Bio-based Industries Consortium

BIC Policy position

Biotech Act II

What Bio-based Industries Need to Scale

Executive summary

Europe has the technology and ambition for advancing a competitive and resilient bioeconomy sector, but it is missing a regulatory framework that makes it happen. Biotech Act II should be the cornerstone instrument for implementing the EU Bioeconomy Strategy, turning that ambition into industrial scale-up.

European companies of all sizes need a more ambitious, concrete, predictable and innovation-friendly policy framework to turn the bioeconomy into a key and effective strategic sector for the EU. Both the concrete introduction of policy measures, underpinned by cross-cutting enablers, and the improvement of the regulatory environment for biotechnology and biomanufacturing are key. Bio-based products must navigate frameworks not designed for them, facing higher administrative burdens, longer routes to market, and the absence of demand-side instruments. The net effect is a regulatory environment that passively favours fossil-based products.

If the Biotech Act II is to deliver on the vision laid out in the Bioeconomy strategy, it must introduce policy measures that create predictable lead markets and economic conditions that make bio-based solutions competitive while Europe still has a window to secure strategic leadership in biomanufacturing.

Thus, our three priorities for the Biotech Act II are:

1. **Overcoming regulatory bottlenecks**: Regulatory clarity, certainty, predictability, speed, agility and coherence are key for the sector to develop its full potential.

2. **Creating lead markets and market demand for bio-based products**: A core priority of Biotech Act II should be to enable demand-driven scale-up through targeted market-pull instruments.

3. **Financial and offtake support**: Europe's bio-based sector needs financial support to scale from lab to market and to avoid offshoring of innovation to non-EU countries which provide greater support and financing.

BIC calls on the European Commission and co-legislators to embrace this agenda in the Biotech Act II legislative proposal, ensuring the Act delivers concrete conditions for bio-based industries to scale in Europe.

Introduction

- Bio-based industries and the bioeconomy are key economic sectors in Europe. Biomanufacturing and the use of all technologies including biotechnology have the potential to modernise entire parts of the European economy.

- BIC welcomes the initiative of the European Commission to propose Biotech Act II as a key industrial competitiveness initiative to complement Biotech Act I, to be focused on scaling industrial biotechnology and biomanufacturing.

- Biomanufacturing is a strategic capability for Europe not only in terms of competitiveness, but also economic security and resilience. The EU remains dependent on fossil-based feedstock imports and key inputs from a limited number of countries. Biotechnology and biomanufacturing offer a pathway to rebuild domestic capacity and reduce dependency on fossil feedstock and via EU-centric supply-chains.

- Europe has a window to accelerate scale-up, and secure strategic leadership in biomanufacturing before that window closes. Therefore, BIC urges the European Commission to strongly embrace biomanufacturing in Biotech Act II including all types of (bio) technologies when using and converting biological resources.

- Regulations are key drivers for driving market demand and in turn ensures that the biomanufacturing industry contributes to EU's competitiveness, strategic autonomy, resilience, and the flourishing of a well-functioning circular economy. Biotech Act II has the potential to accelerate the path from lab to factory by empowering biomanufacturing, including a broader range of bio-based solutions, such as food and feed production technologies, bio-based chemicals, bio-based materials and consumer products, and not just healthcare and pharma.

- European companies of all sizes need a more ambitious, concrete, predictable and innovation-friendly policy framework to turn the bioeconomy into a key and effective strategic sector for the EU. Both the concrete introduction of policy measures, underpinned by cross-cutting enablers, and the improvement of the regulatory environment for biotechnology and biomanufacturing are key.

- Moreover, bio-based products must navigate frameworks not designed for them, facing higher administrative burdens, longer routes to market, and the absence of demand-side instruments. The net effect is a regulatory environment that passively favours fossil-based products.

- If EU Initiatives such as the Biotech Act II are to deliver on the vision laid out in the EU Bioeconomy strategy, policy measures are needed to create predictable lead markets and create economic conditions that make bio-based solutions competitive in relation to fossil-intensive incumbents.

To reach this potential, BIC has identified three dimensions where Biotech Act II can and should make a tangible impact:

1. Overcoming regulatory bottlenecks

Biotech Act II is a unique chance to simplify regulatory frameworks and enable cross-sectoral permitting pathways for products and industrial projects. Regulatory clarity, certainty, predictability, speed, agility and coherence are key for the sector to develop its full potential.

Current complexity causes uncertainty, undermines private and public investors' confidence, and slows industrial and commercial scale-up, especially in comparison with countries that have adopted more agile and innovation-friendly biomanufacturing and biotechnology policies such as the USA, China and Singapore.

