Cii REACH OSH
Cross-Industry Initiative
for better regulation in chemicals management

POLICY RECOMMENDATIONS

Detailed Proposal and Responses to Questions Raised on Workplace Legislation

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

November 2015

Introduction

In a position paper dated 18 March 2015, the Cross-Industry Initiative (CII) presented its recommendations for applying elements of better regulation to the management of chemicals in situations where the need for further risk management measures is confined to the workplace. These recommendations would specifically cover those cases where workplace-specific legislation can address the identified risks better than other risk management options such as REACH Candidate Listing and Authorisation. We are pleased to have this opportunity to elaborate on our proposed solution as an example of better regulation.

We would first like to stress that the proposed solution would not lead to *less* regulation, as some EU stakeholders could fear when hearing about a better regulation initiative. What we propose is a *tailor-made* and *targeted* regulation, which would avoid duplication, but without leaving gaps in regulation. The aim is a holistic consideration of applicable legislation, which allows selecting the most appropriate and efficient tool available in the legislation to address adequately the concerns raised by the use of a specific substance. In doing so, we systematically apply the principles outlined in the European Commission's Roadmap on Substances of Very High Concern (SVHC Roadmap).

While in other cases, REACH Authorisation may indeed be the best regulatory instrument to address the identified risks, in the specific situations that we describe, the workplace legislation with its comprehensive set of prevention and protection measures developed over the last

decades, including but not limited to the setting of EU-wide Occupational Exposure Limits (OELs), be they indicative or binding OELs, is the appropriate, targeted and proportionate regulatory choice to address potential risks. The alignment between REACH and EU Occupational Safety and Health (OSH) legislation that we call for is also in line with the objective of REACH to be aligned with workplace legislation (see e.g. Recitals 5, 12 and 111 of the REACH Regulation).

In a separate document communicated simultaneously with this paper to the European Commission's DG Employment, Social Affairs and Inclusion (DG EMPL), we are suggesting a number of recommendations on how the revision of EU OSH could contribute to simplifying the application of our recommended approach.

Scope of our initiative and our proposed solution

The scope of our initiative is well described, which allows us to make a concrete proposal with clear conditions defining its range of application. The starting point of our proposal is a Risk Management Option Analysis (RMOA) carried out by Competent Authorities. The RMOA is the tool already developed in the framework of REACH to identify the best risk management option for a given case. According to the SVHC Roadmap, this option can be either a REACH mechanism *or* a regulatory instrument offered by other legislation (such as the workplace legislation). The RMOA is not a full risk assessment of a substance but in order to choose the best option to manage a risk, the RMOA has to identify the risk(s) that need(s) to be addressed.[1]

If and when the RMOA identifies a risk limited to the workplace that requires further risk management measures, our solution can be applied. This can be the case of a substance exclusively handled in the workplace (i.e. in all its uses) and when the authority who carried out the RMOA has established that there is no further risk for humans via the environment or for consumers. In such a case, the risk is most comprehensively addressed and in a targeted fashion by workplace legislation, which covers the substance and its uses at the workplace more broadly than REACH Authorisation does. **Flowcharts**, which are attached to this document, reflect how our initiative relies on the SVHC Roadmap and RMOAs carried out by authorities. The flowcharts clearly outline which conditions have to be met in order for workplace legislation to be rightly applied as sufficient risk management measure. Where these conditions are fulfilled, applying REACH Authorisation instead or as an addition to workplace legislation would be disproportionate.

In these cases, the additional administrative layer of costs and work related to an Authorisation would not lead to added value, and it would not necessarily further advance safety or risk management measures at the workplace. Should REACH Authorisation be applied in cases where it does not bring an added value but rather damages value chains or the possibility of using substances for the benefit of society, REACH itself could be harmed and its reputation tarnished. A targeted application of REACH Authorisation to cases where it is the best risk management option will help build its reputation as effective legislation.

