# Editor's Preface: The Wrongheaded Focus of the MAF on REACH Chemicals

This issue of *The CLER Review* follows up *The CLER Review Vol. 18 No. 1* (https://cler.com/the-cler-review/) in examining the available science regarding the European Commission (EC) proposal to apply a mixture assessment factor, also called a mixture allocation factor (MAF) to every chemical requiring a quantitative risk evaluation in the REACH Chemicals Regulation database. That database now consists of over 26,000 chemicals. The data analysis and commentary in this issue notes pesticides and pharmaceuticals are far more likely to be identified as drivers of environmental risk, challenging the EC policy decision to apply the MAF first to the REACH database.

The Additional Data and Commentary provided in this *issue* focuses on the data in a United Kingdom (UK) Government report (2022) and a recent review of European monitoring data (Rodea-Palomares et al. 2023). The UK Government report reviewed 15 studies of mixtures of chemicals in environment monitoring studies. The Rodea-Palomares et al. review examined all of the available monitoring data from the largest freshwater databases in the EU, the Waterbase – Water Quality ICM database (https://www.eea.europa.eu/data-and-maps/data/waterbase-water-quality-icm-1). Data were found on over 300 individual chemicals detected in over 14,000 environmental samples. Both the UK Government report (2022) and the Rodea-Palomares et al. (2023) review focused on identifying risk drivers, chemicals detected in the aquatic environment at levels that exceeded Water Quality Criteria, predicted no effect concentrations (PNECs) or other indicators of potential risk to aquatic organisms.

The UK Government report also reviewed a modeling study (Posthuma et al. 2019) that used predicted environmental concentrations to examine potential mixture risk from over 1700 chemicals including industrial chemicals and pesticides. The conclusion of the study was that 15 chemicals - 10 industrial chemicals and 5 pesticides - accounted for over 99% of the predicted risk in mixtures.

The overall conclusion from the data in the UK Government report and the Rodea-Palomares et al. review is that the most frequently detected risk drivers are pesticides and pharmaceuticals along with a few industrial chemicals.[1]

The finding that the most frequently found drivers of environmental risk are pesticides and pharmaceuticals is perhaps not surprising. Pesticides and pharmaceuticals

1 It should be noted that conclusions on frequency of detection are limited by analytical methods in the case of monitoring studies and by the available exposure and hazard data in the case of the modeling study (Posthuma et al. 2019).

are designed to be bioactive, and thus may have appreciable aquatic toxicity as a consequence of their intended (and highly beneficial) effects. Pesticides are used primarily on agricultural fields and thus have the potential to be widely dispersed in the environment. Pharmaceuticals may also be widely used, with the potential to end up in human waste and thus in wastewater treatment plants (WWTPs). Pesticides are designed to have adequate stability in the environment to reach their intended targets (pests) and deliver their intended effect/benefit. Consequently, pesticides may be resistant to biodegradation by microorganisms in the environment.[2] Similarly, pharmaceuticals are designed to have adequate stability in the human body to reach their intended tissues/organs and deliver their intended effect/benefit. Consequently, pharmaceuticals may be resistant to biological treatment (aerobic biodegradation), the main treatment method in WWTPs.

These considerations also explain why only a relatively few industrial chemicals are identified as drivers of environmental risk as most industrial chemicals are not designed for bioactivity, or to be stable in biological systems. Indeed, the cleaning agents (surfactants) used in laundry detergents and cleaning products, which do have bio-activity as a consequence of their surfactant activity, are designed to have rapid (ready) biodegradability and high removal rates in WWTPs, exceeding 99% for the major surfactants (Cowan-Ellsberry et al. 2014). Any residual levels found in effluents and biosolids (sludge) will completely biodegrade in receiving waters and sludge-amended soil. This conclusion of rapid and complete biodegradation has also been demonstrated for environmental mixtures of surfactants. See the linear alkylbenzene sulfonate (LAS) case study in *Vol. 18 No. 1* (https://cler.com/the-cler-review/) for a complete review and assessment of the environmental mixture data on the largest volume surfactant used in laundry and cleaning products.[3]

Among the few industrial chemicals found to be risk drivers, many are already highly regulated, or are candidates for further regulation. It is difficult to see how addition of the MAF to the risk evaluation of these chemicals will increase risk management and further protect the environment.

In short, the data in the Additional Data and Commentary do not support the proposed application of the MAF to every chemical in the REACH database, and instead indicate the MAF value should be applied in a more focused assessment. The data indicate that industrial chemicals in the REACH registration database should not be the only focus to identify those few chemicals which contribute to environmental mixture risk.

— John Heinze, Ph.D.
Editor, *The CLER Review*

2 It should be noted that this statement is not accurate for all pesticides. Some of the new generation pesticides are designed to rapidly breakdown in the environment after reaching their intended targets.

3 A just published study (Briels et al. Sci. Total Environ. 167322, on-line 25 Sept. 2023) assessed the contribution of surfactants to mixture toxicity in French surface waters. The study concluded that "surfactants contributed minimally to the mixture risk in investigated water bodies."

## REFERENCES

Cowan-Ellsberry, Belanger, Dorn, Dyer, McAvoy, Sanderson, Versteeg, Ferrer, Stanton (2014) Environmental Safety of the Use of Major Surfactant Classes in North America, *Crit. Rev. Environ. Sci. Technol.* 44, 1893-1993.

Posthuma, van Gils, Zijp, van de Meent, De Zwart (2019) Species Sensitivity Distributions for Use in Environmental Protection, Assessment, and Management of Aquatic Ecosystems for 12 386 Chemicals. *Environ. Toxicol. Chem. 38*, 905-917.

Rodea-Palomares, Geo, Weyers, Ebeling (2023) Risk from unintentional environmental mixtures in EU surface waters is dominated by a limited number of substances. *Sci. Total Environ. 856*, 159090.

UK (United Kingdom) Government (2022). Evaluation of the potential approaches to risk assessment of unintentional chemical mixtures for the future UK REACH assessments. Environment Agency's Chief Scientist's Group, Claire Massey, project manager, Environment Agency and UK Health Security Agency, August 17, 2022, https://www.gov.uk/government/publications/evaluation-of-the-potential-approaches-to-risk-assessment-of-unintentional-chemical-mixtures-for-future-uk-reach-assessments.