Progress with the multi-year Metals Environmental Exposure Data Program (MEED) to anticipate the challenges of the EU Zero Pollution Ambition Policy (ZPAP) and the Chemicals Strategy for Sustainability (CSS)

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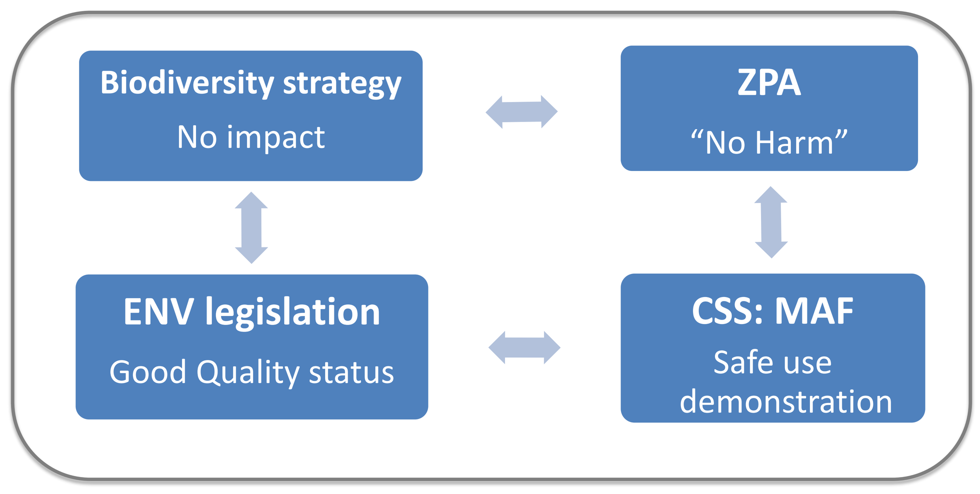
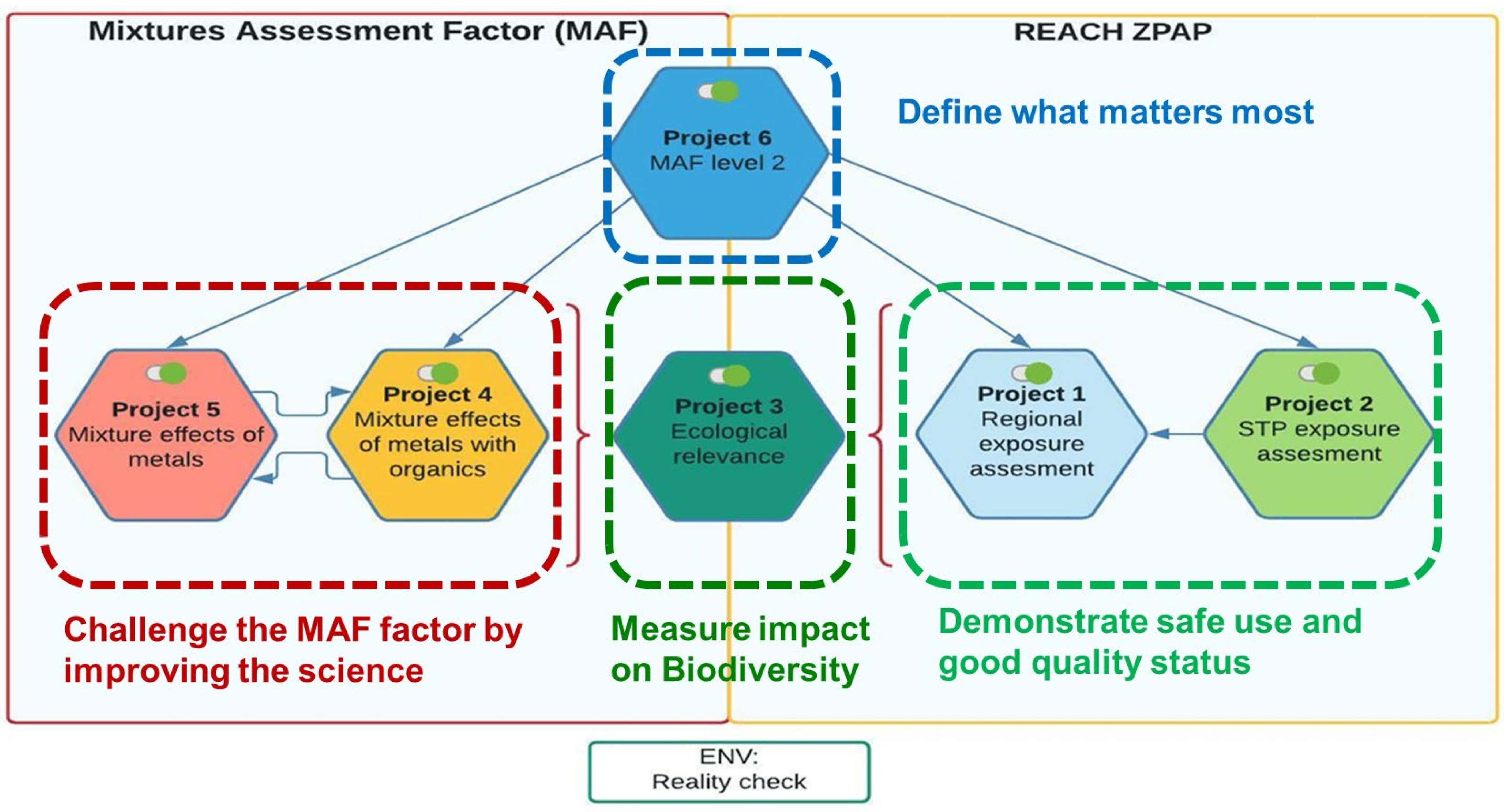
Background

