrial biotechnology and biomanufacturing have the potential to become foundational pillars of Europe's future industrial strategy, enabling the production of chemicals, materials, fuels, food ingredients, and consumer products from renewable biological resources, captured carbon, and circular feedstocks, rather than virgin fossil carbon. Yet despite Europe's strong scientific base, industrial capabilities, and sustainability ambitions, the deployment and scale-up of industrial biotechnology across the EU remains significantly below its potential.

A key driver of this gap is a persistent structural imbalance between fossil-based and bio-based chemicals and materials, which continues to constrain the uptake of lower-carbon alternatives. This imbalance is rooted in the historical evolution of fossil-based systems, which benefit from decades of optimisation, large-scale and fully depreciated infrastructure, mature and proven technologies, and highly integrated global supply chains. As a result, fossil-based chemicals and materials typically offer lower costs, higher operational reliability, and reduced investment risk.

By contrast, bio-based value chains operate under markedly different conditions. They often require higher upfront capital and operating expenditure, rely on fragmented and regionally constrained supply systems, and depend on technologies that are still early-stage or pre-commercial. Scale-up pathways are typically longer and more uncertain, while feedstock availability can be limited and subject to competing uses and sustainability constraints. This structural disadvantage is reinforced at the level of feedstock markets: fossil carbon benefits from global, liquid commodity markets, whereas biomass remains geographically bounded and governed by more complex sourcing and sustainability requirements.

Further systemic barriers compound this imbalance. End-of-life waste management systems remain largely designed for fossil-derived materials, limiting the integration of novel bio-based products into circular value chains. Permitting and infrastructure development processes are often slow and complex, while market-pull signals for sustainable alternatives remain weak or inconsistent. In addition, limited risk-sharing mechanisms and extended deployment timelines further discourage investment. Taken together, these factors create a challenging environment for scale-up and increase the risk of innovation and industrial investment shifting outside the EU.

4. Recommendations for the EU Biotech Act II

BBIA recognises the key challenges facing EU biomanufacturing and welcomes the European Commission's ambition to strengthen the EU biotechnology ecosystem through the forthcoming Biotech Act II. The Commission's proposal rightly reflects both the strategic importance of this opportunity and the urgency of addressing existing structural barriers.

At present, Europe risks falling behind global competitors—particularly the United States and China—which are rapidly accelerating investment, commercial deployment, and market adoption of bio-based and biomanufactured solutions. By contrast, Europe is constrained by fragmented markets, regulatory complexity, uncertain investment conditions, and insufficient demand signals. Fossil-based products continue to benefit from entrenched infrastructure, mature supply chains, and longstanding policy support, whereas innovative bio-based solutions often struggle to compete on cost, despite delivering significant climate, circularity, and resilience benefits.

Addressing this transition requires more than technological innovation alone. It demands a coordinated bioindustrial strategy that actively creates lead markets, strengthens investment certainty, streamlines regulatory pathways, and ensures that sustainable carbon resources are directed towards the highest-value applications. Predictable demand signals—such as mandatory minimum bio-based or recycled carbon content requirements—could provide the long-term certainty needed to unlock private investment and enable industrial-scale deployment. Equally important are clearer and more harmonised regulatory frameworks that reduce administrative burden and support the development of a truly functioning single market for bio-based products.

A key element of this transition is the strategic diversification of Europe's carbon base. Greater use of biomass, waste-derived feedstocks, captured carbon, and recycled carbon streams can enhance industrial resilience, reduce dependence on imported fossil resources, and directly support the EU's climate neutrality and circular economy objectives. However, this must be balanced with robust sustainability criteria to ensure responsible sourcing, biodiversity protection, and prioritisation of biomass for its highest value uses. Infrastructure readiness, industrial symbiosis, and co-location with existing industrial assets will also be critical enablers of cost-efficient, low-CAPEX scale-up.

In the case of carbon capture and utilisation (CCU), infrastructure constraints remain a major barrier. Investment has so far been skewed towards carbon storage rather than the utilisation pathways and downstream processing infrastructure required to build CCU value chains at scale. This is compounded by insufficient financing for research, demonstration, scale-up, and commercial deployment, which slows both technological maturity and market adoption. Regulatory uncertainty—particularly around CO_2 collection and use—and fragmented Member State permitting processes further increase delays and investment risk.

Comparable challenges exist for waste-derived carbon feedstocks. The classification of certain waste streams as hazardous, combined with inconsistent or underdeveloped collection and sorting systems, can restrict access to suitable materials and increase compliance costs. In addition, product carbon footprint (PCF) and life cycle assessment (LCA) attribution rules do not always adequately incentivise the use of waste-derived carbon and can unintentionally disadvantage these feedstocks within existing accounting frameworks.

Beyond feedstock-specific barriers, the scope of Biotech Act II should explicitly recognise the full range of downstream applications enabled by industrial biotechnology and fermentation-derived ingredients. These sectors represent areas of high carbon intensity and strong near-term substitution potential, with clear regulatory and market levers. In particular, bio-based chemicals and materials should be fully included within the scope of the Act, as they represent some of the most immediate and scalable opportunities for system-level defossilisation and circularity. Priority sectors include:

- chemicals and materials
- plastics and polymers, particularly packaging
- consumer products, such as home and personal care and beauty products
- fibres, fabrics, and textiles
- construction materials
- fertilisers and plant protection products
- novel food and feed ingredients, including fermentation-derived nutritional ingredients, resilient protein/lipid systems, and marine-resource replacement opportunities

The Act should also address key gaps left by the EU Bioeconomy Strategy, including the need for consistent sustainability criteria, harmonised chain-of-custody rules, clarity on eligible uses of bio-based feedstocks for target compliance, and coherent approaches to cascading biomass use.

