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From: Professor Christina Rudén,
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on behalf of European academic
scientists

To: Ursula von der Leyen,
President of the European
Commission

Stéphane Séjourné, Executive
Vice-President for Prosperity
and Industrial Strategy

Jessika Roswall, Commissioner
for the Environment, Water
Resilience and a Competitive
Circular Economy

**Chemical mixtures pose a risk to ecosystems, biodiversity and human health.
Addressing mixture toxicity in the REACH revision is therefore central to ensure
adequate protection.**

Dear President von der Leyen,

Dear Executive Vice-President Séjourné,

Dear Commissioner Roswall,

As leading academic senior scientists in risk assessment and management of chemicals, we are writing to you to provide input to the ongoing discussions on the revision of the REACH Regulation. Based on our scientific work and our long-standing expertise in chemical risk assessment and management, we are very concerned that the upcoming revision of REACH may not take into account the significant risks that chemical mixtures pose to ecosystems, biodiversity and human health.

Already now, contamination of the general European population exceeds levels considered safe for individual chemicals, such as for bisphenol A¹ or certain PFAS². In 2003, the blood of former Commissioner Margot Wallström was found to contain 28 out of 77 chemicals analysed³. Since then, systematic EU-wide human biomonitoring programmes, such as HBM4EU, have shown that the general public is continuously exposed to multiple chemicals, coming from different sources, such as consumer products, food, drinking water and ambient air.

Still, chemical risk assessment is typically carried out on a compound-by-compound basis. This practice is based on the (unrealistic) assumption that every single chemical is released into its own, pristine environment. In this way, the current approach systematically underestimates real risk. The science is clear; even if each compound is present at levels deemed safe on its own, the combined effects of a large number of chemicals will pose a risk. This was recently demonstrated in a study on European pregnant women; chemicals in their blood caused mixture effects indicating neurotoxicity, despite each chemical occurring at a “safe” level, not exceeding regulatory thresholds⁴.

A large body of scientific evidence demonstrates that these ubiquitous chemical mixtures have a clear impact on human health and the environment. To name just a few recent examples, research has shown decreasing trends for male sperm quality⁵, and that high exposure to mixtures of hazardous chemicals might result in IQ losses of European citizens of various ages⁶ and delayed language development, which indicates adverse effects on brain development⁷. Similarly, the accumulation of chemicals in marine mammals has been shown to comprise various legacy and emerging organic pollutants. These pollutants elicit mixture effects and have been shown to exceed regulatory thresholds⁸.

In summary, the available scientific evidence clearly shows that the current practice of chemical management needs improvement⁹ and that the joint action of hazardous chemicals needs to be accounted for if a safe use of chemicals is to be ensured. However, REACH in its current form does not address such mixture effects.

We support the European Commission’s aim in its Chemicals Strategy for Sustainability to account for mixture effects by including an additional safety factor, a “Mixture Assessment Factor” (also known as “Mixture Allocation Factor”), in the safety evaluation of industrial chemicals to account for mixture effects. Such an instrument would be pragmatic, feasible and would not unduly increase the regulatory burden on industry and regulatory authorities. Details are provided in the report from the Swedish Chemicals Agency¹⁰ and the corresponding study implemented for the Commission services by Wood¹¹ (unpublished). We note that, the proposal to include a Mixture Assessment Factor in the REACH revision has already received explicit support from the European Parliament¹², as well as the Government of Sweden, supported by Denmark, Finland and Luxembourg¹³ and the German Advisory Council on the Environment¹⁴.

We therefore urge the Commission to follow through with its initial aim to include a Mixture Assessment Factor in the revision of REACH. The scientific evidence on the ubiquitous exposure to chemical mixtures and their adverse effects on human health and the environment calls for adequate regulatory action. The planned revision of REACH provides a unique opportunity to implement an appropriate regulatory tool to protect human and environmental health in the form of the Mixture Assessment Factor.

Signed

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