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NOTE

From:	General Secretariat of the Council
To:	Delegations
Subject:	AOB for the meeting of the Competitiveness Council of 26 February 2026 : An integral EU Biotech Act II for a competitive Europe *- Information from Denmark, Estonia, Finland, Latvia, Lithuania, the Netherlands and Portugal*

On the 16th of December 2025 the Commission published the European Biotech Act. After many months of discussions on the scope of the Biotech Act, the Commission decided to split the Biotech Act into two acts. The first Biotech Act establishes a framework to strengthen the competitiveness of the health biotechnology sector in the EU and focuses on simplification in the fields of health and food. Building on this, the second European Biotech Act will follow this year with a focus on industrial biotechnologies, biomanufacturing, and horizontal enablers.

At the meeting of the Competitiveness Council 28 November 2024, 14 member states supported a broad biotech act. While some elements are addressed in the Biotech I, the split of the European Biotech Act into two acts has caused uncertainty about the expected content of Biotech Act II. By ways of the non-paper attached, the delegations would like to highlight the necessity to have an ambitious Biotech Act II which addresses the concrete issues of biotech companies across different sectors. The signatories invite the Commission to reaffirm its commitment to developing a Biotech Act II and outline the expected content of it.

ANNEX

Non-paper from the Danish, Dutch, Finnish, Estonian, Latvian, Lithuanian and Portuguese delegations on an integral EU Biotech Act II for a competitive Europe.

1. Key messages:

We call for a coherent EU Biotech Act I and II to support a **broad scope** that includes the medical and pharmaceutical, agri-food, biomanufacturing, industrial and environmental biotechnology sectors.

Given the rapid pace of technological and geopolitical developments, we consider it important that national and EU regulations should align with the latest scientific findings. This will enable us to harness biotechnological innovations while maintaining high safety standards.

One of the key priorities, as outlined in a 2024 non-paper[1], is better European regulation. This also includes reducing the regulatory burden for biotechnology companies without compromising safety.

We desire to enhance Europe's competitiveness in biotechnology by drawing up the EU Biotech Act II and establishing a Biotechnology and Biomanufacturing Hub[2] to support innovative companies.

We aim for a harmonised and forward-looking regulatory framework within Europe. The procedures associated with legislation and regulations must be transparent, effective and predictable.

[1] Non-paper by NL, CZ, IT, DK, SE (2024): "Proposal for better regulation in times of transition"
[2] European Commission (2025). "New Biotech Hub to support companies"

2. Important points

A. Comprehensive future proof and resilient regulation

We strive for **proportional and future-oriented European legislation** and regulations with transparent, efficient and predictable approval procedures, so that we offer a level playing field and prospects to developers and financiers of biotechnological innovations and optimally use these innovations in our society while maintaining a high level of safety for human and animal health and the environment. Important points that should be taken into consideration for this EU Biotech Act II are:

Clear regulations and simpler procedures with better support

We call for clear, harmonized and simplified biotech and GMO regulations and procedures which includes:

- Simplification of the complex legislative framework while maintaining high safety standards. For example, the need for clearer, future-proof, definitions and risk-based rules in the GMO legislative framework to avoid diverging interpretations;
- A dynamic approach and flexibility for authorities to respond to scientific/technical progress;
- Harmonized interpretation of GMO legislation;
- A central EU contact point to better guide and support European innovators during approval procedures (in particular start-ups, SMEs).

Harmonization of overlapping regulations

We call for a coherent, flexible EU framework that aligns overlapping rules and eliminates contradictions. We call for coherence between the Biotech Act I and II. EU authorities should cooperate effectively and be empowered to quickly issue implementing acts, when applicable, ensuring consistent interpretation across Member States. Moreover, EU bodies must proactively identify and address cross-sectoral bottlenecks to foster innovation and regulatory clarity.

There are multiple examples where biotech innovations have to comply with more than one regulation. For example, if a food additive contains, consists or is produced from GMOs, two regulatory frameworks apply: one for food additives (Regulation 1333/2008) and a second for genetically modified food and feed (Regulation 1829/2003). Each regulation requires a case specific risk assessment, which do not necessarily align.

Future-proof regulations through experimentation

We call for future-oriented, flexible regulation based on the latest scientific findings with more room for experimentation for biotechnological innovations within existing laws and regulations, for example by means of pilots, tastings, sandboxes and support for science based public dialogue, for example around products of precision fermentation. Regulatory sandboxes for certain applications has been mentioned in Biotech Act I. This regulatory adaptability is key to public trust, competitiveness and innovation.

