Danish feedback to the call for evidence for the forthcoming EU Biotech Act

This document responds to the European Commission's Call for Evidence regarding the forthcoming EU Biotech Act, which is scheduled for presentation in Q3 2026. The input reflects feedback from the Danish Government across the five objectives outlined by the Commission in the Call for Evidence. We welcome the Commission's evidence-based approach and call for a thorough impact assessment.

General comments
The Danish Government strongly supports the European Commission's ambition to promote biotechnology as a key strategic technology for Europe's competitiveness, sustainability, resilience and economic security. Biotechnologies hold great transformative potential across multiple domains. They can help decarbonise industrial processes, ensure access to innovative life-saving medicine and treatment, help future-proof healthcare systems, enhance sustainable food production, and support the circular economy and a sustainable land-use. To fully realise these benefits, Europe needs an ambitious, forward-looking, and cross-sectoral policy response. Without a coherent policy for the biotechnologies, Europe will fall behind its global competitors and increase its strategic dependencies.

The Danish Government calls on the Commission to ensure that the Biotech Act reflects the horizontal relevance of biotechnology across sectors, including industrial transformation, environmental sustainability, and data-driven innovation. The regulatory, financial and infrastructural barriers and the biomass availability gap, which are currently limiting the cross-cutting potential of the technology, must be addressed comprehensively.

The Biotech Act must provide a coherent and enabling framework that accelerates the journey from laboratory to market, increases harmonization and coordination, ensures regulatory predictability, and strengthens European leadership in biotech. In doing so, the Act should contribute to the green transition of the EU and deliver on our climate and biodiversity targets.

The messages in this paper are largely limited to non-pharmaceutical biotechnology, however, it is obvious that a competitive biotechnology sector plays a vital role in the development of innovative medicine and treatments.

1. **Speed and Streamlining**

Efficient and predictable regulatory pathways are critical for biotech companies, particularly if start-ups and SMEs are to succeed in a highly competitive and fast-moving global environment. The Danish Government

supports efforts to simplify and accelerate approval procedures, without compromising safety standards.

The Danish Government urges the Commission to explore the wider use *of **regulatory sandboxes, one-stop shops, and structured pre-submission guidance*** to reduce administrative complexity and approval timelines. Pre-submission guidance to applicants on their data generation, testing strategies and protocols, could increase the quality of the applications, and thereby decrease the need for 'clock stops' and the overall time between submission and approval.

Furthermore, the Danish Government invites the Commission to consider the possibility and effects of introducing ***fast-track mechanisms*** for sustainable biotechnological solutions. This could be in the form of ***differentiated data requirements and approval timelines for conventional and biotechnological solutions***, respectively. This is in order to support the market introduction of new and more sustainable biotechnological solutions.

Furthermore, ***risk assessment procedures should focus more on end products instead of process,*** while ensuring the proper balance when it comes to safety and health. Especially when identical products are derived through different biotechnological means. The concept of "Generally Recognised as Safe" (GRAS), as applied in other jurisdictions, may offer a useful model for selected biotech applications.

At the same time, there is an urgent need ***to reduce unnecessary administrative burdens for the biotechnology sector in Europe to ensure innovation-friendly regulation***. Specifically, there is a need for a review of a number of regulations. This is particularly important for EU chemicals legislation, including REACH (Regulation (EC) 1907/2006), and for Placing of Plant Protection Products on the Market (Regulation 1107/2009) as well as a number of regulations on agri-food.

In the following we would like to highlight some important legislations within the agri-food sector that should be more tailored to the innovative biotech products that the fast-developing industry is able to deliver:

- *GMO legislation*

While we welcome the NGT-proposal and wish the trilogues to come to a swift and balanced conclusion, we note that the NGT-proposal only has a limited scope and leaves many of the fundamental problems with the current GMO legislative framework un-addressed. We would therefore welcome suggestions from the Commission on more substantial improvements of the GMO legislative framework. A first step should be an initiative on microorganisms developed by NGTs.

The scope of Regulation (EU) 1829/2003 on genetically modified food and feed needs to be further clarified with regard to products from fermentation in contained use by use of Genetically Modified Microorganisms. Double authorisations of the same product (e.g. both under food additives legislation and GMO-legislation) should be avoided.

Data requirements for authorisation of genetically modified food and feed products should be proportionate to the risks. Furthermore, the need for re-authorisation requirement for genetically modified food and feed every ten years should be re-considered.

