



Regulatory frameworks for chemicals need more harmonising

There are differences in the assessment and restriction of chemicals exempt from the EU's regulatory instrument REACH. A new study has analysed the differences between several regulatory frameworks that govern these chemicals and recommended greater harmonisation in assessment criteria and regulatory follow-up.

The EU's regulatory instrument on chemicals REACH¹ (Registration, Evaluation, Authorisation and Restriction of Chemicals) is designed to protect the environment and human health from harmful chemicals. It requires manufacturers and importers to register chemicals that are imported or produced in amounts exceeding one tonne per year and to subject chemicals exceeding ten tonnes per year to a Chemical Safety Assessment. Some harmful substances are classified as 'Persistent, Bioaccumulative, Toxic' (PBT), if they do not break down easily in the environment, accumulate in the tissues of organisms, and are toxic.

For substances imported or manufactured in volumes less than one tonne per year, there is no REACH requirement for registration. Some other substances, such as food and feed additives, pharmaceuticals, cosmetics, biocides and plant protection products, are also exempt from parts of REACH, such as registration. But more specifically, for registration and safety assessment they may be subject to other EU legislation, such as the EU Regulation for Plant Protection Products² and the EU Directive on Biocides³. They may also be screened within international frameworks such as the Oslo-Paris Convention (OSPAR)⁴, the UNEP Stockholm Convention⁵ and the UNECE POP (Persistent Organic Products) Protocol⁶. The study provides an overview of PBT and POP criteria and the steps taken following PBT assignment within different frameworks and compares the criteria and follow-up to those of REACH.

Many frameworks do conduct a PBT assessment, but risk assessment criteria and consequences vary. In European frameworks, the criteria to identify a substance as a PBT or a POP are similar to those used in REACH. However, there are some significant differences between REACH and the global frameworks. For example, in UNEP and UNECE frameworks, long-range transport is an additional criterion by which to assign POP status, whilst in REACH this is not the case. In addition, the criterion to assign a substance as bioaccumulative is higher (and thus less strict) for the UNEP and UNECE frameworks than for REACH. When a compound is assigned to be very bioaccumulative (vB), the criteria in REACH equal those in the POP frameworks. In contrast, the OSPAR Convention framework uses lower (more strict) criteria than REACH.

Other EU legislation, such as frameworks on biocides and pharmaceuticals, mainly refer to the former Technical Guidance Document (TGD), which preceded REACH. Within the plant protection product legislation, no reference to REACH or the TGD is made, but the PBT criteria have been largely harmonised with REACH. The differences between TGD and REACH tend to be small, but they do exist. For example, REACH has a criterion for persistence in soil, which was not in the TGD. There are also variations between frameworks in the consequences of identification of a chemical as potentially harmful. For example, according to REACH, once a substance is identified as PBT an exposure assessment is required, which includes an evaluation of appropriate risk management measures. Plant protection products and biocides with PBT properties are not permitted on the market according to the relevant European legislation, whilst PBT properties of human medicinal products are not part of the benefit-risk analysis and these products can be marketed even if there is environmental risk.

Although there is a shared goal among regulatory frameworks to restrict or ban the use of substances with PBT properties, there are several differences in how this goal is achieved. To overcome the challenge of harmonising the assessment criteria and regulatory follow-up, there needs to be more knowledge sharing amongst frameworks and updating of changes in the guidelines and criteria, the study argues.

1. See: http://ec.europa.eu/environment/chemicals/reach/reach_intro.htm

2. See: http://ec.europa.eu/food/plant/protection/index_en.htm

3. See: <http://ec.europa.eu/environment/biocides/index.htm>

4. See: http://europa.eu/legislation_summaries/environment/water_protection_management/128061_en.htm

5. See: <http://chm.pops.int/default.aspx>

6. See: www.unece.org/env/lrtap/pops_h1.html

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Contact: caroline.moermond@rivm.nl **Theme(s):** Chemicals, Risk assessment

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