



## CEEMET ADVOCATES A UNIVERSAL APPROACH TO CHEMICALS AT EU LEVEL

It is essential that EU policy makers adopt a universal and holistic approach to the management of chemicals. This means coordinating the interaction between requirements for the environment, health and safety, major hazards, storage, use and transportation.

CEEMET advocates simplifying the existing EU regulatory system for chemical substances so that this results in greater understanding, more consistency and predictability for employers and SME's who operate in this very complex regulatory environment.

It is of the utmost necessity that the existing EU framework for chemicals be streamlined and consolidated. As it currently stands it is inconsistent, overlapping, confusing, and uncoordinated.

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European MET employers are committed to ensuring that worker health and safety (H&S) is not harmed by exposure to hazardous chemical substances present at the workplace. This includes carrying out risk assessments and acting on them. Information regarding occupational risk management is provided for in EU legislation

governing the classification and labelling of substances registered in the European market. H&S risks from exposure to these substances are addressed by three different and overlapping sets of legislation:

- I. Workplace occupational health and safety (OSH) legislation: CAD (Chemical Agents at Work Directive - 98/24/EC) and CMD (Carcinogens or Mutagens at Work Directive - 2004/37/EC).
- II. Product (environmental) legislation on the placing of products on the market: REACH (EC Regulation 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals) and CLP (EC Regulation 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures).
- III. Major Hazards legislation: Seveso II Directive (96/82/EC) and forthcoming Seveso III Directive (2012/18/EU).

Any universal approach to chemicals should also include product legislation with requirements prohibiting the use of chemicals in their conception e.g. WEEE, ROHS. Moreover, this approach should include any relevant legislation requirements concerning storage, use and transport.

Although OSH and product legislation should complement one another in this area, their requirements interrelate to some extent. This gives rise to inconsistencies in their application, because it is not easily understood. SMEs, especially, find it challenging to understand and adhere to these regulations.

The following points illustrate the complexity in the current EU chemicals regulatory framework and the urgent need for simplification and consolidation.

## EU chemicals legislation – differences in application

European employers require consistency and predictability of the chemical regulatory environment in which they operate. However, distinct differences in the application of current legislation prevent this. Firstly, workplace OSH legislation is mainly process driven whereas product regulations are substance driven. CLP and REACH regulations apply to chemicals that are manufactured, imported, placed on the market or used in the EU. In contrast, H&S directives address substances present at the workplace including process derived substances e.g. fumes and dust. Whereas, REACH and CLP regulations address health and environment risks, OSH addresses only health risks at the workplace.

Just to add to the layer of complexity we also have Major Hazards legislation (Seveso) which introduces additional safety and environmental requirements so that operators handling dangerous substances above certain thresholds must regularly inform the public likely to be affected by an accident, providing safety reports, a safety management system and an internal emergency plan.

## Exposure limit values and EU legislation

Downstream users and employers urgently require consolidation of the existing exposure threshold levels in legislation for exposure to chemical substances. The current system has different threshold levels which create confusion and problems of compliance for employers. For example, CAD provides for *indicative occupational exposure limit values* (IOELs). The latter are non-binding threshold levels of exposure to chemical substances, that Member States can decide to implement or not. Member States can and do set their own substance workplace exposure limits. This does not lead to a level playing field in the EU. Meanwhile, *binding occupational exposure limit values* (BOELs) must be implemented and not

exceeded by Member States. In contrast, REACH requires producers, manufacturers or importers that register a substance to collect information on properties of that substance. This includes registering health-based *derived no-effects levels* (DNELs), i.e. levels of exposure to a substance below which no adverse health effects are expected to occur. DNELs are provided in the registration dossier and communicated to employers with the *material safety datasheet* (MSDS).

Whereas occupational exposure limits (OELs) under OSH legislation are set at EU level for around 120 substances, DNELs are provided for any registered substance under REACH. Additionally, Annex II of REACH provides for an obligation to list the relevant applicable EU or national OELs. Furthermore, IOELs are set by EU institutions for OSH legislation, while in contrast DNELs are proposed by industry under REACH. The Commission<sup>1</sup> has clearly acknowledged that there is confusion and potential overlaps between DNELs under REACH and OELs developed under other OSH legislation. For the end user there is a lack of clarity about which exposure limit should apply in the workplace.

