

Mixture Assessment Factor (MAF)

DUCC Statement

A blanket MAF will have substantial impacts on downstream users with serious knock-on effects on EU competitiveness. These impacts cannot always be mitigated. Via a blanket approach these impacts will apply across all chemical substances. **All formulations will need to be reviewed.** In addition, given the lack of transition periods for mixtures the impact will occur from one day to the next.

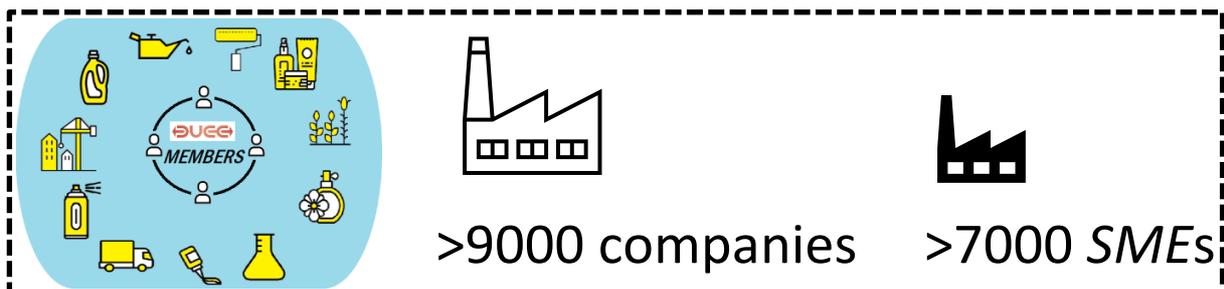
In this document, DUCC shares **examples** to demonstrate that blanket MAF values of 10 and lower will affect a wide range of sectors, on valuable, sustainable substance uses, animal testing, employment in Europe and EU competitiveness. The list of examples is not exhaustive but aims to show the collective impacts on different EU industries.

A lower MAF value and a more targeted approach, focussing on what matters, will allow the objective of addressing unintended mixtures while still permitting the resources of industry to be targeted and well directed towards reaching the objectives of the Green Deal.

The MAF should be applied only to substances that, based on their situation and characteristics, can end up in an unintended mixture and, if so, contribute to the mixture toxicity.

- DUCC questions whether there are co-exposure data that justify application of MAF in professional settings. Users of this category covered by the OSH legislation are protected by control measures, prevention and monitoring which consider all risks, including those of co-exposure. **DUCC calls for the MAF not to be applied to professional uses.**
- Unintentional co-exposure has spatial and temporal dimensions. Because the likelihood of possible unintentional co-exposure to chemicals for Human Health and to the Environment is highest for **substances that can bioaccumulate**, and substances that are **persistent**, respectively, the focus of MAF should be on PBTs that are used in **high tonnages** and **wide dispersive uses**.

A MAF will apply equally to companies of all sizes, but SMEs will have fewer possibilities to mitigate blanket measures. DUCC represents 9,000 companies, 7,000 of which are SMEs.





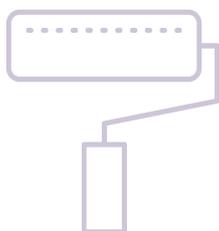
Downstream Users of Chemicals Co-ordination group

A blanket MAF of 10 leads to the following impacts in these example sectors and uses



Crop protection Worker spray application

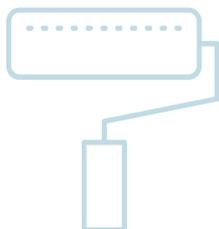
- **Increase of 34% of substances failing risk assessment screening. 7X increase from the baseline for human health**
- **Increase of 40% of substances failing risk assessment screening. 2X increase from the baseline for environment**
- **As a result, many products would need further high tier testing (range 27840 - 66240 fish) and face drastic re-registration costs, leading to potential losses of tools for farmers.**



Decorative paints:

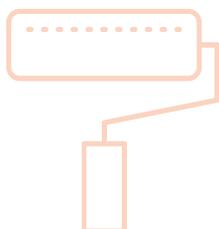
(considering solvents, additives, curing and cleaning agents)

- **92% loss** for professional decorative paints
- **76% loss** for consumer decorative paints



Marine protective coatings:

- **91% loss** for PROC 5 and 8a (mixing and transfer of substances)
- **100% loss** for PROC 10 (roller application)
- **100% loss** for PROC 11 (spray application)
- **100% loss** for consumer use



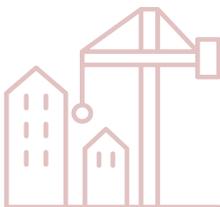
Professional application by brush/roller , indoor with basic room ventilation or outdoor with no RPE:

- **82% loss** of solvents that can be used at 5-25% concentration
- **86% loss** of solvents that can be used at 1-5% concentration
- **46% loss** of solvents that can be used at <1% concentration
- **93% loss** of additives that can be used at <1% concentration



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Construction Products



- For construction products a **similar impact is expected to that of coatings** (see above). These industries utilize similar chemistries (polyurethane and epoxy-resins), which could be similarly impacted by a MAF.

