Dansk Industri

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Input for the European Biotech Act I and II from Danish Industry (DI)

The European Union stands at a crossroads. Faced with intensifying global competition, mounting innovation and investment gaps, and increasing geopolitical uncertainty, Europe risks losing ground to major powers such as the U.S. and China. Both the Draghi and Letta reports have made clear that Europe must act decisively now to safeguard its competitiveness, strengthen its resilience, secure prosperity in uncertain times, and reverse the effects of climate change.

In this context, Danish Industry strongly welcomes the European Commission's decision to put forward the ambitious Biotech Act and split it into two separate acts – I to focus on life science and pharma and II to focus on biosolutions in the food and feed, agricultural, industrial, environmental, marine, and other areas. Biosolutions[1] and biotechnology are not only critical for European resilience and supply security - they are also a key driver of Europe's growth, competitiveness, and green transition.

In 2024, the sector provided **59.8 billion EUR** of direct GDP contribution, thus holding a significant and growing share of the EU GDP, driven by healthcare, industrial, and agricultural biosolutions[2]. Moreover, the European biotechnology industry supported over **913,000 jobs** in 2022, of which 238,170 were direct jobs and 674,990 were indirect jobs[3].

[1] 'Biosolutions' refers to the combination of biology and technology with the aim of accelerating the green transition. Biosolutions are solutions based on living microorganisms, enzymes, bacteria cultures, yeast etc. which, through fermentation, precision fermentation and bio-refinement, can mitigate climate change, optimize industrial processes, improve agricultural yield – and more. Fermentation and yeast have been used for centuries as the key processes in making beer, wine, cheese and bread. Enzymes make it possible to wash our clothes at low temperatures and bacteria are vital for our health.

[2] ADC (2025) "The Value of Biosolutions: Growth and Prosperity to 2035 - European Edition": pp. 53.

[3] WifOR (2025): "Measuring the Economic Footprint of the Biotechnology Industry.
in the European Union": pp. 10.

However, a recent study from June 2025 shows that by 2035, the European biosolutions sector could create **604,000 jobs**, with **33 pct.** of these being **indirect jobs in agriculture**[4], as well as provide an economic footprint that could reach **118 billion EUR** and support up to **543,000 jobs**. With further policy initiatives such as the Biotech Act, the sector's economic footprint could increase to **133 billion EUR**[5].

It is estimated that **60%** of the world's physical input could be made using biological means[6]. This will not only help decarbonise European production but also drastically reduce our dependency on global supply chains, thus helping us reach the targets of the Competitiveness Compass and the upcoming revision of the Bioeconomy Strategy.

Additionally, biosolutions could reduce greenhouse gas emissions by up to **9% by 2050**[7], thereby contributing to reaching the targets of the European Green Deal, the Clean Industrial Deal, and the Decarbonisation Accelerator Act. Biosolutions can thus help modernize entire parts of the European economy to be more sustainable and competitive.

This is the potential, but it could quickly end up on the ground if Europe sits on its hands. Danish Industry therefore urges that the European Biotech Act II be **bold and broad in scope**. It should cover the entire biotechnology field and deliver on the commitments outlined in the Commission's Communication 'Building the future with nature: Boosting Biotechnology and Biomanufacturing in the EU' from March 2024. In the following Danish Industry presents its recommendations for the content of the Biotech Act II and afterwards recommendations for the Biotech Act I.

Modernise the EU regulatory framework

Danish Industry welcomes the European Commission's continuous regulatory efforts to boost European competitiveness, innovation, and accelerate the green transition. The Clean Industrial Deal, the EU Life Science Strategy, the Single Market Strategy, the EU Startup and Scaleup Strategy, and the Vision for Agriculture and Food as well as upcoming strategies and pieces of legislation such as the revision of the Bioeconomy Strategy, the European Innovation Act, and the Circular Economy Act are all important steps in the right direction.

However, the European biosolutions and biotechnology sector still faces significant regulatory hurdles that hinder innovation, investment, and the scaling of sustainable solutions. Biosolutions are currently regulated under different regimes, which are cumbersome and time

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[4] ADC (2025) "The Value of Biosolutions: Growth and Prosperity to 2035 - European Edition": pp. 20.
[5] Ibid.: pp. 19.
[6] Ibid.: pp. viii.
[7] McKinsey & Company (2020): "The Bio Revolution: Innovations Transforming Economies, Societies, and Our Lives": pp. 15.

consuming. These regimes do not consider the risk profiles of products based on biosolutions and do not consider their ability to facilitate our green ambitions.

