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Third review of the Carcinogens or Mutagens at Work Directive

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On 5 April 2018, the European Commission launched its proposal for a third amendment to Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (CMD). It aims to add occupational exposure limit values for five substances. Until now, there have been two amendments to this directive, and with more promised, it is crucial to ensure the best outcome in this process for both employers and workers.

Ceemet's key messages

- Ceemet agrees that there is need for further actions at an EU level to protect workers from exposure to carcinogens or mutagens at the workplace. However, these limit values must be feasible for industry to implement, based on scientific evidence, bound by economic feasibility tests and based on an agreement in the Advisory Committee on Safety and Health (ACSH). We must set OELs which are evidence based, proportionate and measurable. Furthermore, transitional measures should be implemented where the new OEL will adversely affect industry.
- This adverse effect on industry will be particularly acute within our sector as companies, including SMEs, within our industries find it more difficult to work in closed or automated systems. They are therefore more likely to work with 'open' systems, which makes it more difficult to comply with the proposed limit values. OELs need to be set in a way which reduces worker exposure, whilst still allowing SME's to comply. Furthermore, the data used to derive these limit values must be current and relevant, in the current Impact Assessment of this amendment to the directive, the data is referred to as "scarce" or "unreliable".
- While we welcome the revision of this Directive and see its benefit as a method to protect workers from exposure to carcinogens and mutagens, there are a number of topics with which we take issue.

About Ceemet

Ceemet represents the metal, engineering and technology-based industry employers in Europe, covering sectors such as metal goods, mechanical engineering, electronics, ICT, vehicle and transport manufacturing.

Member organisations represent 200,000 companies in Europe, providing over 17 million direct and 35 million indirect jobs.

Ceemet is a recognised European social partner at the industrial sector level, promoting global competitiveness for European industry through consultation and social dialogue.

Setting and measuring EU OELs

Ceemet supports the idea of harmonisation of OELs across the European Union, this creates a level playing field for industry. However, member states are free to set lower OELs which does not create a good environment for businesses who have to adhere to different OELs in different member states, making it more difficult for these companies to operate within the single market.

Companies are faced with at least four sources of information when dealing with how to control exposure to chemicals in the European Union:

I. The value of the International Agency for Research on Cancer (IARC) classification;
II. The OEL value contained within the CMD Directive;
III. The European value reinforced by member states in the national transposition;
IV. The DNEL value from REACH.

Furthermore, there is no one recognised method of measuring exposure to these substances at an EU level. Therefore, not only is their discrepancies in the transposition at a national level, the method of measurement of these limit values can often further skew the level playing field.

'There is no one recognised method of measuring exposure to these substances at an EU level'

Reprotoxic Substances

On the issue of reprotoxic substances, we continue to oppose their inclusion in the CMD. It is not appropriate for reprotoxins to be included within this Directive, unless they are considered to be carcinogenic or mutagenic. The most appropriate way of controlling exposure to reprotoxins is through the Chemical Agents Directive. The CMD has been specifically conceived for dealing with carcinogens or mutagens for which no safe exposure level can be derived. For this reason, there is a main focus on substitution, closed systems and bringing exposure levels as low as is technically achievable. For reprotoxic substances, it is usually possible to identify levels at which exposure does not have an effect. An exposure limit can thus generally be set.

'It is not appropriate for reprotoxins to be included within this Directive, unless they are considered to be carcinogenic or mutagenic.'

Content

Substances

Cadmium and its inorganic compounds

The Commission proposes a binding occupational limit value of 0,001 mg/m^3 for cadmium. The proposed value, if adopted, would lead to high costs for our industries where cadmium is present within raw materials refined during certain production processes. Cadmium is often unavoidable in the raw materials stream, furthermore our members' companies have already highly invested in the reduction of the exposure in the workplace over the past years.

In February 2010, SCOEL issued 'Recommendation 136' which entails a combination of an OEL of 0,004 mg/m^3 (respirable fraction) to protect against (local) lung effects and a biological limit value of urinary cadmium (CdU) 2 µg/g creatinine (biomarker) to protect against (systemic) kidney effects. Within our sector, under the proactive management of the International Cadmium Association (ICdA), many of our companies have already implemented these values on a voluntary basis.

'Our members' companies have already highly invested in the reduction of the exposure in the workplace over the past years'

In February 2017, SCOEL issued 'Opinion 336' which confirmed the validity of its 2010 Recommendation but stated that without biomonitoring in place, the binding OEL should be set at a much lower 0,001 mg/m^3 (inhalable fraction). Based on the view that biological limit values cannot be implemented in the CMD, the Commission is proposing that an OEL of 0,001 mg/m^3 (inhalable fraction) should be incorporated in the CMD by means of an amendment as a Binding OEL.
This 0,001 mg/m^3 is however less protective than the current proposal, it brings only very marginal health benefits compared with the actual 0,005 mg/m^3 or the 0,004 mg/m^3 proposal of SCOEL in 2010 which is implementable in our sector. The current proposal will lead to significantly higher costs for companies ranging between a factor four and five.

Therefore, Ceemet advocates that the value of 0,005mg/m^3 (inhalable fraction) be retained, or alternatively the 2010 recommendation of 0,004 mg/m^3 (respirable fraction) including the biomarker value of urinary cadmium of 2µg/g.