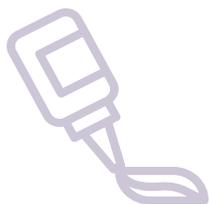
19 applications of Adhesives and sealants (considering human health RCRs)



- **70% loss** of safe uses for industrial applications
- **100% loss** of safe uses for consumer application
- **100% loss** of safe uses for professional applications

Silicone sealants

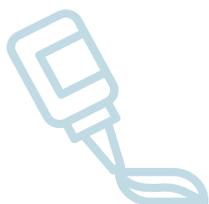
(considering human health RCRs)



- **75% loss** for industrial uses
- **100% loss** for consumer uses
- **100% loss** for professional uses

Polyurethanes/ PUs

(considering human health RCRs)



- **80% loss** for industrial uses
- **100% loss** for consumer uses
- **100% loss** for professional uses



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Detergents - Use of 4 substances: linear alkylbenzene sulfonates (LAS), enzymes, preservatives and sodium hydroxide (NaOH) :

- **Turnover loss ranging 1.5 - 3 billion € in 2040**, central estimate of turnover 17% lower (2 billion)
- **1,500-4,300 fewer jobs in 2040**, central estimate of 7% lower employment (2,400 jobs lost)



Detergent Formulations with NaOH :

- **37% turnover losses** (already considering a reformulation of 27% of affected products)
- **16% estimated employment losses for category**



Detergents Formulations with substances: LAS, Enzymes:

- **30% turnover losses** (already considering a reformulation of 31% of affected products)
- **13% estimated employment losses for category**



Detergent Formulations with substances: LAS, Enzymes and preservatives:

- **22% turnover losses** (already considering a reformulation of 52% of affected product)
- **10% estimated employment losses for category**



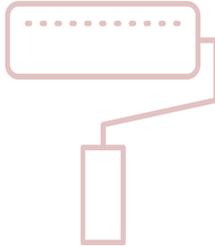
Fragrance use of 4 common ingredients:

- Central estimate of **1.3 billion € turnover losses** in 2040, already considering actions for refinement (e.g. using more refined risk assessment tools, addition of RMMs, reduction of site tonnage)
- Additional in vivo animal testing to reduce the RCRs



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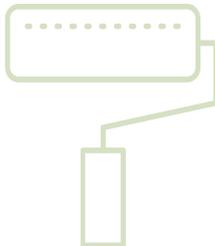
A blanket MAF of 5 leads to the following impacts in these examples sectors and uses



Decorative paints:

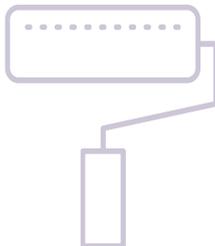
(considering solvents, additives, curing and cleaning agents)

- **85% loss** for professional decorative paints
- **76% loss** for consumer decorative paints



Marine protective coatings:

- **77% loss** for PROC 5 and 8a (mixing and transfer of substances)
- **92% loss** for PROC 10 (roller application)
- **100% loss** for PROC 11 (spray application)
- **100% loss** for consumer use



Professional application by brush/roller , indoor with basic room ventilation or outdoor with no RPE:

- **69% loss** of solvents that can be used at 5-25% concentration
- **43% loss** of solvents that can be used at 1-5% concentration
- **19% loss** of solvents that can be used at <1% concentration
- **86% loss** of additives that can be used at <1% concentration



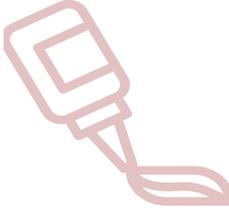
19 applications of Adhesives and sealants (considering human health RCRs)

- **56% loss** of safe uses for industrial applications
- **100% loss** of safe uses for consumer applications
- **80% loss** of safe uses for professional applications



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Silicone sealants



(considering human health RCRs)

- **50% loss** for industrial uses
- **100% loss** for consumer uses
- **100% loss** for professional uses

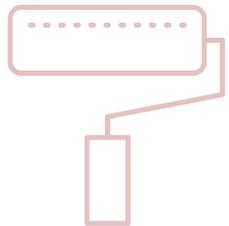
Polyurethanes/ PUs



(considering human health RCRs)

- **60% loss** for industrial uses
- **100% loss** for consumer uses
- **66% loss** for professional uses

A blanket MAF of 3 leads to the following impacts in these examples sectors and uses



