Cii REACH OSH

Cross-Industry Initiative
for better regulation in chemicals management

POLICY RECOMMENDATIONS

CII background paper on workplace exposure limits

November 2016

Executive Summary:

- **OSH and REACH need better alignment to capitalize on potential synergies. If a workplace concern is detected at the RMOA stage, DG EMPL should be consulted. OSH and REACH priorities should be better synchronized (i.e. related to substances causing workplace concerns).**

- **If an EU-wide OEL or a SCOEL recommendation exists, REACH Authorities should recognise this value instead of deriving a ´worker DNEL´. This will avoid double work, conflicts of opinion and confusion at the downstream user level. The recognition of OELs will lead to a more targeted and efficient use of regulatory resources and improved legal certainty.**

- **SCOEL should be tasked with developing a methodology to derive limit values for ´data-poor´ substances. SCOEL should get access to REACH registration data (which might require Confidentiality/Non-Disclosure Agreements to protect the rights of the data owner).**

- **The legal process for OEL setting should be streamlined to allow for swifter implementation. The CII has already submitted proposals to that effect.**

1. Introduction

Occupational exposure limits (OEL) established under occupational safety and health (OSH) regulations are an important factor for meaningful workplace risk management, complementing risk management measures (RMM) to protect against the adverse health effects of certain hazardous chemicals. While limit values might not be considered RMMs per se, they fulfil an important role as they allow a quantitative assessment of the adequacy of RMMs by comparing actual workplace exposure measurements against a defined limit value. In other words, OELs define operational and harmonized conditions aiming at achieving safe use.

Following the implementation of the REACH Regulation, a series of ´new´ limit values was introduced. Registrants are required to derive DNELs (Derived No Effect Levels) or DMELs (Derived Minimal Effect Levels) as part of their Chemical Safety Assessment. While OELs are set to protect workers from long-term (local and systemic) inhalation effects, DNELs need to be set also for other exposure scenarios and target populations (e.g., oral exposure to the general public, acute dermal exposure for workers).

This leads to uncertainties and confusion as to which value is applicable at the workplace in practice.

This paper discusses the different values applicable at the workplace, their legal background and their relevance in occupational risk management. We provide suggestions for a necessary clarification of the status of such values in the context of occupational safety and health (OSH), REACH Authorisation and Restriction. We stress the CII conviction that where an up-to-date OEL exists it should take precedence over DNELs or DMELs for the management of workplace safety and the assessment of workplace risk. Following the discussion of the different approaches under OSH and REACH, we provide some recommendations on how to improve synergies and legal clarity between these two regulatory instruments.

2. Limit values and effect levels – overview

The following sections provide an overview of limit values and effect levels along with their different origins and objectives:

2.1 Limit values established under OSH Directives and national workplace legislation

- **National OELs (nOEL):** individual Member States (MS) have developed and implemented legally binding occupational exposure limit values as part of their national workplace legislation. Methodologies may differ among MS, which can lead to different limit values for the same substance across the EU.

- **EU-wide OELs:** for substances (incl. process generated substances) meeting certain priority criteria, the EU scientific committee for occupational exposure limits (SCOEL) under the auspices of DG EMPL recommends EU-wide limit values. These limit values can be adopted under EU legislation following defined regulatory procedures. Three types of limits are specifically relevant:
- **IOELVs**: indicative[1] occupational exposure limit values are health based limit values foreseen under the Chemical Agents Directive (CAD). Technical feasibility is considered.
- **BOELV**: binding occupational exposure limit values may be health based, but often also take socio-economic aspects and feasibility into consideration.[2] They can be established under the CAD as well as the Carcinogens and Mutagens Directive (CMD).
- **BLV**: biological limit values can be derived in cases when a substance allows direct biomonitoring (presence of substance or metabolites in bodily fluids – urine and blood).