The **Chemicals Strategy for Sustainability (CSS)** a key building block of the Green Deal, is a main pillar of the EU Zero Pollution Ambition (ZPA). The CSS aims to *achieve **good quality status** of the environment by reaching exposure levels of chemicals that are no longer harmful to health and the environment*. This challenges chemicals and environmental regulations given focused on ***substance specific assessments and limits***. Aspects like ***combined effects*** of chemicals in the environment and assuring they ***do not affect bio-diversity*** need therefore to be included in regulatory schemes. Although postponed, the EU proposes the introduction of a **Mixture Allocation Factor (MAF) to demonstrate safe use** and lack of impact on ecosystems from the cocktail of chemical exposures. This is a real scientific challenge for the EU metals industry, given their natural background and increasing use in Green Deal applications like EV batteries, solar cells, windmills and electronics. This challenge drove the sector to design a comprehensive "*Metals Environmental Exposure gathering Programme*" (**MEED**), including the development of scientific concepts and targeted test work, to assess combined exposure and its impact on Biodiversity. The aim is to timely comply with the objectives of the ZPAP and the EU biodiversity strategy. Its timeline (2022-'26) allows to feed the outcomes into ongoing regulatory debates (e.g., REACH 2.0, ZPAP, revision Soil & Water frameworks).

Anticipated regulatory protection objectives by MEED



Pillars (objectives) of the MEED program



Overall structure of the MEED program

Pillar 1 (project 6) Define what matters most
- Define I-PCS "**Inorganic-Priority Contributing Substances**" (P6) to provide focus and efficiency

Pillar 2 (Project 1 & 2) Update regional exposure levels
- Map **today's metal concentrations** and combined risks across the EU, trends & predicted future concentrations due to volume increase (P1) for as many metals as possible
- Improve the assessments of **consumer and professional releases**, given a weak link (P2)

Pillar 3 (Project 4 and 5) Assess impact mixture effects
- Review of **existing knowledge** on metal mixtures and metal-organic mixture interactions
- **Design smart testing program** to fill I-PCS mixture gaps
- **Implement testing** on Cladocera (*Dapnia magna)* and Algae (*Raphidocelis subcapitata*) on metal-metal and metal-organics mixtures

Pillar 4 (Project 3): Measuer potential impact on Biodiversity
- Provide **toolbox** to assess impact on Biodiversity
- Run **pilot trials** to develop efficient assessment

Pillar 5: Define alternative concepts to MAF
- **Science based** tiered alternative approaches
- Applicable for different **regulatory schemes**

