



## POLICY RECOMMENDATIONS

# Enhancing the effectiveness of OSH – in particular the setting of OELs

*Recommendations by the Cross-Industry Initiative for Better Regulation in Chemicals Management*

November 2016

## Introduction

In a set of recommendations submitted simultaneously with this paper to the European Commission’s Secretariat General, the cabinets of Vice-President Katainen and Commissioner Thyssen, and relevant units in DG Employment, Social Affairs and Inclusion (DG EMPL), DG Environment (DG ENV) and DG Internal Market, Industry, Entrepreneurship and SMEs (DG GROW), the Cross-Industry Initiative (CII) proposed elements of better regulation in chemicals management that can be applied efficiently and effectively through the current workplace legislation. In this context, we recognise that the revision of EU Occupational Safety and Health (OSH) legislation is a major opportunity to simplify the application of the approach that we propose in our initiative.

The present document summarizes our suggestions for consideration by DG EMPL. We look forward to continuing a constructive exchange with your services on this matter.

### 1. Some issues concerning the current framework, which are relevant for the cross-industry initiative

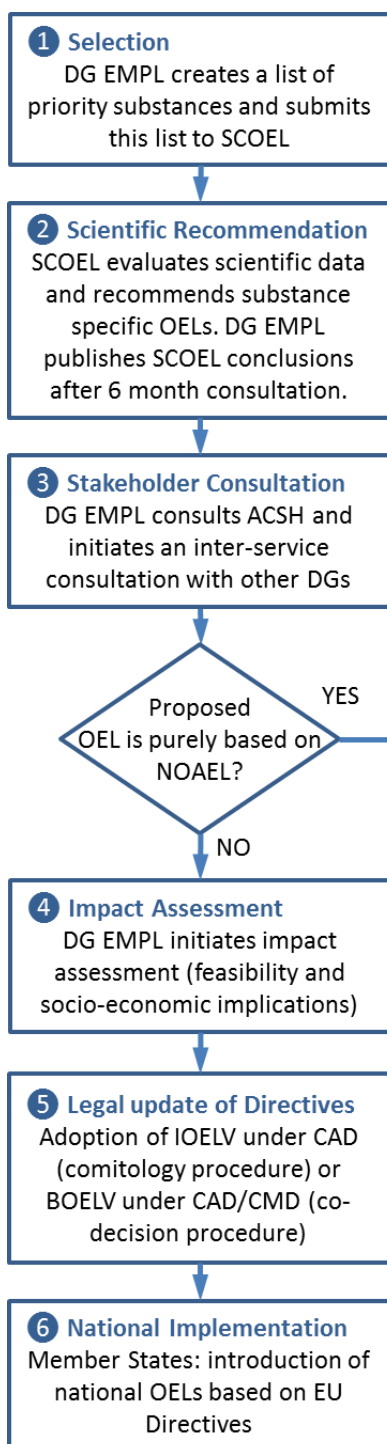
OSH Directives provide a well-defined regulatory framework, inter alia for the safe handling of chemicals at the workplace. However, some concerns have been raised with regard to the effectiveness and workability of the current EU system for setting Occupational Exposure Limits (OELs), in particular binding ones. Amongst others, these concerns relate to the following aspects:

- Unclear selection process for substances. For instance, some substances that are considered of priority under REACH, due to perceived risks at the workplace, are not considered for OEL-setting under OSH.
- A limited number of substances covered by binding OELs (BOELVs): Only five BOELVs have been set so far. At the same time, there are about 100 indicative OELs (IOELVs).
- Apparently slow and burdensome process to put BOELVs in place (this applies to a lesser extent also to IOELVs).

The above concerns should be taken into account when considering proposals on how to improve the OSH regulation. We will discuss some options and solutions to this end in the next section.

## 2. Substance selection and efficiency of the process of setting OELs

The below suggestions for a prompter setting of harmonised OELs follow the main steps of the regulatory process as depicted in the simplified flowchart on the left.



① The selection process could benefit from the REACH 2020 roadmap. Substances identified by REACH authorities during the risk management option analysis (RMOA) as posing a workplace risk, which requires further risk management measures, should be communicated to and discussed with the authorities specifically tasked with workplace legislation and, in particular, DG EMPL. Based on the specialised expertise of workplace authorities, a common position of REACH and workplace authorities should be achieved. If it is agreed that the substance raises a risk at the workplace, then the substance should be prioritised accordingly and be fed into the SCOEL work programme.

