

Statement on the planned introduction of a generic mixture assessment factor for professional applications

Background and state of affairs

The EU Chemicals Strategy for Sustainability (CSS) aims to improve the level of protection for people and the environment alike. The focus is also on exposure resulting from unintended mixtures. Unlike intended mixtures, such as those found in products for sale, unintended mixtures result from the mixing of different chemicals from a range of sources that are unknown at the time of multi-substance exposure¹.

The proposed generic mixture assessment factor (MAF) rests on the assumption that the various chemicals in an unintended mixture amplify their adverse effects synergistically. This means that, in the event of this sort of multi-substance exposure, there would be a significant hazard potential that clearly exceeds the hazard potential associated with the individual substances. The European Commission is of the opinion that this potential increase in hazard potential due to unintended mixtures is only reflected insufficiently in the current REACH legislation. In accordance with the precautionary principle, the introduction of a generic mixture assessment factor is designed to take account of the potential increased risk – even if only insufficient scientific data is available on the specific nature and extent of the risk. The introduction of a generic mixture assessment factor is being discussed for consumers, professional users as well as for the environment. Adoption of the generic mixture assessment factor in further legislation is also a topic of discussion.

The risk assessment under REACH already includes several generic factors that take into account general remaining uncertainties when calculating the risk to humans and the environment. For example, generic safety factors for uncertainty regarding the transfer of observed effects between different species or in extrapolations between different exposure periods are already included in the risk assessment today.

Position adopted by the Committee on Hazardous Substances (AGS)

The Committee on Hazardous Substances explicitly supports the overall objective of the CSS, namely to improve the protection of professional users throughout the EU. In the Committee's opinion, occupational health and safety issues should preferably be covered by occupational health and safety regulations. This also applies to the consideration of multi-substance exposure in risk assessments in the workplace. This topic is, however, not yet sufficiently reflected in the European occupational health and safety directives. By contrast, there are already corresponding regulations in national occupational health and safety regulations today that can serve as food for thought regarding adoption in European occupational health and safety guidelines. The Committee rejects, however, a generic assessment factor for unintended mixtures in the workplace, as envisaged by the European Commission under REACH, as unsuitable and scientifically untenable.

¹ Multi-substance exposure refers to simultaneous exposure to multiple substances, irrespective of whether their number, identity, and properties are known at the time of exposure.

- The section below sets out some basic considerations for improved protection of professional users from multi-substance exposure:
 - The assessment of multi-substance exposure in the workplace should be limited to substances with a causal link to the workplace and whose risk management is therefore the responsibility of the employer. These substances are usually present in significantly higher concentrations in the workplace than is the case for background exposures from the environment, meaning that they are the primary driver of risk.
 - In cases involving multi-substance exposure for consumers, the individual substances usually originate from the environment and are unknown at the time of exposure. In principle, these substances can only be identified retrospectively, meaning that this is a difficult process. This makes the situation with consumers fundamentally different from the situation in the workplace. Statutory requirements in the EU make it mandatory for employers to be aware of hazardous substances in the workplace. This information forms the basis for the risk assessment and can also be used for the targeted risk assessment of multi-substance exposure in the workplace.
 - A specific assessment of possible multi-substance exposures requires knowledge of the workplace concerned and the hazardous substances that occur there. This information is only available in the individual businesses, which is why an adequate assessment of multi-substance exposure can only be carried out on site as part of the risk assessment process. By contrast, the REACH registrant, who is responsible for substance risk assessment, only has substance-specific data and general information on applications in the value chain. This means that a targeted assessment of multi-substance exposures in the workplace is not possible under REACH as a matter of principle.
- The European occupational health and safety directives CAD² and CMD³ have so far only addressed multi-substance exposure in the workplace indirectly. In order to continuously improve the protection of workers across the EU, the following measures are proposed:
 - An review based on existing, national regulations on multi-substance exposure in occupational health and safety to determine which measures it makes sense to incorporate at European level. In Germany, the assessment indices⁴, which are based on an additive effect of several hazardous substances, provide initial approaches for the assessment of multi-substance exposure resulting from substances with limit-based toxicity. In addition, appropriate models for the assessment of multi-substance exposures to carcinogens would need to be reviewed.
 - From a scientific perspective, the Committee believes that the assessment of multi-substance exposure requires further research. This applies, in particular, to the mechanistic clarification of adverse effects due to multi-substance exposure and the methodological further development of the relevant risk assessment.

² Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

³ Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work

⁴ Cf. TRGS 402: Identification and assessment of the risks from activities involving hazardous substances: inhalation exposure