



Cross-Industry Initiative
for better regulation in chemicals management



POSITION PAPER ON THE 2ND REACH REVIEW

The CII welcomes the conclusion that ‘the interface between REACH and OSH legislation calls for systemic solutions’

Considerations for the way forward on REACH and OSH

6 April 2018

Executive summary:

- The CII welcomes the conclusion by the European Commission to prioritise the interface between REACH and OSH. We are willing to contribute to systematic solutions to maximise synergies between those two frameworks.
- We note that the Commission plans to mandate ECHA RAC with developing OEL recommendations. We encourage making available appropriate resources and expertise to any Committee chosen to develop recommendations for OELs.
- We call for a further strengthening of risk management option analyses (RMOAs) to ensure that they lead to consistent and proportionate results, which are more predictable. We recall that the SVHC Roadmap allows to identify appropriate risk management options within REACH or alternatively outside REACH.
- Guidance on RMOAs should include explicit criteria about when OSH legislation (including binding OELs) is the most appropriate risk management option, i.e. when it should be used instead of REACH Candidate Listing and Authorisation. We wish to

stress, that the Government Group of the REFIT Platform also recommended the development of such criteria.

- **We observe that a paragraph in the Staff Working Document may lead to a misinterpretation of rulings of the EU Court of Justice and the General Court. This confusion may limit the appropriate use of discretion granted by Article 58(2) of REACH (exemptions from Authorisation). We therefore respectfully request that the Staff working be corrected and that future communications be more precise when reflecting on these rulings.**
- **The CII and its Members stand ready to contribute to the authorities' work on reaping full benefits from synergies between REACH and OSH while avoiding unnecessary duplication.**

In 2015, the Cross-Industry Initiative for better regulation in chemicals management (CII) raised the need to prioritise an alignment between REACH and EU Occupational Safety and Health legislation (OSH). Since that time, it has shared more detailed proposals on how the interface between REACH and OSH can be systematically improved.¹ We welcome the enhanced interaction between authorities responsible for REACH and OSH. The increase in activity to set binding OELs under OSH is also a positive development.

We find it encouraging that the REACH and OSH interface has emerged as one of the four issues requiring the most urgent action. We support systematic solutions. We acknowledge the recognition given to RMOAs and the commitment to further work on enhancing the way they are run. RMOAs are an excellent tool to manage the interface between different pieces of legislation that relate to chemicals management, such as REACH and OSH.

The Commission Staff Working Document (SWD) that accompanied the Commission's General Report on the 2nd REACH Review provides considerable detail on the topics 'REACH and OSH' and 'RMOAs'. This is a good starting point for systematic and appropriate solutions that will enhance the synergies between REACH and OSH and avoid unnecessary duplication. The CII is keen to contribute to developing these thoughts further. With the present paper, we share our initial reactions to some of the details present in the Commission's 2nd REACH Review documents:

- The Commission's reflections on consistency of limit values for exposure at the workplace:
The Commission wishes to avoid divergences between OELs and Derived No Effect Levels (DNELs). The Commission therefore proposes an alignment of the methodologies. It also wishes to enhance the role of ECHA's Risk Assessment Committee (RAC) in preparing recommendations for OELs. We agree that divergences should be avoided, where possible. Whichever Committee may provide recommendations for OELs in the future, we consider it important that authorities provide it and its Secretariat with the appropriate financial resources and expertise to ensure an analysis of high quality. It will also be crucial to consider the measurability of compliance with OEL-recommendations.
- The Commission's reflections on how to address the impact of REACH authorisation on competitiveness:
We welcome that the Commission recognises that authorisation may impact the competitiveness of EU industry. In its report, however, it considers only one solution to this problem, namely the use of Restrictions for the import of articles containing Annex XIV substances. We observe that this tool may not deliver results in all cases. For example, when

¹ <http://www.cii-reach-osh.eu/positions.html>.

a substance of very high concern is only used during the production of an article, and is not present in the finished article, a restriction on the article will not put foreign and EU based production on an equal footing. Secondly, even when an article contains an SVHC, a restriction on imported articles may not be feasible: If authorisations for producing the article containing the substance in the EU are granted, no restriction could ban the import of the articles. We are eager to discuss these points further with the Commission to find alternative solutions. For example, when the concern is worker health, an OEL limit would address the issue effectively without the costs and uncertainty associated with repeat applications for authorisation.

