

## Pre-reading document for ENES7

### Mixtures under REACH – Practical guidance on how to consider substance exposure scenarios when developing safe use information for mixtures

Under REACH, suppliers of mixtures that are classified have to fulfill safety data sheet requirements according to REACH Art. 31. Downstream users have to consider/include relevant exposure scenarios from substance safety data sheets when compiling safety data sheets for identified uses of a mixture.

Since REACH entered into force in 2007 chemical industry associations are engaged in supporting companies to fulfil their duties *inter alia* by collaborating to create sector-specific generic exposure scenarios and a standard DPD+ methodology (a top-down approach based on classifications according to the Dangerous Preparations Directive). The legal basis for safety data sheets was amended in 2010 and further changes in the classification scheme for mixtures will apply from June 2015 requiring adaptations of procedures.

During ENES 5 in November 2013, Cefic gave an overview on 15 available approaches for the assessment of mixtures characterizing their basic components and strengths and weaknesses. Top-down as well as bottom-up approaches were presented. The different approaches were discussed in break-out sessions in detail. Based on this, in the concluding remarks from the meeting, an action point was taken to determine whether it is possible to narrow them down to several harmonized approaches.

Since ENES 5 Cefic and VCI have been working on the development of a broadly applicable best practice generic methodology (or 'top-down' approach) which can be used to generate safe use information for any type of chemical mixture, regardless of the composition and/or intended use. In addition, the "Cefic/VCI Practical Guide on Exposure Assessment and Communication in the Supply Chains – Part III: Mixtures under REACH" has been reviewed.

At ENES 7 a draft version of this best practice generic methodology - coined as the "Lead Component Identification Methodology" (LCID methodology) - will be presented. The presentation will be focused on:

- A high level description of the workflow to identify priority substances and lead components
- Examples of application of the methodology
- Boundaries of application of the methodology

After ENES 7 participants will receive an updated practical guide with examples and a technical documentation, and will have a 2 month period to:

- Apply the methodology
- Provide examples to the project team (would like a wide range of products with a variety of hazards, and formulations)
- Provide feedback on the LCID methodology and the practical guide