Depending on the market and application, regulation is one of the most effective drivers of demand and adoption for bio-based products. However, the current regulatory environment (fragmented, lacking policy coherence, and insufficiently adapted to bio-based value chains) does not yet deliver nor recognise this potential.

The following regulatory bottlenecks have been identified:

- Regulatory fragmentation (duplication of approval efforts for bio-based chemicals in case there are identical with a fossil-based chemical)
- Lack of recognition for the benefits of using biogenic carbon in the current EU Product Environmental Footprint Methodology (PEF)
- Lengthy and complex permitting and authorisations for new products in the market and for new industrial projects.
- Affordability of and accessibility to primary and secondary sustainable feedstock
- Obstacles linked to the movement and use of waste-based feedstock, including diverging national approaches and uncertainty around end-of-waste status,
- Insufficient recognition of how bio-based products contribute to the EU's circular economy within existing regulatory and assessment frameworks.

BIC policy asks:

- **Ensure a broadened scope for Biotech Act II that reflects the full value of the bio-based industries for Europe**, and allow to facilitate advancements across various industries, from chemicals to materials and beyond. It is essential that the scope of the Commission's legislative proposal following the Call for Evidence on the Biotech Act II includes biomanufacturing and is not limited solely to biotechnology. The Act should therefore remain technology-neutral and focus on enabling the use of biomass across a wide range of applications.

- **Ensure coherence across legislative files and avoid overlaps with existing regulations**. The potential of the EU Single Market should be better leveraged by improving coordination, overcoming fragmentation and ensuring policy coherence. Better alignment across EU legislation and the Biotech Act II, with bioeconomy being plugged into upcoming legislative proposals such as Biotech Act II, Advanced Materials Act, Circular Economy Act, and Public Procurement Act, and with existing regulations or proposals (e.g. Biotech Act I, Industrial Accelerator Act (IAA), End-of-live vehicles Regulation (ELVR), Carbon Removals and Carbon Farming Regulation (CRCF), Packaging and Packaging Waste (PPWR (art. 8)), Ecodesign for Sustainable Products Regulation (ESPR) etc.).

- **Ensure coherent and consistent implementation across Member States**. The legal basis of the proposal should be anchored in the functioning of the EU internal market. Article 114 of the Treaty on the Functioning of the European Union (TFEU) provides the appropriate legal framework

for harmonising national laws to ensure its proper functioning. To guarantee uniform application and avoid fragmentation, Biotech Act II should be established as a Regulation, rather than a Directive.

- **Ensure long-lasting predictable frameworks** with periodic reviews as science advances, and limit the proliferation of delegated acts, in line with better regulation.

- **Ensure cohesive definitions on biotechnology and biomanufacturing** throughout all upcoming EU legislation and ensure consistent definitions across already existing legislative files, policies and regulations. Biomanufacturing includes all technologies, including biotechnology, for the use and conversion of biological resources. The definition of biomanufacturing provided in the original European Commission's proposal fell short of what Biotech Act I and II are meant to achieve. Biomanufacturing should include all technologies, including biotechnology, for the use and conversion of biological resources. This also includes the use of biological systems—such as cells, enzymes, or micro-organisms

- **Enable harmonised, simplified, faster and cross-sectoral permitting pathways** through the European Food Safety Authority (EFSA) or the European Chemicals Agency (ECHA) where companies can pre-submit their applications and structural early engagement with companies, notwithstanding the simplification exercise the food and feed omnibus.

- **Establish Regulatory sandboxes** to accelerate innovation, and authorisation pathways, to shorten time to market for innovative products in defined cases.

- **Revise the Product Environmental Footprint (PEF)** to properly account for biogenic carbon using the -1/+1 approach to reflect carbon uptake and emissions across the life cycle and avoid systematic under- or overestimation of bio-based impacts, as mentioned in the EU Bioeconomy Strategy.

2. Creating lead markets and market demand for bio-based products

The transition from laboratory to commercial production, often referred to as "lab to fab", is obstructed by two distinct innovation valleys of death, where European innovation frequently stalls or fails. The first valley of death occurs during the scale-up phase, spanning the transition from laboratory research to demonstration scale. The second valley of death emerges at the subsequent stage, as technologies move from demonstration towards full commercial production.

To bridge that 2nd valley, market (pull), innovation-prone regulation and availability of sustainable and affordable feedstock are key. The challenge is even bigger when competing against fossil-based solutions (where competing on price and margin, and low willingness of consumers to pay a green premium).

A core priority of Biotech Act II should be to enable demand-driven scale-up through targeted market-pull instruments. Bridging this price gap requires a combination of market-creating and cost-reducing instruments. Critically, different instruments are more adapted to different parts of the bioeconomy value chain, and Biotech Act II should reflect this diversity. Specific end markets for bio-based products require specific market pull measure instruments in the short term, and a vision for long-term adoption and scale-up.