Some results so far

Project 1: Regional exposure update

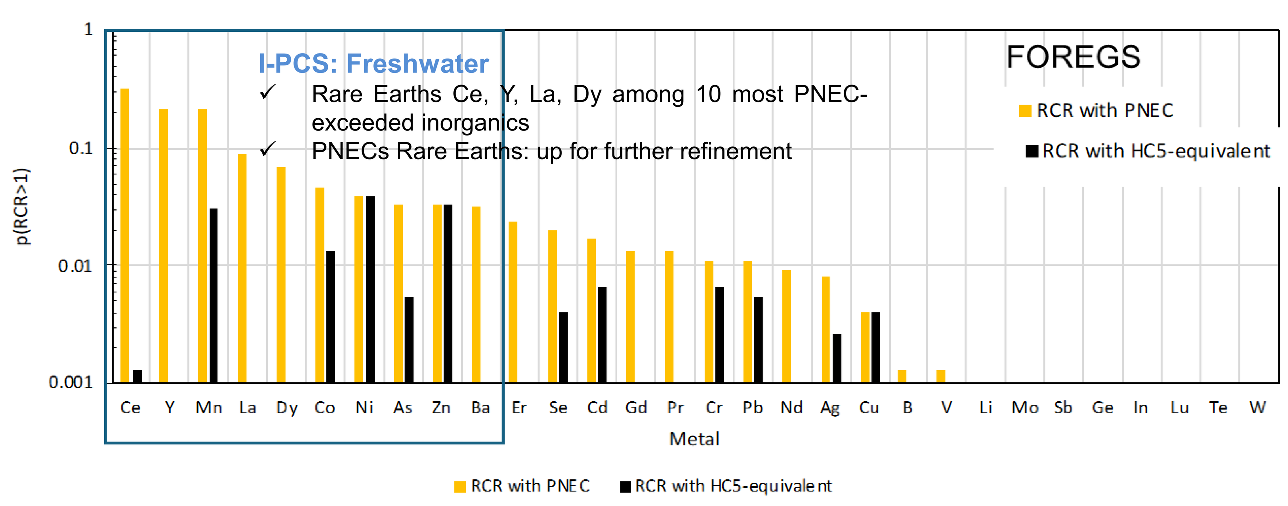
Table 1: Inorganics in the Waterbase (surface water) and number of samples before and after data processing.

Inorganic	Before data processing	After data processing
Ag	20 954	5 595
As	189 824	163 341
Ba	35 274	33 917
B	48 674	40 102
Cd	278 072	233 094
Co	45 785	30 033
Cr	222 037	185 970
Cu	245 462	184 935
Hg	212 579	178 944
Li	1 783	489
Mn	95 172	71 170
Mo	25 465	25 342
Ni	275 291	240 689
Pb	280 208	241 503
Sb	30 551	30 145
Se	49 235	37 156
Ti	14 749	14 267
V	55 094	49 220
Zn	210 488	145 225

Metal samples in Waterbase

Interpretation: Extensive existing monitoring datasets. Data quality (LOQ) and lacking data on critical metals relevant for the Green Deal (e.g. lithium, Rare Earths) remains a challenge.

Project 6: I-PCS

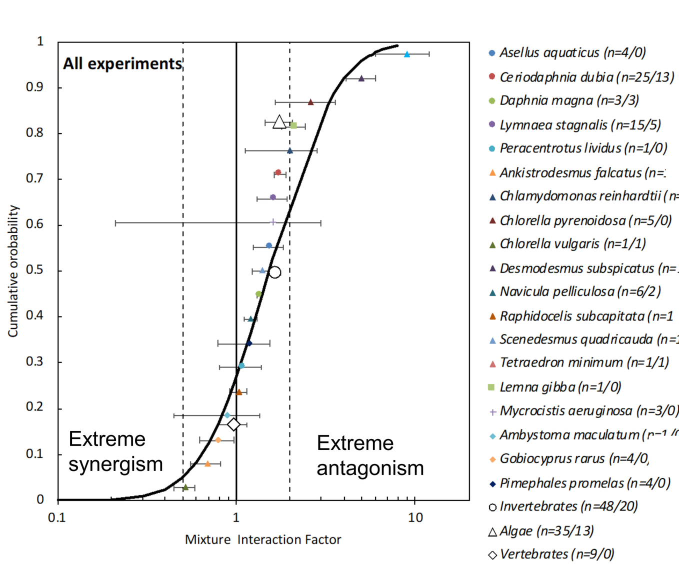


Category	Criterion	Refined I-PCS selection
Usually risk drivers in mixtures	Contributing to the 90th percentile of the Hazard Index (HI) in >50% of the mixtures	As, Ba, **Ce**, Co, Cu, **Dy**, Mn, Ni, Se, **Y**, Zn
Sometimes risk drivers in mixtures	Contributing to the 90th percentile to HI in ≥10-50% of the mixtures	Ag, Cd, Cr, **Er**, **Gd**, **La**, Pb, V
Usually not risk drivers in mixtures	None of the above	B, Ge In, Li, **Lu**, Mo, **Nd**, **Pr**, Sb, Te, **W**, Zr

Project 5 : Literature reappraisal metal-mixtures

Accuracy of CA in predicting mixture effects at low effect concentrations?