These challenges are compounded by evolving data requirements, slow assessment timelines, inconsistent mutual recognition, and limited regulatory predictability - all of which create high costs and uncertainty for companies, particularly startups.

Without swift and ambitious initiatives, Europe risks falling behind in the global advancement of and investment in biosolutions that can support security of supply, competitiveness, green growth and jobs.

To address these issues, the Biotech Act II should:

1 Develop a framework for the fast approval of biosolutions

- To accelerate the green transition, there is a need to allow for faster approval of sustainable biosolutions within several areas. It should build on a risk-benefit approach and ensure regulatory sandboxes, allowing for the development, testing and validation of innovative technologies in a controlled real-world environment, the full implementation of the Innovation Principle.
- Furthermore, it should provide better conditions for applicants to develop higher quality applications e.g. through pre-submission advice. Also, an approach to solve the challenges related to capacity shortages for assessment should be part of this framework.
- This new framework will allow for streamlining and speeding up the registration and approval process for biosolutions, giving companies predictability and reducing costs.
- Additionally, to this framework, food and feed should be incorporated into the Net-Zero Industry Act.

2 Develop and use a risk-benefit approach

- The EU's high safety standards for food and products are pivotal to ensuring human and planetary health and should therefore always be prioritized. However, biosolutions suffer from a disproportionate focus on environmental and human health risks, compared to the environmental and human health benefits of the solutions. In addition, environmental externalities are not priced in most traditional products.
- Also, bio-based products do not receive proportionate benefits for doing relatively less harm to the environment and human health. Introducing and, to a much higher degree, using a risk-benefit analysis framework would guide regulatory decisions by considering and weighing both potential benefits and disadvantages.
- A modernization and more nuanced interpretation of the Precautionary Principle in the field of biosolutions and biotechnology should also be included in the Act.

3 Develop a European model of market access for biosolutions

- The model could be a GRAS-inspired approach. GRAS is an American paradigm, which stands for 'Generally Recognized As Safe', where companies must apply due diligence in demonstrating and getting expert consensus on the safety of new biological solutions.

- Here, products, which can be categorized as 'low-risk' with 'high benefit', should have easier and more streamlined pathways to market.
- This is a clear and straight forward process that secures the safety of products while avoiding the lengthy and administratively demanding approval processes currently in place in the EU.

4 Improve enforcement and legal protection

- Global, incremental alignment towards harmonized and stable patent laws should be supported, ensuring continued access to patents for microbial biotechnological products, technologies, and processes.
- Biosolutions is a highly competitive sector that requires substantial R&D investment, which can only be recouped with stable and reliable patent protection. Any change to the IP framework should therefore strengthen – not weaken – protection and incentives for innovation. Following this, exceptions or relaxations are not recommended; instead, enforcement and legal protection should be further improved.

Improve access to finance to scale solutions

The EU's investment gap to other global powerhouses such as the U.S. and China is growing day by day. Europe has been ahead until now but is quickly losing ground as other regions and countries ramp up significantly in this area. For the EU to keep up with other regions and continue to develop new solutions, substantial investments are required.

Danish Industry supports the proposal put forward by the EU-Commission with regards to establishing a Savings and Investment Union. More harmonized and integrated capital markets in the EU are crucial in order to boost investments and make EU companies and technologies attractive for both EU and global investors.

However, more initiatives are needed to ensure sufficient finance to build the large factories we need to scale biosolutions and biotech. As of right now, both scaling opportunities from pilot to commercial biomanufacturing, as well as access to soft funding from government or from the EU is lacking. Getting funding for this stage is not easy, it takes several months and it's quite complex. Moreover, application processes are not streamlined, and private risk appetite and public timelines are misaligned.

In ensuring sufficient finance to build factories for biomanufacturing, we are not only boosting European competitiveness, growth, and self-sufficiency, but also creating many new, green and safe jobs in rural areas, and providing new sources of income to farmers all over Europe. In other words, if we want, we can implement a 'green reindustrialization' of European rural areas, where there will be plenty of jobs, thriving local communities, and strong cooperation between farmers, engineers, manufacturers, food professionals, and more.

