

The EU Commission  
DG Grow (Unit F2)

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## **Response to open call for evidence for an impact assessment on European Biotech Act II**

Alliance for Biosolutions welcomes the opportunity to provide input with the Commission's call for evidence on the forthcoming European Biotech Act II. We strongly support the ambition to strengthen Europe's industrial biotechnology and biomanufacturing (biosolutions) ecosystem and to establish a horizontal, enabling and independent regulatory framework that improves competitiveness, strategic autonomy and decarbonisation across European industrial value chains.

Biosolutions have significant potential to contribute to Europe's green transition, circular economy objectives, and resilience. However, Europe risks falling behind global competitors due to regulatory fragmentation, slow permitting procedures, investment uncertainty and insufficient market incentives for bio-based and circular products.

Alliance for Biosolutions supports the Commission's intention to simplify existing legislation and reduce regulatory fragmentation across Member States. Today, companies operating within the biosolutions sector face overlapping and often inconsistent regulatory requirements across sectors and jurisdictions. Furthermore, biosolutions are often regulated under frameworks designed for conventional products and technologies, rather than according to their actual risk profiles and sustainability benefits. This creates unnecessary administrative burdens, delays market deployment and innovation, and weakens Europe's attractiveness for investments compared to other regions, e.g. United States and China.

It is therefore crucial that the Biotech Act II prioritises:

- regulatory simplification and harmonisation across the Single Market;
- faster permitting and authorisation procedures;
- technology-neutral framework conditions;
- predictable long-term investment signals;
- active use of regulatory sandboxes as a legislative tool (also on novel food matters);
- and proportionate sustainability requirements that support industrial competitiveness.

The EU should avoid creating a regulatory framework that unintentionally slows innovation or increases production costs to a level where European production becomes commercially unviable compared to international competitors.

### **Risks related to insufficient market uptake**

Alliance for Biosolutions agrees with the Commission's assessment that fossil-based products continue to benefit from established value chains and economies of scale that bio-based alternatives often cannot yet match.

However, there is a risk that mandatory minimum content requirements or "made in Europe" requirements could increase costs for downstream industries if introduced too quickly or without sufficient flexibility. Market pull mechanisms must therefore be designed carefully and introduced gradually to avoid unintended impacts on industrial competitiveness, supply chains and consumer prices.

Any minimum content requirements should:

- be technology-neutral;
- allow for different pathways including bio-based carbon, recycled carbon and Carbon Capture and Utilisation (CCU);
- be introduced gradually with transparent timelines;
- and be accompanied by impact assessments evaluating effects on competitiveness and supply security.

It is essential that regulatory requirements reflect market realities and feedstock availability.

### **Risks related to scaling**

When it comes to scaling biosolutions businesses of Europe, a major challenge remains the lack of sufficient growth capital to help promising companies scale their technologies, particularly when moving from demonstration to commercial production.

To strengthen Europe's competitiveness, the EU should make greater use of public funding as a catalyst for private investment. One way to achieve this would be to place greater emphasis on private-sector due diligence and investment decisions when allocating public support.

If professional investors are willing to commit capital following thorough technical, commercial, and financial assessments, EU funding instruments could automatically match part of the investment through a simple and predictable co-investment mechanism. Such a model could remain subject to independent verification to ensure transparency and avoid conflicts of interest.

This approach would:

- reduce administrative burdens for companies and investors,
- improve the efficiency and allocation of public funding,
- leverage private-sector expertise in evaluating technologies and business models, and
- help close Europe's scale-up funding gap.

Public funding should complement, not replace, capital markets. By recognizing private investment decisions as an important quality signal, the EU can better support the most promising

companies and accelerate the deployment of innovative bio-based solutions that are essential for Europe's competitiveness, economic growth, and green transition.

Furthermore, regulatory fragmentation remains a major barrier to scaling biosolutions within the EU. Differences in terminology, certification schemes and national implementation create unnecessary compliance costs and administrative complexity for companies operating across borders. This particularly affects SMEs and scale-ups, which often lack the resources to navigate multiple regulatory systems. The Biotech Act II should therefore prioritize harmonization and mutual recognition mechanisms where possible.

Alliance for Biosolutions also encourages the Commission to ensure that new regulatory requirements are aligned with existing and upcoming legislation, including the Circular Economy Act, the Advanced Materials Act and the Industrial Accelerator Act, to avoid overlapping obligations and inconsistent definitions.

### **Sustainability criteria and biomass use**

Alliance for Biosolutions supports the ambition to ensure sustainable biomass use and efficient resource allocation across value chains. However, sustainability criteria must be proportionate, operational, and based on realistic market conditions. There is a risk that overly restrictive or overly complex sustainability requirements could reduce biomass availability for industrial applications and undermine investment incentives.

It is important that sustainability frameworks:

- remain technology-neutral;
- recognize regional and sector-specific differences;
- avoid unnecessary reporting burdens;
- and support the use of biomass in high-value applications.

The Commission should also carefully assess how existing subsidies and policy frameworks influence biomass allocation across sectors. Continued incentives for combustion may distort markets and weaken the competitiveness of higher-value industrial biotechnology applications.

### **Simplification and enabling regulation**

Alliance for Biosolutions strongly supports the Commission's focus on simplification.

A key risk for Europe is that regulatory complexity and slow administrative procedures delay industrial deployment and drive investments outside the EU. Simplification efforts should therefore include:

- accelerated permitting procedures;

- streamlined approval processes;
- clearer regulatory pathways for emerging biosolutions;
- and reduced reporting and compliance burdens.

Special attention should be paid to SMEs and start-ups, which are often disproportionately affected by administrative requirements.

Furthermore, regulatory frameworks should be designed to support innovation rather than prescribing specific technologies or production pathways. Technology-neutral regulation is essential to ensure flexibility and future-proof legislation.

Lastly, regulation and investment are intertwined and therefore have to be integrated. Long permitting procedures, regulatory uncertainty, and unclear future market conditions create significant risks for investors. This is particularly problematic for first-of-a-kind industrial facilities and scaling technologies, where capital expenditures are high, and return-on-investment periods are long.

Alliance for Biosolutions therefore strongly supports initiatives aimed at improving regulatory predictability for investors. The Commission should ensure that:

- regulatory requirements are stable and transparent over time;
- implementation timelines are realistic;
- permitting procedures are streamlined and accelerated;
- and access to EU funding mechanisms is simplified.

In addition, regulatory sandboxes can play an important role in reducing risks for emerging technologies and enabling faster access to market.

### **Concluding remarks**

Biosolutions can become a cornerstone of Europe's future industrial competitiveness, regional resilience, and green transition. However, this requires a regulatory framework that supports scaling, innovation, and investment.

The greatest risk to Europe is not insufficient regulation, but rather that complexity, fragmentation and uncertainty prevent industrial deployment from taking place within the EU.

Alliance for Biosolutions therefore encourages the Commission to ensure that the Biotech Act II:

- strengthens Europe's global competitiveness;
- creates predictable and technology-neutral framework conditions;
- reduces administrative burdens;
- accelerates permitting and authorization processes (e.g. by using regulatory sandboxes);
- and supports commercially viable pathways for biosolutions in Europe.

Alliance for Biosolutions remains at the Commission's disposal for further dialogue and elaboration on the above remarks.

Kind regards,

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