At the same time, any targets, sustainability requirements, or reporting obligations introduced through Biotech Act II must be coherent with existing and emerging EU legislation, as well as the outputs of the EU Simplification Initiative. For example, for bio-based plastics, alignment with frameworks such as the European Packaging and Packaging Waste Regulation (PPWR), the Single-Use Plastics Directive (SUPD), and related circular economy legislation will be essential to avoid conflicting definitions, regulatory duplication, and unnecessary complexity for industry. Consistent terminology, sustainability criteria, and reporting requirements across EU legislation would further improve legal certainty for businesses and investors, while supporting more effective implementation and enforcement.

Beyond regulatory coherence, addressing cost competitiveness will be essential to enabling wider market uptake of alternative renewable carbon raw materials. Petrochemical feedstocks continue to benefit from incumbent scale, established infrastructure, and mature supply chains, resulting in a significant cost advantage over emerging alternatives. Policy interventions that help close this gap—through targeted financial support, investment incentives, de-risking mechanisms, or recognition of the environmental value of non-fossil carbon sources—will therefore be critical.

Alongside this, talent availability is an emerging constraint. Too few graduates are entering the sector with relevant expertise in biochemistry and engineering biology, and there is a shortage of skilled technicians needed to operate and scale biomanufacturing facilities.

Addressing these structural barriers would significantly improve the commercial viability of alternative carbon feedstocks and support their broader uptake across value chains, while reinforcing alignment with EU climate and industrial objectives.

More broadly, Biotech Act II should form part of a more integrated and coherent European bioeconomy legislative framework. Bringing together currently fragmented policy areas—including circular economy policy, industrial decarbonisation, sustainable carbon management, and advanced materials legislation—would provide clearer long-term direction for industry and policymakers alike. A more joined-up framework would strengthen innovation, improve regulatory efficiency, and support the scale-up of sustainable bio-based industries across Europe.

This report responds to the European Commission's proposed intervention areas under Biotech Act II and sets out targeted recommendations to strengthen Europe's industrial biotechnology and biomanufacturing ecosystem. It examines the policy measures required to stimulate market uptake, improve investment predictability, streamline regulation, optimise sustainable feedstock use, and enable innovation across industrial value chains. It also highlights the broader economic and strategic opportunities associated with scaling the European bioeconomy, including

enhanced industrial competitiveness, regional development, strategic autonomy, and the creation of resilient, low-carbon supply chains.

The EU Biotech Act II presents a critical opportunity to position Europe as a global leader in sustainable, biotechnology-enabled biomanufacturing—provided these structural and regulatory barriers are effectively addressed.

4.1 Creating Lead Markets

Current challenges and their consequences

The creation of lead markets for industrial biotechnology products in the EU continues to face a number of structural challenges that limit investment, slow deployment, and hinder the scale-up of innovative bio-based solutions. One of the most significant barriers is the absence of sufficiently strong and consistent demand signals. While industrial biotechnology is increasingly recognised as a strategic technology for decarbonisation and defossilisation, competitiveness, and resilience, market-pull measures such as mandatory bio-based content requirements, product-specific targets, and coordinated public procurement remain limited. Demand for bio-based products therefore remains uncertain, making it difficult for companies and investors to justify the substantial capital investments required to bring new technologies to commercial scale.

This challenge is compounded by the fact that fossil-based products continue to enjoy a significant market advantage. Environmental and climate externalities are not fully reflected in the cost of fossil-derived materials, while existing industrial infrastructure, supply chains, and regulatory frameworks have largely been designed around fossil feedstocks. As a result, many bio-based alternatives struggle to compete on price despite delivering broader environmental and climate benefits. The lack of a level playing field slows market uptake and reduces incentives for investment in bio-based manufacturing capacity.

Regulatory complexity and policy uncertainty also continue to constrain the development of lead markets. Industrial biotechnology companies must navigate a wide range of overlapping legislative frameworks covering chemicals, waste, packaging, sustainability, industrial policy, and state aid. At the same time, evolving regulatory requirements and lengthy authorisation processes can create uncertainty about future market conditions. This increases compliance costs, delays project development, and reduces investor confidence.

Administrative and permitting procedures remain another significant obstacle, particularly for first-of-a-kind facilities. Obtaining environmental permits, utility connections, wastewater approvals, and other authorisations can take several years, significantly extending project timelines and increasing costs. Combined with high capital expenditure requirements, elevated energy and labour costs, and long lead times for public funding decisions, these delays can make Europe a less attractive destination for investment. In practice, innovative projects may be redirected to regions offering more predictable and supportive framework conditions.

The development of lead markets is further hindered by the absence of a fully coherent policy framework for renewable carbon. While bio-based, recycled, and carbon capture and utilisation (CCU)-derived carbon are all important pathways for reducing dependence on fossil resources, existing policies do not always recognise their complementary roles. Inconsistent approaches to measuring, verifying, and accounting for renewable carbon can create uncertainty for both producers and investors, slowing the development of sustainable carbon value chains.

There are also challenges in aligning bio-based policies with broader circular economy objectives. Current regulatory discussions, particularly under the Packaging and Packaging Waste Regulation (PPWR), risk creating unintended barriers for certain bio-based materials. For example, requirements focused primarily on mechanical or chemical recycling may disadvantage biodegradable and compostable materials that were specifically designed for organic recycling and biowaste collection systems. Similarly, strict recycled-content requirements may unintentionally limit opportunities for innovative non-drop-in bio-based plastics that cannot technically incorporate conventional recyclate streams. Such regulatory outcomes risk discouraging investment and innovation in emerging material bio-based solutions.