Particular strengths of workplace legislation

- **Dedicated expertise on workplace legislation: the example of the SCOEL Committee**

  Workplace legislation is developed precisely to improve the working environment to protect workers' health and safety. It specifically addresses the risks relating to chemical agents at work including particular provisions for carcinogens and mutagens at work. An

[1] As Professor Löfstedt also underlined (Guest column, Chemical Watch, Global Business Briefing, December 2013/January 2014), it is necessary that numerical targets for listing chemical substances of very high concern or prioritising based strictly on hazard need to be abolished and replaced with the routine completion of comparative risk evaluations or risk-ranking exercises, to uncover how great the risk profile of a chemical in question actually is.

example of strength of workplace legislation is the work by the Scientific Committee on Occupational Exposure Limits (SCOEL), which has been tasked with deriving health-based OEL-recommendations. The accumulated experience and specific expertise in the Committee ensures full understanding of workplace-specific considerations. It performs an in-depth assessment of the available data and derives science-based reliable and protective values. The depth of assessment of the available data allows it to use tailor-made uncertainty as compared to the standard factors currently applied by ECHA's Risk Assessment Committee (RAC) and to achieve protective occupational levels.

- **Broader scope: More uses of substances are covered**
  Workplace legislation covers all uses of the substance at the workplace from cradle to grave. Unlike REACH Authorisation that only applies to the placing on the market and use of chemical substances, workplace legislation applies to worker exposure to chemical agents released by *any work activity*, whether or not produced intentionally and whether or not placed on the market. For example, this includes intermediates, process-generated substances and the unintended release from articles (also imported articles) at the workplace, those situations not being covered by the Authorisation process. Authorisation does therefore not comprehensively tackle the risks at the workplace, whereas workplace legislation does.

- **Costs contribute to more safety**
  Costs generated by workplace legislation, i.e. invested in the purchase and set-up of protective measures and equipment, directly contribute to better risk management. The level of *administrative* costs (i.e. costs that do not directly contribute to the better risk management) triggered by workplace legislation are relatively small. This is not the case for REACH Authorisation, which is a process that is burdensome from an administrative perspective. Besides the application fee for an Authorisation, extensive resources are invested into the preparation of applications, which furthermore recur on a regular basis, i.e. each time that Authorisation needs to be reapplied for. These sums are diverted from investments, which would create added-value in the protection of workers. Moreover, in particular for SMEs, but for larger companies too, these administrative costs can incite or even force them to give up a part of their business, for which they would have had the required arguments to obtain an Authorisation. Importing articles is not subject to REACH Authorisation. In particular, where the substance is not contained in the imported article, the competitiveness of EU companies would be considerably impacted, even if they were able to afford the authorisation process. Here, workplace legislation including OELs is a much more targeted measure, which is readily available to the regulator.

- **Better understanding of workplace legislation down the supply chain**
  Workplace legislation has a long and successful history and is being applied on a daily basis by the entire value chain. Hence, it is very well understood down the supply chain. OELs are familiar to companies, including SMEs, and have been available for many years. This is not the case for REACH. REACH requirements including the Authorisation scheme are unfamiliar to many users. In situations where workplace legislation is available, and where this legislation can fully and even more comprehensively address an identified concern, it is reasonable to choose workplace legislation as a risk management option.

Responses to questions raised on the feasibility of our solution

Some questions have been raised and a few stakeholders have also constructively challenged our proposal. Most comments relate to the functioning of workplace legislation, both as such and when compared to REACH Authorisation. We have noticed that REACH authorities seem to be more willing to recognise the usefulness of workplace legislation through *binding* than *indicative* OELs. On this aspect we want to stress that workplace legislation is much broader than OELs (covering prevention, control, monitoring, and substitution). REACH authorities seem to focus their attention exclusively on OELs, because OELs are a substance-specific instrument in the workplace legislation. Concerns relate to the transposition of the Chemical Agents Directive (CAD) as well as to the compliance with and enforcement of indicative OELs (IOELVs). Regarding binding OELs (BOELVs), the main hurdle to having them recognised as a feasible and adequate option appears to be the time required to set such BOELVs.

We have gathered these questions and comments, for which we are presenting responses in the table below (Table 1).

