



Brussels,
D(2016)

Opinion

Title: Impact assessment on Proposal for a Directive amending the Carcinogens and Mutagens Directive (2004/37/EC) to identify new 'process generated substances' and establish/revise binding Occupational Exposure Limit Values
(draft version of 26 January 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 However, the Carcinogens and Mutagens Directive has become outdated and does not take into account the latest available scientific evidence.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: NEGATIVE

The Board gives a negative opinion due to a number of shortcomings in the report that require improvement. Several aspects of the impact assessment need to be put into a wider perspective.

- (1) The context should be strengthened and establish relevant links with the findings from the Occupational Safety and Health (OSH) evaluation;**
- (2) The "need to act" and the EU added value of the initiative should be further developed;**
- (3) The positions of and impacts on stakeholders should be more clearly described, including regarding simplification and burden reduction;**
- (4) A broader range of options should be considered and the reasons for discarding them should be explained (e.g. the REACH regulation).**

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

(C) Main recommendations for improvements

(1) Context of the initiative and links with the evaluation. The report should further present the heterogeneous landscape in Europe in terms of occupational exposure to carcinogens. The length, method and steps of the procedure to update OELs should be explained more thoroughly as well as the measures taken to further streamline this process. In addition, the problem statement should make links with the OSH REFIT evaluation findings whenever relevant.

(2) Need to act and EU added value of the initiative. Given the existing minimisation obligation imposed on employers by the current directive, the report should further substantiate why diverging national OELs are inefficient and why action is required at EU level that will still permit differing national OELs. Since most businesses already comply de facto with the proposed OELs and since lower national OELs will continue to exist, the added value of providing legal clarity through EU minimum standards should be further substantiated in the framework of the minimisation obligation. The interest of different stakeholders (including employers) in setting EU standards should be better explained. The overall benefits of the initiative (possibly including health gains related to the prevention of diseases other than cancer and results of enhanced clarity for businesses) should be weighed against its total costs.

(3) Impacts on and views of stakeholders. The report should present more systematically the views of different stakeholders and the expected impacts on particular groups (including SMEs), distinguishing whenever relevant between Member States and between specific substances (high or low exposure among EU workers, Process Generated Substances vs chemical agents, covered by REACH or not). Views on the importance of burden reduction and simplification of the OSH legislation in general should be addressed and discussed in the light of the proposed sequencing of the amendments in several steps.

(4) Alternative options. The description of options should better explain why a broader range of approaches, including non-legislative ones, were not considered or were discarded (e.g. bans, more stringent OELs than those recommended by ACSH, voluntary agreements, market-based mechanisms, information measures...). The reasons for discarding them should be summarised (e.g. issues of proportionality, effectiveness, competence). In particular, the report should assess in more details the feasibility and consequences of covering the chemicals included in this initiative through REACH.

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 report should further explain the limitations of the data used in the report and their potential effect on the reliability and validity of the quantification of impacts. Whenever relevant and given the acknowledged uncertainties, a sensitivity analysis should be applied.

(E) RSB scrutiny process

Reference number	2016/EMPL/002
External expertise used	No
Date of RSB meeting	17 February 2016