EUROPEAN COMMISSION
Regulatory Scrutiny Board

Brussels,
D(2016)

# Opinion

**Title:** **DG EMPL - Impact Assessment on a proposal for a Directive of the European Parliament and of the Council amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work**

**(Resubmitted version of 21 March 2016)***

## (A) Context

Exposure to some chemical agents in the workplace can cause cancer, which is the first cause of work-related deaths in the EU. To protect workers against such risks, the EU adopted in 2004 the Carcinogens and Mutagens Directive, which sets out steps to be taken to eliminate or limit exposure to carcinogenic chemical agents, including through Occupational Exposure Limit (OEL) values, setting maximum levels of exposures to which EU workers can be exposed. However, the Carcinogens and Mutagens Directive has become outdated and does not take into account the latest available scientific evidence. The Commission has conducted a scientific and economic assessment on the introduction of OELs for 25 priority chemical agents to which around 20 million workers are exposed in the EU. Out of those, 13 agents, for which data sets are ready, are covered in the impact assessment. Member States have introduced OELs for some of them but they are highly divergent and sometimes set too high to protect workers.

## (B) Overall opinion: POSITIVE

**The Board gives a positive opinion, on the understanding that the report will be improved with respect to the key aspects mentioned below.**

**Overall, the report has been revised to take account of the Board's recommendations. The scope, policy context and problem analysis have been clarified, establishing relevant links with the REFIT evaluation of the EU framework for Occupational Safety and Health (OSH). The added value of setting explicit OELs in addition to the existing obligation of exposure minimisation is further explained, but raises additional questions. Positions of and impacts on different stakeholders groups are substantiated in more depth, providing a clearer picture of the heterogeneous landscape in Europe across countries, industries and chemical substances. The revised impacts section also includes an updated quantification of costs, accounting for the fact that investments to decrease workers' exposure will also take place under the baseline scenario. Finally, the revised report considers a broader range of options and provides additional arguments in favour**

* Note that this opinion concerns a draft impact assessment report which may differ from the one adopted

**of addressing this issue through the OSH legislation rather than the regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).**

**However, there are still a number of issues which should be further improved in the final report:**

**1) The added cost calculations should provide only one range of estimates per substance, consisting of the costs of each option compared to the baseline;**

**2) The arguments for introducing OELs at European level need to be clarified further. The options would need to be adapted in line with the provided arguments;**

**3) The support from stakeholders for establishing OELs at European level should be further specified;**

**4) A comparison of the pros and cons of addressing occupational exposure to carcinogens through the OSH framework versus REACH should be added.**

**The lead DG shall ensure that these recommendations are integrated in the report prior to launching the interservice consultation.**

**(C) Main recommendations for improvements**

**1) Costs.** The revised report includes a new way of calculating compliance costs based on the assumption that investments for exposure reduction will anyhow take place, also under the baseline scenario, albeit at a slower pace. This reflects the fact that the baseline scenario accounts for a linear reduction of exposure of 7% per year. Although this allows for a more valid comparison of costs and benefits (which were already accounting for resulting health gains under the baseline), the addition of marginal compliance costs compared to the baseline may generate confusion, as the report now mentions a "total cost" and a revised "additional total cost" for several substances. The costs presented in the report should only be those incurred compared to the baseline, i.e. resulting from the obligation to respect the OEL proposed through a binding measure in the near future compared to reaching it later through the "natural" linear decrease in exposure.

**2) Value added of European OELs.** In the more complete argumentation for European OELs (point 1.1.3), it is said that diverging national OELs can generate undue competitive advantages. It is not clear how this can be the case when the minimisation obligation stays valid in all countries, even in those with weaker national OELs. It is also argued that European OELs can co-exist with more stringent national OELs because what is technically feasible might vary by industry or use, and therefore by Member State. However, when technical feasibility varies by industry or use, setting OELs by product at European level will not provide legal certainty. **These arguments raise the need to extend the range of considered options.** In particular, in order to provide legal certainty by industry, there could be the need to set OELs by industry or use of a specific product. As this risks to become very burdensome for the regulators, an alternative option could be to provide scientific information by industry and use, without setting OELs.

**3) Stakeholder support.** While the report now better describes the rationale for and added value of setting OELs at European level and includes additional references to stakeholders' support for OELs in general, it should further expand on the perception of stakeholders regarding the establishment of OELs at European level for specific substances as opposed to national level. This is especially important as stakeholder support seems to be inversely proportionate to the size of the problem (and potential health benefits – Table 36, p.80).

**4) OSH vs REACH.** In view of supporting an informed decision-making, the revised report should include a summary table allowing for a comparison of the effectiveness and efficiency of regulating workers' exposure to chemicals via REACH versus the OSH framework.

*Some more technical comments have been transmitted directly to the author DG and are expected to be incorporated into the final version of the impact assessment report.*

**(D) Procedure and presentation**

The length of the revised report increased compared to the previous version and is now over 80 pages, i.e. twice the recommended length. This can however be explained by the amount of information and analysis that have been added.

The addition of a table for the combination of preferred options usefully summarises the analysis done in the previous sections. As suggested in recommendation 3, a similar overview comparing the OSH framework and REACH as possible instruments to reduce EU workers' exposure to carcinogens would further enhance the clarity of the impact assessment.

Finally, the estimation of 100,000 lives potentially saved through the proposed measures (pp.7, 87) should be more clearly explained and substantiated.

| **(E) RSB scrutiny process** | |
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| Reference number | 2016/EMPL/002 |
| External expertise used | No |
| Date of RSB meeting | Written procedure (an earlier version of this report was submitted to the Board on 26 January 2016, for which the Board issued an opinion on 19 February 2016) |