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FEICA position on the MAF

FEICA, the Association of the European Adhesive & Sealant Industry, is a multinational association representing the European adhesive and sealant industry. Today's membership stands at 16 National Association Members, 24 Direct Company Members and 19 Affiliate Company Members. The European market for adhesives and sealants is currently worth more than 17 billion euros. With the support of its national associations and several direct and affiliated members, FEICA coordinates, represents and advocates the common interests of our industry throughout Europe. In this regard, FEICA works with all relevant stakeholders to create a mutually beneficial economic and legislative environment.

Background

FEICA acknowledges that the Commission aims to add a Mixture Assessment Factor (MAF) to Annex 1 of REACH as a way to address combined exposures to unintentional mixtures of unknown compositions.

FEICA considers that **applying a blanket Mixture Assessment Factor (MAF) to all chemicals and all uses will not improve the protection of the environment and human health**. Instead, **different MAFs should be applied to substances with different types of effects/hazards and different types of uses**.

The available data on occupational diseases does not indicate that the exposure of workers is too high in all cases and that the use of an additional MAF is justified.

The concept of a blanket MAF was also met with criticism from the scientific community. It was noted that 'Introducing measures such as the "generic approach to risk management" or a generic MAF—in their proposed generality—will clearly result in a significant quality loss of chemical risk assessment in the EU. It is foreseeable that in the end this will lead to ill-prepared regulatory proposals'.¹ Furthermore, it was stressed that 'from a scientific point of view, it would be premature and without scientifically sound basis to lower all health-based guidance or limit values through the introduction of a standard default factor in addition to the existing safety factors'.²

Existing legislation and obligations already consider exposure of workers to mixtures of substances where necessary. The use of chemicals is usually intended for workers. Therefore, a risk assessment and an implementation of risk reduction measures must take place before the work is started. Employers are obliged to also include substances which arise unintendedly into this assessment. We consider the exposure to intended mixtures as the driver for occupational risk management measures. Additionally, we do not see an indication that there is a meaningful contribution of

¹ [Herzler, M., Marx-Stoelting, P., Pirow, R. et al. The 'EU chemicals strategy for sustainability' questions regulatory toxicology as we know it: Is it all rooted in sound scientific evidence? Arch Toxicol 95, 2589–2601 \(2021\).](#)

² [Position paper of the German Society of Toxicology on the EU Chemicals Strategy for Sustainability.](#)

unintended mixtures to the toxicological hazards already identified in the risk characterisation at the workplace which would lead to the need to regard these mixtures in the respective risk assessment. **The application of an MAF may overestimate the risk for workers for most uses.**

Proposed solutions

Should different MAFs be added to Annex 1 of REACH, they should be **applied to substances that, based on their characteristics, can end up in an unintended mixture and, if so, contribute to the mixture toxicity.** Unintentional co-exposure has spatial and temporal dimensions. Because the likelihood of possible unintentional co-exposure to chemicals with respect to human health and the well-being of the environment is highest for substances that can bioaccumulate, and substances that are persistent, respectively, the **focus of MAFs should be on bioaccumulative and persistent substances that are used in high tonnages and wide dispersions.**

A MAF should not be applied to Derived No-Effect Level/Predicted No-Effect Concentration (DNEL/PNEC) values because it would therefore also apply to risk assessment for intentional mixtures and would not take into account different exposure scenarios. **Where relevant, an MAF would better fit a specific Risk Characterisation Ratio (RCR).**

Potential impact of a blanket MAF on our industry

Adhesives and sealants products typically are already covered for their various uses under REACH in the chemical safety assessment, which already comprises various safety factors. With a blanket MAF, many of the ingredients may no longer be available for our products.

We have identified the following impacts on our industry:

- Need for reformulation of mixtures
- Loss of valuable, sustainable substance uses
- Loss of efficacy of final products
- Reduction of the ingredient portfolio available to make formulations (fewer options, leading to innovation loss). Manufacturers may decide not to supply a substance any longer, with an impact on downstream users (DUs). This will be especially true if that substance is crucial to the DU sector.
- Higher level of efforts in the creation of the DU Chemical Safety Report (CSR) – high impact for SMEs
- Forcing of more Chemical Safety Assessment (CSA) done at the level of the DU or even end-user DU, who can have less expertise and fewer resources to do the assessment
- Further Safety Data Sheet (SDS) exposure scenario fragmentation
- Diversion of resources in recalculation exercises
- Unacceptable increased requirement for animal tests

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