



8 January 2021

Comments on CA/MS/91/2020: 2nd Workshop on a pragmatic approach to address the risk from combined exposure to non-intentional mixtures of chemicals – REACH as an example

General comments

The workshop was an important forum for continuing the discussion about the risks from combination effects of chemicals and we would like to thank the Dutch and Swedish Competent Authorities for their initiative.

The EU Green Deal identified the combined exposure to chemicals of people and the environment as a policy gap that needs to be filled urgently. The new EU Chemical Strategy for Sustainability (CSS) lays out the priorities for how to better protect people and the environment from the combination effects of chemicals. The related Commission staff working document is an excellent summary of the science in this field as well as the current gaps in EU regulation.¹ It acknowledges that effects of chemical mixtures need to be taken into account and that this should be integrated more generally into chemical risk assessments.

Our organisations have emphasized the need to develop an overarching approach as regards combination effects of chemicals for many years. The described actions in the CSS provide a good starting point for tackling the effects from unintentional mixtures. This will require actions under REACH as well as other regulations by 2022 and the implementation needs to achieve a higher protection of human health and the environment. In the interest of developing a clean Circular Economy it will be crucial to make the right decisions about some key principles.

¹ https://ec.europa.eu/environment/pdf/chemicals/2020/10/SWD_mixtures.pdf

Comments on issues raised in workshop summary (document CA/MS/91/2020):

1. Deriving a generic MAF

As mentioned at the workshop, we support a uniform MAF to be used in REACH registration.

We disagree with proposals for applying different MAFs as it is not feasible for authorities to engage in refinement of MAFs in site-specific conditions. Moreover, there is insufficient evidence for establishing different MAFs for health and the environment. Furthermore, we see the added value of the MAF in its generic nature given the multitude of exposure routes and situations. Applying different MAFs will be very confusing for all actors. The workshop summary rightly summarizes the majority support of the participants for a single, generic MAF as a pragmatic way forward.

There is clearly a need to decrease the burden of hazardous substances to reduce adverse impacts on health and the environment and to oblige registrants to ensure safe use - which is currently not the case when it comes to combination effects of chemicals. We therefore advocate for the introduction of a MAF to address combination effects resulting from exposure to an almost infinite number of substances via multiple exposure pathways over time. Preferred point of application of MAF is in the derivation of the DNEL/PNEC under REACH - it will be a more effective communication tool to downstream users as well as to sectors covered by other legislation (For details see earlier position paper²).

The short timeframe (2022) rightfully addresses the urgency of the matter and thereby requires a pragmatic and efficient approach which can be applied immediately. Calls for another lengthy process to finetune specific measures for each chemical and scenario would run counter to the need to control mixture exposure as identified by EU research projects over the past years.

2. Non-threshold substances

In addition to introducing a MAF in REACH registration, a focus on minimising exposure to non-threshold substances via other REACH processes will be crucial for increased protection. This includes e.g. persistent substances or substances with endocrine disrupting properties, where the usual adequate control approach cannot be applied. For these substances, the use of additional risk management measures, including group restrictions would be important. We hope that the promised 2021 roadmap to prioritise CMRs, EDCs, PBT/vPvBs and other harmful substances for generic restrictions under REACH will provide effective control measures. In addition, it should be explored further in the context of the planned

² https://chemtrust.org/wp-content/uploads/Final-NGO-comments-combination-effects-CARACAL-CA_MS_47_2020.pdf

REACH revisions by 2022, how authorisations can be improved considering the aspect of combination effects of chemicals: they should only be granted with conditions taking mixture toxicity into account.

3. Other REACH processes and other chemical legislation

The application of a MAF is now primarily discussed for the REACH registration process. Combined exposure to chemicals should also be taken into account in other REACH processes, such as Evaluation, Restriction and Authorisation as well as across other EU chemicals legislation.

4. Impact assessment

We were concerned to hear about the Commission's plan for yet another study preceding the introduction of a MAF in REACH as it will delay the process and in all likelihood will not add information that would substantially change the current understanding.

Moreover, we wonder about the usefulness of the impact assessment given that ECHA's analysis has already shown that in most cases of investigated registration dossiers the impact would not be significant. In any case if the impact assessment is carried out, it should include:

- a) The limitations of the current proposal for introducing a MAF which is only applicable to substances at tonnage levels above 10 tpa. This means the MAF will not apply to the thousands of chemicals produced in lower volumes. The assessment should include scenarios for how the current proposal could be extended to cover lower volume chemicals over time and how registrants can ensure safe use meanwhile considering combination effects of their chemicals.
- b) The limitations regarding non-threshold substances.
- c) Focus on considerations related to the benefits for human health and the environment.

Conclusion

Evidence from recent EU research projects has demonstrated that the current EU law systematically underestimates the risk from combined exposures to chemicals. It is high time to move ahead and improve the protection of human health and the environment from mixture effects!

What is needed now to deliver the promises of the European Green Deal is the political will to act upon the clear scientific warnings. It is therefore essential to establish a cross-cutting approach to address mixture toxicity, to be integrated in and applied under all relevant EU laws.