- Regarding the Commission’s considerations relating to RMOAs:
 - Nature of RMOAs: We note that the Commission suggests that RMOAs are only a voluntary albeit useful tool. We observe that a study conducted on behalf of the European Defence Agency (EDA) offers a divergent interpretation.² It suggests that RMOAs are a tool to comply with the EU’s principle of proportionality. Indeed, only RMOAs enable the holistic consideration of all risk management options available through EU legislation and proportionate regulatory decision-making. We encourage authorities to recognise that to comply with the proportionality principle, they first need to consider different regulatory options. Thus, the conduct of RMOAs is binding.
 - The CII believes that reaping further benefits from RMOAs is possible. More Guidance on their conduct is necessary: The Commission acknowledges the benefits that the SVHC roadmap and RMOAs have made to a more coherent management of substances of concern. This progress has been achieved through a – so far – rather rudimentary framework of priority criteria and methodologies. We believe that further progress is possible by providing more detailed guidance on the conduct of RMOAs. This could include referencing the different options that authorities may consider in the RMOAs. Also, the Guidance could include criteria for choosing a specific option. This added clarity would enable a larger group of Member States to actively contribute to the RMOA-process, rendering it more effective. In this context, we welcome that the Commission refers to the REFIT platform’s submission, in which both industry and Member States suggested that criteria be developed for when OSH is the most appropriate risk management option. We strongly encourage the inclusion of appropriate criteria in the Common Understanding Paper that the Commission intends to publish in 2019. Subsequently, a dedicated RMOA Guidance could incorporate them.
 - The CII recognises that industry needs to prepare proactively for RMOAs so that decision-making can be performed in a timely manner: We support the Commission’s intention to promote an early consideration of socio-economic information in RMOAs, when such information is available. We recognise that it falls upon stakeholders to prepare so that the processes can proceed swiftly. Any early warning system for upcoming regulatory activity such as ECHA’s PACT is helpful. Clarity on the systematic conduct of RMOAs (e.g. by means of Guidance as suggested above) will enable industry to prepare appropriately.
- CII calls for references to Court rulings on the possibilities for exemptions from REACH Authorisation (Article 58(2) of REACH) to be more precise:
Finally, we want to draw your attention to the wording on page 103 of the SWD. In our opinion it could lead to a misinterpretation of a ruling of the EU Court of Justice. The SWD reads as follows: *“In relation to the exemption of certain uses (or categories of uses) from authorisation in accordance with Article 58(2) of REACH, the Court of Justice of the EU in Case C-651-15 P VECCO vs Commission confirmed that the OSH legislation does not constitute a specific Union*

² See page 266 of the Report, which is available here: <https://www.eda.europa.eu/docs/default-source/reports/eda-reach-study-final-report-2016-december-16-p.pdf>.

legislation under which, by imposing minimum requirements relating to the protection of human health or the environment for the specific use of a substance, the risk is properly controlled". The actual ruling of the Court of Justice had stated the following: "[...] in the present case, having correctly held that [the CMD contained] no provision specific to chromium trioxide imposing minimum requirements relating to the protection of human health or the environment [...], the General Court did not err in law in finding [...] that [the CMD does] not constitute 'specific legislation' within the meaning of Article 58(2) of the REACH Regulation".³ Both the Court and the General Court held that in so far as the CMD does refer to a specific substance, i.e. by establishing a binding OEL, it constitutes a specific Union legislation and imposes minimum requirements relating to the protection of human health. This can lead to proper control. Precision on precedent setting rulings is essential. It is the basis for correctly using discretion given to the authorities by Article 58(2) of REACH. If possible, we would like to see the Staff working document present on the Commission website amended and corrected to avoid confusion.

