

POSITION PAPER

CII response to ECHA RAC/SEAC opinion on an Annex XV restriction dossier for N,N Dimethylformamide (DMF)

The CII considers the restriction proposal applied to DMF is not the appropriate policy instrument to manage risks posed by exposure to chemicals in the work environment. In this context, the CII considers that the REACH-OSH interface should be clarified with priority.

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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 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.

The CII would like to share the following comments on the Annex XV restriction proposal for the use of N,N-Dimethylformamide (DMF) as an aprotic solvent.

Scope of the CII comments

The CII does not comment on the risk management of specific substances. The present CII comments relate to questions of principle regarding the REACH-OSH interface that are raised by the approach taken for the proposed DMF Restriction. These questions fall into the remit of the CII's work.

CII comments

1. Exposure limit values at the workplace should be set as OELs under workplace legislation than by REACH restrictions that emulate OELs:

In the case of DMF an **indicative OEL** under the CAD already exists. If needed, this value **could be updated and/or turned into a Binding OEL** under the CAD.

The CII considers that the REACH Risk Management Options (authorisation, restriction) are **not the appropriate policy instruments to manage risks posed by an exposure to chemicals in the workplace**. The CII believes that the proposed REACH restriction, combined with the introduction of binding derived no effect levels (DNEL) serving as use conditions, circumvents the procedures foreseen by the legislator for the setting/updating of Occupational Exposure Limits (OELs) and is at odds with REACH Article 2(4). Furthermore, it would lead to confusion for those involved in the risk assessment and risk management in the workplace. In the ECHA RAC/SEAC opinion it is mentioned that "Forum notes that in some countries the proposed restriction poses some organisational difficulties. In several Member States the responsibility for the enforcement of workplace safety and the environmental protection are split between different authorities. Thus, this workplace related restriction in REACH may lead to mixed competencies".

2. Clear criteria to decide when binding OELs are the best RMM are necessary:

The CII recalls that the **Council and the REFIT Platform recommended the development of criteria** for when a Binding Occupational Exposure Limit is the best RMO. Based on the proposals of the REFIT Platform, the CII recommends the following criteria for choosing an OELV as the best suited risk management option:

- the substance presents a risk related to a Substance of Very High Concern (SVHC)-property limited to the workplace only (i.e. not for consumers, man via the environment or the environment); and
- the substance cannot be reasonably expected to be substituted in that use in the near to mid-term future.

The CII regrets that the present case-by-case approach to the management of risk of chemicals in the workplace does not offer enough consistency and legal certainty. It remains unclear to the CII why in some cases RAC and SEAC consider that the setting of an OEL would be an appropriate risk management option (RMO) instead of a REACH restriction that emulates an OEL (see the case of the 5 Cobalt Salts) and in others like DMF they do not raise OELs as appropriate RMO. We therefore call upon regulators to create a **forum for discussions on when to use REACH tools (authorisation, restrictions) or OSH tools to address workplace specific risks**. The outcome of such an inclusive debate may lead to criteria that can frame future substance-specific discussions and lead to more efficiency.

Conclusions

The CII considers the restriction proposal applied to DMF is not the appropriate policy instrument to manage risks posed by an exposure to chemicals in the work environment and is opposed to the use of Restrictions to bypass or duplicate existing OSH procedures to determine exposure limits. It calls upon authorities to consider whether the existing indicative OEL under the CAD should be updated and/or turned into a binding OEL.

The CII considers the clarification of the REACH-OSH interface as an urgent issue to be solved with priority. The creation of criteria for when to choose OSH/OELs as the best RMO would render decision-making much more effective and avoid repetitive and extensive case-by-case discussions, which in their result lead to inconsistent approaches for directly comparable cases. The CII recommendations on how to improve RMOAs and when to choose OSH/OELs as most appropriate RMO are available on our website.