



The unintended impact of the REACH revision on Enzymes – and consequences for EU Green Deal Objectives

AMFEP, representing enzymes manufacturers and formulators (around 90% of the EU and 80% of the global enzymes market), welcomes the Commission's Chemicals Strategy for Sustainability (CSS) that strives for a toxic-free environment and its objectives to focus on essential uses for chemicals - accompanied by the requirement to demonstrate their contribution to reducing potential human and environmental exposure risks.

The Commission's proposal to amend the REACH Regulation to extend the use of the generic risk assessment (GRA) approach (i.e., restrictions under Art. 68 (2) of REACH) to respiratory sensitizers in consumer and professional uses raises major concerns for the enzyme industry. While enzymes are classified as respiratory sensitizers category 1, their inherent properties as bio-based solutions precisely make them a more benign alternative to the very type of chemicals that the CSS aims to reduce.

Enzymes have a history of safe use. AMFEP takes the inherent hazard of enzymes as respiratory sensitizers very seriously and has for decades remained committed to developing product formulations safe for handling and consumer use, proactively training and providing industry with various specific guidance documents, posters and video materials on the safe use of enzymes. For decades AMFEP and its members have worked with various sectoral associations to make the programs specific to their enzyme handling needs. Our efforts have resulted in no reported sensitizations or allergies in consumers for more than 50 years. Only a few cases in occupational settings have been reported in that period, where exposure control was not in place.

Enzymes are enablers of the EU Green Deal. With decades of experience, they have been helping a wide range of industries in their sustainability journey and more recently, in meeting the EU's ambitious sustainability targets and objectives in policies such as the Bioeconomy Strategy, Industrial Strategy, Farm-to-Fork, Circular Economy Action Plan, CSS and Zero Pollution Action Plan. Enzymes are biocatalysts that help reduce energy consumption and raw material input, improve process efficiencies, and replace or reduce chemical pollutants in applications ranging from textiles processing to animal nutrition, beer making, paper & pulp and even to detergents.

Enzymes are relevant for broader policy objectives. The potential extension of the GRA to respiratory sensitizers needs to be carefully evaluated against the significant sustainability benefits which enzymes provide to other policies. By only looking at the intrinsic hazard of enzymes being respiratory sensitizers, without taking documented safe use (via exposure controls) into account, the Commission would be ignoring all the sustainability drivers for their use as well as the industry's efforts on innovations and product stewardship.

AMFEP therefore recommends that the GRA process for Category 1 'most harmful chemicals' begins with a process for a derogation (e.g., by a competent authority or by industry's proposal) based on their documented safe use. Only thereafter would the process apply the 'Essential Use' concept, to further demonstrate the essential contribution of a substance to the EU's bigger policy objectives. Such an approach would also significantly reduce any unnecessary administrative burden and encourage innovation.

Enzymes are already contributing to the EU Green Deal goals of improving air quality, clean water and healthy soil, healthy and affordable food, cleaner energy, recycled products, jobs & global competitiveness. AMFEP remains concerned about the potential consequences of the proposed GRA extension to respiratory sensitizers and thereby enzymes. We would welcome the opportunity to be involved in its development, by providing additional information on the impacted professional and consumer products from a potential



ban on enzymes and the significant market disruptions that this would entail. In this context, we attach a technical annex of examples of safe use of enzymes, while illustrating their sustainability benefits in various industrial sectors.

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 co-operation on regulatory and safety aspects of enzymes.

For further information about AMFEP, please visit [AMFEP's site](#). If you have any questions, please contact AMFEP@kellencompany.com.

About EUROPABIO

EuropaBio, the European Association for Bioindustries, promotes an innovative and dynamic European biotechnology industry. EuropaBio and its members are committed to the socially responsible use of biotechnology to improve quality of life; to prevent, diagnose, treat, and cure diseases; to improve the quality and quantity of food and feedstuffs and to move towards a biobased and zero-waste economy. EuropaBio represents corporate and associate members, plus national biotechnology associations and bioregions.

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