



## Integrating chemical mixture assessments into REACH and the WFD

**New research has supported** a more thorough integration of toxic mixture assessments into two major pieces of EU legislation: REACH and the Water Framework Directive. It recommended constructing a database of harmful chemicals in the environment which, among other uses, could assess mixture toxicity using a 'Concentration Addition' method.

**The effect of chemicals** on ecosystems and human health is mainly due to exposures to mixtures rather than to individual chemicals. However, two large pieces of EU legislation aimed at regulating chemicals – the Registration, Evaluation and Assessment of Chemicals (REACH)<sup>1</sup> and the Water Framework Directive (WFD)<sup>2</sup> – primarily use approaches that assess the toxicity of single chemicals. Only specific types of mixtures, such as oil compounds, are covered by REACH.

The study reviewed existing research on risk assessments of chemical mixtures. Currently there are two main models: Concentration Addition (CA) which estimates mixture effects of chemicals that act in a similar way, and Independent Action (IA), which estimates mixture effects of chemicals that act differently to each other.

However, knowledge of exactly how chemicals act is rare and it is difficult, if not impossible, to group chemicals in the environment according to their similarity or dissimilarity. Several pieces of research have argued for the use of CA as it is the most conservative method and therefore the most protective.

The study evaluated the practicality of the models by investigating their use in existing legislation. The relevant environment and health agencies in the US use both CA and IA. Before using either approach, the US Agency for Toxic Substances and Disease Registry (ATSDR) reduces the number of mixtures to be assessed using so-called hazard quotients. In principle these are similar to the PEC/PNEC ratio used in EU legislation where PEC is the background concentration of the mixture in the environment (Predicted Environmental Concentration) and PNEC is the concentration level of the mixture above which it causes harm (Predicted No-Effect Concentration). The researchers suggested that assessment could be limited to mixtures containing chemicals with individual ratios of PEC/PNEC > 0.1.

The Danish regulation on wastewater and air pollution uses a CA method. For mixtures with dissimilar chemicals, the air pollution regulation considers the risk of the chemical that contributes most to the toxic effect, whereas the wastewater regulation recommends that all chemical mixtures are predicted with CA. The study pointed out that initially REACH included the use of CA to assess preparations but it was removed from the final version, perhaps because assessment was considered too complex at the time.

The study recommended the use of CA as a default assessment method of mixtures within the WFD and REACH. Taking inspiration from the US and Denmark, steps could be made to limit the mixtures to be assessed based on the PEC/PNEC ratio.

1. See [http://ec.europa.eu/environment/chemicals/reach/reach\\_intro.htm](http://ec.europa.eu/environment/chemicals/reach/reach_intro.htm)
2. See [http://ec.europa.eu/environment/water/water-framework/index\\_en.html](http://ec.europa.eu/environment/water/water-framework/index_en.html)

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