Financial and economic barriers remain substantial. Industrial biotechnology projects typically require significant upfront investment and often face challenges in securing financing during the transition from demonstration to commercial scale. Public funding programmes can be slow to allocate support, while private investors frequently perceive biotechnology projects as carrying higher technology and market risks. This "valley of death" between innovation and commercial deployment continues to limit the number of projects reaching industrial scale.

At the same time, the EU faces growing international competition. Other major economies, including the United States and China, have introduced substantial support measures for industrial biotechnology through dedicated bioeconomy strategies, tax incentives, public procurement programmes, and industrial policy initiatives. In comparison, European funding mechanisms and regulatory processes can appear slower and less predictable, increasing the risk that investment, manufacturing capacity, and innovation migrate outside Europe.

Taken together, these challenges create a self-reinforcing cycle in which uncertain demand discourages investment, limited investment constrains production scale, and higher production costs reduce competitiveness. Without stronger lead-market measures, more predictable regulatory frameworks, and targeted demand-pull policies, Europe risks losing further industrial capacity and investment opportunities, undermining its ambitions to build a competitive, resilient, and defossilised bioeconomy.

The BBIA strongly supports the creation of lead markets within Biotech Act II as a central demand-pull mechanism to accelerate industrial deployment, reduce investment risk, and enable the large-scale uptake of bio-based and biomanufactured solutions across Europe.

Recommendations and Impact

Recommendation	Impact
Provide long-term policy certainty	
• Establish stable, long-term regulatory frameworks that extend beyond individual legislative cycles to provide confidence for investment in industrial biotechnology and biomanufacturing. • Ensure policy coherence across climate, industrial, chemicals, and circular economy legislation to support market growth and reduce regulatory uncertainty.	• Increased investor confidence. • Reduced regulatory uncertainty. • Greater industrial deployment and market growth.
Strengthen public procurement for bio-based products	
• Develop standardised procurement criteria to support consistent implementation across Member States. • Use public procurement as a primary demand-pull mechanism to de-risk early markets and accelerate adoption of bio-based products, particularly in sectors such as healthcare, construction, packaging, and infrastructure. • Expand green and sustainable public procurement criteria to explicitly recognise bio-based products and biotech-enabled applications across a wider range of sectors. • Introduce time-limited preferential VAT rates for biotech and bio-based products, including manufacturing inputs and intermediates, to improve competitiveness and stimulate adoption	• Creation of lead markets. • Reduced commercial risk for early-stage investments. • Faster market adoption of bio-based products.
Establish complementary targets for sustainable carbon sources*	
• Bio-based, recycled, and carbon capture and utilisation (CCU)-derived carbon (collectively known as 'renewable carbon') should be recognised as complementary pathways for defossilising industrial value chains. Together, they can reduce dependence on virgin fossil feedstocks and support a more resilient and diversified carbon system. • Mandatory minimum renewable carbon content targets are one of the most effective policy instruments to stimulate demand for renewable carbon. The EU should therefore introduce mandatory minimum content targets for renewable carbon across relevant products. • A single combined target covering bio-based, recycled, and CCU-derived carbon could provide a coherent framework for defossilisation.	• Increased demand for renewable carbon. • Reduced dependence on fossil feedstocks. • Greater investment certainty and industrial scale-up. • Technology-neutral market development. • Increased flexibility for industry. • Better sustainability outcomes and policy coherence.

• This would allow manufacturers flexibility in feedstock selection and product formulation, reduce compliance complexity, and support broader deployment across product portfolios. • However, separate targets may still be appropriate in specific sectors where technical performance, regulatory constraints, or market requirements justify differentiated approaches. • Regardless of the structure chosen, clear and harmonised definitions of renewable carbon categories are essential, alongside robust systems for verification, traceability, and comparability.	• Reduced compliance costs. • Greater scalability and flexibility. • Broader deployment of sustainable carbon solutions.
Maintain a clear distinction between bio-based and mass-balance approaches	
• A clear distinction should be maintained between physically verifiable bio-based content and bio-attributed content derived through mass balance accounting. • Physically bio-based products can be verified using established radiocarbon (C14) methods under European standards such as EN 16640 and EN 16785-1**. The term "bio-based" should remain reserved for materials with verifiable biogenic carbon content. • The mass balance approach (ISO 22095) plays an important complementary and transitional role. It enables allocation of renewable feedstocks across complex chemical and polymer value chains where physical segregation is not yet feasible. This approach supports the gradual substitution of fossil carbon within existing industrial infrastructure.	• Improved market transparency and consumer confidence. • Robust verification and traceability. • Accelerated transition within existing industrial infrastructure.
Align bio-based and recycled content policies	
• Bio-based and recycled content policies should be developed in a coordinated way, as both contribute to reducing reliance on virgin fossil resources and lowering emissions. • In line with Article 8(2)(c) of the PPWR, recycled and bio-based content should be recognised as complementary contributions, particularly where technical, safety, or quality constraints limit the use of recyclates.	• More effective defossilisation pathways. • Greater feedstock flexibility. • Improved resource efficiency while maintaining product performance and safety.
Apply clear design principles for target setting	
Wherever targets are introduced, they should: • Be technically feasible and economically viable.	• Greater credibility, fairness, and

• Be grounded in lifecycle sustainability assessments. • Be supported by transparent certification, accounting, and verification systems. • Apply equally to imported and domestically produced goods. • Be designed to create sufficient long-term demand to drive investment. • Reflect trade-offs between circularity, recyclability, feedstock availability, biodiversity, and land use. • Be introduced progressively through a phased or sliding-scale approach to support industrial transition and minimise administrative burden.	effectiveness of policy measures. • Reduced implementation burdens. • Improved investment conditions.
Promote resilient and regional supply chains	
• Encourage shorter and more regionalised European supply chains to reduce emissions, strengthen resilience, and improve industrial competitiveness. • Consider WTO-compliant "Made in Europe" requirements that support strategic autonomy while maintaining fair trade principles.	• Stronger European industrial resilience. • Reduced supply chain vulnerability.
Fast-track permitting for bio-based manufacturing	
• Establish accelerated permitting and approval pathways for R&D, pilot, demonstration, and manufacturing facilities to reduce time-to-operation and expand EU production capacity. This should include utilities access, wastewater treatment, grid connection timelines, and brownfield industrial integration. • Align these processes with existing fast-track approaches used in net-zero technologies and critical medicines frameworks.	• Reduced project development timelines. • Faster industrial deployment. • Increased EU production capacity and investment retention within Europe.