CEEMET calls on the Commission to develop exposure limit values which are consistent across all EU Member States and which are consistent across EU legislation which legislate both areas of workplace and environmental chemical exposure. Harmonised EU exposure limit values will enable employers to operate within one set of rules dealing with chemical regulations, thereby reducing administrative and compliance burdens.

## Risk Management divergences

Risk Management divergences exist between worker protection H&S directives and REACH/CLP regulations. These also cause compliance

<sup>1</sup> European Commission's Review of REACH <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52013DC0049:EN:NOT> (5/2/2013)



difficulties for employers. For example, H&S directives apply without distinction to employers who use chemicals in the workplace. CAD and CMD require employers to determine whether any hazardous chemical substances are present at the workplace. Next, if such substances are present, employers must assess the risk to the H&S of workers. This risk assessment is based on the hazardous chemical's properties, information provided by suppliers, type of exposure, etc. Identified risks may have to be eliminated or reduced to a minimum level by taking adequate prevention and/or protection measures. This includes providing workers with information and/or training regarding identified hazardous chemicals and appropriate actions to be taken.

In contrast, under REACH, information relating to the substance's properties collected by producers, manufacturers or chemical importers is communicated in the supply chain with the MSDS and/or a chemical safety report (CSR). As a result, this serves as a basis for the classification under the CLP regulation. Under REACH, the main roles are attributed to producers, manufacturers or importers of chemicals. However, downstream users have a secondary key role by communicating relevant information both to their suppliers e.g. identification of uses to be considered in the exposure scenario, and to their customers e.g. labelling. These risk management divergences set out above should be rationalised, thereby simplifying compliance requirements.

## Elimination and substitution of hazardous chemical substances

Currently, an uncoordinated approach to the elimination and substitution of hazardous chemical substances exists in EU legislation. Existing EU legislation set out differing steps for employers to follow when eliminating or substituting hazardous chemicals with less hazardous substances. As a consequence this adds yet another layer of regulatory complexity for employers.

Firstly, under worker protection OSH legislation i.e. CAD, substitution of a hazardous chemical agent is the action to be undertaken by employers. If this is not possible, the risk must be reduced to the minimum level achievable.

Secondly, under CMD, carcinogenic or mutagenic substances should be replaced so far as it is technically possible. If this is not technically possible the carcinogen or mutagen has to be manufactured and used while working in a closed environment. This is permitted provided worker exposure does not exceed the relevant BOEL. Meanwhile, under REACH's architecture, substitution should be considered by those applying for the authorization of the use of a *substance of very high concern* (SVHC). A SVHC does not refer only to health risks but also to environmental risks. Therefore, the scope of substitution on this basis is broader than under H&S directives, adding further complexity for employers.

CEEMET calls on the Commission to implement a coordinated and pragmatic EU approach to the elimination and substitution of hazardous chemical substances through simplification and consolidation of the existing regulatory system.

## Link between CLP Regulations and the Seveso Directive

On a general point about classification, we are concerned with the automatic link between CLP Regulations, REACH and the Seveso Directive. This includes the way in which substances fall into the Major Hazards regime if they fall into one of the categories in Annex 1 of the Seveso III Directive regardless of whether or not they have major accident potential.

Unfortunately when Seveso III was negotiated an agreement was not reached to take substances that are reclassified so as they come into scope



back out of the Seveso III Directive when they do not have major accident potential.

This development is likely to have consequences across a number of industrial sectors and have a significant business impact on many SMEs as well as larger manufacturing organisations.

The unintended effects of the automatic link are a topical issue. The automatic link between CLP/REACH and Seveso needs to be discussed and the Commission must come up with proposals to deal with substances which are reclassified but are not considered to have major accident potential.

Legally the only way this can be achieved is through the ordinary legislative procedure whereby the European Commission puts forward a proposal to change the Directive and it is then negotiated with the Parliament and the Council. Clearly this takes time. We urge the Commission to start the process now before Seveso III comes into force in each Member State.

## **A universal policy on chemicals is needed in the EU**

CEEMET calls for a universal, simplified and consolidated approach to chemicals and its interaction with H&S in the workplace from EU policy makers in order to reduce administrative burdens.