To make better opportunities for scaling biosolutions and biotech, the Biotech Act II should:

1 Establish a European BioScale Fund

- The Fund could be designed as a public-private co-financing mechanism where EU resources are matched with national contributions and private capital, with risk-sharing tools (such as guarantees or first-loss capital) to attract institutional investors.
- The Fund could provide financing instruments including direct investments primarily to biosolutions scale-ups, including concessional loans and mezzanine finance for pilot and demo plants, equity co-investments for scale-ups, and green/bio-bonds backed by EU guarantees for larger industrial facilities.
- The financial support from the fund could preferably be linked with regulatory incentives, such as accelerated approval pathways for EU-backed projects and harmonized sustainability criteria to ensure financing accelerates the green transition.
- The fund could also encourage industrial symbiosis by giving priority or additional incentives to projects located in bio-innovation clusters or hubs that share by-products and minimize overall environmental impact.

2 Encourage the use of IPCEI funds for bioreactors

- Danish Industry welcomes the ongoing work of the Joint European Forum for IPCEI (JEF-IPCEI) in exploring the opportunities of IPCEIs for bio-based chemicals and materials as well as components for food and feed.
- The Biotech Act II should play a crucial role in developing a model for IPCEIs in biotech where the EU could be co-investor in public-private partnerships, in infrastructure for scaling e.g. through the European Investment Bank (EIB) and the European Innovation Council (EIC).

3 Earmark funds for biotechnological clusters

- EU funds should be earmarked to the development and consolidation of biotechnological clusters, so they can effectively support innovation, scaling, and investment attraction.

4 Split access to biomanufacturing facilities in three

- The first one should be for early-stage startups (i.e. recently spin off) which have simple needs in terms of infrastructure (like lab or small pilot plants), the second one for startups on scale-up stage, and the third one for large companies where sufficient production facilities currently are difficult to access and financing for scaling and production is difficult to get.

5 Ensure fair EU classification and revise the NACE codes

- Biosolutions should be included in the EU taxonomy to attract sustainable finance as it is vital for attracting private investments. By acknowledging the importance of sustainable financing, we can encourage more private sector involvement and support the development of innovative and eco-friendly biotechnologies.
- To promote inclusive growth, the EU must ensure fair classification systems that reflect the evolving nature of industries and innovation. Revising the NACE codes is essential to better capture an emerging sector, such as biosolutions, and enable targeted incentives for scaling sustainable and digital solutions.

Ensure sufficient skills and talent

Attracting qualified labor from third countries is pivotal to ensure European competitiveness and green growth. International talents are fundamental for innovation, development, production, security of supply, and welfare. Other global competitors, e.g. the U.S. and Canada, have more attractive, targeted, and less bureaucratic schemes for international recruitment. The EU risks falling behind in this global competition if we do not act proactively.

The European workforce is also of high importance, as it holds much talent already but also much potential. However, the professional capacity of member states' authorities in the field of biocontrol and biosolutions is challenged. It should therefore be a focal point of the Act II to build capacity and competence in this field, so that case processing and approvals in Member States do not become a bottleneck for innovation.

To ensure sufficient skills and talent, the Biotech Act II should:

1 Create targeted schemes to attract skills and talent

- Highly educated foreign workers in the biosolutions and biotechnology sectors, including easier access to work permits and recognition of qualifications within the EU.

2 Increase investments in education

- Investments should be canalized into continuing and further education within biosolutions and biotechnology, including technical specialist skills, regulatory affairs, and digital competences.
- This would give European workers a competence boost, benefiting innovation at the universities and companies as well as officials in European and national authorities responsible for application and approval processes.

Advance the use of Artificial Intelligence in biomanufacturing

Danish Industry acknowledges the European Commission's efforts in advancing European capacity and skills in the field of data and Artificial Intelligence (AI), most recently with the Apply AI Strategy and the promise of an 'AI Skills Academy'. These initiatives are highly necessary to keep up with other countries and regions who are placing massive investments in building up AI capacity and infrastructure. But more can and should be done.

Danish Industry stresses the importance of access to high quality data as well as clear and consistent standards for data sharing and interoperability, enabling businesses to access and use data more easily across borders and sectors. A trustworthy data ecosystem that ensures confidentiality, integrity, and security - while emphasizing that these safeguards must not hinder effective and responsible data use, should be established.

