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COMMISSION STAFF WORKING DOCUMENT
EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT

Accompanying the document

**Proposal for a Directive of the European Parliament and of the Council
amending Directive 2004/37 on the protection of workers from the risk related to
exposure to carcinogens or mutagens at work**

{COM(2018) 171 final} - {SWD(2018) 88 final}

Executive Summary Sheet
Impact assessment on further Proposal to amend the annexes to the Carcinogens and Mutagens Directive 2004/37/EC.
A. Need for action
Why? What is the problem being addressed?
Exposure to carcinogens and mutagens at the workplace can cause cancer, which is the main work-related health problem in the EU-28, as well as other significant non-cancer health problems. To contribute to the protection of workers from such risks, the EU has adopted the Carcinogens and Mutagens Directive 2004/37/EC (CMD). It lays down requirements in this area to eliminate or reduce exposure, including occupational exposure limit values (OELs). However, CMD needs to be regularly updated based on available information, including scientific and technical data. Two legislative proposals updating the CMD - COM(2016)248 and COM(2017)11, addressing together 20 carcinogens, have been proposed. The first amendment has already been adopted by the co-legislators – Directive (EU)2017/2398. This impact assessment accompanying the third proposal covers further five chemical agents to which around 1 000 000 workers are exposed at their workplaces.
What is this initiative expected to achieve?
The initiative pursues three specific objectives: • To reduce occupational exposure to carcinogens and mutagens in the European Union; • To increase the effectiveness of the EU framework by updating it on the basis of scientific expertise; • To achieve a more balanced protection of workers across the EU against carcinogens while ensuring more clarity and level playing field for economic operators.
What is the value added of action at the EU level?
Establishing new or revising the existing OELs in Annex III to the Directive will provide more clarity for employers and enforcers, thus facilitating and improving compliance and enforcement of the provisions of the CMD, and thereby workers protection. By 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 in this area and to level the playing field among EU businesses. 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. For example, 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 five carcinogens (OELs in Annex III) 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 the relevant 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.
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. To mitigate technical or economic challenges for employers, transitional periods are envisaged for two substance groups (cadmium and its inorganic compounds, beryllium and inorganic beryllium compounds) for all sectors, and for one substance group (arsenic acid and its salts, inorganic arsenic compounds) for the copper smelting sector.

C. Impacts of the preferred option
What are the benefits of the preferred option?
The benefits of the preferred policy option will consist in increased protection for over 1 000 000 EU workers and prevention of over 22 000 cases of work-related ill health. Consequently, it will lead to better quality of life for workers and their families, and reduced direct and indirect individual healthcare costs. Social security systems will benefit from a reduction of 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. Last but not least, setting EU OELs will improve clarity for employers and enforcers. A study undertaken on behalf of the Commission shows that the highest expected benefits for different stakeholders are the following: for workers EUR 1 to 5 billion, as well as EUR 181 million for administrations, from the introduction of an OEL for formaldehyde; and for businesses EUR 15 million from the introduction of an OEL for beryllium.
What are the costs of the preferred option?
For some carcinogens, the preferred option will entail operating costs for enterprises which will have to put in place additional protective and preventive measures. This will be in particular the case for formaldehyde and cadmium and its inorganic compounds, where the total costs to industry of the retained option over a 60 year period are estimated to reach EUR 1.72 billion for formaldehyde and EUR 447 million for cadmium. However, in case of formaldehyde the number of companies is very high and in case of cadmium mainly large companies would be affected. Therefore, the cost per company in relative terms for both substances is expected to be modest. 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?
For cadmium and arsenic compounds, SMEs are not significantly represented in the relevant industries, contrary to beryllium, formaldehyde and 4,4'-Methylene-bis(2-chloroaniline) (MOCA). The analysis shows that costs which will be incurred by SMEs are affordable for the companies concerned. The most significant costs are foreseen for SMEs dealing with formaldehyde and beryllium and in particular, for those companies which have not yet made the investments to protect workers either through closed systems or substitution. However, costs for SMEs remain well below 1% of their turnover, and no SME closures or employment effects are expected at the proposed OELs. .
Will there be significant impacts on national budgets and administrations?
Additional administrative costs and enforcement costs might be incurred by enforcing authorities. However, it is not expected for the costs to be significant. At the same time, setting OELs at EU level will save costs to develop OELs at national level. The retained option should also contribute to mitigate financial loss of Member State social security and health care systems by preventing ill-health.
Will there be other significant impacts?
The retained options would have a positive impact on competition within the internal market by decreasing competitive differences between firms operating in Member States with different national OELs. The retained options 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 relatively 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 framework as foreseen in the Article 17a of the Directive 89/391/EEC. The next evaluation exercise could possibly cover the period of 2017-2022.