Bio-based content targets, combined with complementary policy measures and enablers, are essential to accelerate Europe's transition from a fossil-based to a competitive, resilient, and circular bioeconomy.

BIC policy asks:

- **Bio-based content targets.** Minimum bio-based content targets in specific end markets can represent a highly effective instrument to create predictable demand at scale and provide the long-term investment visibility needed to develop integrated bio-based value chains within the EU.
    - Targets should take into account the contribution of bio-based products to reducing Europe's dependence on fossil-based feedstock, strengthening Europe's strategic autonomy and industrial resilience.
    - Targets should be set at realistic and achievable levels, based on comprehensive impact assessments. These assessments should consider sustainable biomass availability, the technical and economic feasibility of biomass conversion into chemicals and products, market development, existing national legislation, and broader socio-economic impacts.
    - The most appropriate point in the value chain at which to introduce targets will depend on the specific market and application, considering complementarity between different EU regulations and targets e.g. recycled content, and including renewability and appropriate sustainability criteria as a requirement in the Ecodesign for Sustainable Products Regulation. This should be determined on the basis of further impact assessments, including impact potential, administrative complexity, impacts on performance, demand signals for downstream markets, exposure to carbon leakage risks, cost burden and implications for e.g. end-product manufacturers, global competitiveness and potential integration into sectoral and other legislation (e.g. PPWR art.8, ELVR, IAA art. 16, etc.).
    - Promote the use of biodegradable and compostable bio-based products for specific applications where these properties provide proven advantages.[1]

- **Fiscal Measures such as reduced VAT, tax exemptions**: Fiscal measures can help to narrow the price gap between bio-based and fossil-based products.
    - Instruments include reduced VAT rates, excise tax exemptions, or accelerated depreciation for investments in bio-based production capacity, which can have a complementary effect on other market-pull measures.
    - The EU Value Added tax (VAT) Directive already allows member states to apply reduced rates to certain environmentally beneficial goods, and several Member States have used this for solar panels, repair services, and second-hand goods. Applied to bio-based products, such measures could stimulate consumer demand by mitigating green premiums and improving the business cases for producers.

- **Green Public Procurement (GPP):** Public procurement as a market pull measure for bio-based products can be highly effective in specific markets or applications.
    - By embedding bio-based content and/or carbon footprint into tender specifications, public buyers can drive demand in sectors such as construction e.g. via a share of bio-based materials in new residential buildings or for major renovations, and or a requirement for public buyers to meet recycled and bio-based content thresholds.
    - Scaling GPP to the EU level through mandatory criteria in the forthcoming revision of the Public Procurement Directives would provide a significant and immediate demand signal, while also demonstrating the technical and economic viability of bio-based solutions to private-sector buyers.

[1] According to standards EN13432 (industrial compostability) or EN17033 (soil biodegradability), depending on the application.

- Biotech Act II should be coherent with the upcoming Public Procurement Act and the proposed provisions in the Industrial Accelerator Act to ensure public demand actively supports the scale-up of bio-based products.

- **Eco-modulation:** Extended Producer Responsibility (EPR) requires producers to finance and organise the collection, sorting, and recycling of products they place on the market, thereby internalising end-of-life costs.
  - An opportunity for bio-based products lies in eco-modulation, adjusting EPR fees so that products with higher bio-based content, better recyclability profile, or lower carbon footprint pay reduced contributions.
  - EPR modulated fees should also consider circular material use in alignment with ISO 590020 and Global Circularity Protocol. At the same time, EPR frameworks can support the fair introduction and integration of bio-based materials into the European market.

Enablers

Market-pull policy measures can only achieve their intended effect if they are underpinned by a set of cross-cutting enablers that allow to identify, verify, and differentiate bio-based products from their fossil-based alternatives. A common terminology, measurement tools, and other mechanisms are enablers to validate targets, apply fiscal incentives correctly, modulate EPR fees meaningfully and to apply procurement criteria at local level.

- **Sustainability criteria**. To fully support the developments of lead markets through targets, mandates or (financial) incentives, establishing sustainability criteria for using agricultural biomass in the production of biomaterials and biochemicals is important e.g. on the basis of European directives or regulations, including the Renewable Energy Directive (RED) III Art 29 and other sustainability certification schemes (see below). Regarding the sustainability of forest biomass, there is already an extensive regulatory framework at both EU and national level (including RED, the Regulation on Deforestation-free Products (EUDR), Nature Directives etc.), some of which is still in the early stages of implementation. To avoid unnecessary duplication or complexity, we advise against introducing any additional criteria unless and until there has been a full impact assessment and/or gap analysis relating to this framework.

