Occupational exposure limit (OEL) values should be considered during REACH's risk management option analysis (RMOA)

Executive summary

During the past few months, industry, the European Commission, ECHA and Member States started a reflection on how to make the REACH Authorisation process efficient by selecting only relevant substances of very high concern (SVHC) to be prioritised. In this context, the American Chamber of Commerce to the European Union (AmCham EU) reflected on the different available risk management options (RMO) and especially on the OEL setting process, which could be the most relevant in this specific context.

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AmCham EU speaks for American companies committed to Europe on trade, investment and competitiveness issues. It aims to ensure a growth-orientated business and investment climate in Europe. AmCham EU facilitates the resolution of transatlantic issues that impact business and plays a role in creating better understanding of EU and US positions on business matters. Aggregate US investment in Europe totalled €2 trillion in 2013 and directly supports more than 4.3 million jobs in Europe.

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Introduction

The American Chamber of Commerce to the European Union (AmCham EU) welcomes the substances of very high concern (SVHC) implementation plan and thinks the initiatives it proposes to help identify and follow the most appropriate regulatory path will be important for improving the efficiency and effectiveness of the overall chemicals risk management process.

During the past few months, industry, the European Commission, the European Chemicals Agency (ECHA) and Member States started a reflection on how to make the REACH Authorisation process efficient by selecting only relevant SVHCs to be prioritised. This growing concern is clearly illustrated by the EU Commission abandoning the fifth prioritisation list because **Carcinogenic**, Mutagenic or Toxic for Reproduction (CMR) substances it included raised only health in the workplace concerns.

In this context, AmCham EU reflected on the different available RMOs and especially on the OEL setting process that could be the most relevant in this specific context.

Position and recommendations

The Chemicals Agent at Work Directive (98/24/EC) and the Carcinogen Mutagen Directive (2004/37/EC) have been regulating hazardous chemicals at work for years, setting, *inter alia*, occupational exposure limits (OELs). AmCham EU believes that in certain circumstances, setting an OEL will be an efficient and effective RMO. An OEL is often the best way to address occupational health issues at the workplace, especially in case of exposure by inhalation (OEL addressing mainly workplace air issues), setting limits for hazardous substances including for carcinogenic and mutagenic substances. This will ensure safe use of substances and will address the identified concern adequately.

Moreover, this option is proportionate for industry and easily enforceable by authorities in comparison with Authorisation, which could be extremely costly and time consuming for both industry and authorities. Restriction could also be a regulatory tool used in worker safety cases however it requires that an EU-wide 'unacceptable risk' has been demonstrated. This demonstration can be very difficult, thereby limiting the use of Restriction as a risk management tool for chemicals where there is a 'concern', yet no demonstrable EU-wide risk.

An OEL is a successful risk management tool, with which industry and authorities have a wealth of experience. It also sets longer-term regulatory obligations for industry, unlike authorisation, which when it is granted, is time limited. This means that OELs are a regulatory tool that provides industry with legal certainty, while at the same time being easy to enforce by authorities.

The substitution principle will remain since it is embedded in the Chemicals Agent at Work Directive and in a more stringent form in the Carcinogen Mutagen Directive.

The length of time required to set an EU OEL might be seen as a barrier to the wider use of this regulatory tool. However, when looking at the current situation, and the ongoing discussions related to the some substances under prioritisation (e.g. cobalt compounds, RCFs, etc), an efficient OEL setting process, when started on time, and following a strong RMO analysis, could be faster and more

effective than a lengthy process of prioritisation that could be challenged by Member States or the Commission at any stage. Moreover, the OEL process can be sped up when the work of the Scientific Committee on Occupational Exposure Limit Values (SCOEL) can rely on existing data in Registration dossiers and use existing Derived No Effect Levels (DNELs) as a basis for discussion.

Finally, this line of argumentation is aligned with the European initiative for a smarter and integrated European policy ('Refit') using adequate, available, regulatory tools to meet given policy objectives. The OEL and REACH example could help promote this Commission initiative and help to better spread the burden between different DGs. Such an increase in collaboration would make the overall system more efficient, and therefore help meet the EU's ambitious goals regarding human health and environment protection.

Conclusions

AmCham EU recommends considering setting OELs for manufacture or use of hazardous substances which have raised concerns in the workplace instead of Authorisation. This OEL setting must be recognised as a 'specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance' (REACH, art; 58.2) allowing this substance, and its identified uses, to be exempted from the Authorisation process.