Finding new ways to meet REACH targets

The EU regulatory framework REACH (Registration, Evaluation, Authorisation and Restriction of CHemicals)\(^1\) has set 2010 as its first registration deadline. A Dutch study considers time-efficient and cost-effective alternatives to traditional methods of risk assessment of chemicals in the context of this fast-approaching date.

In 2007, the REACH framework replaced around 40 pieces of legislation that regulated chemicals in the EU. Its primary aim is to improve knowledge about the properties and uses of chemicals in order to protect human health and the environment. It also seeks to improve the speed and efficiency of risk assessment and management by placing the responsibility with industry.

Industry must assess the potential risk of about 30,000 chemicals in the next 11 years. This means that the efficiency of chemical assessment needs to increase with a factor of about 300. Under the previous Existing Substances Regulation\(^2\), just 141 chemicals were fully assessed in 14 years. 2010 is the first registration deadline for high-production volume chemicals (over 1000 tonnes produced per year), dangerous chemicals (carcinogens, mutagens and substances toxic to reproduction) and substances that are very toxic to aquatic environments.

In order to achieve the ambitions of REACH, the authors recommend an urgent change in mindset to alter what is defined as ‘good testing’ by regulatory authorities, industry, NGOs and the general public. Standard assumptions and practices need to change to create a new form of working.

Good risk assessment should move away from a labour-intensive approach that involves animal testing, to a more intelligent, theory-based testing that combines existing exposure and hazard data. To do this, stakeholders need an awareness of the ‘uncertainty paradox’. The uncertainty paradox suggests that, rather than assessing chemicals one-by-one, the focus should be on reducing the overall uncertainty surrounding the 30,000 chemicals. In other words, it is better to gain a more general understanding of a larger number of chemicals than it is to spend time and resources on gathering detailed information at the individual level of a relatively small number of substances.

The study also suggests assessments need to be better integrated. For example, exposure assessment tools currently cover only one of three aspects: workers, consumers and the environment, rather than assessing them together.

For these reasons, the researchers recommend Intelligent or Integrated Testing Strategies (ITSs). These have multiple components that speed up risk assessment whilst reducing costs and animal testing. The tools include category approaches, which group similar chemicals together and optimise current data by applying it to all chemicals within a group. However, this does require a definition of when substances can be considered ‘similar’.

Another method is Exposure-Based Waiving (EBW), which uses a threshold of exposure, below which it is assumed that additional data would not improve risk assessment. The study also suggests combining these methods with \textit{in vitro} (study of biological systems in a controlled environment outside of a living organism) and \textit{in vivo} methods (study of biological systems in a living organism). Levels of animal testing used by \textit{in vivo} methods would be significantly reduced within an ITS. A pro-active exchange of data between stakeholders should be encouraged to further save time and costs.

2. See http://ec.europa.eu/environment/chemicals/exist_subst/index.htm


Contact: gerwin.schaafsma@tno.nl

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