*Targets are most effective at the level of end products, where they directly create market demand, increase visibility for consumers and downstream users, and ensure clear market pull for renewable carbon solutions. Product-level targets are also the most practical and enforceable regulatory approach, as they apply directly to goods placed on the market. By contrast, feedstock-level targets would be difficult to implement and would not reliably translate into increased uptake of bio-based materials in final applications.

**Relevant European standards for testing bio-based content:

- EN 16640: "Bio-based products – Determination of the bio-based carbon content of products using the radiocarbon method".
- EN 16785-1: "Bio-based products – Bio-based content – Part 1: Determination of the bio-based content using the radiocarbon analysis and elemental analysis".
- EN 16785-2: "Bio-based products – Bio-based content – Part 2: Determination of the bio-based content using the material balance method".

4.2 Predictability for Investment

Current challenges and their consequences

A key challenge facing the European industrial biotechnology sector is the lack of predictability and long-term investment certainty. Industrial biotechnology projects typically require substantial upfront capital investment, long development timelines, and complex regulatory approval processes. However, investors and companies continue to face uncertainty arising from changing policy priorities, fragmented regulatory frameworks, lengthy permitting procedures, and inconsistent market signals across Member States.

Access to public funding can also be slow and unpredictable. Delays in funding decisions, complex application processes, and uncertainty regarding eligibility criteria can hinder project development and increase financial risk. At the same time, Europe's comparatively high energy and operating costs, particularly around electricity pricing, utilities access, and grid competitiveness, continue to disadvantage industrial biotechnology scale-up relative to other major regions.

These challenges have significant consequences for the competitiveness of EU industrial biotechnology products. Investment decisions may be delayed, scaled back, or redirected to regions offering more stable policy frameworks and stronger market incentives, such as the United States or parts of Asia. This can result in slower commercialisation of innovative technologies, reduced deployment of first-of-a-kind facilities, and the loss of manufacturing capacity, jobs and intellectual property from Europe. Ultimately, insufficient investment predictability risks undermining the EU's ability to achieve its climate, circular economy and industrial competitiveness objectives, while limiting the growth of domestic markets for sustainable bio-based products.

The BBIA strongly supports the creation of predictable investment conditions within Biotech Act II. Without long-term policy stability, financing certainty, and clear market demand, Europe will not achieve industrial-scale deployment of bio-based and biomanufactured solutions.

Recommendations and Impact

To unlock investment and accelerate commercialisation, we recommend the following measures:

Recommendation	Impact
Strengthen public–private co-investment mechanisms	
• Expand programmes such as the Circular Bio-based Europe Joint Undertaking (CBE JU) to de-risk early-stage innovation and industrial deployment through blended public and private finance. • Strengthen coordination between EU funding and industrial instruments, including Important Projects of	• Improved mobilisation of private capital into industrial biotechnology and biomanufacturing • Stronger coordination across funding

Common European Interest (IPCEIs), innovation hubs, and centres of excellence, to create clearer investment pathways and maximise impact.	instruments will improve efficiency of public spending and accelerate the emergence of integrated European value chains.
Improve access to blended finance and EU funding instruments	
• Increase the availability, visibility, and accessibility of funding pathways across EU programmes supporting industrial biotechnology and biomanufacturing. • Simplify application processes and improve alignment between funding programmes to reduce administrative burden and accelerate deployment timelines. • The EU funds renewable energy adoption and hydrogen production directly to derisk new clean energy technologies. The Net-Zero Industry Act establishes fast-track permitting and state funding exclusively for clean energy technologies (e.g., solar, wind, battery storage, and grids). Equivalent support for bio-based products should be put in place.	• Faster project development timelines.
Remove barriers within sustainable finance frameworks	
• Ensure sustainable finance taxonomies and eligibility criteria do not unintentionally exclude renewable and sustainable carbon feedstocks based solely on origin. • Enable flexible inclusion of diverse and sustainable bio-based feedstock pathways to support innovation, feedstock resilience, and technology neutrality. • Align sustainable finance frameworks with lifecycle-based sustainability assessments and circular economy objectives.	• Improved access to green and sustainable finance for bio-based industries • Increased investor confidence in renewable carbon pathways
Expand access to scale-up infrastructure and finance	
• Increase the availability of subsidised pilot, demonstration, and scale-up infrastructure across Europe, particularly for non-pharmaceutical industrial biotechnology sectors. In particular, expand DSP demonstration infrastructure, open-access drying/dewatering/extraction infrastructure (non-pharma) pilot facilities. • Support open-access facilities and regional innovation clusters to help SMEs and scale-ups bridge the gap between laboratory innovation and commercial production.	• Reduced scale-up bottlenecks and improved access to essential infrastructure. • Increased survival rates of SMEs

• Improve access to patient capital and scale-up finance for companies progressing from pilot to commercial manufacturing. • Combine stable long-term demand signals with predictable financing frameworks to support investment in first-of-a-kind (FOAK) and next-of-a-kind (NOAK) industrial facilities. • Funding to support 'retrofitting' existing production assets to enhance suitability for biomanufacturing	
Strengthen support for industrial scale-up	
• Extend R&D tax credits and innovation incentives to include demonstration, pilot, and scale-up phases, recognising that commercial deployment remains a major financing gap for industrial biotechnology.	• Improved continuity of support across the innovation lifecycle, reducing the "valley of death" will increase investor confidence.

