Action 6: Avoid integrating the Mixture Allocation Factor (MAF) in REACH

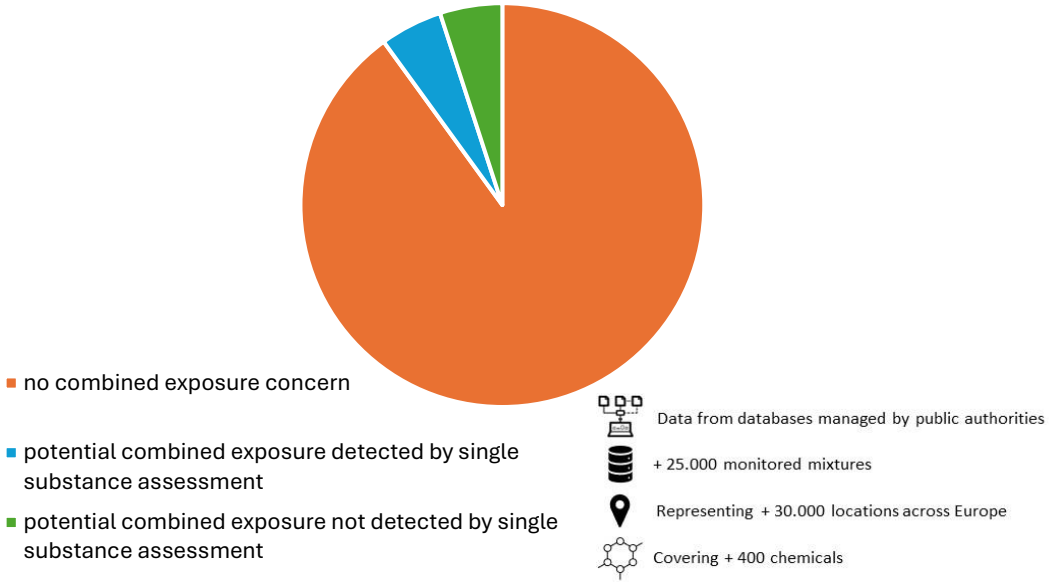
The Issue?

Addressing exposure to multiple chemicals (combined exposure) by tackling individual substances is not an effective solution. REACH is a chemical legislation addressing individual components or substances. A number of studies indicate that introducing a MAF in REACH on individual substances[1] would impose significant administrative burden for the companies without effectively addressing combined exposures and ultimately protecting human health and the environment.

The vast majority of monitored unintended mixtures of chemicals do not present a concern to the environment

Over the past decade, considerable research has been carried out to gain a better understanding of the issue of combined exposure to multiple chemicals. A recent, comprehensive research study in this field, commissioned by Cefic and conducted by Arche Consulting, included a detailed review of monitored mixtures of chemicals in surface waters.

This study, and others, demonstrate that in a very limited number of cases, environmental levels of chemicals might result in a potential combined exposure risk that would not be identified in current risk assessments and regulatory regimes.



If potential combined exposure concern were identified (around 10% of all samples), the current single-substance assessments would detect about half of these cases. For the other half, combined exposure risk estimations would be:

[1] A MAF would serve as an additional safety margin when running a safety assessment for individual substances (not mixtures). The idea behind is that when combined exposure would occur, summed up exposure levels of individual substances would not pose a risk to human health and the environment.

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EU Transparency Register n° 64879142323-90

- Dominated by the presence of a few substances which are largely managed by existing specific regulatory frameworks[2];
- Influenced significantly by local factors[3]; and
- Influenced by the sometimes arbitrary assumptions of a combined assessment.

A broad-brush and generic approach, such as a MAF, to be applied to all chemicals in REACH, is out of sync with the available evidence and not an effective solution to manage potential combined exposures in the environment.

