

Essential policy FAQ for the EU enzyme industry

This document was prepared by **AMFEP**, which **represents 90% of Europe's enzyme industry**, uniting **27 members** that improve the efficiency and sustainability of major sectors like food, feed, detergents, and other industrial uses. Please refer to the bottom of this FAQ document for an overview of <u>key applications and enzymes' performance across them</u>.

- What are enzymes? Enzymes are proteins, working as biological catalysts that accelerate specific chemical reactions.
- What are their key properties? They are biodegradable (unlike persistent chemicals) and reduce the environmental impact of industrial processes by notably lowering energy and water consumption and minimizing waste.
- How are enzymes produced? They can be produced through extraction (e.g., from plants or animals) or more commonly via industrial fermentation processes, which are highly scalable, using microorganisms.

• How does the global market and growth forecast look?

- In 2022, North America led the global enzyme market with a share of 37% and is set to maintain its dominance through the forecast period of 2024-2032. Europe follows and Asia ranks third.
- **EU falls behind with significant growth and innovation potential driven by rapid industrialization**, increasing demand for convenient affordable improved nutrition foods, and rising awareness of enzyme applications across diverse industries.
- Recently, all regions are embracing the sustainability and competitiveness potential of the enzyme industry throughout different policy and legislative initiatives (e.g., US Inflation Reduction Act, EU Biotech and Biomanufacturing Communication, India BioE3 policy framework, etc.) to be rolled out in the years to come.
- What is the EU economic footprint of the enzyme sector? This €2 billion industry enables hundreds of thousands of jobs across its value chain, spanning research and development, production (primarily in countries like Denmark, Finland, Germany, France and Belgium), and downstream sectors such as food production, biofuels, pulp and paper, and pharmaceuticals across Europe.
- How impactful are enzymes in reducing industries' environmental and climate footprint? Enzymes significantly reduce the use of energy, raw materials, and waste in all its usage while improving the efficacy and efficiency of many industrial outputs, thereby improving their overall economic impact as well.
 - Depending on the application, there can also be additional benefits, also supporting the SDGs and the EU's green ambitions for more sustainable and competitive industries. Examples of enzymes as crucial enablers of sustainable and efficient industrial processes:
 - Energy and CO2 reduction: In the pulp and paper industry, enzymes lower electricity use and CO2 emissions in fibre modification and bleaching processes.
 - Water reduction: In the textile industry, enzyme use to replace other chemicals enable water reduction by 25 % (see EC JRC <u>report</u> on Ecodesign from November 2024).
 - Circular economy support and non-toxic material cycles: Enzymes are biodegradable, thus they do not persist in the environment after consumption like other chemicals. Additionally, as catalysts, enzymes enhance recyclability and resource efficiency, reducing waste and supporting a circular economy.
- How are enzymes regulated in the EU? In the EU, enzymes are regulated based on their use. However, all enzymes are in scope of potential restrictions under REACH (Registration, Evaluation, Authorisation, and Restriction of Chemicals EC No <u>1907/2006</u>) due to them being classified as respiratory sensitisers under the CLP (Classification, Labelling and Packaging of substances and mixtures EC No <u>1272/2008</u>) Regulation.

• Food enzymes:

- Food Enzymes Regulation (EC No <u>1332/2008</u>) and the General Food Law (Regulation EC No <u>178/2002</u>), ensuring safety for consumers.
- Future EU Union List (2028 TBD): Each enzyme must undergo safety evaluation by EFSA and an EU Commission
 risk management phase before approval for use in food production. So far, enzymes in the market have to comply
 with the General Food Law.
- Feed enzymes: Feed Additives Regulation (EC No <u>1831/2003</u>), which requires safety assessments to ensure they pose no risk to animal health or the environment.
- **Technical enzymes** (detergents, textiles, etc.): REACH, to ensure safe industrial (workers) and consumer use, together with sectoral legislation for specific applications.

These frameworks ensure enzyme safety while supporting their widespread application in various industries.



- Why is safety critical for enzyme production and use? Enzymes have a long history of safe use in both food and technical applications.
 - Like many other proteins, enzymes can act as respiratory sensitisers (i.e., property that can potentially give rise to sensitisation towards a specific enzyme if inhaled), but thanks to EU regulations and to industry best practices (i.e., safe handling guidelines for different sectors), their safe use has been well-documented for several decades.
 - Moreover, at the consumer level, there have not been reported cases of consumers developing allergy to enzymes, as also confirmed in a recent <u>study</u>.
- Are there better alternatives? Currently, there are no other substances on the market which can both be as technically effective and offer similar sustainability benefits.
- What are the future policy milestones affecting the enzyme industry?
 - REACH revision and Generic Approach to Risk Management (GRA) extension to all the most harmful chemicals: AMFEP supports the goals of the EU Chemicals Strategy for Sustainability, which seeks to ban the most harmful chemicals.
 - However, AMFEP recommends that the GRA is not applied to enzymes, even though they are respiratory sensitizers and therefore classified as substances of concern/most harmful chemicals.
 - We recommend exempting enzymes due to their history of safe use, their contribution to sustainability and competitiveness, their biodegradability, lack of alternatives and also to ensure policy consistency. Notably, because there is precedence for exempting enzymes:
 - ✓ Enzymes are already derogated from the ban on respiratory sensitisers in <u>EU eco-label criteria for</u> <u>detergents</u>.
 - ✓ The EC Sustainable Finance Platform also <u>acknowledged</u> "the difficulties of applying to them this general hazard-based substitution approach".
 - ✓ The Taxonomy Regulation exempts enzymes from substances of concern in the feedstock for plastic
 - Additionally, if GRA is extended to enzymes, professional uses of food and feed enzymes as well as a few consumer uses of food enzymes (e.g., bakery and brewing applications) would be affected as well.
 - Development of the upcoming EU Biotech Act as per the March 2024 EC Communication and Commissioners' Mission Letters:
 - To position Europe as a global leader for sustainable economic growth and prosperity through innovation, it is essential to accelerate the pathway to technology, including <u>different types</u> of biotechnologies, and biomanufacturing at scale.
 - Finalization of the EU Positive List of Enzymes (2028 TBD): Only enzymes on the Union List of Food Enzymes will be allowed to be placed on the market and used in food production within the EU.
 - AMFEP is advocating for a smooth transition of enzymes currently in the marketplace into this new list. We urge the Commission and Member States to ensure that the process does not hinder innovation, market continuity or further growth by setting clear transitional measures and allow for a smooth switchover.

Key applications of enzymes and performance across them

Food & Beverages (35%):

<u>Bread and bakery</u>: Enhancing dough quality and crumb structure, reducing acrylamide and ensuring long-lasting freshness. Dairy: Assisting with milk coagulation for cheese production and lactose reduction in milk.

Plant-based alternatives of dairy: reducing viscosity, improving texture and taste as well as the digestibility of proteins.

Juices: Clarifying and increasing yield through pectin breakdown.

Beer: Facilitating fermentation and improving clarity and taste

Wine: Stabilizing and enhancing flavour profiles during fermentation.

Cleaning agents (25%): Dishwashing detergents (removing food residues), laundry detergents (stain removal and odour control for consumer and professional use).

Animal feed (20%): Enhancing digestibility of grains, improving nutrient absorption, promoting growth in livestock.

Biofuels (10%): Converting biomass (corn, sugarcane) into fermentable sugars for bioethanol production.

Textiles (<10%): Softening fabrics, removing impurities, and improving fabric finish (e.g., stone washing jeans).

Pulp and Paper (<10%): Improving pulping efficiency, increasing fibre yield, enhancing paper quality (e.g., recycled paper