# EEF response to Consultation on the regulatory fitness of chemicals legislation (excluding REACH) – Question 35

## About EEF

EEF, the manufacturers' organisation, is the representative voice of UK manufacturing, with offices in London, Brussels, every English region and Wales.

Collectively we represent 20,000 companies of all sizes, from start-ups to multinationals, across engineering, manufacturing, technology and the wider industrial sector. We directly represent over 5,000 businesses who are members of EEF. Everything we do – from providing essential business support and training to championing manufacturing industry in the UK and the EU – is designed to help British manufacturers compete, innovate and grow.

## Response to Question 35 – Additional Comments

**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 Commission1 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.

**Risk Management divergences**

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

**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.

**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.

**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.

Under the Biocide Products Directives, authorisation of each Biocide formulation can cost a minimum in the region of £100,000 as the cost depends upon the amount of biocidal active constituents within any particular formulation and its complexity. With additional regulatory costs in the region of £100,000 for a relatively uncomplicated Biocide formulation, new product development of biocide based product lines becomes untenable.

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 had to 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.

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