- **NACE Codes** are an enabler as they provide the statistical infrastructure used to classify economic activities and products. The current NACE classification system largely does not distinguish between bio-based and fossil-based production within the same product category e.g. bio-based and a petrochemical chemical can fall under the same code. To monitor market development and measure the effectiveness of policy interventions, the development of specific bio-based NACE codes should be considered.

- **Credible validation and verification methodologies** like C14 for bio-based content or mass balance for bio-attributed are enablers to underpin e.g. targets and quotas. In addition, the EU Product Environmental Footprint (PEF) Methodology should account for the benefits of biogenic carbon e.g. via the -1/+1 approach.

- **Voluntary schemes and national certification schemes** are important enablers to ensure that bio-based products are sustainably produced by verifying that they comply with the EU sustainability criteria e.g. under the Renewable Energy Directive.

- **Standards** establish a common technical language across the single market. A number of bio-based standards already exist e.g. determining bio-based content like EN 16785. A comprehensive

and up-to-date standards framework can enable that each policy instrument applies the same definition e.g. of what counts as "bio-based".

3. Financial and offtake support

Biotech and biomanufacturing companies must be supported in growing and staying in the EU. Europe's bio-based sector needs financial support to scale from lab to market and to avoid offshoring of innovation to non-EU countries which provide greater support and financing.

Reducing the investment risk and mobilising private investment, including venture capital, will be key for Europe to overcome both valleys of death, particularly the second one.

BIC policy asks:

- **Develop tailored financial instruments to support bio-based scale-up**, including loan guarantees, de-risking mechanisms, and public-private capital.

- **Ensure the Circular Bio-based Joint Undertaking (CBE JU)[2] is continued under the EU Multiannual Financial Framework (MFF) from 2028 onwards**. With the CBE JU, the EU has a successful instrument to de-risk and attract private investment, support demonstration projects and commercial deployment. CBE JU is a key contributor to the EU's vision for a competitive and sustainable bioeconomy, and the main EU instrument covering the "first innovation valley of death" in this sector. For strategic industrial sectors with multi-stakeholder, cross-sectoral and cross-border value chains, JUs like the CBE JU remain an indispensable tool.

- **Ensure synergies and coherence with other funding mechanisms** such as the European Competitiveness Fund (ECF) proposed for the next EU Budget (2028-2034), with a dedicated window for Bioeconomy, the Scale-up Fund, the Innovation Fund and the Important Projects of Common European Interest (IPCEI) in the fields of bio-based chemicals, bio-based materials and biotechnologies for food and feed.

- **Support First of a Kind facilities, facilities for the deployment of novel technologies in existing processes and assets, shared infrastructure and industrial hubs**. The EU policy framework should recognise the financing gap faced by first-of-a-kind (FOAK) industrial plants in Europe. For bio-based products, moving from demonstration to commercial scale involves high capital costs, long timelines, and significant risk, making projects difficult to finance on purely commercial terms. Supporting FOAK plants is strategically important, as they anchor industrial know-how, supply chains, and future investment in the EU. Support is equally key for the deployment of novel technologies in existing processes and assets (including larger companies in transformation), to restore EU competitiveness, and for shared infrastructure/industrial hubs to accelerate scale up. Without support, technologies risk being commercialised elsewhere, along with associated economic value.

- **Foster the creation of new industrial ecosystems and the diversification of existing installations** by supporting and simplifying the valorisation of side-streams and by-products from renewable feedstock in production processes e.g. use of side-streams from one industrial facility by another (co-location concept). Better use the untapped potential of bio-waste for material

[2] CBE JU is a €2 billion partnership between the European Union and the Bio-based Industries Consortium (BIC) that funds projects advancing competitive circular bio-based industries under Horizon Europe, the EU's research and innovation programme.

purposes including for bio-based products that are also biodegradable and compostable. Remove barriers for the creation of industrial ecosystems and circular loops by promoting the valorisation of by-products and side streams e.g. via BREF, Sewage Sludge Directive.

- **Further incentivise the development of bio-CCU value chains** in terms of investment, R&D and for applications such as chemicals and materials

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The Bio-based Industries Consortium (BIC) is a non-profit organisation that represents the private sector in a Public-Private Partnership (PPP) with the European Commission, the Circular Bio-based Joint Undertaking (CBE JU). BIC's +350 Industry Members cover the whole value chain, from primary production to market. Members represent diverse sectors, such as agriculture and agri-food, aquaculture and marine, bio-based chemicals, bio-based materials (including bioplastics), forestry, pulp and paper and technology providers and waste management and treatment.

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