2.2 Effect levels established under REACH

- **DNELs / DMELs:** Derived No Effect Levels (DNEL) or, in case of substances for which no effect threshold can be demonstrated, Derived Minimum Effect Levels (DMEL) must be calculated by REACH registrants and provided as part of each substance's Chemical Safety Report (CSR).[3] REACH Annex I describes the procedure to establish DNEL(s) for a substance as part of the registration obligations of manufacturers and importers. DNELs are most commonly calculated for all relevant routes of exposure based on a "no observed adverse effect level (NOAEL)" provided that a toxicology study is available for the relevant endpoint. To calculate a DNEL several assessment factors (AF) are applied to the NOAEL to adjust for variations in study quality and necessary extrapolations (animal to human, intraspecies differences etc.). Default AFs are provided via REACH Guidance documents, however, deviations are allowed where adequately justified. The derived levels are used to calculate risk characterization ratios and determine RMMs for all registered uses, which are then used in exposure scenarios.

[1] Indicative OELs are indicative to Member States in a sense that the Member States are under the obligation to take regulatory action and put in place a national OEL, which should be equivalent or stricter than the indicative OEL. Only where justified, a national OEL may be less strict than the indicative OEL.

[2] The assessment of technical feasibility and socio-economic implications has been criticised by some stakeholders and has been portrayed as a weakness of the OEL setting process as opposed to a reference DNEL/DMEL. It should, however, be noted that Authorisation also foresees a socio-economic justification for the continued use of substances.

[3] This derivation is only applicable for hazardous substances.

- **RAC reference DNELs / DMELs:** ECHA´s Risk Assessment Committee (RAC) has developed the practice of deriving ´reference´ effect levels or dose-response curves, predominantly for substances of very high concern (SVHC) and/or substances identified for further regulatory action under REACH. The purpose of a RAC derived reference DNEL/DMEL is to assess the adequacy of controls or the remaining risk associated with the use of a substance. RAC derived reference DNELs and dose response curves serve as non-legally binding 'reference' values. In the context of Authorisation they provide applicants and other stakeholders with a clear signal as to how RAC is likely to evaluate these important elements of the risk assessment.

3. Legal background

3.1 OSH Directives

The concept of European OELs was established as part of the OSH Framework Directive and its related Directives define worker protection requirements for chemicals (CAD) as well as carcinogens and mutagens (CMD). These Directives are anchored under "worker protection" in the EU Treaty and are therefore specifically designed to provide a targeted framework for occupational situations.

The Scientific Committee for Occupational Exposure Limits (SCOEL) was initially set up in 1995 by Commission Decision 95/320/EC to evaluate the health effects of exposure to chemical agents within the workplace.

The SCOEL legal mandate was recently renewed via Decision 2014/113/EU, providing specific details on the mission, membership and procedures of the Committee. The selection and appointment of members ensures their independence and that their scientific qualification enables them to fulfil SCOEL´s mission and its role as scientific advisor to the Commission. A maximum of 21 members is selected and appointed by the Commission based on proven scientific expertise and experience covering a broad field of relevant scientific disciplines including chemistry, toxicology, epidemiology, occupational medicine and industrial hygiene, and general competence in setting OELs. The committee membership also ensures a balanced geographical distribution of the members.

The legal implementation of OELs under the framework of current EU Directives (i.e. CAD/CMD) follows defined procedures and includes various important steps to ensure the relevance and practical feasibility of OELs:

- **Scientific validity**: SCOEL draft recommendations are published and interested stakeholders can provide comments during a consultation period lasting several months. This process aims to ensure that all scientifically relevant information will be taken into consideration to form the basis of a SCOEL recommendation.
- **Stakeholder involvement**: the tri-partite advisory committee on safety and health (ACSH) as well as the chemicals working party (WPC), both comprised of MS government representatives as well as representatives from employer and

employee organisations, are consulted as part of the legal OEL implementation process.

- **Impact assessment**: the impact of proposed BOELVs is evaluated. The impact assessment is part of the justification for a BOELV and must be evaluated by the Commission before a proposal is submitted to the EU Parliament and the Council.

In summary, OELs, established under national and EU OSH Directives are enforceable, legally binding limit values which must be complied with at the workplace.

3.2 REACH Regulation

In contrast, REACH has been established following the much broader scope of "market harmonization" under the EU Treaty, with the objective to harmonize the internal market, while at the same time aiming to achieve an improved protection of human health and the environment.