MIF - per experiment (n=92)



Mixture Interaction Factor = *degree of conservatism that **concentration addition (CA;*** standard regulatory mixture model) provides relative to observed mixture effects at low effect levels (i.e. 10% mixture effect)
MIF < 1 = synergism
MIF > 1 = antagonism

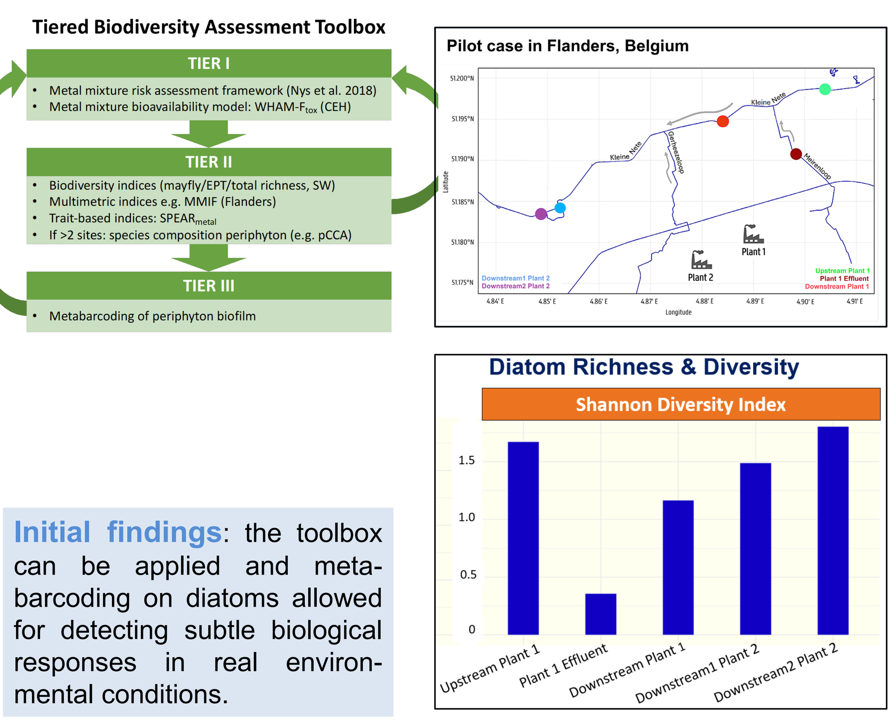
$$MIF = EC10_{\sum TU_{EC10}}$$

with $\sum TU_{EC10} = \sum \frac{x_{Me_i}}{EC10_{Me_i}}$

- **Median MIF = 1.3**
- MIF ranged between 0.52 (*Chlorella vulgaris)* and 8.93 (*Tetraedron minimum)*
- No strong synergisms (MIF<0.5)

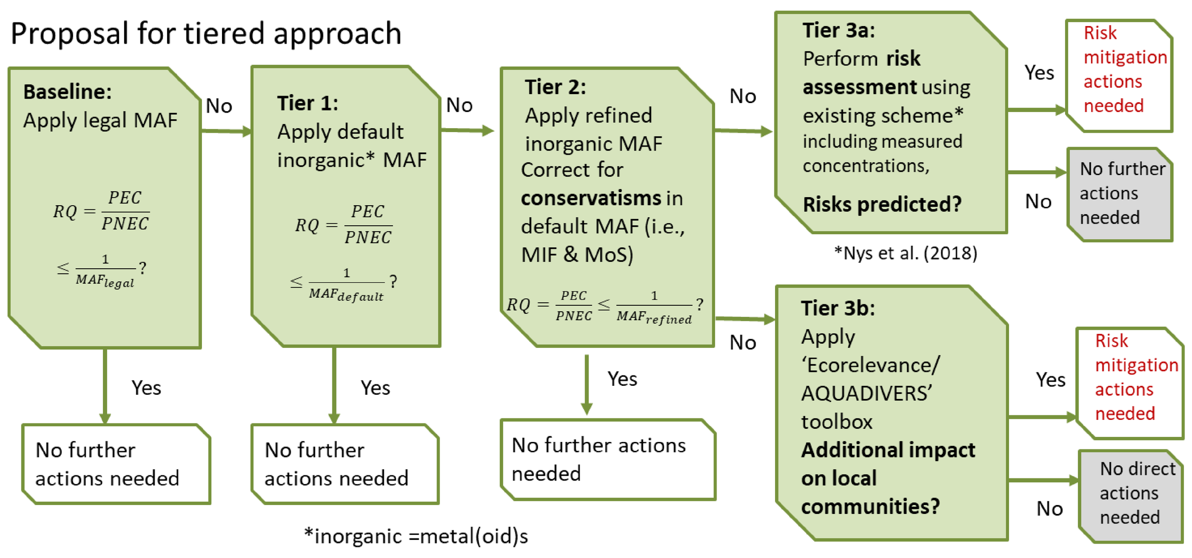
Conclusion: CA seems to overestimate mixture toxicity by 1.3-fold