4.3 Sustainability Criteria

Current challenges and their consequences

The BBIA strongly supports the establishment of clear, harmonised sustainability criteria within Biotech Act II. Europe currently lacks a coherent and workable framework for sustainability assessment in industrial biotechnology and bio-based value chains. This absence of harmonised rules - particularly on carbon accounting, lifecycle assessment, and biomass allocation - creates significant uncertainty across markets, regulators, and investors. Without consistent sustainability frameworks underpinning market access and product uptake, Europe will struggle to achieve industrial-scale deployment of bio-based and biomanufactured solutions.

A key structural challenge is the fragmentation of carbon accounting approaches. There is no aligned methodology across biogenic carbon accounting (including +1/-1 treatment and timing of emissions across product lifecycles), mass balance systems used for transitional feedstocks, and lifecycle assessment (LCA) frameworks. This lack of consistency leads to confusion over what constitutes genuine emissions reduction or renewable carbon substitution. As a result, stakeholders face difficulties in comparing solutions, validating claims, and building business cases, which in turn suppresses market adoption and weakens investor confidence.

This uncertainty is compounded by inconsistent policy signals on biomass use. Sustainable biomass availability in Europe is limited and requires strategic prioritisation, yet current frameworks risk inefficient allocation - particularly over-incentivising energy uses at the expense of higher-value material applications such as chemicals and materials. At the same time, sustainability tools such as Product Environmental Footprint (PEF), Do No Significant Harm (DNSH) criteria, and Safe

and Sustainable by Design (SSbD) are not yet fully aligned or fit for the specificities of material systems, particularly regarding fossil substitution and carbon storage effects.

Together, these gaps create structural market distortions. They reduce the bankability of projects, delay investment decisions in first-of-a-kind and next-of-a-kind industrial facilities and weaken Europe's competitiveness in the global bioeconomy. Without intervention, these issues risk accelerating industrial relocation outside Europe, where regulatory frameworks are often more predictable and investment conditions more stable.

Recommendations and Impact

Recommendation	Impact
Establish harmonised sustainability and carbon accounting frameworks	
• Adopt science-aligned biogenic carbon accounting methodologies (+1/-1 lifecycle treatment) • Harmonise mass balance approaches for transitional feedstocks with a clear long-term transition to renewable inputs • Align lifecycle assessment (LCA) methodologies across sectors under a coherent EU framework • Ensure consistent treatment of fossil, biogenic, recycled, and CCU-based carbon • Ensure consistent treatment of biogenic carbon across cradle-to-grave systems • Ensure sustainability and carbon accounting frameworks support feedstock flexibility and recognise the operational variability inherent to industrial by-product streams used in circular biomanufacturing • Recognise carbon storage in materials and recycling loops • Include avoided emissions from fossil substitution and Scope 3 impacts • Harmonise PEF, RED, and related methodologies • Establish EU-wide sustainability criteria with harmonised traceability systems (mass balance, Digital Product Passports) • Use recognised certification schemes with mutual recognition of third-country systems • Ensure consistent rules for imports and domestic products • Balance enforcement via CBAM-like and EUDR-like mechanisms where appropriate	• Improved comparability, reduced greenwashing risk, increased investor confidence, and stronger bankability of industrial biotech projects. • Improved market integrity, reduced fraud risk, and fair competition between EU and imported products. •
Create a level playing field across all materials	

• Apply horizontal, product-level sustainability criteria across fossil-based, bio-based, recycled, and emerging materials • Align frameworks across ESPR, SUPD, PPWR, and Biotech Act II to reduce fragmentation • Include full lifecycle impacts: GHG emissions, feedstock sourcing, circularity, resource efficiency, and end-of-life outcomes • Support both CapEx and OpEx competitiveness, including certification, auditing, and verification costs	• Fair competition between material systems, reduced regulatory fragmentation, and stronger market uptake of sustainable materials.
Strengthen cascading biomass use and strategic allocation	
• Prioritise biomass use based on carbon efficiency and system-wide climate impact • Recognise higher-value material uses (chemicals and materials) over energy applications in line with RED III principles • Avoid rigid allocation rules that constrain innovation and regional flexibility • Support integrated biorefineries and industrial symbiosis	• Higher overall carbon abatement, improved resource efficiency, and more value creation from limited sustainable biomass.
Target biomass use through effective intervention points	
• Focus on end-product, intermediate, and bio-attributed systems where they provide real demand signals • Ensure clarity on attribution methods to avoid confusion between physical and accounting-based bio-content	• More effective market pull for bio-based solutions and better targeting of policy incentives.
Adapt RED III sustainability criteria for materials	
• Use Article 29 as the foundation for material applications with targeted adaptations • Maintain environmental safeguards (soil carbon, biodiversity, peatlands, forest management) • Adapt GHG accounting rules to reflect functional differences between materials and fuels • Avoid biofuel-style thresholds for material applications with lower lifecycle emissions	• Robust yet proportionate sustainability framework for materials without unnecessary administrative burden.
Ensure SSbD and DNSH remain enabling, not restrictive	
• Use SSbD to prevent regrettable substitutions without becoming a compliance-heavy system • Maintain DNSH as an investment screening tool rather than a product standard • Align EFSA, ECHA, and EMA guidance to avoid duplication • Keep frameworks flexible and innovation-friendly	• Reduced regulatory burden, maintained innovation capacity, and clearer division between safety and sustainability tools.