The CII and its members are looking forward to discussions on how to further streamline the EU chemicals management framework. Industry and regulators have the common aim to effectively protect health and the environment, while avoiding negative impacts on the competitiveness of the European industry.

Annexes:

- Annex 1: List of signatory organisations
- Annex 2 (separate PDF document): "About Us" document with background on signatory organisations

Annex 1: List of signatory organisations

European and global associations and platforms

ACEA – European Automobile Manufacturers' Association
 ADCA Taskforce
 AmCham EU
 BeST – Beryllium Science and Technology Association
 BSEF – The International Bromine Council
 Cadmium Consortium
 CAEF – European Foundry Association
 CDI-Cobalt Development Institute
 CECOF - The European Committee of Industrial Furnace and Heating Equipment Associations
 CEMBUREAU – The European Cement Association
 CEPE – European Council of the Paint, Printing Ink and Artists' Colours Industry
 CerameUnie – The European Ceramic Industry Association
 CETS – European Committee for Surface Treatment
 CheMi – European Platform for Chemicals Using Manufacturing Industries
 ChemLeg PharmaNet
 CIRFS – European Man-made Fibres Association
 CPME – Committee of PET Manufacturers in Europe
 EAA – European Aluminium Association
 EBA – European Borates Association
 ECFIA – Representing the High Temperature Insulation Wool Industry

³ The Court therefore upheld the ruling of the General Court (T-360/13, dated 25 September 2015) that "[i]n so far as the [CMD] does not refer to any substance other than benzene, vinyl chloride monomer or hardwood dusts, for which it lays down maximum values for occupational exposure, it cannot be considered either 'specific' or to impose minimum requirements" (emphasis added).

ECGA – European Carbon and Graphite Association
ECMA – European Catalyst Manufacturers Association
EPMF – European Precious Metals Federation
ETRMA – European Tyre & Rubber Manufacturers' Association
Euroalliages – Association of European Ferro-alloy Producers
EUROBAT
EUROFER
Eurometaux
Euromines
FEPA – Federation of European Producers of Abrasives products
Frit consortium
Glass Alliance Europe
I2a – International Antimony Association
ICdA – International Cadmium Association
IIMA – International Iron Metallics Association
IMA Europe- European Industrial Minerals Association
IMAT – Innovative Materials for Sustainable High-Tech Electronics, Photonics and Related Industries
Ipconsortium
Lead REACH Consortium
MedTech Europe
Nickel Institute
PRE – The European Refractories Producers Federation
RECHARGE – European Association for Advanced Rechargeable Batteries
SMEunited – European Association of Craft, Trades, Small and Medium-Sized Enterprises
UNIFE – The European Rail Industry

National associations

A3M – Alliance des Minerais, Minéraux et Métaux (French Ores, Minerals and Metals Association)
ASSOGALVANICA – Associazione Italiana Industrie Galvaniche (Italian Plating Industry Association)
BCF – British Coatings Federation
BVKI – Bundesverband Keramische Industrie e.V. (German Association of the Ceramic Industry)
ION – Vereniging Industrieel Oppervlaktebehandelend Nederland (Dutch Association for Industrial Surface Treatment)
NFA – Non-Ferrous Alliance
SEA – Surface Engineering Association
VDA – Verband der Automobilindustrie (German Automotive Industry Association)
VDFFI – Verband der Deutschen Feuerfest-Industrie e.V. (German Association of the Refractory Industry)
VdL – German Paint and Printing Ink Association
VDS – Verband Deutscher Schleifmittelwerke e.V. (German Abrasives Association)
WKÖ – Wirtschaftskammer Österreich (Austrian Federal Economic Chamber)
WVMetalle – Wirtschaftsvereinigung Metalle (German Metals Trade Association)
ZVO – Zentralverband Oberflächentechnik e.V. (Central Association of Surface Technology)

Corporations

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