Project 3: developing a pilot tool for Biodiversity impact assessment °



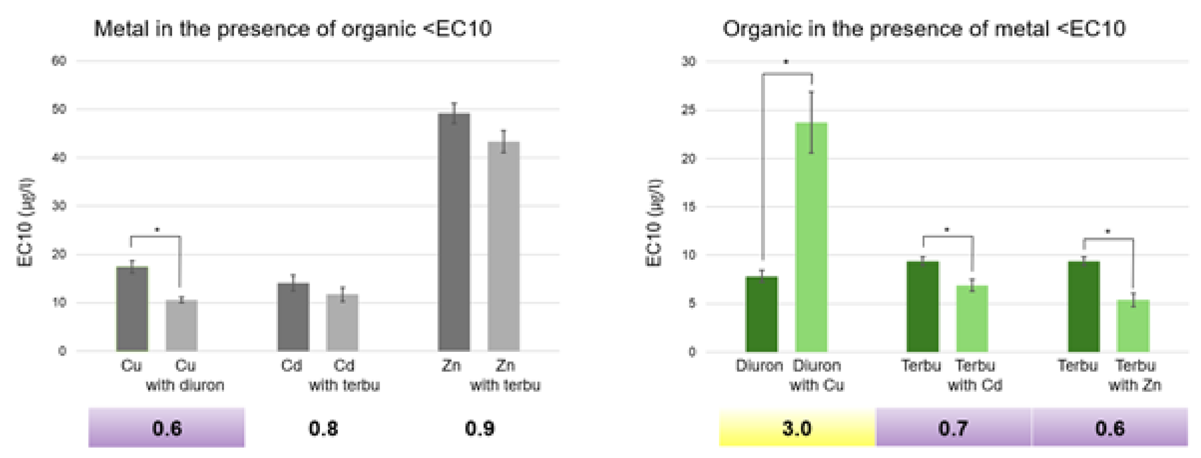
Initial findings: the toolbox can be applied and meta-barcoding on diatoms allowed for detecting subtle biological responses in real environ-mental conditions.

Pillar 5: defining alternative concepts to MAF °°



State of play: the **outcome of the MEED program** allows for designing and applying an **alternative science based approach** to the EU-MAF approach, to assess the impact of combined exposure at regional and local level. It is recommended to discuss and develop this approach further in a series of workshops.

Project 5: First outcome testwork on M-O mixtures °°°



Comparisons between the metal or the organic tested individually and in the presence of low concentrations (half the EC10) of the selected organic or metal. Outcome is expressed as the ratio by which the toxicity was either increased or inhibited by the presence at low concentrations of the other substance.

Initial findings: Metals at no-effect concentrations may influence the toxicity of specific herbicides requiring further investigations for which modes of actions this could apply.

Detailed SETAC-Vienna Posters: ° 1.04.P-We018 by Vanessa Moreira ; °° 6.07.P - Tu471 by Charlotte Nys ; °°° 3.04.B.T-05 by Maria Laura De Donno

Conclusions on MEED so far

- ✓ **Metal volumes** manufactured, used and recycled, will increase significantly due to the Green Deal objectives, hence questioning the combined impact on water, soil, and on Biodiversity.
- ✓ **MEED aims** to collect up to date exposure evidence to anticipate the ZPA, MAF and new and updated EU environmental compartment legislations
- ✓ **Aquatic, soil and sediment regional monitoring data**sets for a long series of metals were collected and checked for metals combined concentrations and priority risks drivers. Datasets for some metals that are key for the Green Deal like Li and Rare Earths are limited or lacking while being potential risk drivers, but improvement of environmental threshold level feasible.
- ✓ The **Mixture Interaction Factor (MIF)** allows to define the level of conservatism provided by the Concentration Addition model
- ✓ The literature on metals mixtures (MMs) and metal-organic mixtures (MO's) was **reviewed and reappraised demonstrating** that MIFs for metals mixtures are on average larger than 1 (median MIF 1.3), hence leaning more to antagonistic than synergistic. The complementary smart testing design showed MIF's >1 for MM's but mixed conclusions for some MO-herbicides
- ✓ A toolbox to assess the potential impact of know and unknown mixtures in real environmental conditions, using modelling, biomonitoring and metabarcoding was piloted, demonstrating being applicable and sensitive;
- ✓ The combined work of MEED allows to design **a tiered approach** based on available mixture evidence **as an alternative to the EU-MAF** concept for different regulatory uses
- ✓ The **outcome of the MEED program** will be published and underlying data will be made available for research on mixtures and regulatory compliance demonstration

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