

Joint SMEUnited and Cross-Industry Initiative for Better Regulation in Chemicals Management views on DGs ENV-GROW paper on REACH Restriction and Occupational Safety and Health (OSH) OELVs

January 2021

SMEUnited and the Cross-Industry Initiative for Better Regulation in Chemicals Management (CII) welcome the European Commission's initiative to clarify the interface between the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and Occupational Safety and Health (OSH) policy frameworks.

The members of SMEUnited and the CII are committed to protecting workers' health and strictly implementing EU legislation in this respect. In line with the Council Conclusions on occupational safety and health of December 2019, the CII and SMEUnited consider it essential that the interface between OSH and REACH be clarified and that transparent procedures and criteria be used when selecting the most appropriate regulatory options.

In line with the Council Conclusions, we welcome the DGs ENV-GROW's thought-starter to promote a decision tree that would clarify the interface and optimise worker protection.

1. Do the Members of CARACAL agree with the proposed analysis and approach?

We see REACH restrictions and OSH directives as complementary tools. To achieve a fully **balanced analysis of the contribution of the different legislations**, including more accurate recognition of the benefits of OSH directives for worker safety, it is of utmost importance that further work on the paper involve OSH authorities on an equal footing with REACH authorities.

We recall that OSH directives were established to define all important aspects of workplace risk management and are the correct legal route for establishing specific occupational exposure limits (OEL). However, we agree with the Commission that, **to complement OSH (and OELVs), restrictions can be sensible measures** to address risks that cannot be addressed under OSH and **under specific circumstances**. For example, while OSH (OELVs) may be sufficient to address risks of a substance in most workplaces, there may be individual uses where the RMOA finds that the substance cannot be used safely and that the ban of that specific use by means of a restriction is proportionate. Also, if there are workers outside the scope of OSH (self-employed), then it can be explored whether it is beneficial to side the OELV by a restriction for those other workers. This combination of OSH / OELVs with a restriction would avoid regulatory overlap and confusion.

We are, however, **concerned by the proposal to set restrictions that cover the same scope as an OELV** would. We see restrictions establishing derived no-effect levels (DNELs) as a way to bypass OSH procedures, including the contributions of Social Partners. We, therefore, object to the suggestion that reference DNELs could serve as 'use conditions' in restrictions.

Indeed, the introduction of 'binding' DNELs as an alternative to OELs via REACH restrictions undermines existing legal systems and is clearly at odds with REACH Article 1(4). In its explanatory memorandum to the second revision of the CMD, the Commission acknowledged: **'REACH, on the other hand, is not intended to set occupational exposure limit values [...].'**

2. What criteria do the Members of CARACAL propose be used in evaluating which is the more appropriate risk management measure – EU OEL under OSH or restriction under REACH? Could this be further developed by the Restriction Task Force?

The Caracal paper suggests that the existence or not of an OEL for substance should be a relevant factor in deciding on the regulatory route to take. Whether an OELV already exists for a certain substance is however rather a matter of coincidence. It should not play a role in determining which regulatory route is the right one. Instead, a decision to select the most efficient regulatory risk management option should be taken as a result of a systematic and standardised regulatory management option analysis (RMOA). If the risk is limited to a workplace within the scope of OSH, and the RMOA finds that the best way to manage that risk is to set an exposure limit value, then an OELV should be set, irrespective of whether this means that an existing OELV needs to be updated or whether a new one needs to be developed. Only when measures are needed that cannot be adopted under the specific legislation for OSH, then a REACH Restriction could be a means of implementing this measure.

As highlighted above, SMEUnited and the CII believe that an **RMOA** is the best instrument to enable authorities to clarify whether OSH or other risk management options need to be applied to address concerns in the workplace. We suggest that criteria be developed not only for making the appropriate choice between OSH/OELVs and Restrictions, but to also include criteria on when REACH Authorisation may or may not be the right risk management approach for the use of a substance.

When dealing with worker safety, **the risk assessment should involve not only REACH experts but also, on an equal footing, experts and Competent Authorities on Occupational Health and Safety** (both at the European Commission level and Member State (MS) levels). Hence, SMEUnited and the CII consider neither CARACAL nor the Restriction Task Force to be the right platform for developing criteria.

3. Should there be a specific forum for discussing and assessing the most appropriate risk management measure that coordinates all the actors responsible for OSH and REACH legislation?

SMEUnited and the CII contend that generic criteria should be developed, possibly as part of a guidance for RMOAs, to guide the choice of the risk management option. Given the topic of the interface between REACH and OSH, we consider a REACH Forum would not be appropriate to discuss those criteria. We propose instead that criteria for evaluating the best approach for worker protection are developed in the framework of a specific REACH-OSH multi-stakeholder forum. Those stakeholders should include both REACH and OSH experts, Competent Authorities and relevant institutions (DG EMPL, DG ENV, DG GROW, the tripartite Advisory Committee on Safety and Health at Work (ACSH) including specifically its Working Party on Chemicals). When it comes to the application of these criteria, in line with the suggestions of the Commission in the Chemicals Strategy for Sustainability, the responsible authorities should engage with each other.

4. Do the Members of CARACAL have additional suggestions/considerations?

SMEUnited and the CII support the view that the debate over the REACH/OSH interface should also address other practical questions. We believe that the thought-starter presented by DGs ENV-GROW could be broadened in scope so as to address these. For example, a decision-tree could include criteria to choose for which uses of a substance an OELV, a restriction or an Authorisation would be the most effective risk management option.

SMEUnited and the CII remain available to provide further information and clarification.

SMEUnited is the association of crafts and SMEs in Europe with around 70 member organisations from over 30 European countries. SMEUnited is a recognised employers' organisation and European Social Partner and acts on behalf of crafts and SMEs in the European Social Dialogue and in discussions with the EU institutions.

***The Cross-Industry Initiative (CII) for better regulation in chemicals management** was set up between December 2014 and March 2015 as a coalition aimed at streamlining the management of chemicals. It is currently comprised of over 60 organizations: sectoral associations at the EU and national level as well as companies. Our members represent manufacturers as well as downstream users of chemicals, large companies and SMEs. The remit of the CII targets exclusively cases in which the potential risks posed by chemicals are limited to the workplace environment.*