Table 1. Questions, comments, and challenges to the CII proposal and our responses

Questions, comments, and challenges	Our response
"Indicative OELs cannot be recognized as a feasible risk management option because they are 'only indicative' to industry."	This point reflects a clear misunderstanding of the workplace legislation. Some stakeholders take 'indicative' OELs to mean that these are merely indicative or *voluntary* references to industry. This crucial misunderstanding is even reflected in official ECHA Guidance.[2] In fact, 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.
"Are the Chemical Agents Directive and indicative OELs effectively being transposed in all Member States?"	Article 3(3) of the Chemical Agents Directive is clear that Member States *shall* establish a national exposure limit value for any chemical agent for which an indicative occupational exposure limit value is established at Community level. From the EU review of Occupational Safety and Health (OSH) legislation, we understand that the transposition of the CAD and this provision is not a systematic issue. If there were individual cases of infringement of the EU law, they should be dealt with by applying the existing well-established EU procedures for such cases of non-compliance. It would be bad regulatory practice to use another EU legislation to address cases of non-compliance.
"Is the enforcement of workplace legislation really effective?"	We have not found there to be anything suggesting that enforcement of workplace legislation lags behind the enforcement of other legislation. There is no study suggesting that the level of enforcement of REACH is higher than that of workplace legislation. Furthermore, even if there were a perceived lack of enforcement of one piece of legislation, this would not be a legitimate reason to prefer using another piece of legislation instead. Using other EU legislation would not resolve or correct the problem of lacking, insufficient or incorrect enforcement. This is in particular the case since this other piece of legislation and the measures taken on that basis will require effective enforcement. More specifically, REACH

[2] See ECHA Guidance on information requirements and chemical safety assessment, Chapter R.8: Characterisation of dose[concentration]-response for human health, Version 2.1, November 2012, page 137: "*Indicative occupational exposure limit values are health-based, non-binding values, derived from the most recent scientific data available […]. They set threshold levels of exposure (with corresponding reference time period) below which, in general, no detrimental effects are expected for any given substance after short term or daily exposure over a working life time. They are European objectives to assist employers in determining and assessing risks […]*" (emphasis added).

	Authorisation will also require enforcement, particularly because this mechanism is pretty unknown down the supply chains and non-compliance may arise due to the lack of awareness.
"OELs are not fully harmonised. REACH serves the objective of harmonising the market. OELs, as opposed to Derived No Effect Levels (DNELs), cannot lead to full harmonisation and, therefore, are not an adequate alternative to REACH Authorisation."	It is correct that even the setting of an EU-wide OEL does not result in full harmonisation of the exposure limit values in the EU. At national level, stricter OELs can be set or, in the case of indicative OELs, Member States can – with justification – also set higher national OELs. However, REACH would not lead to harmonisation of limit values either. The limit values applicable under REACH are called Derived No Effect Levels (DNELs). They are to be derived by the registrants and can vary. It seems that the hope for harmonisation stems from the fact that ECHA's Risk Assessment Committee (RAC) has established in the context of REACH Authorisation the practice of deriving "reference DNELs". These "reference DNELs" can, however, not lead to harmonisation either, as they "*would not be explicit recommendations for the applicants and thus, have no legal implications*"[3]. Furthermore, no legal provision stipulates that national OELs should be aligned with REACH DNEL or reference DNEL values. As such, the non-harmonisation will also remain from this point of view. As a matter of fact, REACH has not mandated RAC to establish harmonised EU exposure limit values that would invalidate national OELs adopted in the context of workplace legislation.
"SCOEL-derived OELs are less protective than reference DNELs derived by ECHA's RAC"	SCOEL-derived OELs are health-based, just as DNELs under REACH. The simple fact that a certain SCOEL-derived OEL is higher than a RAC-derived reference DNEL does not mean that it is less protective. It is the underlying dataset, the assumptions and the overall approach and context or objective, which may trigger differences in values. Just like RAC-derived reference DNELs, SCOEL derived OELs do not take into account socio-economic considerations. We welcome the fact that SCOEL and RAC will start to exchange on their respective methodologies for deriving OELs/DNELs and are confident that this should contribute to the future avoidance of establishing "reference DNELs" which contradict SCOEL-derived OEL recommendations.
"REACH foresees dermal DNELs whereas there is no dermal OEL under workplace legislation."	This is incorrect as risks from dermal exposure are an integral part of the workplace legislation. Where there is a need, SCOEL includes a skin notation in its recommendations.
"Workplace legislation does not provide data on use, volumes, etc., which is considered a useful fringe benefit of the REACH Authorisation mechanism."	While it is correct that workplace legislation does not provide such data, it is not the objective of REACH *Authorisation* to gather such information either. Data on uses and volumes are provided by registrants pursuant to the *registration* provisions of the REACH Regulation. Where there is a justified need for more detailed information, authorities can obtain this information by dedicated regulatory instruments - e.g. by means of *Substance Evaluation* under REACH.
"In some cases that are undergoing the REACH Authorisation process, individual applicants have been found not in compliance with the workplace legislation and – triggered by the REACH Authorisation process –have	Individual cases of non-compliance with one piece of EU legislation cannot justify the application of another regulatory mechanism in order to identify and then rectify these specific cases. Proper enforcement is the right means to address such shortcomings. Otherwise, future cases of non-compliance with REACH (and REACH Authorisation) would be a justification to duplicate REACH with yet another set of legislation that should – as a fringe benefit – help uncover cases of non-compliance with workplace legislation.

