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From:	General Secretariat of the Council
To:	Delegations
Subject:	AOB for the meeting of the Competitiveness Council of 28 November 2024: Reaping the full benefits of the biotech revolution - Information from Denmark, Finland, France, Germany, Ireland, Latvia, Slovakia and Spain

Information from the Danish, Finnish, French, German, Irish, Latvian, Slovak and Spanish delegations on reaping the full benefits of the biotech revolution.

Addressing regulatory obstacles across EU policies and industrial sectors to the benefit of competitiveness, green transition and resilience.

Innovative biotech solutions have the potential to become a driving force behind the green transition of the EU's industries and increase the EU's resilience. A successful and competitive biotech sector is pivotal for the EU. This is underlined by its status as a critical technology in the industry security perspective[1] and the fact that it is one of three technologies prioritised in the Strategic Technologies for Europe Platform (STEP) regulation.

[1] Commission Recommendation (EU) 2023/2113 of 3 October 2023 on critical technology areas for the EU's economic security for further risk assessment with Member States.

It is crucial for a successful European Biotech sector that we address horizontal regulatory barriers across sectors. In order to ensure a coherent policy framework across biotechnologies, we welcome the Commission's efforts to assess how relevant EU legislation and its implementation can be further streamlined to reduce fragmentation, explore potential for simplification, and shorten the time for biotech innovations to reach the market in line with the EU's goals. These efforts should inspire and underpin efforts to develop a coherent and holistic market for biotech. If not successful, there is a genuine risk that European companies will continue to move production to rival markets that better facilitates their business-model and future growth.

The Commission's communication on Biotechnology and Biomanufacturing[2] focused on a broad spectrum of regulatory obstacles. These need to be comprehensively addressed through legislative initiatives for Europe to be able to reap the full benefits of these technologies in line with the commitments undertaken in the Commission's Political Guidelines. This should be a priority to be taken for the new Commission.

The Mission Letter to Commissioner Designate for Health and Animal Welfare focuses on health technology assessments, clinical trials and medical devices. While we fully support that these are addressed as soon as possible, the limited scope of such a proposal will not deliver on the political expectations created by the Commission in "Action 1" as laid out in the Communication.[3] Limiting the scope for action would be a missed opportunity to reap the full benefits of biotech innovation, which can also deliver solutions across industrial sectors such as decarbonisation of industries.

Building on an evidence-based approach and consultations with Member States and stakeholders, we call on the Commission to address regulatory obstacles for biotechnology horizontally across EU policies and industrial sectors in order to create a regulatory environment for biotech that is conducive to innovation.

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2 Building the future with nature: Boosting Biotechnology and Biomanufacturing in the EU (COM(2024) 137 final)"

3 "**Action 1**: Simplified regulatory framework and faster access to market: to prepare for this the Commission will launch a study analysing how the legislation that applies to biotech and biomanufacturing could be further streamlined **across EU policies**, exploring targeted simplifications to the regulatory framework, including for faster approval and bringing to the market. The study will be finalised by mid-2025 and could lay the foundations for a possible EU Biotech Act.", (COM(2024) 137 final), p. 20.