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Proposal for the introduction of a Mixture Assessment Factor (MAF)

FEICA, the Association of the European Adhesive & Sealant Industry (A&S), is a multinational association representing the European adhesive and sealant industry. Today's membership stands at 16 National Association Members (representing 17 countries), 25 Direct Company Members and 24 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

Under the Chemical Strategy for Sustainability, the EU Commission plans to address the risks arising from the unintentional combination effects of chemical mixtures. For this reason, the Commission aims to add a Mixture Assessment Factor (MAF) for the chemical safety assessments (CSAs) of substances under REACH registration.

FEICA supports a targeted application of the MAF only for bio-accumulative and persistent substances used in high tonnages and wide, dispersive uses (see paper [FEICA position on the MAF](#) for more details). FEICA considers that a blanket MAF for all chemicals and uses will not improve the protection of the environment and human health.

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 consider different exposure scenarios. **Where relevant, a MAF would better fit a specific Risk Characterisation Ratio (RCR).**

FEICA conducted an analysis of the impacts of applying the MAF to the CSAs of substances used by A&S companies. Specifically, the analysis applies different MAF values to the human health and environmental risk characterisation ratios (RCRs) of different uses of 22 raw materials used in A&S products. If the RCR of a certain use of A&S is higher than 1, it is considered that such would not be safe anymore (see Appendix 1 about the methodologies). The following section outlines in detail the extrapolations made by RCR type.

Impacts

Human Health RCRs

The analysis considers 19 applications and related human health RCRs of substances used in adhesives and sealants products, including silicone sealants and polyurethane foams. Among these uses, 48% are industrial formulations, 26% are professional uses and 26% are consumer uses. The tables below show to what extent these uses will not be considered safe anymore in terms of the MAF value.

	All A&S products		
	MAF = 2	MAF = 5	MAF = 10
All uses	32%	74%	90%
Industrial uses	22%	56%	70%
Consumer uses	20%	100%	100%
Professional uses	60%	80%	100%

	Silicone Sealants		
	MAF = 2	MAF = 5	MAF = 10
All uses	33%	67%	84%
Industrial uses	25%	50%	75%
Consumer uses	No impact	100%	100%
Professional uses	100%	100%	100%

	PUs		
	MAF = 2	MAF = 5	MAF = 10
All uses	30%	70%	90%
Industrial uses	20%	60%	80%
Consumer uses	No impact	100%	100%
Professional uses	66%	66%	100%

The evaluation shows that with a resultant MAF of ≥ 5 , most uses would no longer be considered safe. Moreover, even with a MAF of 2, most professional applications (more than 60% of the sample size) would be severely affected.

Overall, A&S companies might need to take action to demonstrate safe use for those applications with human health RCRs > 1 . Additional risk management measures (RMMs), e.g., respiratory masks, could be implemented for industrial and professional application; however, it is uncertain whether such measures would actually demonstrate safe use. It is likely that it would not be possible to implement additional risk management measures for consumer uses.

Environmental RCRs

The analysis assesses the impacts of the MAF for 37 uses (28 industrial uses and 9 widespread uses). Different MAF values have been applied to environmental RCRs based on tier 1 assessments; the table below summarises the outcome of the analysis.

	MAF = 2	MAF = 5	MAF = 10	MAF = 100
Industrial Uses	14%	35%	46%	89%
Widespread Uses	9%	9%	14%	27%

It is noted that the environmental risk assessment could be refined to demonstrate safe use for those uses with RCR > 1 , but this is questionable in practice as registrants might lack knowledge of how substances are used downstream in the supply chain. In addition, the refinement of environmental risk assessments is particularly challenging for widespread consumer and professional uses since additional risk management measures are unlikely to be implementable.

Conclusion

FEICA supports a targeted application of the MAF which should be only for environmental risks and for bio-accumulative and persistent substances used in high tonnages and wide, dispersive uses.

In this regard, the scientific community¹ has stressed that **a blanket application of the MAF would be premature and without a scientifically sound basis**. Instead, the risks arising from exposure to unintentional mixtures are relevant only for those mixtures of substances released into the environment that are likely to remain in the environment (e.g., PBTs, vPvBs).

In addition, existing legislation and obligations already consider exposure of workers to mixtures of substances where necessary, and there is no indication that there is a meaningful contribution of 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. Therefore, the application of a MAF may overestimate the risk for workers for most uses.

FEICA notes that a blanket application of the MAF (even with low MAF values, e.g. MAF = 2) would severely affect the adhesives and sealants sectors, with many industrial, professional and consumer uses not considered safe anymore.

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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?

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Appendix 1 – Methodologies

Human health RCRs

The proportion of uses that will not be considered safe anymore has been estimated by multiplying the RCR of a certain use of a certain raw material in A&S by a certain MAF value. An example below, which considers the application of different MAF values to the RCRs of a cross-linking agent used in silicone sealants, is provided for explanatory purposes.

Changes of current RCR values (baseline) of a cross-linking agent used in silicone sealants, based on different MAFs

	Baseline	MAF = 2	MAF = 5	MAF = 10	Impacts
Industrial uses (Mixing)	0,952	1,90	4,76	9,52	<ul style="list-style-type: none">Respiratory masks might be implemented to demonstrate safe useNote: Industrial users already use protective gloves
Professional uses (Roller application or brushing)	0,582	1,16	2,91	5,82	<ul style="list-style-type: none">Respiratory masks might be implemented to demonstrate safe use
Consumer uses	0,486	0,97	2,43	4,86	<ul style="list-style-type: none">Consumer uses of silicone sealants would not be allowed anymore with a MAF of 5 and 10

● RCR above 1, use is not considered safe anymore ● RCR close to 1

Based on the example:

With a MAF of ≥ 2 professional and industrial applications of silicone sealants would not be considered safe anymore

Additional RMMs could be implemented for professional and industrial users (e.g. respiratory masks). It is uncertain whether such RMMs would demonstrate safe use

With a MAF of ≥ 5 , consumer applications of silicone sealants would not be considered safe anymore. It would not be possible to implement additional RMMs to demonstrate safe use for such applications.

Environmental RCRs

The assessment considers six environmental compartments for each use of a raw material in an A&S application. Specifically, the environmental compartments are:

- Sewage treatment plant
- Water
- Water sediment
- Soil
- Marine water
- Marine sediment

For each environmental compartment there is an RCR. If one RCR is higher than 1, then the use is not considered safe anymore.