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**COMMISSION STAFF WORKING DOCUMENT**

**EXECUTIVE SUMMARY OF THE SUPPLEMENTARY IMPACT ASSESSMENT**

*Accompanying the document*

**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**

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{SWD(2017) 7 final}

## Executive Summary Sheet

Impact assessment on further Proposal to amend the annexes to the Carcinogens and Mutagens Directive

### A. Need for action

#### Why? What is the problem being addressed?

Exposure to some chemical agents in the workplace can cause cancer, which is the first cause of work-related deaths in the EU. Every hour in EU28, 7-12 people die of cancer because of past exposure to carcinogenic substances at work. To protect workers against such risks, the EU has adopted the Carcinogens and Mutagens Directive (CMD), which sets out steps to be taken to eliminate or limit exposure to carcinogenic chemical agents and includes Occupational Exposure Limit (OEL) values. However, the CMD needs to be updated. The Commission has conducted a scientific and economic assessment of 25 priority chemical agents to which around 20 million workers are exposed in the EU. Out of those, 13 agents, were covered in an earlier Commission proposal (COM(2016)248) and accompanying impact assessment (IA) (SWD(2016)152). This supplementary IA applies the same methodology for the remaining substances.

#### What is this initiative expected to achieve?

The initiative pursues three specific objectives:

- To further improve protection from occupational exposure to chemical carcinogens in the European Union;
- To increase the effectiveness of the EU framework by updating it on the basis of scientific expertise;
- To ensure more clarity, facilitate implementation, and contribute to a level playing field for economic operators by reducing divergences in national protection levels.

#### What is the value added of action at the EU level?

Compliance and enforcement of the provisions of the CMD, and thereby workers protection, can be facilitated and improved by identifying and listing occupational carcinogens as process-generated substances (PGS) in Annex I to the Directive, and by revising existing or establishing new OELs in Annex III to the Directive. By providing adequate common definitions of PGS and lowering existing and closing gaps of non-existing national OELs, EU action can contribute to further enhancing the minimum basis of protection for all EU workers against the risks arising from occupational exposure to carcinogens. Competitive differences between firms located in Member States with different national limit values may be reduced through the establishment of clear specific minimum requirements for worker protection in the form of EU-wide limit values for those agents. Action taken by Member States alone cannot address these concerns, and consequently EU level action to achieve this objective appears necessary and in line with Article 5(3) of the TEU.

### B. Solutions

#### What legislative and non-legislative policy options have been considered? Is there a preferred choice or not? Why?

A number of options were identified and discarded for the covered carcinogens. Banning them from the workplace was considered disproportionate and reliance on non-legislative guidance or on self-regulation would not be able to substantially contribute to the solving of the identified problems. Proposals for legislative options with regard to seven out of the 12 carcinogens (OELs in Annex III and/or inclusion in Annex I) were based on the outcomes of discussions by scientists, employers, workers and Member States' representatives. For most of the carcinogens more stringent and less stringent options were also analysed. The retained options are considered complementary and to add value to existing REACH measures in several cases. Legal certainty for stakeholders is best achieved through clear listing of chemical agents under the CMD together with OELs allowing management of the risk of occupational exposure to chemical carcinogens.

With regard to five remaining carcinogens (diesel engine exhaust, rubber process dust and fumes, beryllium and inorganic beryllium compounds, 4,4'-Methylene-bis-(2 chloraniline) (MOCA) and hexachlorobenzene) action through amendment of the CMD is withheld at this stage due to legal considerations or absence of agreed position in the Advisory Committee on Safety and Health at Work.

#### Who supports which option?

Social Partners and Member States, represented in the Advisory Committee on Safety and Health at work, support all of the retained options. In general, where positions differed, workers pushed for more 'protective' and employers for 'less burdensome' measures. The considered inclusion of diesel engine exhaust and rubber process dust and fume as process-generated occupational carcinogens has not been fully agreed by the social partners, as a result of which no action is proposed at this stage with regard to those substances.