[3] 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.

improved their risk management measures."	
"Workplace legislation cannot be used as alternative to REACH Authorisation, because it does not serve the regulatory objective of 'substitution', which is however an important objective of the REACH Authorisation mechanism."	This is factually incorrect: the objective of substitution has been embedded in OSH for several decades. Council Directive 89/391/EEC on the introduction of measures to encourage improvements in the safety and health of workers at work, and its daughter directives 98/24/EC[4] (known as the Chemical Agents Directive) and 2004/37/EC (known as the Carcinogens and Mutagens Directive (CMD)) all incorporate substitution as a specific protection and prevention measure. Article 6 of the CAD recommends that '*substitution of a chemical agent be undertaken by preference* while under the CMD, substitution is mandatory if technically feasible. Furthermore, Article 4(2) of the CMD sets an additional obligation for "the employer to submit the findings of his investigations to the relevant authorities, upon request". It has not been demonstrated that REACH Authorisation contributes more effectively to substitution than workplace legislation. Where alternatives are already under development and appear to become feasible, Authorisation may be a contributing factor. However, it can also lead to giving up uses altogether (in the EU), i.e. neither the substance nor an alternative would be used in the EU. This is particularly the case when the articles that are ultimately produced by the use of the substance can be imported from outside the EU. Some substances can – despite decade-long research – not be substituted. Research may continue, but administrative costs and uncertainties linked to REACH Authorisation may be obstacles to actual investment in research for alternatives, and eventually to substitution. Furthermore, we highlight that the REACH Regulation allows for an exemption from the REACH Authorisation process when, for a use or a category of uses, the risk is properly controlled on the basis of other existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance (Article 58(2)). Substitution does not feature amongst the conditions for applicability of this legal basis for exemptions. Workplace legislation is specific to the workplace, can – through OELs – even be applied in a substance-specific manner, establishes more than just minimum requirements relating to the risks that are identified in the cases that we cover, leading to proper control of the risk.[5]
"Member States have so far not been ready to consider that workplace legislation including OELs can be an alternative to applying REACH Authorisation."	The REACH Authorisation mechanism is still new and it is natural that the practices evolve over time. We perceive that there is currently a momentum in Member States to reconsider the alignment of OSH and REACH and in particular the possibility of recognising workplace legislation including OELs as alternative to REACH Authorisation.

[4] Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work – Official Journal of the European Communities N° L131/11 – 5.05.1998.

[5] Finally, not only regulations push towards substitution. As highlighted in a report prepared by the Centre for Strategy and Evaluation Services, which was dated June 2012 on 'Interim Evaluation: Impact of the REACH Regulation on the innovativeness of the EU chemical industry', "*innovation is driven by many factors outside of REACH that have a greater impact than the regulation itself, in particular the state of markets and technology*".
As substitution is a component of companies' innovation and R&D strategy, which contributes to their competitiveness in the EU and international market, it is not a topic that is widely communicated by companies. We have gathered information on this topic. Whether it is due to intellectual property or competitiveness reasons, the information gathered so far is only the tip of the iceberg of ongoing work relating to substitution.

