

EEB comments to REACH revision - Mixture Assessment Factor

CARACAL meeting 44 - AP4.1

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Introduction

The EEB supports the implementation of a Mixture Assessment Factor (MAF) in REACH to improve the level of protection of human health and the environment by reducing adverse effects caused by the inevitable exposure to multiple chemicals. The EU Green Deal recognised the need to address the combined effects due to the simultaneous exposure to various pollutants in daily life. The Commission committed in the CSS to tackling this mixture toxicity by the implementation of a MAF in REACH. The EEB asks the Commission to keep the revision of REACH up to the level of ambition expressed in the CSS and implement a MAF that ensures a high level of protection against combination effects of multiple chemicals.

Size of MAF

A range of values for MAF have been proposed in the debate about the size of the MAF. Proposals for MAF vary from 2, 10, 20, 50 to 100.

A recent study on mixture risk assessment by a leading scientist ([Kemi, 2021](#)) concluded that whereas a MAF of 10 would be sufficient for around 70% of the mixtures included in this study, a **MAF of 20 would be sufficient for 95% of the mixtures**, and a MAF of 50 would be protective of all mixtures included in this study. In addition, it was concluded that a MAF of $n/2$ (n = number of mixture components) is needed in the case of mixtures with more than 20 - 30 components.

We would like to emphasise that the size of MAF should be high enough to achieve protection of people, wildlife and the further environment from **daily exposure to hundreds of chemicals**. The MAF should be protective against the **unintentional, unknown mixtures** that people and the

environment are exposed to. In this respect the size of MAF should reflect the limitations and uncertainties inherent to all data sets used to derive a value for MAF. By default, data based MAFs underestimate the true magnitude of mixture effects because they do not take into account the not-measured chemicals, the unknown chemicals and **uncertainties due to spatial and temporal variations** caused by the endless variation of unintentional mixtures that people and the environment are exposed to over time and at different locations. The size of MAF should be corrected for such uncertainties.

Therefore, **a MAF of 10 is not sufficient** to achieve protection of people and the environment. In a recent report, ([CHEM Trust, 2022](#)) it was concluded that **a MAF of 100 is needed to take into account the vast number of chemicals found in wildlife and people, their respective contribution to mixture effects, and the uncertainties related to the contribution by unknown chemicals.**

Inherent limitations of the datasets that are used to propose values for the MAF:

- limited number of chemicals analysed in the data set, e.g. because data sets focussed on narrow groups of substances, often relatively small numbers of well-known pesticides;
- data sets limited to certain chemicals falling under one (sectorial) regulation, ignoring e.g. metals, pharmaceuticals or industrial chemicals.
- data sets ignoring legacy chemicals which are already in the environment, banned nowadays, but still leading to exposure.

For a fish or a frog it does not matter by what legislation a chemical is covered.

Development of one or more MAFs

The EEB supports introduction of a single MAF for both human health and the environment as we have not seen evidence that warrants differentiation of MAFs between humans and the environment.

Different values of MAF have been proposed based on different data sets for human health and the environment, but we would like to emphasise that these differences are mainly caused by different monitoring strategies for human health and environment: whereas relatively many

chemicals are measured in environmental samples, only few chemicals are included typically in human biomonitoring studies, explaining the different values proposed for human health and the environment.

The KEMI report (2021) concluded that evidence concerning the exposure of humans to real-world mixtures is still limited at present as a consequence of the current focus on monitoring only a relatively small amount of chemicals.

Therefore, we support a **single, generic MAF for human health and the environment** to finally protect people and the environment against cocktail effects.

Incorporating MAF in REACH

The EEB supports the introduction of a MAF in Annex I of REACH. The MAF should be applied to all hazard classes, and to workers, consumers, and environmental targets alike, independent of use pattern. MAF will have the most impact on the scenarios with the highest contribution to the total toxic pressure of the mixture.

We prefer application to the DNEL/PNEC as it will have a more effective contribution to supply chain communication and extrapolation across legislation, compared to applying MAF to the risk characterisation ratios in the CSA.

Impact assessment

We note that the consultant is concerned that “The higher the number [for MAF], the more registrants will be affected, and the more significant the effects on their registrations will be.” We would like to emphasise that the **aim of implementing MAF is to finally protect people and the environment against toxic effects of daily exposure to multiple chemicals**. A fact that is ignored until today in the regulation of chemicals that still assesses the risks of individual chemicals in isolation.

Therefore, the impact assessment should prioritise benefits for human health and the environment over the short term economic impacts on industry. In this respect, we note that it is

easy to estimate costs for industry, while it is always difficult to estimate the benefits for human health and the environment.

Implementation of MAF in REACH and its use across other legislation will have far reaching positive impacts on people and the environment that need due consideration in the impact assessment, to mention a few:

- increased protection of people, including at the prenatal and infant stages
- increased protection of wildlife, including sensitive species and vulnerable life stages
- increased ecosystem protection
- more realistic estimation of risks in environmental quality standard setting
- more realistic estimation of risks in media oriented legislation (eg food contact materials)
- reduced underestimation of risk in targeted assessments in sectorial product legislation

Furthermore, other benefits need to be taken into account, including:

- stimulation of innovation and substitution of harmful chemicals by safer alternatives
- negative economic impacts on certain operators of chemicals of concern, will be balanced by positive economic impacts on the operators providing safer alternatives
- increased consumer trust in EU products leading to positive impacts on competitiveness of EU industry
- increased confidence in policy makers if commitments made in Green Deal and CSS are made reality.

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- **Stakeholder representation in consultations**

Finally, we would like to express our concerns about the consistent imbalance in representation of different actors in the workshop and targeted stakeholder consultation.

- Targeted survey organised by consultant: responses 63% industry; 20% public authorities; 8% NGO

- Workshop on MAF November 2021: 177 participants; The selection made by the consultant resulted in what the consultancy considered a “balanced” representation with 36% participants from industry versus 6% from NGOs.

We agree with the NGO ChemSec that stated previously: *Wood proposes the justification of this imbalance by stating that MAF is expected to "impact industry more than other stakeholders". But, the MAF should be about increased protection (=positive impact) of all citizens and the environment, which is a significantly larger group than the chemical industry.*