The role of the Risk Assessment Committee (RAC) is defined in REACH Art. 76 (1.c). A maximum of two RAC members can be nominated by every Member State and should be appointed based on their ´role and experience´. The RAC prepares the ECHA opinion on the risk to human health and the environment in the context of Applications for Authorization and restriction proposals as well as classification and labelling proposals. While deriving reference DNELs/DMELs is an actual activity of RAC, it is not defined in the REACH legal text. RAC itself has acknowledged that reference DNELs are "not explicit recommendations for the applicants and thus, have no legal implications".[4] RAC is sometimes supported by consultants nominated by ECHA, e.g. to assess what may be "adequate control" during the Authorization process. RAC reference levels often deviate from those submitted by registrants even though the derivation is supposed to follow the same process.

3.2 Summary

In summary, OELs, established under national and EU OSH Directives are enforceable, legally binding limit values which must be complied with at the workplace. The objective of DNELs/DMELs is different from the one of OELs, in that they are designed to cover – where applicable – other potential exposure situations (e.g. man via environment, consumers) to support the definition of RMMs for the purpose of REACH registration. The use of RAC reference DNELs/DMELs in the context of authorisation and restriction is not specifically foreseen in the REACH legal text, however, these values have

apparently been used (even when EU-wide OELs already exist) as a means to

[4] See page 1 of the Risk Assessment Committee's Document "Setting DNELs and dose-response curves prior to the application for authorisation phase", RAC/22/2012/06 (Agreed at RAC-22), dated 6 September 2012.

communicate and ´quantify´ the RAC opinion related to substance risks (which can deviate from the legally mandated EU-wide OELs).

4. Practical consequences of multiple values

While only OELs provide the legal basis for the assessment of workplace situations, DNELs/DMELs are commonly misinterpreted as alternatives to OELs, in some cases they might even be interpreted as overruling OELs. The co-existence of multiple values – especially when these values are different – has led to confusion for downstream users and enforcement authorities alike. The following example (taken from a safety data sheet (SDS)) might illustrate this issue:

SECTION 8: Exposure controls/personal protection

· **Additional information about design of technical facilities:** No further data; see item 7.

· **8.1 Control parameters**

· **Ingredients with limit values that require monitoring at the workplace:**		
872-50-4 N-methyl-2-pyrrolidone		
WEL ()	Short-term value: 80 mg/m³, 20 ppm Long-term value: 40 mg/m³, 10 ppm Sk	
· **DNELs**		
872-50-4 N-methyl-2-pyrrolidone		
Dermal	Long-term - systemic effects, worker	4.8 mg/kg (-)
Inhalative	Long-term - systemic effects, worker	10 mg/m3 (-)

Users of this substance might be confused by multiple values (OELs, RAC reference DNELs) and may struggle to understand which one should be complied with, under which conditions, and how to measure compliance (i.e. in the case of DNELs measurement methods are not provided). This might be further complicated in cases where an SDS also lists a range of national OELs (i.e. when there is no EU-wide limit value) as national limit values can vary by more than an order of magnitude for the same substance.

On an EU-wide level, attempts to harmonize the methodologies employed by SCOEL and RAC have so far not led to improvements. This has recently been recognized by ECHA[5]: "REACH has mechanisms to ensure that opinions developed by the ECHA Committees are scientifically consistent with those derived for the same substance elsewhere by EU bodies. Nevertheless, DNELs and OELs are still derived separately using different experts, making different judgements and using different methodologies. The result has been different numerical reference values for exposure limits and risk thresholds being established."

[5] ECHA: Report on the Operation of REACH and CLP 2016; ECHA-16-R-08-EN, May 2016, p. 80.

RAC derived (worker) reference DNELs appear to be systematically lower than OELs recommended by SCOEL. One possible explanation for this phenomenon might be the origin and purpose of DNELs and the process followed to derive them. The process has been simplified to allow registrants to calculate DNELs even when toxicology data are limited. In such cases, the calculation of a DNEL based on default AFs will provide a result without in depth expert knowledge. The results of such simplified calculations often lead to overly conservative levels, which may however not be appropriate, especially for those substances where robust toxicology and epidemiology data are available and would justify a deviation from the default factors.

It should be noted that lower limits do not necessarily lead to improved worker protection. This is the case in situations where a (practical) threshold exists (and may already have been defined by SCOEL). By definition a threshold is a ´health based´ limit below which the health risk is nonexistent. Requesting compliance with a lower DNEL value does not bring any additional health benefit, and might result in very high and unnecessary investments, or lead to the excessive use of personal protective equipment (PPE), unnecessarily burdening workers.

