CHE Collaborative for Health & Environment

Webinar Highlights

Addressing Chemical Mixtures: Opportunities for the REACH revision

Chemical mixtures pose hazards to human health and the environment — yet risk assessments generally focus on one chemical at a time. This approach does not reflect the real-life exposures that people experience. In this EDC Strategies Partnership webinar, **Dr. Christina Rudén** explained why assessing the risk of individual chemicals is not sufficient to protect health. Dr. Rudén then presented a proposed method for more accurate risk assessments for mixtures.

Featured Speakers: Christina Rudén, Professor in Regulatory toxicology and ecotoxicology at the Department of Environmental Science, Stockholm University, Sweden, speaking on October 1, 2025.

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The Problem

Over 100,000 synthetic chemicals are in commerce across the European Union (EU), and over 350,000 chemicals globally. Humans and wildlife are regularly exposed to countless combinations of these chemicals. While risk assessments generally focus on one chemical at a time, real-life exposure involves unintentional mixtures of hundreds or even thousands of chemicals simultaneously.

> **"The science is very clear. Current regulatory approaches systematically underestimate real-world risk by not taking mixtures into account."**

Risk assessments can assume that the health effect of a chemical mixture is the sum of the health effects of the mixture components. Research has shown that this is often not true. An early study from 2002 examined the mixture effect of eight weak estrogenic chemicals. The study looked at the effects of chemicals in a mixture where every chemical was present at a concentration where they individually did not cause any effects. However, the mixture of the

eight chemicals showed significant effects. Since then, many studies have shown the increased risks of other chemical mixtures. The potential health end points of studied chemical mixtures include the same end points as for individual chemicals, e.g. endocrine disruption, cancer, metabolic disorders, reproductive disorders, neurotoxicity, allergies, and immunotoxicity.

An expert report from 2009 found that mixture risk assessment is both necessary and feasible. However, there are some challenges to conducting mixture risk assessment, which Rudén highlighted. An infinite number of possible mixtures exists, and they can't all be tested for. In addition, the mixtures that we are exposed to are always changing. Rudén presented a solution to this problem – incorporating a Mixture Assessment Factor (MAF) into assessments of individual chemicals.

Currently in risk assessments, regulatory risk thresholds are determined for individual chemicals. The MAF is a factor by which those thresholds can be divided. So, for example, if the MAF for a chemical is 5, then the amount of the chemical allowed on the market would be the current threshold divided by 5.

This is a pragmatic approach that takes into account both the increased risks of chemical mixtures and the difficulty of assessing every possible mixture. The MAF approach also builds on assessment methodologies already in use for other purposes.

One challenge for introducing MAF will be to determine appropriate values. The MAF value depends on assumptions about the number of chemicals in the mixture, their respective potency or toxicity, and their concentration ratios. Case studies that looked at real-life mixtures suggest that the values could range from 4 to 500.

Recommendations

Adding the Mixture Assessment Factor to risk assessments would adjust the acceptable exposure level for individual chemicals downwards to provide a protective margin for mixture effects. Over 250 scientists have urged the European Commission to address mixtures in the forthcoming revision of the European Union's Registration, Evaluation and Authorization of Chemicals (REACH) regulation.

While determining the best values for MAFs could be complicated, Rudén stressed that, in the absence of more data, adopting the value of 5 for high volume chemicals, as tentatively proposed by the previous European Commission, would make a meaningful difference in improving current risk assessments. The values could be adjusted in the future as more knowledge is gained.

To Find Out More

- Watch the October 1, 2025 webinar: Addressing Chemical Mixtures: Opportunities for the REACH revision
- Read Rudén's presentation slides: Addressing Chemical Mixtures: Opportunities for the REACH revision

About the Speaker

Christina Rudén is Professor in Regulatory toxicology and ecotoxicology at the Department of Environmental Science, Stockholm University, Sweden. Her research focuses on analyzing and evaluating the foundations and workings of EU chemicals legislation, and in particular, how science is used for regulatory decision-making. She has served as an expert to the Swedish Government, the European Commission, and the European Parliament.