Substantial investments in AI research, application and development should be prioritized. It is crucial that these investments lay the groundwork for next-generation AI technologies and that research outcomes are translated into commercial products. Danish Industry stresses the need to ensure that basic research is followed by concrete steps to bring technologies from lab to market.

The European Biotech Act II should therefore:

1 Present an AI4Bio Competence Strategy

- The strategy should advance AI literacy and skills in biosolutions and biotechnology specifically.

2 Ensure access to AI infrastructure and guidance

- European startups and scaleups, including in the field of biosolutions and biotechnology, should have sufficient access to AI infrastructure as well as guidance on how to use AI in their processes.

3 Reduce administrative burdens

- Ensure that initiatives regarding data and AI in Act II do not lead to further administrative burdens for European biotech companies but rather optimize their processes and foster innovation.

Recommendations for Biotech Act I: Life science and "red biotech"

This section concentrates on biotech in the medical and pharmaceutical sectors and provides recommendations for the Biotech Act I. As this new piece of legislation will regulate an area of huge importance for the life science sector, we strongly encourage the European Commission to do a proper impact assessment, covering also the potential of the biotechnology industry for competitiveness, also for the medical and pharmaceutical sectors.

Danish Industry believes that the Biotech Act I should cover the following areas.

Complex regulatory approval processes

- Regulatory complexity is a barrier in the EU. To expedite regulatory approval processes, the EU should benchmark and align approval times with the US.
- Regulatory fragmentation between Member States leads to inconsistent implementation and delays.
- Regulatory framework conditions should ensure legal certainty and predictability, be better integrated, coherent across policy areas, and open to a more flexible approach for innovative measures.
- Further, the EU regulatory framework is more complex, expensive and less clear due to fragmented national reimbursement processes and lack of HTA harmonization.
- Harmonization of the clinical trials ecosystem is a high priority. The framework conditions for multi-country clinical trials should be improved to enhance efficiency and save resources. This could be done by implementing a new single-approval model and harmonizing reviews by National Competent Authorities for ethics and dossiers.

- Due to the above, the EU is slower in bringing biotech products to market. The US (FDA's Breakthrough Therapy designation) and UK (Innovative Licensing and Access Pathway) enable faster market access for innovative therapies, often within 12–18 months, compared to the EU's average of 531 days.

IP rights

- It is essential that this initiative assumes that existing intellectual property (IP) regulation remains unchanged and is not weakened - whether directly or indirectly - through new sectoral legislation. The Biotech Act should therefore build on the principle that IP rights are a stable and indispensable part of Europe's innovation infrastructure. Any new measures - whether regulatory, financial, or industrial - must complement, not conflict with, the existing IP framework.
- To conclude, the EU should benchmark its IP system against the highest global standards by ensuring strong, predictable protection mechanisms, including robust regulatory data protection (RDP). A robust, predictable, and a well-functioning and forward-looking IP framework should be recognized not only as a legal backbone but also as a strategic competitive advantage for Europe. Strengthening this framework over time and providing adequate incentives such as data protection will be essential to safeguarding long-term investments.

R&D – life science clusters and venture capital

- To strengthen the research and innovation policy, the EU should allocate funding into life science-related research and innovation programs. This includes supporting selected, specialized clusters of biotech and pharmaceutical excellence by strategic, targeted use of EU funds including Horizon Europe and future framework programs, looking at core enablers in globally successful clusters. At the same time better access to venture capital is key as we are lacking behind the US and China.

AI Act and access to data (EHDS)

- The AI Act and EHDS Act must prove to be workable in real life so as not to become a barrier that undermines European competitiveness.

Conclusion

Europe cannot afford to hesitate. If the EU is to remain competitive, resilient, and a global leader in innovation, the upcoming Biotech Act I and II must match the scale of the challenges we face. Biosolutions and biotechnology hold the key to securing supply in uncertain times, driving the green transition, and strengthening Europe's long-term growth, prosperity, and resilience.

Danish Industry therefore calls for a **broad and bold Biotech Act I and II** that covers the full spectrum of biosolutions and biotechnology, including solutions in the fields of food, agriculture, industry, pharma, and more. Act I and II should unlock innovation and investment and deliver on the commitments made in the Commission’s Communication from March 2024. Only with such ambition can we close the widening gap with global competitors and make Europe a place that is attractive to innovate and invest in, safe to live in, and future proof for generations to come.