

CII comments on the CARACAL paper on the Reform of the REACH Authorisation and Restriction Processes

February 2022

The Cross-Industry Initiative for Better Regulation in Chemicals Management (CII) welcomes the opportunity to provide its views on the reform of the REACH Authorisation and Restriction, as presented by the European Commission to CARACAL on 27 January 2022 (CA/03/2022). In this context, we support the Commission's intention to clarify the interface between REACH and other pieces of EU legislation, most notably the Occupational Safety and Health (OSH) framework.

General considerations

- We understand that OSH only being mentioned in the context of Option 3 was done purely to keep the document concise and to facilitate the calculations in the Impact Assessment. Elements in the various options might be inter-changeable if necessary.
- We also understand that the Commission anticipates that none of the three policy options presented in the paper will be adopted as such. Instead, a 'preferred option' will consist of various elements from the different options presented. The purpose of the discussion at this stage is to refine the options to be analysed in the Impact Assessment.
- Against this background, the CII would like to stress the importance of considering the REACH/OSH interface under the final, 'preferred' option.
- The CII believes that a proportionate regulatory risk management option should not be determined purely on the basis of hazard. The CII, therefore, supports an early Regulatory / Risk Management Option Analysis (RMOA) for determining the appropriate way forward.

Considerations on the Role of other legislation

In line with our January 2021 [comments](#) on the DGs ENV-GROW paper on REACH Restriction and OSH OELVs (CA/64/2020):

- We call on the Commission to reflect further on a better integration of REACH with other legislation, notably OSH. Where other legislation (e.g., OSH) offers the most proportionate way to manage a chemical risk, such an option should be chosen

after the RMOA, and the relevant uses of the substance should be exempted from duplicative REACH Risk Management Options.

- We are concerned that the Commission might still be considering whether to adopt limit values in the form of Restrictions that cover the same scope as an occupational exposure limit value (OELV) would.
- We see REACH restrictions and OSH directives as complementary tools. 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 OELVs. We do agree 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.
- Nonetheless, 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 idea 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 [...].'
- We recall that in the Background Paper for the Workshop on the Reform of the REACH Authorisation and Restriction System (GROW.F.1/OL), one option for consideration was to transfer part of the competences to set BOELVs from OSH legislation to REACH. The CII has concerns with this option and calls upon the Commission to maintain the role of OELVs as a tool within the OSH Directives under the responsibility of DG EMPL.
- We understand that the main reason for proposing the "transfer" of OELVs-setting into REACH would be that in this manner BOELVs could be set through "comitology", rather than ordinary legislative procedure, thus achieving a faster pace of regulation. However, rather than moving the OELVs process under REACH, we encourage the Commission to consider the possibility of using "comitology" for setting BOELVs under OSH. In addition, the role of the tripartite Working Party Chemicals (WPC) and the Advisory Committee on Safety and Health at Work (ACSH) in the OELV-setting process should not be changed.
- The CII further notes that in that Background Paper another option was to continue the current work division. The paper raised the concern that no systematic way of handling the REACH-OSH overlap has emerged. The CII agrees that there is a lack of coherence in decision-making and therefore reiterates its call to establish criteria when to use OELVs as the most appropriate Risk

Management Option (RMO) and when other RMOs would be appropriate. We propose to start a debate involving stakeholders on what these criteria should be. Once established, those criteria could then be applied on a case-by-case basis, which would lead to more consistent risk management decisions.

***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.*