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Call for Evidence for Impact Assessment of the European Biotech Act Will Close June 11, 2025

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The European Commission (EC) began a call for evidence on May 14, 2025, for an impact assessment of the European Biotech Act. The EC states that the overall objective is to improve the size and competitiveness of the biotechnology sector in the European Union (EU) while maintaining high safety standards. The new European Biotech Act will aim to ensure that the EU makes the most of the biotechnology revolution for the benefit of society, the environment, and the economy, while making it easier to develop and bring to market products across all biotechnology sectors in the EU. According to the EC, the European Biotech Act would address the following issues:

- European companies have difficulty expanding within the single market because of "a complex regulatory framework that is perceived as slow and burdensome." According to the EC, there are cases where implementation of the relevant EU regulatory framework diverges among EU member states, resulting in regulatory environments that are complex to navigate for companies and that can hinder the development or commercialization of biotechnology products. In addition, barriers at national or regional levels can further delay or hinder market entry.
- The growth and development of biotechnology companies in Europe is hindered by market fragmentation, risk capital constraints, and scattered innovation support. EU companies lack sufficient access to risk-tolerant capital, and there is a lack of coordinated private and public investment to support the translation of innovation into products and the scaling-up of production for innovative biotechnology products.
- The EC states that the EU does not tap into the full potential of its scale when it comes to pooling capacities to make it more competitive globally. Because national interests often lead to support for local companies, many biotechnology clusters exist throughout the EU. Some clusters are mostly of regional relevance, do not cover all the steps from laboratory to market, duplicate efforts at low scale, do not fully use their capacities, or have limited resources.
- Manufacturing biotechnology products requires highly specialized equipment and a highly qualified and multidisciplinary workforce. According to the EC, in the EU, there is a mismatch between the labor supply and the biotechnology and biomanufacturing skills required.
- Artificial intelligence (AI) and big data — including access to supercomputing capacity and to large, integrated, high-quality datasets — offer huge potential for all sectors underpinned by

biotechnology, provided that appropriate safeguards are put in place.

The impact assessment will explore the following areas:

- Speed and streamlining: “Time-to-market” is an essential parameter for the successful translation of innovation into commercial products. Where appropriate, the regulatory environment for biotechnology needs to be simplified, including the procedures for risk assessments. The aim is to facilitate and speed up the development and approval of biotechnology products and to bring them to the market faster and more easily, without compromising safety for health and for the environment or biosecurity standards. Best practices for accelerated time-to-market at EU, national, and regional levels need to be promoted.
- Financing: Having access to sufficient capital is key to supporting the process of translating innovation into product development and the scaling-up of production capacities. Risk-tolerant capital is essential for the development of the biotechnology industry at seed phase, scale-up stage, and at later stages of development.
- Scale: Tapping into the potential of the EU in terms of both scale of production and market size can help to ensure that companies thrive in Europe. Further options could be to look at possible support for the development, operation, governance, and coordination of biotechnology clusters or centers of excellence in the EU. The EC states that an open, competitive and at-scale business environment will be essential to keep the EU ahead in the global race.
- Skills: Specific measures will be considered to improve the upskilling and reskilling of the workforce in the biotechnology area. This is to ensure that companies have access to adequately trained staff and to equip academic developers with the necessary entrepreneurial skills to create and grow a company.
- Use of data and AI in the biotechnology sector: Access to data, storage services, and computing resources is essential for biotechnology research and innovation and for the development of AI tools and solutions to support the development of biotech products. According to the EC, having access to supercomputing capacity and AI testing facilities is essential to enable biotechnology companies and organizations to use data effectively. Targeted projects and tailored programs at the EU level have the potential to facilitate and push forward the development and adoption of digital solutions and AI in all biotechnology sectors.

Comments are due **June 11, 2025**. The EC plans a public consultation on the draft legislation in the **fourth quarter of 2025**, and to adopt final legislation in the **third quarter of 2026**.

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