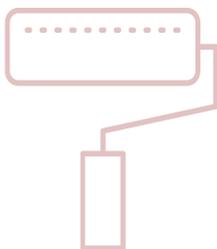
Professional application by brush/roller , indoor with basic room ventilation or outdoor with no RPE:

- **43% loss** of solvents that can be used at 5-25% concentration
- **29% loss** of solvents that can be used at 1-5% concentration
- **14% loss** of solvents that can be used at <1% concentration
- **75% loss** of additives that can be used at <1% concentration



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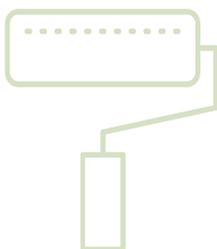
A blanket MAF of 2 leads to the following impacts in these examples sectors and uses



Decorative paints

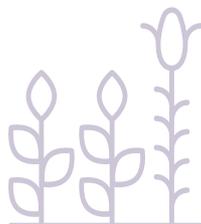
(considering solvents, additives, curing and cleaning agents)

- **62% loss** for professional decorative paints
- **52% loss** for consumer decorative paints



Marine protective coatings:

- **51% loss** for PROC 5 and 8a (mixing and transfer of substances)
- **51% loss** for PROC 10 (roller application)
- **84% loss** for PROC 11 (spray application)
- **84% loss** for consumer use



Crop protection Worker spray application

- **Increase by 6% of substances failing risk assessment screening from the baseline for human health**
- **Increase by 10% of substances failing risk assessment screening for environment**

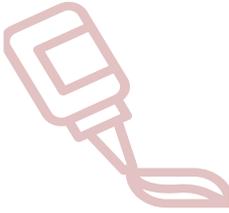


19 applications of Adhesives and sealants (considering human health RCRs)

- **22% loss** of safe uses for industrial applications
- **20% loss** of safe uses for consumer applications
- **60% loss** of safe uses for professional applications



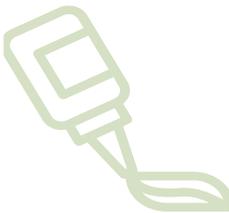
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Silicone sealants

(considering human health RCRs)

- **25% loss** for industrial uses
- **No impact** for consumer uses
- **100% loss** for professional uses



Polyurethanes/ PUs

(considering human health RCRs)

- **20% loss** for industrial uses
- **No impact** for consumer uses
- **66% loss** for professional uses

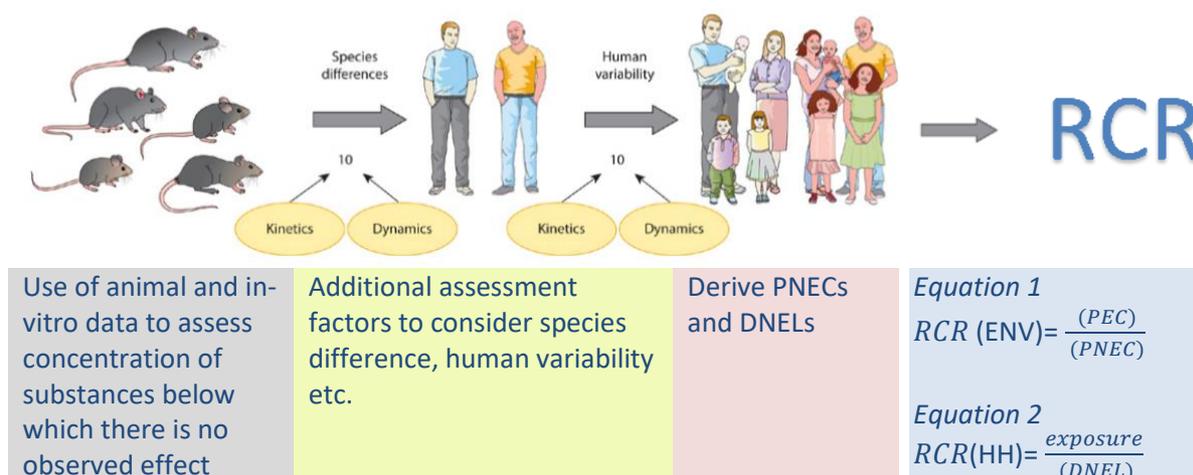
Can the RCR be refined?

In current chemical safety assessments (CSAs), Risk Characterisation Ratios (RCRs) for single substances are calculated and used to manage the risks that use of these substances may pose to human health and the environment. RCRs are ratios between exposure levels and no-effect concentrations.

For the environment, these concentrations are the predicted environmental concentration (PEC) and predicted no-effect concentration (PNEC) – i.e. concentration of a substance below which adverse effects are unlikely to occur. See Equation 1.

For human health, RCRs are calculated using equivalent values: estimated exposure levels for a given exposure pattern, and derived no-effect levels (DNELs). The DNEL value is calculated by dividing a health effect dose descriptor (e.g. a no-observed-adverse-effect level) by assessment factors. See Equation 2.