4.4 Simplification and Enabling Regulation

Current challenges and their consequences

As already highlighted, the current regulatory and financial support framework does not yet adequately reflect the value of bio-based carbon. While the EU has developed important funding instruments to support industrial decarbonisation, these methodologies do not always fully capture the lifecycle benefits associated with the substitution of fossil carbon, particularly Scope 3 emissions linked to feedstock replacement. As a result, bio-based projects—despite often delivering significant lifecycle greenhouse gas reductions—can be disadvantaged compared with incremental improvements in mature fossil-based installations. In practice, this means that public funding is often more accessible to incumbent systems than to innovative bio-based value chains.

These challenges are further reinforced by downstream economic signals that remain poorly aligned with environmental performance. For example, Extended Producer Responsibility (EPR) schemes, while designed to operationalise the polluter-pays principle, are generally based on end-of-life considerations such as recyclability and waste management costs and rarely account for carbon origin or full lifecycle emissions. Consequently, bio-based plastics may face similar or even higher EPR fees than fossil-based plastics, despite reducing fossil carbon use and lifecycle emissions, thereby weakening their business case and limiting market uptake.

This disconnect reflects a broader structural issue within the EU regulatory framework, which remains largely designed around fossil-based and linear industrial systems. Although progress has been made on circularity and recycling, current frameworks do not yet systematically recognise the role of bio-based materials or alternative end-of-life pathways such as composting. At the same time, the large-scale production of petrochemicals continues to confer significant advantages in cost, scale, and cradle-to-gate carbon performance, while existing infrastructure, supply chains, and manufacturing systems remain predominantly configured around fossil feedstocks.

The consequences of this structural bias are becoming increasingly visible in emerging legislation. Additional regulatory challenges are arising under the Packaging and Packaging Waste Regulation (PPWR), where current discussions on recyclability and design-for-recycling requirements risk creating unintended barriers for biodegradable and compostable plastics. In particular, requirements that extend beyond mandatory compostable applications to impose mechanical or chemical recycling obligations may be disproportionate and misaligned with materials specifically designed for organic recycling and biowaste collection. This direction risks discouraging investment in innovative biodegradable and compostable solutions. Similarly, strict recycled-content requirements may unintentionally disadvantage non-drop-in bioplastics that cannot technically integrate conventional recyclate streams. For such materials, equivalence

between recycled and bio-based content should be recognised where appropriate, particularly in high-performance and contact-sensitive applications.

The limitations of a recycling-centred approach become even clearer when considering the long-term requirements of a defossilised economy. Mechanical and chemical recycling alone will not fully replace fossil carbon, particularly in contact-sensitive applications where virgin feedstock will continue to be required. Moreover, recycling processes inevitably lead to gradual material quality loss, meaning that recycling loops must be continuously replenished with virgin materials. In this context, renewable bio-based carbon represents an essential complementary source of feedstock and should be recognised as a core component of climate-neutral material systems.

However, the challenges facing bio-based industries extend beyond individual policy instruments and reflect deeper structural characteristics of the regulatory environment itself. There is growing evidence that certain environmental assessment methodologies may contain biases that favour fossil-based systems, while international trade and investment frameworks may continue to provide legacy protections for fossil fuel infrastructure, further reinforcing incumbency advantages. These effects are compounded by the fact that many regulatory frameworks were developed when fossil-based inputs dominated industrial production. As a result, approval pathways, definitions, and compliance systems remain largely tailored to petrochemicals, and in many cases there is still no harmonised definition of key terms such as "bio-based" or "biodegradable".

The absence of common definitions is symptomatic of a wider lack of coherence across EU legislation. Significant inconsistencies persist in the way bio-based chemicals and materials are treated, including the lack of an overarching industrial strategy linking bioeconomy, chemicals, and Net Zero objectives; regulatory approaches that often prioritise biomass for energy rather than higher-value material applications; and divergent definitions and classifications of bio-based, biodegradable, and renewable-carbon materials. In practice, a single bio-based chemical may fall under multiple regulatory regimes applying different methodologies—some focused on human health, others on environmental impacts—creating uncertainty and potentially contradictory compliance requirements.

These inconsistencies become particularly problematic where different flagship EU policies intersect. While the EU seeks to defossilise the chemical sector and increase demand for bio-based feedstocks, frameworks such as the EU Deforestation Regulation (EUDR) and the Renewable Energy Directive (RED II/III) can impose strict and sometimes conflicting sustainability and land-use criteria, complicating access to certified biomass for chemical use. At the same time, the Bioeconomy Strategy promotes the use of agricultural residues, biowaste, and forestry by-products for green chemicals, yet waste legislation and REACH definitions may classify the same materials as waste or hazardous mixtures. The absence of harmonised EU-wide end-of-

waste criteria further increases complexity and cost when converting these streams into viable biochemical feedstocks.

Taken together, these challenges create a regulatory system that continues to prioritise recyclability and recycled content while insufficiently recognising renewable bio-based carbon as a core pillar of climate neutrality. The result is a structural disadvantage for bio-based products despite their proven climate benefits, reducing investment certainty, slowing deployment, and reinforcing fossil-based value chains.

Regulatory fragmentation is also evident in the governance and implementation of sector-specific legislation. Limited coordination between EFSA, ECHA, and EMA leads to fragmented assessments, inconsistent methodologies, and inefficiencies for biotech-derived products. In addition, the absence of a clear legal basis for the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF) interpretations results in uneven application across Member States and reduces legal certainty, despite repeated reliance on these discussions to clarify borderline cases.

These governance challenges are closely linked to a broader lack of legal clarity and harmonised interpretation across Member States. This is particularly evident in areas such as feed additives for export, the regulatory status of food cultures, and the interpretation of key definitions. The removal of the export provision from Directive 70/524/EEC in Regulation (EC) No 1831/2003 has led to divergent interpretations regarding feed additives that are not authorised in the EU but are produced exclusively for third-country markets, undermining investment decisions and reducing global competitiveness.

