

**CHEM Trust`s Feedback on the report
Future chemical risk management – Accounting for combination effects and assessing chemicals
in groups for the Swedish government (Inquiry Chair: Cristina Rudén)**

We would like to thank the Swedish Environment Ministry for commissioning the report on [Future chemical risk management – Accounting for combination effects and assessing chemicals in groups](#). The report provides an excellent overview and gives important recommendations for how regulation should be adapted to respond to the latest scientific evidence. Current regulation of man-made chemicals – based on individual substances – systematically underestimates the health and environmental risks associated with combined exposures. It has been long overdue for the EU to agree a regulatory way forward to address and manage the risks from combined exposures to chemicals in order to increase the protection of human health and the environment.

The report comes at a crucial time when the European Commission has committed to producing a new Chemicals Strategy for Sustainability as part of its European Green Deal. The roadmap for this new Strategy includes the recognition of the need to strengthen the regulatory framework to increase the level of protection from combinations of chemicals.

CHEM Trust has been concerned about the impacts from chemicals mixtures for over a [decade](#). In real life we are all exposed to **hundreds of chemicals** from multiple sources including from food, consumer products, household dust and drinking water. The environment – rivers, oceans and countryside – is also [polluted by hundreds of different substances](#), including pesticides, plasticisers, flame retardants and pharmaceuticals. Still, current safety assessments of chemicals mainly focus on **single substances**.

At the *Workshop on a pragmatic approach to regulatory measures addressing the risk from combined exposure to chemicals – REACH as an example* co-organised by Sweden and The Netherlands in March 2020 the proposal to include a mixture assessment factor in Annex 1 of REACH was discussed. CHEM Trust supports this initiative and [presented](#) the NGO perspective on behalf of ChemSec, HEAL and EEB. Our position is described in more detail in our [joint NGO comments](#) to CARACAL and sets out the following priorities needed to address the combined effects in chemical mixtures:

1. **An overarching framework across EU laws for consideration of mixtures**
2. **Stricter risk management to minimise exposures to harmful substances of very high concern (SVHCs), in particular non-threshold SVHCs**
3. **Inclusion of an additional mixture assessment factor of 100 by default in all prospective risk assessments. This would account for the contribution of mixtures, as well as the fact that chemicals from non-REACH sectors will also have an impact on mixture exposure.**

The report **Future chemical risk management – Accounting for combination effects and assessing chemicals in groups** was written by some of the most relevant experts in the field and is an excellent compilation of the state of science and a valuable reflection of the current regulatory framework. The recommendations in Chapter 6 are very useful and well justified and should be taken forward in order to achieve a better protection from combination effects.

In line with our priorities highlighted above we see the following recommendations from the report as the most urgent to be addressed at the EU level.

#1 Establish consistent requirements for mixtures risk assessments in all pieces of regulation.

While it does make sense to include specific wording on mixtures whenever a law is up for revision, we would like to see the overall mandate for that specified in the EU chemicals strategy for sustainability as well as taken forward in Europe`s zero-pollution ambition.

#6 Use an allocation factor to account for the total risk of chemical mixtures

Human biomonitoring studies have shown exposure to many substances of very high concern (see e.g. publications from [HBM4EU](#)). Many of these are non-threshold chemicals or the uncertainties in the risk assessment are very high and therefore emission reductions and minimization of exposures is required, thus reducing also harmful mixture effects. Substitution incentives to move to safer alternatives will have to play a very important role, see also recommendation number 7 (Establish the substitution principle in all relevant pieces of legislation).

In those cases where a risk assessment is carried out we propose to use an additional mixture assessment factor of 100 which consists of two parts: A factor of 10 (combination factor) that in general will cover the toxicity for up to ten chemicals (as described in the [scoping paper](#) of the Leiden mixtures workshop). Several research papers have shown that the largest part of a mixture effect is often dominated by 5 – 10 compounds. Another factor of 10 (allocation factor) is added to cover the additional exposure from other sources to the same substance and other chemicals and further uncertainties, so in practice every source is allocated 10% of the total exposure, only. In our view it is important to include a factor that is sufficiently large to cover both components.

#8 Strengthen the mandate of REACH to mandate groups of chemicals

We agree that the increased use of grouping of chemicals is crucial, and we have illustrated this using the example of the bisphenols group in our report 'From BPA to BPZ' in 2018. In a [recent article](#) we recognize the progress made by ECHA on the 'universe of chemicals' but highlight the urgency to move to group restrictions. In our view the right place to strengthen the mandate and integrate the need to regulate chemicals in groups by default would be the upcoming EU Chemicals Strategy for Sustainability.

Together with this recommendation we also regard recommendation number 9 (Establish a system for flagging chemicals as suspected SVHCs under REACH based on group-wise assessment and read-across) as very important, in particular [for EDCs](#).

We would like to encourage the Swedish government to pursue the issue with highest urgency and advocate for clear and consistent requirements in all EU legislation for assessing and managing the risk from cumulative exposure to chemicals. We acknowledge the initiative taken by the Swedish government in 2009 leading to Council conclusions on combination effects of chemicals. Unfortunately, since then European Commission has failed to meet its obligations to address combination effects of chemicals as outlined by the 7th EAP. Addressing chemical mixture effects has been [neglected for too long](#). After years of investments in EU research projects on mixture effects, it is now high time for decision makers to act.