

CII contribution to the consultation regarding the 4th revision of the Carcinogens and Mutagens Directive, CMD (Directive 2004/37/EC)

The CII welcomes the Commission's proposal for a revision of the Carcinogens and Mutagens Directive (CMD) and would like to express its support to the further setting of occupational exposure limit values (OELVs) for substances presenting a risk in the workplace specifically.

November 2020

A response by the Cross-Industry Initiative for better regulation in chemicals management

The Cross-Industry Initiative (CII) for better regulation in chemicals management was set up in 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.

Scope of the CII comments

The CII does not comment on the risk management of specific substances. The present comments relate to questions of principle regarding the implementation of the CMD.

CII comments

1. Protecting workers against carcinogens and mutagens

The CII members are committed to protecting workers' health and strictly implementing EU legislation in this respect. The CII wishes to highlight the important role of the EU Occupational Safety and Health (OSH) legislation, including the CMD and Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work (the Chemical Agents Directive – CAD), in the prevention of work-related diseases and fully embraces the Council Conclusions of December 2019 on OSH to better prevent risk of exposure to chemicals in the workplace.

In line with the Council Conclusions, we welcome the European Commission's proposal to optimise worker protection and note with interest that further binding OELVs under the CMD directive should be established. We reiterate the importance of **establishing appropriate OELVs at the EU level** to assess and prevent risks at work from the use of chemical agents. Since 2015, major progress has been made in the identification of OEL candidates and in the setting of EU-wide OELVs. At the same time, the Commission's pace of work to propose new OELs under the CMD has slowed, while OSH-related activities using – in some cases – less appropriate tools of chemicals legislation are increasing.

Although additional substances have been identified as a high priority by the Advisory Committee on Safety and Health at Work (ACSH), we regret that the Committee for Risk Assessment (RAC) has so far not received a mandate to undertake preparatory work on these other substances in order to contribute to the protection of workers' health. As highlighted in the recently published Chemicals

Strategy for Sustainability (CSS), “for chemicals where the workplace exposure is determined to be the dominating risk, the occupational safety and health directives are particularly relevant”¹.

We further support the CSS’s call to “strengthen protection of workers by defining, in the process of the upcoming Strategic Framework for Health and Safety at work, further priorities for addressing workers’ exposure to hazardous substances, including by identifying most harmful substances for which the Commission will propose to set OELVs following the established consultation process in the area of health and safety at work”².

In doing so, we further encourage to provide DG Employment, RAC, as well as the ECHA Secretariat which supports the RAC in its work, with the necessary resources to bring the objectives of the CMD and CAD to life and further protect workers’ health. We emphasize that a high degree of quality for the scientific and the socio-economic assessments needs to be ensured and, whenever appropriate, the setting of OELVs needs to have priority before setting regulatory measures based on chemicals legislation.

Moreover, we believe that the prioritization of substances for which an OELV should be set should be improved. Recently, there have been too many proposals for REACH Restrictions circumventing the OSH directives such as for the 5 cobalt salts or N,N Dimethylformamide (DMF), whereas the OELVs could have been set under the CMD or the CAD. To avoid repeating such unfortunate decisions, we recommend a **more systematic way of prioritizing substances for which an OELV needs to be set**.

Such a process could particularly benefit from increased transparency, coherence and predictability of the Risk Management Option Analysis (RMOA) that would enable the selection of the most appropriate risk management measures. The CII sees an opportunity for RMOAs in the CSS, which has developed the concept of a so-called “One Substance One Assessment”. The CII, therefore, calls for defining a clear scope of RMOAs and for improving their effectiveness and consistency, ideally by authorities publishing an RMOA Guidance document or an explanatory note. Such clarity will make it easier for Member State Competent Authorities (MSCAs), producers and downstream users to better anticipate the appropriate regulatory measures to be applied to substances.

The CII recommendations

- Provide DG Employment – and for their support in the setting of OELVs also RAC and the ECHA Secretariat – with the necessary resources to ensure that workplace related risks can be efficiently regulated and managed by OSH.
- Use the “One Substance One Assessment” concept of the CSS in an appropriate manner to improve the prioritisation of substances to be considered for OELV-setting under the CMD or the CAD.
- Proceed to the setting of OELVs, when this has been identified as the best Risk Management Option to tackle concerns at the workplace.

2. Managing the risk posed by substances that are toxic for reproduction

The CII notes ongoing discussions on whether the scope of the CMD should be broadened to include reproductive toxicants. While the CII takes a neutral stance on this question, we would like to raise two aspects that should be considered in the context of these discussions.

Firstly, in Section 1 of this paper, we highlighted the importance for worker protection in moving on swiftly with the setting of OELVs under the CMD and the CAD. The CII also emphasized the resources

¹ [Chemicals Strategy for Sustainability](#), page 9, footnote 38.

² *Ibidem*, page 11.

needed on the side of DG Employment to advance with the setting of OELVs. A mandate for a legislative overhaul might indeed bind resources and thus risk interrupting or significantly slowing down the current flow of new/revised OEL values. In the discussions on whether the CMD should become a CMRD, it should be considered whether enough resources are available and if there are insufficient resources for both more OELVs and a CMD revision, which of these two tasks is of higher priority for protecting workers better. In this context it can also be important to note that the CAD already offers the opportunity to establish binding OELVs and reprotoxic substances can be covered within the CAD already now. It would be the CII's impression that if a mandate for a CMD revision would further slow down the OELV-setting process or even bring it to a halt, then in the near future more can be achieved by keeping up the waves of OELV-setting as the main priority.

Secondly, should the CMD be revised so as to cover reproductive toxicants, then this opportunity should be taken to reflect on which of the provisions are applicable to all substances which have carcinogenic, mutagenic or reprotoxic properties (CMRs), as well as those that would be applicable only to non-threshold CMRs. Not all provisions of the CMD are nowadays still relevant for CMRs for which there is a threshold of effect. A threshold is also recognized to be the standard when it comes to reproductive toxicants.

The CII recommendations on discussions on the inclusion of reprotoxic substances into the CMD

- Consider the impact of a mandate for a legislative overhaul and whether this would negatively impact or even interrupt the flow of waves on OELVs.
- Should there be a mandate to include reproductive toxicants in the CMD, it should be explored which provisions are relevant for all CMRs and which ones are only relevant for CMRs without a threshold of effect.

Conclusions

The CII welcomes the initiative of the European Commission to revise the CMD and strongly encourages DG Employment to use OSH-legislation as the main instrument for regulating risks at the workplace. For this purpose, DG Employment, RAC, as well as the ECHA Secretariat need to be granted sufficient resources to carry out their duties under the OSH policy framework and the prioritization of substances needs to be facilitated by clear criteria to be applied in RMOAs.