A similar pattern can be observed in the treatment of food cultures. Despite their recognised status as food ingredients under Regulation (EC) No 178/2002 and Regulation (EU) No 1169/2011, some Member States continue to classify certain uses as food additives under Regulation (EC) No 1333/2008. This issue has remained unresolved for more than two decades despite repeated discussions within expert groups and SCoPAFF, resulting in inconsistent enforcement and ongoing uncertainty for businesses.

More broadly, unclear and non-harmonised definitions—including terms such as "bio-based", "fermentation-derived", and certain plant extracts—continue to produce divergent classification and authorisation outcomes across the EU. Ongoing discussions within SCoPAFF illustrate both the persistence of these ambiguities and the limitations of relying on non-legally binding interpretations to resolve them.

The resulting uncertainty extends beyond product approval and classification into market implementation and consumer communication. Regulatory requirements on labelling are not always aligned with consumer understanding or established market practices, creating avoidable barriers to product uptake. In particular, the use of highly technical or unfamiliar

names for microorganisms and their products can confuse consumers and does not reflect how such products are commonly understood. Furthermore, the absence of early regulatory guidance on labelling can create uncertainty for applicants and lead to late-stage changes that delay market access.

Taken together, these challenges highlight the need for a more coherent, streamlined, and future-oriented regulatory framework. The BBIA therefore strongly supports the development of simplified and enabling regulation within Biotech Act II as part of a broader agenda of regulatory simplification. Clear, proportionate, and predictable rules are essential to reduce administrative burdens, increase legal certainty, unlock investment, and accelerate the industrial deployment of bio-based and biomanufactured solutions across Europe.

Recommendations and Impact

Recommendation	Impact
Make regulatory simplification a core enabler of industrial scale-up	
• Treat simplification as industrial enablement, not deregulation, to accelerate deployment of bio-based and biomanufactured solutions in Europe. • Provide indicative approval timelines and more streamlined, single-route authorisation pathway. • Harmonising the use of "stop-the-clock" by defining clear criteria, limiting iterative requests, and setting reasonable timelines. • Establish an earlier, structured and formal pre-submission consultation process between innovators and regulators, including pre-submission guidance and joint scientific advice. To maintain scientific independence, a dedicated 'front desk', separate from scientific evaluators, should oversee these consultations. • Establish an EU-level one-stop shop for access and benefit-sharing (ABS) under the Nagoya Protocol to reduce complexity and duplication.	• Timeline approval assurance • Investment de-risking
Conduct comprehensive legislative mapping and reform	
• Map and review all relevant EU, national, and global legislation affecting biotechnology. • Introduce mandatory review clauses in legislation to ensure ongoing alignment with scientific and technological progress.	• Ensures regulations stay up to date and agile
Improve regulatory coherence and coordination	
• Strengthen collaboration between EMA, EFSA, and ECHA to reduce inconsistencies across frameworks. • Enhance international regulatory cooperation to support global harmonisation and faster time-to-market.	• Less red tape for SMEs and products get to market faster

Adopt risk-based and proportionate regulation	
• Ensure "fit-for-purpose" industrial biotechnology regulation by avoiding pharmaceutical-style regulatory burden for industrial fermentation applications. • Improve and accelerate authorisation processes for biotech products through innovative regulatory tools. To enable faster market access for R&D outputs, pilot-scale innovations, and commercial products.	• Less red tape for SMEs and products get to market faster
Expand and formalise regulatory sandboxes	
• Use regulatory sandboxes to accelerate testing, validation, and authorisation of innovative biotech products. • Ensure sandboxes deliver faster and simpler pathways, not additional administrative layers.	• Less red tape for SMEs and products get to market faster
Modernise genetic and biotechnology regulatory frameworks	
• The current regulatory framework for GMOs hampers market demand by significantly slowing down and increasing the cost and uncertainty of market access. • Update frameworks for genomic techniques to simplify and accelerate approvals for biotech products. • Shift to regulatory approaches based on risk and application context rather than development process (e.g. genetic modification vs non-GM origin). Focus assessment on the strain/product itself rather than production pathway. • Dedicated, horizontal EU Regulation on microorganisms. A risk-based, product-focused framework for microorganisms should be adopted to streamline approvals while maintaining safety. Apply across sectors (incl. food/feed and environmental applications, excluding health), use conditions (contained use & deliberate release) and would cover all types of microorganisms. • A product-based definition of genetically modified microorganisms should be introduced. • Revise and align the definition of genetically modified microorganisms in other legislations included in other related EU legislative frameworks to remove process-based triggers.	• Fit for purpose streamed regulations
Future proof the development of Non-Animal Methodologies (NAMs)	
• Validation of alternative non-animal methodologies must include ingredients derived from biotechnology, particularly UVCBs to ensure outputs from ongoing funded initiatives, such as EU initiative on Animal-Free	• Removal of antiquated unnecessary animal testing methodologies

Chemical Safety Assessment, support and accelerate industrial transition.	
Legal clarity and harmonization	
• Providing targeted legislative clarification to address persistent divergences: • Reintroduce a definition and provisions for feed additives intended for export only in Regulation (EC) No 1831/2003. • Explicitly exclude food cultures from Regulation (EC) No 1333/2008 by adding them to the list of exemptions. • Clarifying and harmonising key regulatory definitions to ensure consistent classification across Member States. • Establishing a legal basis for SCoPAFF interpretations to ensure their consistent and effective application.	• Harmonised interpretation across Member States, strengthen legal certainty, and support more predictable investment and innovation.
Support SMEs and innovators in navigating regulation	
• Provide dedicated support mechanisms to help SMEs and scale-ups manage regulatory and administrative requirements.	• Reduced administration burden and costs for SMEs
Market implementation barriers & consumer understanding	
• Amend labelling provisions to explicitly allow the use of non-technical or common microorganism or product names (including Latin names where appropriate), unless more precise naming is strictly necessary for safety reasons, in order to align with consumer understanding and market practice.	• Improve consumer understanding and acceptance • Reduce regulatory uncertainty and facilitate smoother and faster market uptake of authorised products.

