

WHY REACH AUTHORISATION AND WORKERS PROTECTION SHOULD BOTH APPLY

In the light of “fitness check”, streamlining of REACH Authorisation process and “better regulation” in general, there is an ongoing debate around the legislation for Occupational Safety & Health (OSH) and REACH. There have been calls to exclude substances from REACH Authorisation that are also covered by limit values under OSH to avoid overlap between these two sets of legislation. ChemSec is very concerned, since REACH in synergy with OSH provides important protection for workers. We recognise the challenge and confusion of simultaneously following these two pieces of legislation. However, the two have different legal bases, serve different purposes and provide different levels of protection. Together, they supply the necessary safety for workers, encourage substitution and facilitate supervision.

► BACKGROUND

In REACH, chemicals listed on Annex XIV are only allowed to be used or placed on the market when authorisation has been granted. Within the authorisation process, specific limit values are set for threshold substances. These are referred to as DNELs (Derived No Effect Level), which are considered to be safe levels of exposure.

Under OSH there are two directives setting chemical exposure limit values for workers: the Directive on the protection of workers from the risks related to exposure to chemical agents at work (Chemical Agents Directive 98/24/EC), and the Directive on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Carcinogens Directive 2004/37/EC). These limit values are called OELs (Occupational Exposure Limit).

WHY SUBSTANCES WITH EU OELs SHOULD NOT BE EXEMPTED FROM AUTHORISATION

There have recently been calls that substances with limit values under the Carcinogens Directive and that are only used in production should be exempted from REACH Authorisation, by applying REACH article 58.2.

For Article 58.2 to be applicable, there must be another piece of legislation imposing EU-wide minimum limit values. Under the Chemical Agents Directive, the limit values are not binding and differ between Member States. Article 58.2 in REACH is therefore not applicable in this case.

58.2. *Uses or categories of uses may be exempted from the authorisation requirement provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled. In the establishment of such exemptions, account shall be taken, in particular, of the proportionality of risk to human health and the environment related to the nature of the substance, such as where the risk is modified by the physical form.*

Under the Carcinogens Directive, however, there are possibilities to set EU-wide binding limit values. These limit values are set in a very different way than the DNELs under REACH. When a binding limit value is set under the Carcinogens Directive, socio-economic aspects are included in the analysis. This could, for example, include the availability of alternatives. As described in the report “The Bigger Picture” (ChemSec, 2016)⁷ availability and other relevant factors for alternatives change dramatically over time,

which in this case leads to limit values that can be both incorrect and quickly become out of date. So the binding OEL under the Carcinogen Directive is not strictly based on the safe exposure level. Under REACH authorisation for threshold substances, the limit values are hazard-based. Socio-economic aspects are taken into consideration at a later stage. This means that the limits stay the same, while a new assessment of alternatives, etc., is carried out every time a company applies for a new authorisation period. If, for instance, an alternative is expected to be available in the near future, the authorisation period will be short. With this approach, ChemSec is of the opinion that the authorisation procedure under REACH drives substitution much more efficiently than OSH.

There have so far been only three cases of binding limit values under the Carcinogen Directive, so a comparison between these binding OELs with DNELs set in REACH is not feasible. When looking at the non-binding limit values, the limit values under OSH and REACH on many occasions differ greatly, and the levels under REACH are in general much stricter, which indicates that the level of protection is considerably lower under OSH. These indicative OELs can differ between different Member States, but a study (Schenk, Johansson, 2010)² comparing the Swedish OELs with DNELs showed that the REACH safety margins were approximately six times higher.

Under the Carcinogen Directive, measures must be taken to substitute or reduce the use or exposure even when the

binding limit values are met. The reason for this is primarily that the exposure still causes a threat to the health of workers, and occasionally to people living in the vicinity of these facilities. This indicates that the level of protection under the Carcinogen Directive is not sufficient and does not reach the equivalent level of protection found in REACH. So far, binding limit values for occupational exposure under the Carcinogens Directive only exist for

- ▶ Benzene
- ▶ Vinyl chloride monomer
- ▶ Hardwood dust

These values are old and out-dated. The annex has been under revision for 10 years without progress, but now the Commission is presenting a proposal for 13 additional binding limit values. Based on how other OELs are set it is likely that these limit values will prove to be considerably higher than the DNELs and DMELs set out in REACH, which would result in a significantly lower level of protection, and therefore REACH article 58.2. should not be applied. A clear example of this is the proposed OEL set for Chromium VI at 25µg/m³. This OEL combined with the dose-risk data calculated by RAC would mean that for workers exposed to CrVI over a working life, one in ten will die from lung cancer caused by CrVI. With an estimated 916,000 workers exposed to Cr VI (according to EU COM press release) there would be 91,600 deaths over 40 years or roughly 2290/year. This is not what we would term a “properly controlled risk”.

1. ChemSec 2016, *The Bigger Picture, Assessing Economic Aspects of Chemicals Substitution*.

2. Linda Schenk and Gunnar Johanson, 2010. *A Quantitative Comparison of the Safety Margins in the European Indicative Occupational Exposure Limits and the Derived No-Effect Levels for Workers under REACH*, *Critical Reviews in Toxicology*, 2010; 40(9): 791–798.

SUMMARY

REACH, with its DNELs, provides a higher level of protection compared to OSH, with its OELs, making it clear that both regulations should co-exist and REACH article 58.2 should not apply. Moreover, REACH generates information that is needed to better protect workers, especially by improving risk assessment and risk management. REACH also has a more efficient approach to encouraging substitution.

Companies producing hazardous substances need to continue to comply with both OSH and REACH, to protect their own workers, neighbours, human health and the environment from these chemicals.

If companies, especially those that are small and medium-sized, find it difficult to stay up to date with both regulations, they should turn to their support organisations to provide them with information on the different pieces of legislation relevant to their business. The solution is not to ask for exemptions from legislation that is applied without prejudice for good reasons.