Image 1: Schematic representation for the calculation of PNECs, DNELs and RCR ¹



Given the impacts of a blanket MAF value, the question has been raised regarding whether the RCR in these cases can be refined through other means. However, based on our assessment, in many of the situations presented this is by no means an easy solution and can have ethical questions related to animal testing:

- For the CEPE Decorative paint examples above, all these were high tier assessments already taking into account RMM such as LEV and PPE.
- For the CropLife Europe examples, in almost 1/3rd of the cases the assessed co-formulants already have a full complement of long-term aquatic tox data, and PNEC cannot be refined. In cases when PNECs could be refined this will have implications on animal testing.
- The figures presented by the A.I.S.E. case study already consider potential actions of refinement by the downstream user.
- The FEICA examples considered the possibility of implementing additional RMM, but this would be unlikely for consumer uses.

¹ Image from Casarett & Doull's Essentials of Toxicology, Third Edition, Curtis D. Klaassen, John B. Watkins, Acquired on 20 June 2022



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MAF – benefits?

DUCC strongly questions the benefits of a blanket MAF approach.

We cite the paper published by the German Federal Institute for Risk Assessment (BfR), which concluded that *“with all its associated uncertainties, seems to hint at a rather low likelihood that EU consumers are currently confronted with significant health risks from the exposure to unintentional/coincidental mixtures.”*² Based on their analysis the MAF will only be of benefit for 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.

For this reason, to have a more proportionate and effective route that avails of the benefits and reduces impact, DUCC is proposing a targeted approach to the MAF.

What are some of the other impacts of a blanket MAF?

Finally, in addition to the examples outlined in this document, DUCC presents some of the other impacts of a blanket MAF:

- To account for a blanket MAF companies may decrease substance concentration to ensure RCRs are below 1 resulting in less effective products. Customers may respond with compensating behaviors, for example by using more of a product. There is also an expectation that consumers may switch to better performing non-EU products that may still be accessible to them through online sales.
- Professionals will suddenly be required to use more PPE. This may cause workers to disregard the measures as these could be seen as disproportionate.
- A need to reformulate many mixtures, accompanied by a 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.
- Removal from the market of safely used, sustainable applications. Potential worsening of the competitiveness of the EU-27 industry and a shift towards increasing imports of final products, increasing the dependency on third countries for chemical substances and/or products previously manufactured and used in supply chains across the EU³.
- Forcing more CSA done at DU or even end-user DU level, who can have less expertise and resources to do them. Higher level of efforts of the creation of DU CSR – high impact for SMEs
- Increase in administrative work. Diversion (waste) of resources in recalculation exercises.
- Under some regulations product dossiers will need to be resubmitted with increased costs
- All RCRs for substances will need to be recalculated. This means that safe levels for all substances will need to be recalculated.

² Archives of Toxicology (2021) 95:2589–2601 The “EU chemicals strategy for sustainability” questions regulatory toxicology as we know it: is it all rooted in sound scientific evidence? <https://doi.org/10.1007/s00204-021-03091-3>

³ CEFIC Economic Analysis of the Impacts of the Chemicals Strategy for Sustainability – Case study: Mixture Assessment Factor (2022) ED 14790, Issue 1



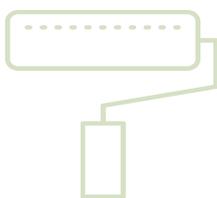
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How were these numbers derived?

You can find more details for each sector via the links:



The Assessment of CropLife Europe has been done using public databases of co-formulants. Please contact Kevin Heylen for more details ([kevin.heylen\[at\]croplifeeurope.eu](mailto:kevin.heylen@croplifeeurope.eu))



The CEPE assessment was carried out using data from CEPE members and more details were published in the REACH Open Public Consultation.

https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12959-Chemicals-legislation-revision-of-REACH-Regulation-to-help-achieve-a-toxic-free-environment/public-consultation_en



A.I.S.E. analysis carried out by Ricardo PLC:

<https://www.aise.eu/cust/documentrequest.aspx?UID=72880e45-ba8a-4686-abf8-03b70665bff2>



IFRA analysis carried out by Ricardo PLC:

https://ifrafragrance.org/docs/default-source/green-deal-and-css/ifra-economic-analysis-of-the-impacts-of-the-css---maf-case-study-final-25-may-2022.pdf?sfvrsn=48151c67_2



FEICA analysis with further details:

https://www.feica.eu/information-center/all-information-centre/preview/1214/proposal-introduction-maf?id=b98072be-d6f4-4c07-9622-28f6d7cf7725&filename=POP-EX-M01-003_Proposal+for+the+introduction+of+a+MAF.pdf