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VdMi position on the introduction of a generic Mixture Assessment Factor (MAF) under REACH Regulation

The Chemicals Strategy for Sustainability (CSS) published on 14 October 2020 by the European Commission is part of the European Green Deal and underlines the importance of protecting human health and the environment.[1]

In the new CSS, the Commission has planned the implementation and integration of numerous legislative measures with the aim of improving the environment, health, and safety and promoting innovations in the field of safe and sustainable chemicals. These include fundamental changes within the REACH and CLP Regulations.

The introduction of a generic Mixture Assessment Factor (MAF)[2] *in the REACH Regulation aims to protect human health and the environment against unintentional mixtures. However, it undermines the proven, science-based approach currently followed under REACH and other sectoral regulations including its several safety factors to account for different circumstances and vulnerable groups. The MAF would negate the principles of a reasonable and proportionate risk assessment and would not bring any benefit but increase the regulatory burden and endanger many chemicals applications.*

Our key messages and concerns:

- The EU REACH, CLP and sectoral Regulations are the world's most extensive chemical regulations established
- The current risk assessment under REACH and sectoral regulations already include several safety factors to ensure sufficiently low exposure limits, also for vulnerable population groups
- Unintentional mixtures found in the environment are very rare and limited to a countable number of substances, mainly misused pesticides and/or pharmaceuticals
- Unintentional mixtures harming human health have not been proven
- The introduction of a MAF is unjustified as there is no evidence it would bring any benefit, and it would dilute the well-established and approved, science-based assessment currently implemented within existing EU chemicals regulation

Only limited assessment of the impact of a MAF possible due to many uncertainties

There are still many open questions regarding the introduction of a MAF: Neither a specific value, nor how a MAF should be included in REACH or how many MAFs would be appropriate are currently defined.

Proposals for the value of a MAF vary from 2 to 100 or even more. With this range of possible values, it is nearly impossible to assess, how many mixtures currently on the market would need

[1] See also publication by the EU Commission (link).
[2] See also Commission Staff Working Document: Progress report on the assessment and management of combined exposures to multiple chemicals (chemical mixtures) and associated risks (download available).

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to be reformulated or withdrawn to comply with the new regulation. Additionally, there are discussions whether one generic MAF would be the best approach, whether one MAF for environmental application and one for human health would be better, or whether substance or substance group specific MAFs would be the best way to address the EU Commission's intention to handle unintentional mixtures. Thus, there might also be several MAFs for each substance to address different hazard endpoints and for its different applications. Besides, it is still unclear how the MAF should be applied: directly in the deviation of relevant thresholds like DNELs and PNECs or as a factor to consider in specific risk assessments.

With all these uncertainties, only a very limited assessment of the impact is currently possible.

Current risk assessment already includes sufficient safety values

The current risk assessments within EU Regulations already include several safety factors to be considered, both in the deviation of respective, scientifically justified threshold values like DNELs (Derived No-Effect Level) or PNECs (Predicted No Effect Concentration) and in the specific risk assessment.

Besides testing on the most sensitive species, different assessment factors are used to guarantee a high safety level. The assessment factor can range from 10 to 1000.[3] Higher factors are for example used in cases of low statistical evidence, uncertainties in extrapolations or suspect of short-term effects. Vulnerable groups are also taken into account. For considerations on the exposure, the Predicted Environmental Concentration (PEC) is of high importance. The calculation of this theoretical value considers among other factors typically used amounts of the substance or mixture, specific application fields resulting in different release paths, degradation rate, and distribution possibilities. Thus, the values used to determine the risk of a substance or mixture already include several safety factors.

This conservative approach ensures a high level of protection for human health as well as for the environment which is one of the reasons why EU's REACH Regulation is used as a blueprint for chemicals' regulations worldwide. An additional, generic MAF is unnecessary and unjustified.