Key Regulatory Entry Points for Market Development

Below we provide some specific remarks on regulations for industrial biotechnology.

a. Packaging and Packaging Waste Regulation (PPWR) – Article 8

The PPWR represents the most immediate opportunity to create a lead market for bio-based plastics.

Article 8 explicitly foresees:

- a review of technological maturity and environmental performance of bio-based packaging;
- the potential introduction of sustainability requirements and targets for bio-based feedstocks;
- recognition of bio-based feedstocks in relation to recycled content targets for certain applications.

A recent European Commission / nova-Institute review (April 2026) confirms that:

- bio-based plastics are technically mature and commercially available;
- they can deliver significant greenhouse gas reductions versus fossil alternatives;

- there are no fundamental technical barriers to deployment in packaging;
- the main barriers are lack of demand and policy incentives, not technology.

The study further recommends:

- binding targets for bio-based content;
- recognition of equivalence between recycled and bio-based carbon;
- sustainability criteria aligned with the Renewable Energy Directive.

It is therefore essential that the Article 8 review leads to concrete legislative proposals that generate market demand, particularly as packaging represents around 50% of the bio-based plastics market.

b. Ecodesign for Sustainable Products Regulation (ESPR)

The ESPR is expected to become a key horizontal framework shaping material choices across sectors. However, plastics are not currently included among priority product groups, and dedicated measures are unlikely before 2030.

Through sustainability requirements, Digital Product Passports, and future material footprint criteria, ESPR could create systemic demand for bio-based materials across multiple sectors. At present, however, bio-based materials are not sufficiently recognised within the framework, limiting visibility and uptake.

c. Sectoral legislation (textiles and automotive)

Additional opportunities exist in downstream sectors:

- **Textiles (under ESPR)**: sustainability, circularity, and fibre composition requirements could enable uptake of bio-based fibres and polymers.
- **End-of-Life Vehicles Regulation (ELVR)**: circularity, recyclability, and material recovery requirements could support future bio-based content provisions. However, current legislative hooks remain long-term and not yet operational.

These are high-volume sectors, but explicit incentives for bio-based materials remain limited, constraining scale-up potential.

d. Structural improvements to the Novel Food Framework

A key structural challenge in the Novel Food framework is the determination of novel food status, which is currently assessed at Member State level. Recommendations:

- Introduce a more centralised and science-based EU approach, with earlier EFSA involvement where appropriate, to support consistent interpretation of novel food status across Member States
- Improve and modernise the Novel Food Catalogue through clearer criteria, and a more transparent, user-friendly and regularly updated format to reduce the need for repeated

case-by-case assessments and double-checking by applicants and authority, together with a standardised, detailed template for Member State report.

e. Natural Polymers and Regulations

Establish a single, consistent definition of "plastic" across all regulations that explicitly excludes unmodified natural polymers and clearly distinguishes between fossil-derived, bio-based, and natural polymers. This will reduce unnecessary regulatory burden, provide clarity to industry, and ensure alignment with scientific understanding of the fundamental differences between these material types.

These improvements (a-e) would reduce duplication, improve legal certainty and accelerate time-to-market for innovative products, while maintaining high safety standards. Clear timelines and procedural guidance would also be important to ensure predictability for applicants.

4.5 Non-Legislative Cross-Cutting Support Measures

We strongly support the delivery-critical non-legislative measures to accelerate market formation and ecosystem development. These should include:

- Support for regional biomanufacturing clusters, industrial symbiosis networks/shared industrial infrastructure ecosystems
- Strengthening European and international biotech networks to support knowledge sharing and scaling
- Facilitating access to funding across the innovation lifecycle, from research to industrial deployment

We further recommend coordinated EU action to:

- Improve integration across innovation, industrial, and regional funding instruments
- Support cross-border collaboration in biomanufacturing ecosystems
- Enhance visibility and accessibility of funding opportunities for SMEs and scale-ups

These measures are essential to ensure that regulatory ambition is matched by practical industrial delivery capacity.

5. Summary

Industrial biotechnology is no longer a niche sustainability issue; it is a strategic industrial priority. If supported by coherent policy, targeted investment, and market-shaping mechanisms, Europe has the opportunity to lead the global transition towards a circular, bio-based industrial economy while delivering on its climate, competitiveness, and sustainability ambitions.

The EU Biotech Act II a strategic opportunity to strengthen Europe's leadership in sustainable, biotechnology-enabled manufacturing. To succeed, the Act should provide a coherent policy framework, harmonised carbon accounting and standards, stronger support for scale-up and commercialisation, and a strategic approach to feedstock prioritisation. With clear and forward-looking measures, the Act can accelerate innovation, reinforce industrial competitiveness, and advance the EU's climate and sustainability objectives.

Across all pillars, BBIA's position is that Biotech Act II should function as a market-shaping industrial strategy, not solely research or enabling framework.

To succeed, it must:

- Create predictable demand through lead markets
- Ensure investment certainty through phased implementation
- Maintain sustainable but flexible biomass governance
- Simplify regulation to enable scale-up
- Provide coordinated non-legislative support across ecosystems

This integrated approach is essential to deliver a competitive, resilient, and globally leading European industrial biotechnology sector.