Furthermore, the use of overly stringent DNELs to justify Restrictions, or to judge the adequacy of Applications for Authorisation (AfA), will likely have negative socio-economic impacts without corresponding health benefits or improvements in worker protection.

5. CII position and recommendations

As outlined above, it can be argued that only the limit values established under OSH regulation fulfil the criteria set by EU law to set enforceable workplace exposure limits (inhalation route). The table below summarizes the previous sections:

Advantages ↑ and Disadvantages ↓ of EU limit value approaches (workplace control perspective)		
Criterion	**OSH: BOELV / IOELV**	**RAC reference DNEL / DMEL**
Legal certainty	↑ Defined legal status (CAD/CMD)	↓ Not foreseen by law, not legally binding
Measurement method (workplace compliance)	↑ Included in SCOEL assessment	↓ Not assessed/required
Expertise	↑ SCOEL: multi-disciplinary qualification requirements	➲ basic requirements[6]
Validity – data rich substances	↑ In-depth expert assessment, weight of evidence approach	↓ Application of default AFs may lead to overly conservative values

[6] The derivation of DNELs/DMELs is often outsourced to third parties, with varying scopes of review and budgets.

Validity – data poor substances	↓ SCOEL does not set limit if insufficient or inadequate data	↑ Approach allows derivation of effect levels based on limited data
Quality control	↑ several months consultation	↓ Not foreseen
Stakeholder involvement	↑ Tri-partite committee (ACSH, WPC)	↓ Not foreseen
Impact Assessment	↑ Required (for BOELVs)	↓ Not foreseen.[7]
Implementation speed	↓ Complex legal procedure	↑ Comparatively quick

When comparing OELs based on SCOEL recommendations with DNELs/DMELs derived under REACH, it becomes apparent that the latter cannot be used as alternatives to workplace exposure limits. The only advantages of the DNEL approach are related to its applicability to ´data-poor´ substances and the faster implementation (derivation, dissemination) compared to the OSH route. However, this relative speed comes at the costs of quality, transparency and ultimately the effective protection of workers. This leads to the following recommendations:

1. OSH and REACH need better alignment to capitalize on potential synergies. If a workplace concern is detected at the RMOA stage, DG EMPL should be consulted.[8] OSH and REACH priorities should be better synchronized (i.e. related to substances causing workplace concerns).
2. If an EU-wide OEL or a SCOEL recommendation exists,[9] REACH Authorities should recognise this value instead of deriving a ´worker DNEL´. This will avoid double work, conflicts of opinion and confusion at the downstream user level. The recognition of OELs will lead to a more targeted and efficient use of regulatory resources and improved legal certainty.
3. SCOEL should be tasked with developing a methodology to derive limit values for ´data-poor´ substances[10]. SCOEL should get access to REACH registration data (which might require Confidentiality/Non-Disclosure Agreements to protect the rights of the data owner).
4. The legal process for OEL setting should be streamlined to allow for swifter implementation.[11] The CII has already submitted proposals to that effect.

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[7] If compliance with a DNEL / DMEL is not feasible, the authorisation can be granted based on socio-economic considerations. Thus no higher protection is achieved, just because a stricter value is applied.
[8] We note that this recommendation of the CII is now already being implemented.
[9] If new data has become available since the establishment of the EU-wide OEL, then a revision of the OEL may be required.
[10] Pending the quality and relevance of existing information it is likely that the resulting limit values will be conservative, taking scientific uncertainties into account. This could motivate the affected industry to invest in further scientific evaluation of the substance.
[11] This would allow data-rich substances without an EU-wide OEL to be prioritised when the only risk in need of additional risk management is identified at the workplace.

Annex:

- *Annex 1: List of signatory organisations*

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About the CII

The Cross-Industry Initiative (CII) was set up between December 2014 and March 2015 as a loose coalition aimed at streamlining chemicals management. It currently comprises over 50 organisations: sectoral associations at EU and national level, as well as companies. Please find more information on our website (www.cii-reach-osh.eu) or contact us by email (info@cii-reach-osh.eu).

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
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

Colorobbia
DALIC
Esmalglass itaca
Ferro
Smalticeram