Directive 2001/18/EC reflect that the GMO techniques were new to the world at the time the directive was written and therefore it was built on the Precautionary Principle. At that time, these techniques did not have a long history of safe use. After more than 30 years of growing genetically modified crops outside the EU, the experience has shown, that the benefits of growing genetically modified crops are large. That is both for the climate and the environment, as well as for farmers' economy and food security (isaaa.org, info graphics). Many of the horror scenarios from back then, have proven false. In the EU, only one genetically modified event has been approved for cultivation – The MON810 approved for cultivation in Spain and Portugal. Maybe it is time to have a closer look at the effect of the precautionary principle – does the directive have the intended effect or not? What societal benefits have EU missed due to the strict regulation of GMO's in Directive 2001/18/EC? It is striking, that the research report from WifOR Institute finds, that pharmaceutical and industrial biotechnology deliver a direct gross value added of €32.75 bn and €5.18 bn, respectively, while agricultural biotechnology account for only €0.18 bn (0,47%) in the EU[1].

If Directive 2001/18/EC is included in a Biotech Act, there are opportunities to simplify the rules of GMO legislation. As an example, the directive state, that applicants need to prepare a 90-days feeding study as input to the risk assessment. There is a general view, that this demand does not make sense from a scientific point of view. It is therefore possible to relax the demands to the risk assessment without putting food security and the environment at danger. In addition, consent holders of approved GM crops must prepare an annual 'Post-Marketing Environmental Monitoring' (PMEM) report. Many resources are used to prepare these reports, but it is questionable, if they serve any purpose that benefit the food security or the environment in the EU.

- *Novel food legislation*

Efforts are also needed in order to lower the European Food Safety Authority's (EFSA) workload related to novel foods. It is relevant that EFSA always considers the need for data for their risk assessments on a need-to-

[1] Andreas Haaf & Vera Sale, Measuring the Economic Footprint of the Biotechnology Industry in the European Union, WifOR Institute, March 2025, EuropaBio.

know rather than nice-to-know approach. In addition, risk managers should carefully consider how mandates to EFSA are drafted in order to narrow the scope of EFSAs work to the necessary.

Denmark also finds it crucial to consider the reintroduction of the substantial equivalence approach for novel foods and food ingredients that are equivalent to existing food products independently of how they are manufactured. Also, the date of which foods are considered novel could be advanced until e.g. 2010.

Regarding Regulation 2015/2283 on novel foods, simplification of the implementation could be considered with the purpose of reducing the number of products falling under the scope of the regulation.

- *Feed additives legislation*

The feed additive regulation (EU Reg. 1831/2003/) is expected to be revised soon. Efforts are also needed on this area to lower EFSAs work-load, but also the workload of the Commission, the member states and others. This can be done via reduction of regulatory burdens, preferably by introducing permanent feed additive approvals for safe and well-known substances. It would also help the field of biotechnology if the rules on claims related to the effect of a feed additive are clarified and preferably expanded to provide better legal possibilities for sustainability claims for the already established functional groups of feed additives. An introduction of simpler rules for the marketing of non-EU approved additives for export is also a relevant change to consider.

- *Other feed related initiatives*

There is a need to look further into the possibilities to introduce circularity on some very specific risk assessed safe Animal By-Products. This could e.g. be the use of incinerated sludge for the production of very clean phosphorus for use as feed and fertilizer, due to a worldwide deficiency of naturally occurring phosphorus.

There is a need to clarify the rules on environmental claims on feed materials. This e.g. to ensure access to feed materials for methane reduction.

Denmark would like to draw attention to the Heads of Agencies (HoA)[2] sustainability catalogue from 2023. The Danish Veterinary and Food Administration coordinated a working group among 10 EU member states to recommend some principles and suggestions to deliver on the sustainability agenda. The catalogue also delivers some considerations in relation to biotech e.g. the use of fermented feed additives.

<u>Relevant legislation in the health sector</u>
In the area of health, it is important that the policy response creates added value when it comes to biotechnology application and innovation uptake,

[2] "Toward sustainable food systems"- Reflections by HOAs September 2023.

while balancing the need for patient safety and an evidence-based approach. This could include looking at the framework for multi-country clinical trials and the Medical Device Regulation and in vitro diagnostics to ensure their compatibility with the rapidly changing landscape. The policy response should focus on addressing overarching challenges that existing regulations have not or cannot address. It is important that the act simplifies or facilitates implementation of the existing ruleset rather than adding an additional layer of complexity to an already highly regulated sector.