There is an urgent need for a consolidated EU chemicals framework, setting out one harmonised system encompassing all elements of CAD, CMD, CLP, Seveso and REACH. This harmonised system could also extend to the transport and storage of chemicals and other hazardous substances.

This view is supported by the evaluation report of the 2007–2012 European H&S Strategy. The report identified a need to improve the integration and coordination between OSH policy and REACH, *“coordination with environmental policy and the important area of the REACH regulation on*

*chemicals and their safe use has been inadequate”<sup>2</sup>.*

## **Joint Policy coordination between Commission DGs needed**

It is essential that there is joint policy coordination between the Commission’s Directorates-General (DGs) to create a unified EU chemicals framework. We believe that there is insufficient co-ordination between the Commission’s DGs on EU chemicals legislation i.e. REACH, CMD and CAD on hazardous materials and worker protection exposure limits.

Currently, REACH is the responsibility of DG Enterprise and DG Environment. The legal landscape populated by REACH is not addressed by DG Employment’s ACSH (Advisory Committee on Safety and Health at Work) even though its application impacts worker protection and despite a clear overlap with the CAD and CMD directives which are covered by the ACSH.

CEEMET calls on DG Secretariat General, DG Enterprise, DG Environment and DG Employment to exhibit joint policy co-ordination and harmonise the existing EU chemicals regulatory framework. The Commission should seriously consider this as part of the on-going REFIT exercise. This will help reduce overlapping legal requirements under existing chemicals legislation.

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<sup>2</sup>Evaluation report of the European Strategy on Safety and Health at Work 2007-2012, <http://ec.europa.eu/social/BlobServlet?docId=10016&langId=en> (31/5/2013), page 16.



## Pushing industry away from Europe – increased regulatory complication affecting EU competitiveness

Complex and inconsistent regulatory requirements for chemicals and hazardous substances is affecting EU competitiveness. For example, under REACH, authorisation is one of the processes for managing risks associated with hazardous substances. Substances that are subject to authorisation may not be used in the EU unless a company have been authorised to do so. Nevertheless, companies have developed effective management systems to safeguard risks from such substances e.g. chromium 6, qualifying for an opt out from authorisation.

The current regulatory chemical system is putting Europe at a competitive disadvantage. Businesses may apply to the European Chemicals Agency for an access letter to opt out from authorisation, permitting the use of substances. However, these authorisation costs can approach €50,000 in some cases. The consequence of this is that businesses are pushed out of Europe as companies can use such substances at much lower costs outside the EU.

The Seveso II Directive provides another example of where H&S and environmental legislation overlap and cause further problems for downstream users and employers. This Directive is aimed at the prevention of major-accident hazards involving dangerous substances, while limiting the consequences of such accidents not only for workers' H&S, but also the environment. The new Seveso III Directive takes into account CLP legislation and must be implemented in Member States by 2015. Nonetheless, the controls that companies have to introduce to comply with this Directive can reach up to €100,000. Consequently, this is putting a further financial and administrative squeeze on business. Therefore, such compliance costs are affecting EU competitiveness.

## Chemicals - a key OSH challenge

The regulatory framework for managing chemicals in respect of CAD, CMD, CLP and REACH is a key EU OSH challenge. There should be one simplified EU regulatory framework covering both environmental and occupational health exposures to chemical and hazardous substances. Importantly, a consolidated regulatory framework must allow the development of new chemical entities without unnecessary restrictions.

We see industry being pushed out of Europe due to increasing administrative burdens and financial obligations i.e. REACH and Seveso, thereby undermining competitiveness and jobs growth. MET Employers in Europe are committed to actively contributing to a universal approach to chemical substances and achieving a harmonised regulatory EU system. This will have the added value of not only giving certainty and predictability to businesses - a key driver of competitive growth, but also ensure the continued protection of workers.

### About CEEMET:

**CEEMET (Council of European Employers of the Metal, Engineering and Technology-Based Industries)** is the European employers' organisation representing the interests of the metal, engineering and technology-based industries. Through its national member organisations it represents 200 000 companies across Europe. The vast majority of them are SMEs, providing over 13 million jobs.