More research needed to understand combined exposure to humans

Most information on human exposure to chemicals, including legacy chemicals such as dioxins and polychlorinated biphenyls (PCBs), originates from human biomonitoring (HBM) studies. The Flemish Institute for Technological Research (VITO) conducted a review of available HBM studies, including the data collected under the HBM4EU project. The review indicates that available studies have gaps in reporting transparency, data accessibility and availability. These deficiencies hinder the assessment of relevant combinations of chemicals to which individuals are exposed. As such these data should not serve as a basis for recommending new regulatory approaches. Similar conclusions were drawn by the European Commission Joint Research Centre.[4]

Several EU-funded research projects, namely the European Partnership for the Assessment of risks from chemicals (PARC) and project to develop an innovative tool for chemical mixtures exposure assessment (PANORAMIX) are ongoing to obtain more precise information on human exposure to chemicals. It is expected that screening and refined risk assessment approaches addressing chemical mixtures will become available in the next couple of years.

In this context, it is important to note that the scenarios where humans experience high combined exposure to chemicals are already addressed under the EU Occupational Health and Safety (OSH) legislation, as explained below.

What are the consequences of inserting MAF in REACH on businesses?

The introduction of a MAF in REACH would have significant business implications. It would impact all risk assessments and the current risk characterisation reported in the registration dossiers. This would result in many of the individual substances being deemed “unsafe on paper”, while in reality would not pose a concern.

A case study analysis conducted by Ricardo assessed the potential impact that businesses may face from the application of a generic MAF. This analysis reveals that the introduction of a certain MAF value could have substantial implications on the chemicals industry, with knock-on implications across the supply chain and wider economy such as: withdrawal of substances from the EU market and introduction of stricter risk management measures which may reduce the demand from customers further down the supply chain, due in part to the large investment needed.

[2] For example the Water Framework Directive, Industrial Emission Directive, REACH authorisation, POP regulation, Biocidal Product Regulation, Plant Protection Product Regulation.

[3] Such as spatial location and intensity of anthropogenic activity (household, industry agriculture). The more downstream a river catchment, the more complex mixtures can be expected both in terms of number and type of chemicals. Same applies vice versa.

[4] Supporting the Commission in developing a proposal for introducing a Mixtures Assessment Factor in REACH, workshop organised by Wood, 24/11/2021.

The introduction of a blanket MAF would also impact downstream users and their products, like paints, fertilizers, crop protection, adhesives/sealants, as described by DUCC. The consequences include reformulation of products, implementing additional risk management measures, downstream users needing to do their own chemical safety assessment etc.

The Solution

Rather than integrating MAF in REACH, existing regulation and measures offer more targeted and effective ways to address harmful combined exposures, while avoiding duplication of regulatory requirements.

- **Existing legislations aimed at emission reduction** – the legislations listed below aim to reduce emissions and environmental levels of chemicals indirectly reducing risks of harmful combined exposures.
  - Industrial Emissions Directive aims to reduce the emissions to the environment caused by industrial production.
  - Increased treatment of waste waters under the provisions of the Urban Waste Water Treatment Directive will lead to minimisation of emissions, as already observed for instance in Switzerland. Reducing the emissions to the environment indirectly lowers the risk of combined exposure.
  - Water Framework Directive seeks to address priority substance and maintain a good chemical status of surface waters. Surface waters must meet minimum quality standards for selected pollutants, and must reduce or phase out the emissions of those substances to water.
- **Existing legislations assessing real-life exposure** - The European Commission's staff working document on mixtures from 2020 does not indicate that these existing practices are failing and should be replaced or complemented by another approach such as a MAF.
  - EU OSH legislation includes a legal obligation to assess and control combined exposure to chemicals at the workplace, complemented by EU rules to protect vulnerable groups.[5] The Chemicals Agents Directive includes a legal obligation to assess combined exposure at the workplace and the European Commission supported by ECHA is developing guidance on that. Workers' protection legislation is in this sense unique. It is the only type of EU legislation that has an obligation to assess risks stemming from combined exposure to chemicals. Both REACH and workers' protection rules go hand in hand – while REACH assesses risks of individual chemicals, OSH is looking at what is happening at a specific workplace building upon the data generated in REACH.
  - Guidance documents have been developed by the European Food Safety Agency (EFSA) to support risk assessment of combined exposure to chemicals for all relevant areas within EFSA's remit.

[5] For example adolescents or pregnant and breast-feeding women.