Cross industry request for a phased implementation of the Mixture Allocation Factor (MAF)

Necessary elements for downstream users to manage MAF impacts:

- Gradual implementation of the MAF with a clear roadmap.
- Allow realistic timelines for implementation.
- Focus on substances with the greatest potential to contribute to unintentional co-exposure.

The undersigned industry sectors, representing 22.5 million SMEs, express our concerns with regards to the Commission's plans on the Mixture Allocation Factor, as presented at the 48th Meeting of Competent Authorities for REACH and CLP.

Even a proposed MAF of 5 for substances registered at ≥1,000 t/y, with the (limited) option of a specific risk assessment, will have substantial impacts along the entire chemicals value chain, with serious knock-on effects on EU competitiveness and sustainability-driven innovations but without a wide positive outcome on the safer use of chemicals. These impacts cannot always be mitigated. A blanket approach when applying a MAF will affect all chemical substances with unintended negative consequences for high-performing and already safe substances and mixtures.

Furthermore, the lack of transition periods for mixtures and downstream products means that the impact would occur from one day to the next. For mixtures, examples developed by DUCC show **that the majority of uses, currently confirmed to be safe, will be impacted**. Impacts on mixtures will have **knock-on consequences on other downstream industry sectors**.

In order to identify the impacts on their portfolio, companies need to identify the Exposure Scenarios where the Risk Characterisation Ratios (RCRs) are currently ≥0.2. In many cases this can only be done by manually opening each exposure scenario and can be a highly demanding process.

Upon discovering that a use is formally no longer considered as safe, downstream users will need to:

i) Engage with their suppliers to understand, if a risk assessment can be refined in order to update the CSR (to be done by manufacturers/importers)

ii) In case the manufacturer/importer cannot refine the assessment or is not willing to support certain uses:
   a. Assess if additional Risk Management Measures (RMMs) could be appropriate for their product use
   b. Prepare their own downstream user Chemical Safety Report (CSR) (**12 months, reference Articles 37 and 39 of REACH**). This step can be difficult for companies without the adequate expertise.
   c. Potentially find an alternative to a substance (**assessment of alternatives can take 10 years or more in some cases)**
   d. Cease the use of the substance, if no alternative can be identified (without an alternative, uses of the mixtures containing this substance will disappear from the market).

Refinement of the Risk Assessment – Supply Chain Communication

The first step a downstream user will take upon discovering that a use is no longer considered safe due to implementation of a MAF, or that the conditions of use have been adapted to be unrealistic, is to contact their supplier. There will be a discussion on possible refinement of the exposure values such as the PEC or the hazard values such as the PNECs/DNELs.

Refinement of the PEC/exposure:

Refinement of the PEC requires an efficient/ transparent exchange in the supply chain to identify if different refinement models can be used, to obtain information on local release data from larger sites, understand the fate of waste or specific site sludge production from individual sites. Since the beginning of REACH, DUCC has been active in the creation of tools to support the risk assessment of substances (e.g. Use Maps / ECETOC TRA) that would allow the risk assessment of the majority of substances, using simple tools that have inherent conservatism, to support the industry and especially the work of SMEs. Using more refined models requires expertise to share and process information. It can be difficult, especially for smaller companies.

Refinement of the hazard values, PNECs/DNELs:

A proportional timeframe is necessary for impact assessment refinement in connection with the implementation of the MAF, as this may trigger the need for additional higher-tier studies to refine the PNEC (Predicted No Effect Concentration) and/or DNEL (Derived No Effect Level) within the CSR (Chemical Safety Report).The implementation of the MAF will trigger the need for the refinement of DNEL's and PNEC's with studies exceeding the current REACH requirements for the specific tonnage bands. For example, an OECD 443 Extended One-Generation Reproductive Toxicity Study, which is not a standard requirement at 100-1000 t, could be necessary to sufficiently refine the hazard value resulting in an increased need for animal testing. Refining the PNECs could involve the calculation of a 'probabilistic PNEC' which would require 10 chronic tests to be run, over more than 2 years. Contract Research Organisations (CROs) need to be given adequate time to conduct chronic studies, and it is essential to consider the timing constraints associated with higher-tier studies as well as implications for use of animals.

Necessary elements in REACH for downstream users to manage MAF impacts:

SMEunited and DUCC strongly question the rationale for applying a MAF to all substances. Unintentional co-exposure has spatial and temporal dimensions and is relevant in situations where substances have common modes of action and are used in medium or high dose levels. In all other cases the blanket MAF will simply result in an impact without benefits to end-users and society.

It will be impossible for any company – particularly for SMEs - to manage an impact on such a wide number of uses without sufficient time. Therefore, if a MAF must be implemented under REACH due to a political decision, the undersigned sectors ask for a **phased, stepwise, implementation of a MAF, through the establishment of a roadmap.** We deem logical to **start MAF implementation with substances with the greatest potential to contribute to unintentional co-exposure.**

A timeframe of **at least 36 months** should be given from the point the downstream user receives information from a chemical supplier to allow said downstream user to implement and refine the risk assessments based on the new information received.

These elements will be key to mitigate the most severe impacts of a MAF.

Since the European industry is currently in a very intensive process of transition, the Mixture Allocation Factor would be only one of the different elements to be implemented by industry actors due to the Chemicals Strategy for Sustainability. Taken together these changes will require substantial defensive R&D efforts to reformulate (where possible) already safe mixtures – severely constraining industry's capacity for proactive sustainability-driven innovations. A lack of transition periods would severely exacerbate this challenge. Sufficient time will be needed to implement all of the envisaged regulatory changes, especially in the case of SMEs, and this is what we are asking for.

Kind regards,

Downstream Users of Chemicals Co-ordination group

The Downstream Users of Chemicals Co-ordination Group (DUCC) is a platform of 11 European associations which represent "downstream" industries ranging from cosmetics and detergents to aerosols, paints, inks, toners, pressroom chemicals, adhesives and sealants, construction chemicals, fragrances, lubricants, crop protection and chemical distributors industries.

CRAFTS & SMEs IN EUROPE

SMEunited is the association of Crafts and SMEs in Europe with around 70 member organisations from over 30 European countries. It represents national cross-sectoral SME federations, European SME branch organisations and associate members.

SMEunited is a recognised employers' organisation and European Social Partner.