

Hazard and Risk – what is it all about?

The Refit process, now on-going in the EU, aims to identify overlaps and gaps in chemical regulation. One main aim is also to evaluate the uses of hazard-based and risk-based approaches in EU regulation. In this paper ChemSec aims to provide arguments and rationale that explain why both hazard-based and risk-based approaches are needed to achieve efficient and protective regulation of chemicals, but also show how a risk-based approach can slow down the process rather than provide valuable input when not used correctly.

The term hazard refers to the intrinsic properties of a particular chemical – its potential to do harm – while risk is the combination of hazard and exposure. The risk is what you want to eliminate, by changing either one or both of the components, hazard and exposure. In purely mathematical terms: if one of them is zero, the risk is also zero.

In current EU regulation for chemicals, both approaches are used. REACH is a world-leading regulatory example of a mixture of hazard-based and risk-based elements. For example during the first step of the authorisation procedure, chemicals are identified as “Substances of Very High Concern” based purely on their hazardous intrinsic properties, and subsequently placed on the Candidate List. The message REACH gives is that these hazardous chemicals should be avoided as far as possible. However, in cases where it is not yet possible to replace them, and where the benefits of continuous use outweigh the risks, authorisation for specific uses may be granted.

An efficient, transparent, protective and innovation-driven regulatory system for chemicals should as a general rule always restrict chemicals on the basis of hazard and authorise their use based on risk.

Hazard identification and exposure assessment:

The main difference, and advantage, of a hazard-based approach compared to a risk-based one, is that it is foolproof. The complete removal of a hazardous chemical is the only way to be 100% sure that it will no longer pose a risk. Hazard assessments are complex, but not as complex as exposure assessments, which add even more levels of complexity to the equation.

Hazard assessments are particularly well suited for substance properties where the effects are difficult, or even impossible, to predict over time, such as for PBTs, vPvBs, endocrine disruptors and other substances without safe thresholds.

The classification of a chemical as hazardous sends a clear signal to the market that such properties are not wanted, and should be phased out. The hazard classification then becomes an incentive to develop alternatives with better hazard properties or find alternative techniques, hence becoming a driver, rewarding innovation and substitution to provide a safer alternative. The identification and restriction of substances based on hazardous intrinsic properties is also easy to communicate throughout the supply chain. The information is not “filtered” depending on how it is used, meaning that the same

information is available to all actors independent of usage and place in the supply chain. Classification data is also readily available through the CLP regulation and in the REACH registration dossiers.

Due to the lack of available and reliable exposure data many companies see hazard-based cut-offs as the only way to go. Also, many companies close to consumers just can't risk their reputation based on a shaky risk assessment, and give this as a reason when their customers ask them questions about the presence of hazardous substances in their products. The hazard-based identification will hence assist companies in their internal prioritisation of chemicals for phasing out, while the particular presence and potential for exposure (risk profile) will contribute to deciding the order in which they are phased out. The same approach applies to regulators when deciding on what chemicals to prioritise for regulation.

Risk-based regulation

Having a strictly hazard-based cut-off might sometimes be too blunt instrument to use, and that is why the risk-based approach sometimes is a good way forward to complement the hazard assessment. Hence, neither hazard nor exposure alone can facilitate the prioritisation of which substances to address with highest urgency. In order to prioritise, we need to have both sets of information, on exposure and use as well as hazard.

The basis for risk assessment is the un-scientific belief that risk can be foreseen and controlled. In an infinitely complex system, such as chemicals, the risk is simply impossible to anticipate. The unknown factors are usually far too many and impossible to foresee. The unforeseeable cannot be predicted nor assessed. To make the best possible risk assessment we require a complete picture of both uses and users in the supply chain, something which is not the case today due to lack of communication as well as business confidentiality. Moreover, chemicals often act in combination with others, creating a so-called "cocktail effect". This is difficult to foresee and hence impossible to include in a risk assessment.

Risk assessments are also expensive and time-consuming, and even if modern technology is available to assess use and exposure in the supply chain, it is in many cases not possible due to confidentiality claims. It is likewise a daunting task to communicate the hazard profile and safety instructions down the line of a globalised industry.

In the US the legislative system is risk-based. Companies can use a substance until the EPA (Environmental Protection Agency) proves that it poses a risk. The result of the US system is a total of just 10 regulated substances in cosmetics at federal level. This should be compared to the EU, which uses a hazard-based approach and restricts around 1300 hazardous substances in cosmetic products. Looking at these numbers you realise the level of protection is much lower in the US due to the inefficiency of their risk-based system.

On a regular basis scientists discover damage to human health or the environment caused by factors that were never considered in any risk assessment, or because assumptions made in the risk assessments were simply wrong. Experiences from the past have shown that actual exposures have often been underestimated when certain uses were not known, or when what were thought to be "closed systems" are actually found to result in exposure. This holds especially true for wide dispersive uses and consumer products, which are not always

used in the way they were intended. In industrial and professional uses, exposure can be fairly well predicted, but even under such controlled uses with trained professionals, risk mitigation instructions for handling and use tend not to be adhered to, especially if they are far-reaching and seen as cumbersome by the operators.

Do not reintroduce an inefficient system

The REACH white paper (called the white paper on a strategy for a future chemicals policy) published in 2001 was clear in its analysis of the previous EU system for hazardous substances. It concluded that the system was inefficient and that hazard identification and hazard assessment need to be used in the new system to make it more efficient.

As a result, REACH builds on hazard identification and has so far led to over 160 chemicals being identified as substances of very high concern (SVHC) and added to the Candidate List. In the subsequent stages of REACH, risk comes into play and the process slows down. For example, only 18 substances have been restricted in REACH since 2007. The cost to member states for submitting the background data for these restrictions has been excessively high, since risk assessments are very costly. The authorisation part of REACH also includes risk elements – leading to very few substances on the authorisation list.

In the recast of the biocides regulation, hazard based cut-off criteria were also introduced to make the regulation fit for purpose. This was because the previous risk-based approach had proven to be inefficient, resulting in very few restrictions even for well-known hazardous substances.

“When it comes to banning substances, the company focuses on hazard, since its products are meant for the final consumer. We do not expect our customers to take risk mitigation measures to limit their exposure to chemicals in our articles.”

Peter Adler, IKEA, Business Guide to Safer Chemicals in the Supply Chain, 2015, Chemical watch report

Companies benefit from hazard-based regulation

Consumer-oriented companies with a brand reputation at stake do not want to risk their reputation by selling products that contain hazardous chemicals. If regulation is not strict enough they need to develop their own list of restricted chemicals. These companies benefit from hazard-based identification, since this helps them to prioritise substances for substitution. For example the delay of EDC criteria has led many companies to produce their own lists of restricted EDCs based on the EDCs present in the public debate.

Conclusions:

- Hazards and risks must both be considered in EU regulation in order to provide efficient and protective chemicals legislation in which a substance is primarily regulated based on its hazard, while the authorised use of the same substances should be based on risk.

- Many companies use a hazard-based chemical management system as a baseline. These companies benefit from hazard-based regulation, since it helps them to prioritise which chemicals to focus on and find substitutes for.
- A hazard-based system will be a driver of innovation and substitution towards inherently safer products.
- Risk assessments are very burdensome and take a lot of time and resources to complete, but they only provide a model of reality, they will always be limited by assumptions and calculations, and in the real world have proven many times to be more complex than we can imagine.