	In the Employment Council, EU Ministers have called for better consistency of workplace legislation and REACH.[6] Also amongst REACH authorities we have found interest in and support for our initiative. In fact, in some cases Member States are already considering the use of OSH instead of REACH Authorisation. This is also crucial in light of the EU agenda for Better Regulation. A key aspect underpinning this approach is that if existing legislation is already in force, it should be properly evaluated, to see whether existing tools could be used to meet the objectives – before considering new initiatives.
"The process to put in place binding OELs is too slow. Also the setting of indicative OELs should be sped up."	In an Annex to this document, we describe the process for setting binding and indicative OELs. We agree that, in order to facilitate the application of the solution that we propose, it would be helpful if the process of setting OELs would become more effective. In particular, this applies to the setting of binding OELs, but to some extent also to the setting of indicative OELs. In a separate document that we are submitting to DG EMPL, we are sharing some thoughts on how the process of setting OELs could be sped up. Having said that, our suggested approach can and should already be applied today. Indeed, a number of OELs do already exist and further OELs are under development. By means of appropriate prioritisation and cooperation between the industry, authorities and other relevant stakeholders, the OEL route can be applied. Besides, the REACH Candidate Listing and Authorisation procedure also takes considerable time to be applied and would be the least proportionate option for the cases that we describe, while still not achieving a gain in timing and efficiency.

Contribution to unlocking synergies between REACH and workplace legislation

REACH and workplace legislation do overlap in some areas. This can potentially lead to duplication and inconsistencies (e.g. RAC-derived reference DNELs, which differ from SCOEL-derived health-based OEL recommendations). However, the overlaps between REACH and workplace legislation can also be useful if they are consciously used to the benefit of both authorities tasked with REACH and workplace legislation. Below are two examples:

- **Exchange of information on substances:**
  The wealth of information generated and collected by REACH registrations could be unlocked for the benefit of authorities applying workplace legislation (both at EU and national level). The new data generated under REACH for registration and which are transmitted along the value chain in particular via the Safety Data Sheet (SDS) (including results of the Chemical Safety Assessment such as exposure scenarios and information on exposure control) do already nurture the implementation of the workplace legislation, as employers are able to use this new data in their assessment of the risks at the workplace and the definition of appropriate risk management measures. In addition to this, an easier access to the registration should be enabled for the scientific assessment for workplace risks upon request by the SCOEL and equivalent national bodies.

- **Exchange of expertise for assessments:**
  Both REACH authorities and workplace authorities can benefit from each other's assessments and expertise. For example, REACH authorities may seek to understand better

[6] Paragraph (21), Council conclusions on the "EU Strategic Framework on Health and Safety at Work 2014-2020: Adapting to new challenges", adopted at the EPSCO Council meeting on 9 March 2015: http://register.consilium.europa.eu/doc/srv?l=EN&f=ST%207013%202015%20INIT

the work done by SCOEL and use it more readily instead of duplicating the assessment (a duplication which is to be avoided, as specifically stated in Article 110(1) of REACH). When a notification adopted in accordance with the Regulation on Classification, Labelling and Packaging of substances and mixtures (CLP notification), a so-called self-classification, has identified specific endpoints of concern for a given substance which was not classified before, CLP can assist with the selection of substances for which workplace exposure limits may be needed. In turn, when an RMOA is carried out under REACH and REACH authorities identify a risk requiring further risk management measures that is limited to the workplace, they may – in line with Article 95 of REACH – wish to involve national and EU authorities that are the experts in workplace legislation in that assessment. If there is an agreement between REACH authorities and workplace authorities that there is a risk which requires better management at the workplace, the RMOA will have reduced the work required from the workplace authorities in order to address this risk. The information in the REACH registration dossiers and the information gathered during the RMOA can be used in the adoption of measures targeted specifically at the workplace (e.g. for the setting of an OEL).

Importance of the contribution of concerned substances to EU policy objectives

Our initiative focuses on the relation between workplace legislation and REACH. However, the proportionality of what we propose is not only based on the argument that, in the situation that we describe, the legitimate objective to manage the risk of substances can be more comprehensively and more cost-effectively achieved by the use of workplace legislation including EU-wide OELs.

Substances that undergo RMOAs under REACH often make important (frequently irreplaceable) contributions to the achievement of other EU policy objectives, including green policy objectives. In order to recommend the proportionate risk management option, RMOAs should take into account the benefits of the uses of substances and consider the effect of the increase of costs through authorisation and the stigmatisation of substances that are needed for achieving these other policy objectives.

Conclusion

In summary, we have demonstrated that the cases described by our initiative can most effectively and comprehensively be addressed by workplace legislation, including OELs. This is the most targeted regulatory approach and does not leave the regulatory gaps that REACH Authorisation would lead to (exemption of several uses of the concerned substances at the workplace).

We have not identified any significant obstacle that would prevent the effective application of our solution. We hope that our responses have clarified any questions raised about our proposal.

