

Encountering chemical mixtures in daily life: a concern for our health and environment?

Background

There is a concern that exposure to chemical mixtures in the environment, albeit at low concentrations, may have a greater risk than might be expected based on the toxicity of single chemicals or products. However, the evidence shows that whilst chemicals may sometimes act in an additive way, synergism or more than additive (i.e. what some stakeholders refer to as the 'chemical cocktail' effect) which is a rare occurrence.

The pressing question for society is whether exposure to multiple substances in chemical mixtures can present an unacceptable risk to human health and wildlife. This could potentially be extremely complex considering the numerous chemicals and possible combinations we come into contact with through our environment. In addition, the multitude of mechanisms involved, for example, substances typically have different mode of actions, different absorption, metabolism and kinetics. The probability of two or more substances being released concurrently whilst having similar or synergistic mechanisms of absorption may be considered of a low occurrence. Consequently, there is a growing body of scientific evidence that existing regulations based on single substances do cover the risk from exposure to the majority of chemical mixtures because any potential risk from a mixture can generally be attributed to one or a small number of chemicals^{1,2}. The emphasis is therefore on how to identify, prioritise and assess those chemical combinations of most concern.

The Chemical Industries Association (CIA) – the organisation that represents chemical and pharmaceutical businesses across the UK – and our colleagues in Europe (CEFIC – The European Chemical Industry Council) have been working on

this as part of our industry sector's duty to society in considering any potential risks resulting from chemical manufacturing and their use.

Current status

- The European Commission's current mandate from the EU Council in 2009 is to determine whether the existing single substance approach for assessing chemical safety is sufficient to protect both humans and wildlife from the effects from potential cumulative exposures of multiple chemicals.
- After initial work by the European Commission, the regulatory policy focus shifted from a general consideration of chemical mixtures to a more focussed assessment to address risks from endocrine disruptors.
- The Organization for Economic Development (OECD) and the European Food Safety Authority (EFSA) have both continued the work on developing guidance for evaluating combined exposures to multiple chemicals.
- Several different approaches have been developed to date for prioritising mixtures of chemicals in the environment, including the UK's Interdepartmental Group on Health Risks from Chemicals (2009)³; World Health Organization/ International Programme on Chemical Safety (2011)⁴; European Commission's EU Scientific Committees (2011)⁵; European Chemical Industry Council (2012)¹ and the European Food Safety Authority, EFSA (2019)⁶.

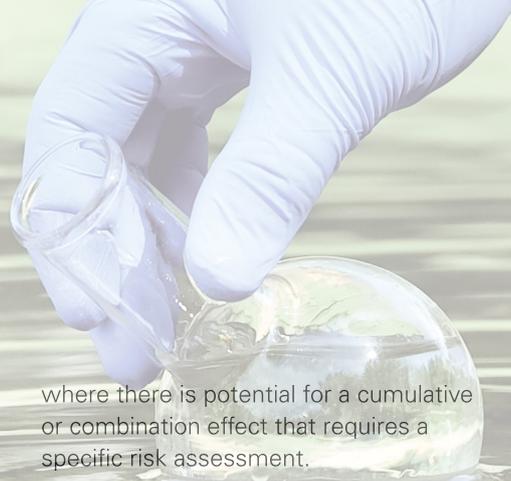
Our opinions and actions

What society needs to know is which chemicals, if any, will potentially combine to give harmful effects on human health and/or the environment. First though, it is important to understand that there are different types of chemical mixtures and therefore a clear understanding of these is needed before policy decisions can be made since different approaches are required.

Types of chemical mixtures include:

- **Intentional mixtures** – manufactured products in which two or more chemicals are blended together in specific proportions including, for example, household consumer products, pharmaceuticals, biocides and plant protection products.
- **Unintentional mixtures** – originate from a single source such as effluents discharged through manufacturing or from waste-water treatment plants.
- **Coincidental Mixtures** – originate from multiple sources and through multiple pathways. These can often be of unknown and/or variable composition, consisting of anthropogenic discharges to the different environmental compartments (i.e. air, water, sediment and soil) and may include chemicals from natural sources.

Considering the growing body of scientific evidence that existing regulation based on single substances covers the risk from the majority of these mixtures, CIA advocates the need for a risk based, scientific approach to identify and prioritise those environmental mixtures of most concern.



CEFIC decision tree:

To help achieve this, the European Chemical Industry Council (CEFIC) proposed a decision-tree screening tool that enables prioritisation of chemical mixtures present in the environment, enabling a risk assessment for these mixtures to be performed and proportionate risk management decisions to be taken. Essentially, it can help to identify those combinations of chemicals that may be of concern (i.e. those that truly have a cumulative risk). The decision tree combines the risk assessment framework approaches developed by both the World Health Organization (WHO) and European Commission's EU Scientific Committees together with a concept known as the Maximum Cumulative Ratio (MCR). The MCR values indicate the amount of a mixture's toxicity or the cumulative risk that would be missed by not doing a cumulative risk assessment, as well as indicating the fraction of toxicity that comes from the most toxic component in the mixture. The MCR approach is recognised as an effective prioritisation method within the recent chemical mixture risk assessment guidance from EFSA (2019).

Does it work?

Published proof-of-concept studies, using U.S. & European surface water data and European residential indoor air monitoring data, have demonstrated the effectiveness of the decision-tree tool, proving it can be used retrospectively for measured exposures or prospectively using modelled data for mixtures of known or predicted (theoretical) composition. CIA believes that the 'combination effects' approach described above offers a pragmatic and scientific way forward to effectively screen numerous substances in a given environmental compartment (e.g. soil, water, air, etc). The tool is designed to identify the drivers of risk and prioritise those combinations of substances

where there is potential for a cumulative or combination effect that requires a specific risk assessment.

Our position

CIA welcomes the European Commission's and other institutions analyses as an opportunity to review the scientific evidence. We firmly advocate the need for a risk based, scientific approach to identifying and prioritising those mixtures of most concern in the environment. Changing existing regulations on the basis of presumption is not the way forward and CIA does not believe there is a need to introduce any new arbitrary assessment factors, as suggested by some stakeholders, into the standard chemical risk assessment process to account for combination effects. In our view this would represent an unscientific, additional layer of conservatism to what is typically already a highly conservative process for individual substances.

Conclusion

In the course of this debate, the CIA asks you to lend your support to encouraging regulation of combination of chemicals based on sound science to enhance the protection of public health and the environment.

References

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