Within the current REACH Regulation, the calculated RCR value (Risk Characterisation Ratio) for each substance is a scientifically sound, proportionate, and appropriate value to evaluate the impact of a substance on human health or the environment. If the PCR value is >1, it is generally accepted that there may be a concern resulting in different initiatives both from authorities, industry, and users to change this circumstance. Additive effects of hazards are considered in the EU CLP classification for mixtures, these are based on an international reviewed and agreed set of classification rules under the UN GHS. Exposures to unintentional mixtures are rare and if a generic MAF would be implemented without a sound scientific justification, the credibility of both the RCR value above 1 and the UN GHS mixture hazard classification international agreement could be questioned. As a result, the motivation for actions could even decrease and thus delay changes towards alternatives with lower risk.

Unintentional mixtures are rare and linked to misused pesticides and/or pharmaceuticals

The German Federal Institute for Risk Assessment (BfR) concludes that the overall likelihood that EU consumers are confronted with unintentional mixtures is "rather low".[4] This statement is based on the fact that consumers come into contact with only a low number of substances registered under REACH which show relevant hazard profiles. The overall protection level implemented under REACH is already the highest in the world.

Investigations by the Dutch National Institute for Public Health and the Environment (RIVM) on the presence of unintentional mixtures in European freshwater revealed that unintentional mixtures were found only in 0.3 % of all observation points.[5] Of these findings, 39 % give reason for concern. However, based on the evaluation of the identified chemicals, they concluded that

[3] See also *European Chemicals Bureau: Technical Guidance Document on Risk Assessment* (download available).
[4] See also Herzler et al., Archives of Toxicology (2021), 95:2589-2601 (download available).
[5] Results presented by Emiel Rorije (RIVM) in the workshop *Support for the proposal to introduce a MAF in REACH*, organized by Wood PLC on 24 November 2021.

only 10 % of the investigated substances cause 90 % of the mixture toxicity with a mean number of 7 substances per mixture. These numbers match the results of CEFIC's study.[6]

A closer look at the included substances demonstrates the limited effect a generic MAF under REACH would have: ca. 40 % of the identified substances were said to be pesticides, an additional 15 % pharmaceuticals. Pesticides and pharmaceuticals are not in the scope of the REACH Regulation, thus a MAF would not influence their use or release into the environment.

Negative effects on human health due to unintentional mixtures have not been proven so far.

Cumulative effects can only occur in case of similar modes of actions

Besides low probability to exposure to unintentional mixtures, substances would need to have the same mode of action (MoA) to mutually reinforce the effect on human health or the environment. So far, this fact has often been neglected in the discussion of a generic MAF.

However, it is important to underline, that even in the few cases of identified unintentional mixtures, there is not automatically a reason for concern even if the included substances show hazardous properties. A simple addition of concentrations of hazardous does not take into account the diverse and partially also contradicting effects, a chemical substance may have.

Conclusion

The introduction of a generic MAF contradicts the tried and tested chemical assessment followed in the current EU chemicals regulations. To date, scientific data, different exposure levels, and different sensitivities are considered, thus applying respective assessment factors to ensure safe use of chemicals for everyone. As a result, the current EU chemicals legislation does not only offer a high level of environmental and consumer protection, but also offers reasonable decision tools for authorities and industry, on which users can rely on.

Available data demonstrate that there is no need for further tightening of the general chemical's management but targeted measures for specific substances in specific applications need to be implemented to handle concerns. The management of these concerns will not improve by introducing a generic MAF.

In Eurocolour's point of view, the proposed introduction of a generic MAF is neither reasonable nor justified. It will bring EU's industry at disadvantage and threatens many chemicals applications without any benefit for human health or the environment. Therefore, it is not the right solution for perceived issues with unintentional mixtures and should not be implemented.

[6] Results presented by Frederik Verdonck (Arche Consulting) in the workshop *Support for the proposal to introduce a MAF in REACH*, organized by Wood PLC on 24 November 2021.

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