We remain available to exchange further on these topics and answer any questions that you may wish to discuss.

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Annexes:

- *Annex 1: An overview of the current processes to set indicative and binding OELs and an outlook on considerations for the revision of OSH*
- *Annex 2: List of signatory organisations*
- *Annex 3 (separate PDF document): "About Us" document with background on signatory organisations*
- *Annex 4 (separate PDF document): Flowcharts: Our proposal – an application of the principles of the Commission's SVHC Roadmap*

Annex 1: Setting indicative and binding OELs / Outlook on a possible revision of OSH

1. The current process of setting indicative and binding OELs

The regulatory framework for the establishment of EU-wide occupational exposure limits (OELs) consists of a number of Directives. Of particular importance are the following ones:

- 89/391/EC Occupational Safety and Health Framework Directive
- 98/24/EC Chemical Agents Directive (CAD)
- 2004/37/EC Carcinogens and Mutagens Directive (CMD)

The European Commission (DG Employment) plays a critical role in the process of establishing EU workplace limits. DG Employment starts the process through a selection of "candidate substances", which are then assessed by the independent Scientific Committee on Occupational Exposure Limits (SCOEL), on the basis of scientific evidence only. SCOEL members review the available information on priority chemical substances and recommend exposure limits where possible. SCOEL publishes their draft findings and recommendations in summary documents which then undergo a 6 months consultation period involving national authorities.

Once the consultation is finalised and the SCOEL has taken into account the comments and new data, it issues a recommendation, which becomes a starting point for discussion in a tripartite Advisory Committee on Safety and Health (ACSH), composed of national representatives of government, employees and employers. The ACSH is consulted by DG Employment in the regulatory process to establish OELs under EU legislation.

The OELs recommended by SCOEL are reviewed by the ACSH's Chemicals Working Party (WPC) , which is tasked with preparing a draft Opinion to be adopted by the ACSH plenary. Amongst others, the role of the ACSH WPC is to assess and provide its views on the workability of the recommended OELs. Depending on the type of OEL and the OEL-setting process, the ACSH Opinion may include feasibility and socio-economic considerations.

The Commission takes the ACSH opinion into account but is not bound to it. The final EU decision-making procedure will depend on the type of the OEL that the Commission wants to establish under EU law and on the legal basis under which the OEL will be established.

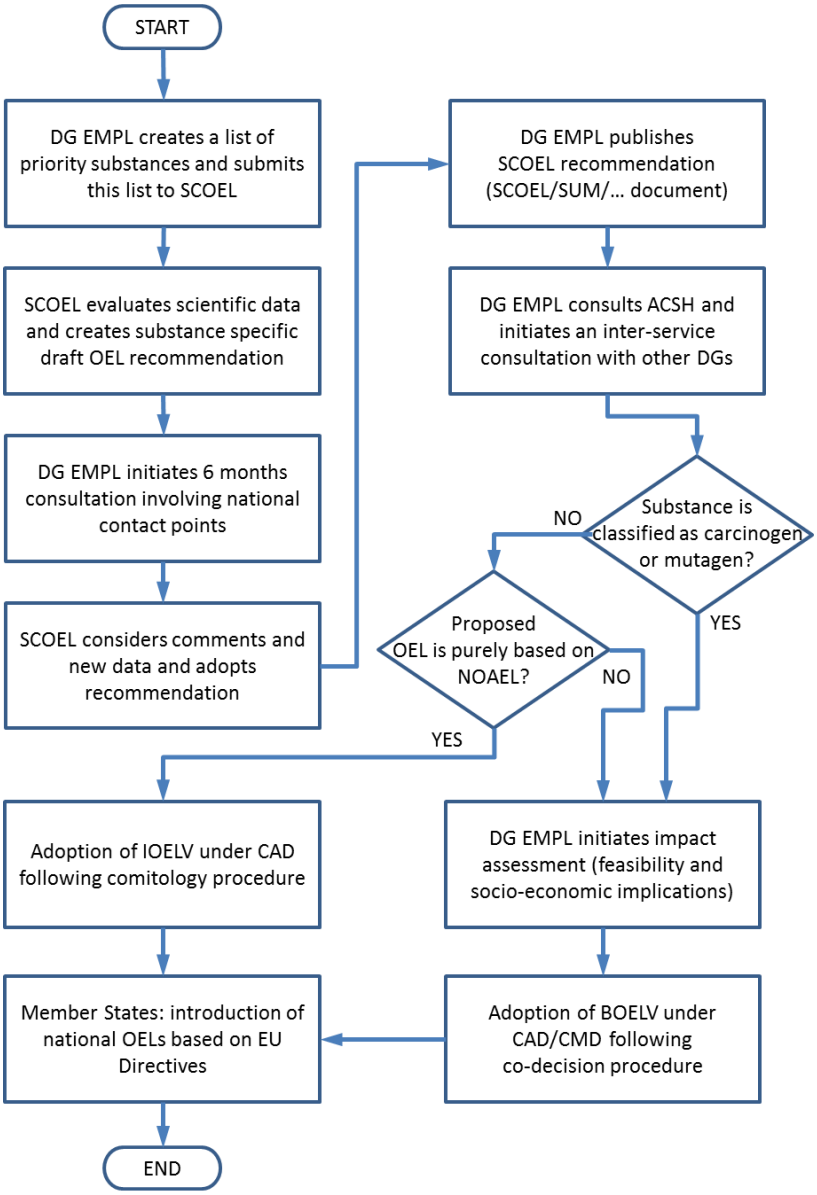
- **EU Indicative Occupational Exposure Limit Values (IOELV)** are established under the CAD. These values are health based limit values (often based on no observed adverse effect levels – NOAEL) in line with a threshold, below which it is assumed that an exposure will not have a detrimental health impact on workers over a working lifetime (up to 45 years). For any chemical agent for which an IOELV is established at the EU level, the Member States must (within a transposition period of 18 months) establish a national exposure limit value, taking into account the EU IOELV. This means that EU Member States may deviate from the EU IOELV, setting lower or higher corresponding national limits, whenever they consider this to be justified in accordance with national legislation.