Coordinated and Integrated approach for regulation

We call for a coordinated, learning-based system to improve clarity, reduce duplication, and support innovation across the EU. This includes:

- Updated guidelines reflecting new technologies, using adaptive standards;
- Clear communication of EU-level rulings, and
- A stronger mandate for EU agencies (EFSA, ECHA, EMA) to adapt rules swiftly and prevent divergence.

B. Competitiveness / Horizonal issues

It is important that **competitive investment frameworks** are leveraged within the EU to make optimal use of the economic opportunities that biotechnological innovations brings us leveraging research and boosting innovation uptake. An important point is to offer prospects of **long-term public-private financing** with a stronger focus on strategic research areas and technologies.

Long-term, high-risk innovation financing

Without prejudice to the ongoing negotiations on the next MFF, we call for support, in the next MFF to focus on closing funding gaps for scaling and commercialization of innovations, because start-ups in industrial biotech or precision fermentation often lack access to late-stage finance and too often rely on foreign investors to grow. Therefore, the ECF including the ECF InvestEU instrument, and the new Horizon Europe must offer support - such as grants, direct and indirect equity, venture debt, guarantees, and blended finance – as well as the right framework conditions – such as focus on the most strategic technologies and sectors, including biotech, based on excellence and impact. A strong connection between the ECF and the EIC Accelerator – and cooperation with the EIB Group and National Promotional Banks is essential to attract private capital and help small and medium enterprises expand in Europe. In addition, completing the Capital Markets Union and removing cross-border investment barriers will be crucial to success.

Knowledge transfer / upscaling / clusters

We call for improvement of the knowledge and technology transfer between academia and industry and upscaling of innovations (specifically start- and scale-ups) to ensure biotech research leads to commercial applications and industrial deployment. This requires better connection between leading European biotech clusters.

Access to **facilities for experimentation/scaling** is an important prerequisite for SME, start-up and scale-up for strategic innovation.

Availability of public-private research and technology infrastructure is an important prerequisite for SME (start-up and scale-ups). Funding for pilot-to-demo infrastructure is a prerequisite for exploitation of these facilities. **We are in favor** for public support mechanisms to derisk and attract private capital. **We also promote** to make existing shared facilities better accessible for innovative SMEs (startups and scaleups).

The EU could consider launching a European platform to promote **scale strategic / lead market value chains** in growth areas like precision fermentation, agriculture, food & feed, biobased chemicals and materials on market-based grounds. Such a coordinated approach would strengthen Europe’s competitiveness and help resolve practical bottlenecks such as access to lab space, funding, regulatory clarity, and talent.

Stimulating market demand for biotech products

We emphasize the link between the European Commission's update of the Bioeconomy Strategy and the introduction of a Biotech Act II. We believe that the creation and promotion of market-based of European lead markets for bio-based products is also essential to the success of the European biotech sector. We therefore also consider it important to foster the competitive, sustainable and circular supply of biomass. Public procurement is to be efficient, legally secure, and to leverage market competition, and promoting innovative solutions. Furthermore, we would support steps towards promoting innovation-focused public procurement to stimulate market demand and development including standards development, specifically for biotech innovations.

State aid – Enterprises in difficulties

We welcome the announcement in the Start-up and Scale-up strategy to revise the definition of Undertakings in financial Difficulty (UiD), which is also relevant for the biotechnology sector. We call on the DG COMP to collaborate with other Directorates-General (CLIMA, SANTE, RTD, REGIO) to ensure that the State aid rules are fit for purpose for aid measures for the biotechnology industry, particularly with respect to the definition of UiD.

Safeguarding National Security:

To secure the potential of biotechnology to contribute to societal and economic goals in the future, it is a prerequisite that the national security aspects of biotechnology within Europe are properly safeguarded. We must ensure that Europe is resilient against economic and knowledge security risks related to the research, production, and application of biotechnology. Therefore, economic and knowledge security instruments should be taken into account, whilst these should only be used to mitigate clearly defined national security risks in a targeted and proportionate manner. Likewise, when identifying, monitoring and addressing these risks, due account should be taken of the opportunities for cooperation with like-minded third countries.

C. Ensuring adequate conditions for specific sectors of the biotech and biomanufacturing industry

Unlocking the Potential of Animal-Free Methods

We suggest promoting developers and accelerate market formation for innovative, animal-free testing methodologies. Combined with clear regulatory pathways, this approach can unlock the business potential of animal-free innovations and accelerate their adoption