European Commission

Science for Environment Policy

Chemicals risk assessment: evidence-evaluation methods analysed for nine EU regulations

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The use of two methods to systematise evidence-evaluation methods is reviewed in nine EU regulations dealing with chemicals risk assessment. The majority of frameworks were found to promote the use of 'weight of evidence' or 'systematic review'-style approaches, but the study found a lack of structured, consistent and detailed guidance for these approaches. The researchers recommend this guidance is developed collaboratively by European regulatory agencies and points to best practice for this guidance.

Weight-of-evidence (WoE) evaluation and systematic review (SR) are methods (developed in the fields of economics, law and medicine) to summarise, synthesise and interpret a body of evidence to draw conclusions, for example, the relationship between chemical exposure and adverse health effect. These practices are expected to play a more important role than they did in traditional risk-assessment methods, which relied on fewer studies.

For the majority of chemicals on the EU market today, health and environmental risk assessments are performed by the producing or importing company, with guidance from different regulatory frameworks, depending on their intended use. Improving guidance on how to conduct and report WoE or SR would improve the robustness, reproducibility and transparency of assessing the health or environmental risk of a chemical.

The aim of this review was to investigate if either WoE evaluation or SR in chemical risk assessment is promoted within nine different regulatory frameworks set out by the European Commission[1] and implemented by the European Chemicals Agency (ECHA)[2], the European Food Safety Authority (EFSA)[3], and the European Medicines Agency[4]. Risk-assessment documents selected from the most prominent areas within chemical risk assessment in the EU were scrutinised for whether WoE evaluation and SR were promoted and whether there was sufficient guidance for WoE evaluation and SR.

The results showed that WoE or SR is mentioned in seven of the nine frameworks, and are explained in slightly more detail in five, with the EFSA providing the most detailed guidance. The variation in the way WoE and SR are promoted, defined and described highlights that current legislation and guidance documents do not provide sufficient directions for handling the complexities arising from a heterogeneous pool of data in chemical risk assessment.

Recommended stepwise guidance includes: development of protocol, search strategy, criteria for including and excluding studies in the assessment, evaluation methods for single studies and groups of studies, and synthesis of evidence.

Continued on next page.

Source: Ågerstrand, M & Beronius, A. (2015). Weight of evidence evaluation and systematic review in EU chemical risk assessment: Foundation is laid but guidance is needed. *Environment International*. DOI: 10.1016/j.envint.2015.10.008

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1. **European Commission (EC)**: Cosmetics [Regulation (EC) No. 1223/2009]; Water Framework Directive [Directive 2000/60/EC]

2. **European Chemicals Agency (ECHA)**: Industrial chemicals [Regulation (EC) No. 1907/2006 (REACH)]; Biocides [Regulation (EU) No.528/2012]; Classification, labelling and packaging [Regulation 1272/2008/EC]

3. **European Food Safety Authority (EFSA)**: Plant protection products [Regulation (EC) No.1107/2009]; Contaminants in food [Regulation (EC) No.178/2002]

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The researchers support the joint development of guidance between the EU agencies on best practices for evidence-based methods. Such development could build on existing collaboration between some agencies, for example between the ECHA and EFSA. One advantage of this approach could be the smooth transfer of the consequently more robust risk assessments between EU frameworks in cases where, for example, a chemical is risk-assessed both as an industrial chemical and as a contaminant in food (although these risk assessments would need to consider exposure situations specific to each framework).

The researchers quote the ECHA in saying that "the mix and reliability of information available for a particular substance will probably be unique"[5], which acknowledges the difficulties in clearly explaining and fixing rules for WoE when each case is so different, but they point to four examples of cross-sector practice for SR and WoE evaluation, including the EC's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR, 2012), the International Agency for Research on Cancer (IARC) and two from the US, and say these documents could be used to help update the frameworks investigated in their review.

4. **European Medicines Agency (EMA):** Human pharmaceuticals in the environment [Directive 2001/83/EC]; Veterinary pharmaceuticals in the environment [Directive 2001/82/EC]

5. Guidance on the Biocidal Products Regulation. Volume III Human Health - Part B Risk Assessment. Version 1.1