An integral Biotech Act for a competitive Europe: *Input from the Dutch government for the EU Biotech Act*

1. Dutch key messages:

The Netherlands calls for an EU Biotech Act with a **broad scope** that includes the medical and pharmaceutical, agri-food, industrial and environmental biotechnology sectors.

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

One of the Netherlands' key priorities, as outlined in our 2024 non-paper[1], is better European regulation. This also includes reducing the regulatory burden for biotechnology companies.

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

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

2. Important points from the Netherlands

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 guarantee. Important points that should be taken into consideration for this EU biotech act are:

Clear regulations and simpler procedures with better support

The Netherlands calls for clear, harmonized and simplified biotech regulations and procedures which includes:

- Simplification of the complex legislative framework while maintaining the highest safety standards. For example, the need for clearer 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 innovators during approval procedures (in particular start-ups, SMEs).

Harmonization of overlapping regulations

The Netherlands calls for a coherent, flexible EU framework that aligns overlapping rules and eliminates contradictions. Authorities should cooperate effectively and be empowered to quickly issue implementing acts 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.

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[1] Non-paper by NL, CZ, IT, DK, SE: Proposals for better regulation in times of transition | Publicatie | Rijksoverheid.nl

[2] European Commission (2025). New Biotech Hub to support companies.

Future-proof regulations through experimentation

The Netherlands calls 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 or tastings or sandboxes. Support for science-based public dialogue, for example around cellular agriculture. This regulatory adaptability is key to public trust, competitiveness and innovation. Examples:

- The Dutch Code of Practice enables controlled, pre-approval tastings of cultivated meat and fish, ensuring safety through expert review and strict protocols. Two companies have held several tastings.
- In animal-free innovation, regulatory acceptance lags behind method development. A regulatory sandbox and clear roadmaps would allow safe testing of new methods, helping update outdated frameworks.

Coordinated and Integrated approach for regulation

The Netherlands calls 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 dynamic 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. 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

The Netherlands calls for tailored instruments in the next MFF to close funding gaps for scaling and commercialization of innovations, because start-ups in industrial biotech or cultivated meat often lack access to late-stage finance and must rely on foreign investors to grow. Therefore, the ECF and the new Horizon Europe must offer tailored instruments - 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 Scale-up facility under 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

The Netherlands calls for improvement of the knowledge and technology transfer between academia and industry and upscaling of innovations (specifically SME, start- and scale-up) to ensure biotech research leads to commercial applications and industrial deployment. This requires better connection between leading European biotech clusters. The Netherlands offers several best practices such as: Leiden Bio Science Park hosts a high concentration of R&D-intensive companies and public-private research infrastructure, while the ecosystem around Wageningen University & Research foster innovation in agri-food and cellular agriculture.

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). (Long term) funding for pilot- to -demo infrastructure is a prerequisite for exploitation of these facilities. **The Netherlands are in favor** for public support mechanisms to derisk and attract private capital. **The Netherlands also promotes** to make existing shared facilities better accessible for innovative SMEs (startups and scaleups).

The EU could consider launching a European platform to **scale strategic value chains** in growth areas like precision fermentation. 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

The Dutch government emphasizes the link between the European Commission's update of the Bioeconomy Strategy and the introduction of a Biotech Act. The government believes that the creation and protection of European lead markets for bio-based products is also essential to the success of the European biotech sector.[3] We therefore also support the Commission's aim to secure the competitive and sustainable supply of biomass. Furthermore, we would support steps towards enhancing innovation-focused public procurement, specifically for biotech innovations.

State aid – Enterprises in difficulties

The Netherlands welcomes 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. The Netherlands calls on the DG COMP, to collaborate with other Directorates-General (CLIMA, SANTE, RTD, REGIO) to ensure that the State aid rules are fit fur purpose for aid measures for the biotechnology industry, particularly with respect to the definition of UiD, taking into account the specific characteristics of this sector.

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 misuse of 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 economic security tools 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

Accelerating market access for low-risk biological plant protection products

The Netherlands supports targeted amendments to Regulation 1107/2009 to better fit biological plant protection products. Of specific importance is offering a definition for biocontrol that defines biocontrol substances as both with natural occurrence and without a broad toxic mode of action. The exclusion of broad toxic (high impact) substances justifies other amendments and simplified procedures that contribute to efficacious approval and authorisation. Finally, increased capacity at EFSA and at Member State level in expertise and staffing is required to further support an efficacious approval system.

Optimizing the Clinical Trial Regulation (CTR)

The Netherlands calls to facilitate the EU's climate for clinical trials to:

- Allow multiple RFIs to ensure reviewers have the information they need, leading to fewer rejections and faster trial start times;
- Harmonize the process with GMO and other pharmaceutical legislation to speed up innovation;
- Embrace new technology like AI and data from the European Health Data Space to streamline the entire regulatory process.

Unlocking the Potential of Animal-Free Methods

The Dutch government suggests targeted funding instruments—such as conditional loans or innovation tenders—to reduce the financial risk for 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.

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[3] | Tweede Kamer der Staten-Generaal