### C. Impacts of the preferred option

#### What are the benefits of the preferred option (if any, otherwise main ones)?

The benefits of the preferred policy option will consist in increased protection for some 4 million workers and clarity for employers and enforcers. Additional reduction of work-related cancer cases and deaths, reduced

quality of life losses for workers and their families, and direct and indirect individual healthcare cost savings are also expected. Social security systems will benefit from a reduction of cancer treatment costs and reduced expenditure on associated inactivity/early retirement and compensation for occupational diseases. Employers are likely to benefit from reduced absenteeism and productivity losses. A study undertaken on behalf of Commission shows the main benefits are expected from the introduction of 'mineral oils as used engine oils' into the CMD list of 'process generated substances', resulting in 880 saved lives, 90,000 less cancer cases, and a monetised health benefit of €0.3-1.6 bn related to avoidance of health costs over 50 years. Establishing inhalation and dermal OEL provisions for trichloroethylene, is expected to result in 390 saved lives and a monetised health benefit of €118-430m.

**What are the costs of the preferred option (if any, otherwise main ones)?**

For some carcinogens, the preferred option will affect operating costs for enterprises which will have to put in place additional protective and preventive measures. This will be in particular the case for trichloroethylene and mineral oils as used engine oils, where the total costs to industry of the retained option until 2069 are estimated to range between €154-257m for trichloroethylene and €46m-918m for mineral oils as used engine oils. The package of preferred options will not impose any additional information obligations or lead to an increase in administrative burdens on enterprises and is not likely to generate any significant environmental costs.

**How will businesses, SMEs and micro-enterprises be affected?**

Businesses would profit from a greater clarity.. No impact is expected on businesses situated in Member States where national OELs are either equal or lower (more strict) than the proposed values. No lighter regimes were foreseen for SMEs, which are not exonerated from the CMD obligations as this would lead to an unequal protection of workers depending on the company size. The most significant costs associated with the retained options relate to investment in closed systems for use of trichloroethylene, where SMEs are vulnerable to the capital cost requirements in comparison to larger firms. However, according to the terms of the EU solvent emissions directive (1999/13/EC), a voluntary European Chlorinated Solvent Association responsible use charter, and notably REACH authorisation, investment in closed systems is expected to already have occurred. It may be possible for firms to use an alternative substance to avoid the cost of a closed system, or to increase prices. Ten Member States have currently established equivalent national OELs at or below the proposed value for trichloroethylene, indicating that it should be feasible for the sectors concerned to absorb the additional costs.

**Will there be significant impacts on national budgets and administrations?**

While the current situation imposes substantial economic costs on workers due to their exposure to hazardous substances, the package of preferred options also mitigates 'knock on' financial losses for Member States' social security systems. Administrative and enforcement costs for public administrations will differ according to present status of each chemical agent in each Member State, but are not expected to be significant. In addition, cost saving is expected as setting EU OELs will limit the need to conduct scientific analysis separately by Member States.

**Will there be other significant impacts?**

Implementing the package of preferred options would have a positive impact on competition within the internal market, contributing to the reduction of competitive differences between firms located in Member States with differing national protection levels, facilitating compliance and enforcement, resulting in improved living and working conditions and efficiency gains for businesses and national social security systems. The retained option should not have a significant impact on the external competitiveness of EU firms. In most cases the retained options fit into the lower range of equivalent measures established in non-EU countries – suggesting that these measures are achievable, reflect available good practice, and are at the same time ambitious in aiming to set internationally high standards of worker protection. The impact on fundamental rights is positive - in particular with regard article 2 (Right to life) and article 31 (Right to fair and just working conditions which respect his/her health, safety and dignity).

**D. Follow up**

**When will the policy be reviewed?**

The effectiveness of the proposed CMD revision would be measured in the framework of the evaluation of the EU Occupational Health and Safety (OSH) framework as foreseen in the Article 17a of the Directive 89/391/EEC. The next ex-post evaluation exercise (2012-2017) would define the baseline values (benchmark) and the evaluation of the practical implementation of the proposed amendments could possibly be based on the following period (2017-2022).