

# AMFEP Response to the Call for Evidence on the Biotech Act

11 June 2025

AMFEP, the **Association of Manufacturers and Formulators of Enzyme Products**, representing 90% of the EU enzyme market, welcomes the opportunity to comment on the Biotech Act call for evidence. The Biotech Act is an opportunity **to build on the earlier recognition of enzymes as contributing to sustainability and competitiveness in the March 2024 Commission Communication on biotechnology and biomanufacturing**<sup>1</sup>. These are even more relevant under the current geopolitical climate, in which the EU needs to remain competitive and resilient compared to other regions investing in biotech.

**Recognizing enzymes as distinct from other chemicals is vital for coherent, technology-neutral policy that aligns with the Biotech Act, bioeconomy goals, and supports a shift from fossil to biological alternatives.** We address below several issues that are critical for the enzymes sector under the Biotech Act, to ensure there is no disruption in the current benefits to the EU bioeconomy, but also to encourage private sector investments remain in the EU - for keeping its global leadership in enzymes.

Enzymes are natural proteins that have been used in industrial applications for over a century and have a long history of safe use. They are **crucial assets for of life sciences and industrial biotechnology** companies which use them – and continue to innovate – for improving the sustainability footprint of a wide range of industries, including food, feed, and technical applications (see AMFEP's [factsheet](#) for more information on benefits of enzymes).

Enzymes are **readily biodegradable** (unlike persistent chemicals) **and reduce the environmental impact and carbon footprint of industrial processes by lowering energy and water consumption and minimizing waste and use of hazardous chemicals**. They also play a vital role in the green transition and in modernising European industries by contributing to economic growth, job creation, and sustainable development while mitigating climate change and boosting circularity.

**Beyond food processing, animal nutrition, detergents, and textiles among others, most recent enzymatic innovations include applications in biodegrading plastics, carbon capture, and biomaterial production.** It is worth noting that the **EU enzyme industry is at the forefront of innovation, driving R&D investments with an expected 27% growth over the next decade** compared to the previous. This innovation is crucial for developing new applications, improving cost efficiency, and supporting sustainability goals like increasing circular economy practices and carbon reduction.

Enzymes are **recognised** as crucial for biotech climate and energy solutions **in the Net-Zero Industry Act** and its implementing and delegated legislation<sup>2</sup>. Their contribution to **reducing emissions in various industries is recognised under the EU Industrial Emissions Directive**: there are numerous enzyme

<sup>1</sup> European Commission, 'Building the future with nature' (Communication), COM/2024/137. (<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52024DC0137>).

<sup>2</sup> Enzyme processes are identified as "final products", "main specific components" and "primarily used components" in several net-zero technologies in the implementing and delegated [acts](#) of May 2025 laying the nomenclature of net-zero technologies and their enabling components: (i) Enzymes and microorganisms for sustainable biomethane production, (ii) Enzymes and microorganisms for sustainable biogas production, (iii) Enzymes and microorganisms for sustainable alternative fuels production, (iv) Enzymes (such as amylase and cellulase) that are used to pretreat and convert feedstock into biofuels, biobased chemicals, biobased materials and bio-based product

applications in BREFs<sup>3</sup>, including in textiles; food, drink and milk; intensive rearing of poultry and pigs; slaughterhouses, animal by-products and/or edible co-products; production of large-volume organic chemicals; and waste treatment. Moreover, safety and sustainability of enzymes is also endorsed within the EU Ecolabel for Cleaning products<sup>4</sup>.

Building on their abovementioned recognised key role and cutting-edge potential **as cross-sector enablers**, several issues faced by the enzymes sector need to be addressed in the upcoming Biotech Act. **AMFEP calls for** a coherent policy approach to the Biotech Act that **includes industrial biotechnology and biomanufacturing in the scope, as well as alignment with the EU Bioeconomy Strategy**. A broad and inclusive framework **would help ensure that the EU capitalizes on emerging technological opportunities** – even those not yet scalable – while supporting market continuity and stimulating further research, innovation, and business growth.

The EU is a global leader in enzyme production and has the world's largest fermentation capacity. **However, the enzyme industry faces a number of challenges across sectors, including those** identified for the biotechnology sector as a whole, such as the need for addressing regulatory complexity and streamlining time to market, scaling production and market size, and developing a skilled workforce. By focusing on addressing these barriers, including **streamlining access to market for enzymes** through a proportionate risk assessment and predictable process for market authorisation across regulatory frameworks, Europe can maintain this leadership position.

Enzymes are widely used across sectors and are subject to different legislation following their uses. At the same time, **enzymes are largely governed by regulatory frameworks that were developed for chemicals** and therefore do not recognise or support biological specificities. In that regard, we believe that the upcoming Biotech Act should pave the way for increasing speed and scalability for enzymatic solutions in the EU by recognizing enzymes' uniqueness and establishing **a clear, risk-benefit and science-based approach to regulating them**. **In addition, we strongly encourage the Biotech Act to foresee a clear exemption for enzymes to the hazard-based approach to restrictions, including in the upcoming REACH revision**, to support wider uptake of biobased applications and unlock synergies with industrial biotechnological innovations that contribute to replacing fossil-based products.

The **recognition of enzymes** as different from other chemicals is **already reflected in certain EU acquis** – for example, the EU Taxonomy includes enzymes as eligible feedstock for plastic packaging due to their role in enabling biodegradable materials. In a nutshell, adopting **a purely hazard-based regulatory model** – at the expense of a balanced, risk-benefit approach – **would hinder the broader environmental and economic benefits** enzymes offer across value chains.

As a key component of the Life Science Strategy, the **Biotech Act should also provide a coherent, technology-neutral policy direction that is aligned with existing and future frameworks, including the forthcoming Bioeconomy Strategy, and moves away from the fossil-based paradigm in support of a new biological paradigm**.

#### About AMFEP

AMFEP is a non-profit European industry association created in 1977. AMFEP currently has 30 members, representing over 90% of the European and over 80% of the world enzyme market. AMFEP serves as a hub for information exchange and dialogue between enzymes producers and formulators, industry organisations, the scientific community and policy-makers and promotes cooperation on regulatory and safety aspects of enzymes. For further information about AMFEP, please visit [our website](#).

<sup>3</sup> European Commission, Best Available Technique Reference Documents (<https://eippcb.jrc.ec.europa.eu/reference>)

<sup>4</sup> EU Ecolabel for Cleaning products ([https://environment.ec.europa.eu/topics/circular-economy/eu-ecolabel/product-groups-and-criteria/cleaning\\_en](https://environment.ec.europa.eu/topics/circular-economy/eu-ecolabel/product-groups-and-criteria/cleaning_en))