2. Financing

Securing access to adequate, risk-tolerant capital across the innovation chain remains a central challenge for the biotech sector in Europe. In particular, there is potential for increased access to late-stage venture capital and scale-up funding to improve commercialisation of biotech solutions. It is key that biotech startups can attract adequate capital on their full growth journey – from the idea phase to large-scale production. In addition, it is also essential to ensure coherence between efforts to mobilise biotech financing and broader EU objectives on decarbonisation, industrial resilience and sustainable food systems.

The Danish Government supports an enhanced role for the Savings and Investment Union and encourages the Commission to ***explore increased use of de-risking instruments and blended financing models.***

The long payback period and capital intensity of first-of-its-kind large-scale biotech production facilities require tailored solutions, including ***simplification of access to existing EU instruments***.

The sector is in great need of more venture capital. Therefore, further ***strategic use of EU budget guarantees or venture equity instruments*** has to be considered while at the same time creating incentives for increased investment of private venture capital. There is a need to ***explore opportunities to further enhance access to risk capital for life science companies*** in order to support the private capital market through market-based efforts and collaborations with private investors, for example, under the auspices of the European Investment Bank (EIB).

While other initiatives seem more relevant for pursuing the above-mentioned goals – e.g. a future Competitiveness Fund, and the Savings and Investment Union – the Biotech Act must also address the question of attracting investments to the EU. This means ***addressing the elements creating uncertainty for investors***, including acceleration of approval times, developing technical screening criteria for biotechnological climate solutions as enabling technologies in the EU taxonomy for sustainable activities, and overhaul outdated regulation as described in section 1.

3. Scale

Biotech solutions must be deployed at scale to realize their societal and economic benefits. Yet companies often struggle to bridge the gap between pilot-scale innovation and full industrial production. The scaling-process for these solutions is typically very expensive, lengthy and uncertain.

Access to facilities for testing, demonstration and scaling of the production is vital for biotech companies, but most of the fermentation capacity in Europe is already in use and only a minor share is for large-scale demonstration, which is necessary to convince investors and future customers. This lack of facilities can force European biotech companies out of the EU.

The Danish Government encourages the Commission to put forward initiatives that can ***support the development of shared open access large-scale demonstration and biomanufacturing infrastructure*** — including fermentation and purification facilities — accessible to SMEs and start-ups.

The Danish government also encourages the Commission to explore possible ***models for supporting the establishment of first-of-its-kind large-scale production plants***. Today, the EU supports new solutions for decarbonisation. However, there is a need to simplify the rules for applying for EU funding so that the framework is in place for the establishment of first-of-its-kind large-scale biotechnology plants in Europe..

To ensure optimal use of existing facilities and preventing overlap in new establishments, it is also crucial to have an easy and ***up-to-date overview of all relevant European facilities and technologies*** – e.g. based on the existing Pilots4U platform.

We also encourage ***support to biotech clusters and centers of excellence***. A geographically balanced deployment of infrastructure can strengthen regional innovation capacity and avoid duplication. Infrastructure development should be complemented by simplified permitting procedures and a supportive investment environment, ensuring integration into broader industrial ecosystems, such as bioeconomy strategies and net-zero supply chains. In this regard, specific attention should be paid to environmental and spatial planning procedures and their interaction with biotech scale-up.

Scale-up will increase supply chain demand for biomass as feedstock to the biotech sector and therefore lead to an increased pressure on natural resources. A Biotech Act should therefore also contribute to a sustainable supply and use of biomass. This should be done by ***promoting the principle of cascading use of biomass in the biotech sector*** through regulation or other incentives and at the same time have a strong ***focus on payment for ecosystems services*** throughout the value chain. Cascading use of biomass contributes towards reducing the expected biomass availability gap

and can simultaneously reduce the dependency of fossil resources and increase the responsible use of renewable biological resources within the planetary boundaries.

4. **Skills**

To attract the necessary talent to the European biotech sector, Europe needs to build on its strong research community and **create European innovation hubs** where stakeholders can collaborate across sectors and disciplines.

5. **Use of Data and AI**

Artificial intelligence, real-world data and high-performance computing are crucial enablers for the biotech sector. Whether in enzyme discovery, molecular design or regulatory simulations, AI offers transformative productivity and insight gains. However, biotech actors continue to face challenges related to data access, and infrastructure availability.