② The need to allocate additional resource to the relevant Unit within DG EMPL, supporting and acting as scientific secretary for the SCOEL Committee, should be assessed. These additional resources should help to speed up literature searches and the drafting of summary statements. REACH Registration data (i.e. key toxicology and epidemiology studies) should be used to facilitate the evaluation process. Easier access to these data should be enabled for the scientific assessment for workplace risks upon request by the SCOEL and equivalent national bodies.

③ The role and “weight” of the tripartite ACSH could be enhanced in the context of setting BOELVs. If the ACSH can reach a consensus based on a SCOEL recommendation, a “fast track” approach could be considered to incorporate a BOELV into legislation (i.e. via Commission Implementing or Delegated Acts), which would lead to a change in step ⑤. Only if such a consensus cannot be achieved in the ACSH should the setting of the BOELV follow the current decision-making route.

④ Where a consultation has already been carried out under REACH (e.g. in the context of an RMOA), this information could feed into the impact assessment, enabling it to be completed more quickly.

5 Considering the number of existing EU IOELVs as opposed to BOELVs, the comitology procedure is clearly the fastest regulatory process to establish EU-wide OELs. Especially if combined with the changes suggested above, a faster and less burdensome decision-making process seems adequate for BOELVs. Decisions with far reaching implications and very significant impacts under REACH (e.g. inclusion of a substance on REACH Annex XIV) are currently being taken by the Commission through the comitology procedure. Therefore, there is no reason why the setting of EU BOELVs should require to be done via the EU ordinary legislative procedure (old “co-decision”), instead of Commission Implementing measures or Delegated Acts, which can be adopted much more quickly, especially in those cases when the abovementioned conditions are met (i.e. unanimous agreement within the ACSH on the basis of a SCOEL recommendation). Regarding the adoption of IOELVs, further measures should be reflected on, to enhance the process and the robustness of IOELVs (e.g. update mechanism of the IOELV in case of available evidence pointing to the need for a re-discussion of the IOELV, adoption via comitology of IOELVs that have already gone through the steps without delay to wait for progress on other IOELVs).

### 3. Further ideas for a future revision of OSH

We would also support a “re-branding” of indicative OELs. The term “indicative” seems to cause misinterpretation.

If a revision of OSH was undertaken, the following approach could be chosen for the OELs:

- Whenever possible, a health-based EU-wide OEL should be derived. This should also be possible for (non genotoxic) carcinogenic substances with a threshold. National OELs would transpose this value at national level and render it enforceable.
- Where the derivation of a health-based OEL (or DNEL) is not possible (i.e. where the toxicity has no determinable threshold), a risk-based OEL should be derived. Alternatively, and when the dominating effect is a non-carcinogenic one, a practical threshold might be determined. This is already proposed for some substances by SCOEL.<sup>1</sup> Again, national OELs would transpose this value at national level and render it enforceable.
- Where a health-based or risk-based OEL cannot (yet) be complied with (for technical feasibility or socio-economic reasons), a possibility for granting an exemption from immediate compliance with this OEL should be provided. As part of such an exemption, transition periods should be set to allow for efficient adjusting to the new OELs.

Finally, we would suggest explicitly incorporating the concept of threshold into the Carcinogens and Mutagens Directive, in order to align it with today’s scientific understanding.

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#### Annexes:

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

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<sup>1</sup> According to the existing SCOEL guidance (SCOEL Methodology for the Derivation of Occupational Exposure Limits (Key Documentation, version 7, June 2013)).

## ***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  
 CECOF - The European Committee of Industrial Furnace and Heating Equipment Associations  
 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  
 Cobalt Institute  
 CPME – Committee of PET Manufacturers in Europe  
 EBA – European Borates Association  
 ECFIA – Representing the High Temperature Insulation Wool Industry  
 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  
 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  
 UEAPME – European Association of Craft, 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 – Dutch Association Industrial Surface Technology  
 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)  
 WVM – Wirtschaftsvereinigung Metalle (German Metals Trade Association)  
 ZVO – Zentralverband Oberflächentechnik e.V. (Central Association of Surface Technology)

### **Corporations**

Colorobbia  
 DALIC  
 Esmalglass itaca  
 Ferro  
 Smalticeram