- **EU Binding Occupational Exposure Limit Values (BOELV)** can be established under the CAD or CMD. They also pursue the aim of ensuring the health of workers at work. The BOELV concept was initially established to allow the incorporation of socio-economic considerations and feasibility assessments for substances deemed to be "non-threshold" substances or in cases where the scientifically derived health-based limit value was too low to be achievable in practice. BOELVs are binding "upper limits" for all EU Member States: national limit values can be lower (i.e. stricter) but must not be higher than the EU BOELV.

While both IOELVs and BOELVs can be implemented under the CAD, the CMD only foresees the implementation of BOELVs. This was driven by the underlying assumption that carcinogens and

mutagens had no threshold. In the meantime, the scientific understanding (e.g. related to genotoxicity and the mechanisms of carcinogenesis) has further developed and SCOEL adopted a new classification scheme for carcinogens in 2007, to make a distinction between threshold and non-threshold substances. This scientific development has not yet been reflected in the CMD.

Depending on the type of OEL (binding or indicative), the process currently follows one of the two prescribed decision-making routes (EU ordinary legislative procedure ("co-decision") or comitology), as depicted below:



2. Review of OSH Directives

Various activities are currently underway to review the relevant EU Occupational Safety and Health (OSH) Directives. Indications for possible improvements are expected out of a cross-European study, assessing the functioning of the Directives at Member State level. Initial reports indicate that the Directives are appropriately implemented across all the Member States, largely understood and complied with by the industry, and that the concept is considered highly beneficial and adequate for the protection of workers' health.

Current discussions deal with a potential merger of the CAD and CMD, general streamlining of the decision-making procedures, the overlap between OELs and REACH derived limit values (e.g. inhalational DNELs), and some other specialised topics. Notwithstanding those underlying considerations, activities have also been carried out to enhance the number of OELs and hence, the number of substances explicitly covered:

- In the framework of the CAD, Commission activities are ongoing to adopt the 4th EU IOELV Directive and will start thereafter to prepare the 5th IOELV Directive. SCOEL has already evaluated a total of about 200 substances and substance groups: hence there are a significant number of scientific recommendations waiting to be translated into regulatory limit values.

- Under the CMD, a list of 25 substances (classified as carcinogens) was created and potential limit value options were evaluated as part of the socio-economic analysis carried out on behalf of DG Employment (SHEcan project). For some of these materials, SCOEL recommendations and ACSH opinions already exist, hence the preparatory steps to establish further BOELVs in Annex III of the CMD are already at an advanced stage.

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Annex 2: 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
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 – 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