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EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT REPORT

Accompanying the document

Proposal for a Directive of the European Parliament and of the Council

amending Directive 2004/37/EC as regards the addition of substances and setting limit values in its Annexes I, III and IIIa

{COM(2025) 418 final} - {SEC(2025) 217 final} - {SWD(2025) 191 final} -
{SWD(2025) 192 final}

1. NEED FOR ACTION

1.1. Why? What is the problem being addressed?

Cancer remains the first cause of work-related death in the EU, followed by cardiovascular diseases. Every year, according to estimates about 80,000 people in the EU lose their lives due to exposure to carcinogens at the place of work[1].

To improve the prevention of occupational diseases in the EU, the Commission is pursuing a continuous update of the Carcinogens, Mutagens and Reprotoxic substances Directive 2004/37/EC[2] ('CMRD'). This revision process contributes to further reduce prevalence of occupational diseases in the EU by improving prevention, a key objective of the EU strategic framework on health and safety at work 2021-2027[3] ('EU OSH strategic framework').

For this 6th revision of the CMRD, the Commission, after discussions with the members of the Advisory Committee on Safety and Health at Work's (ACSH) Working Party on Chemicals, has prioritised the following 5 substances, groups of substances or process-generated substances for possible action:

- Setting limit values for: cobalt and inorganic cobalt compounds, polycyclic aromatic hydrocarbons ('PAHs'), 1,4-dioxane, and isoprene; and
- Inclusion in the scope of the CMRD via its Annex I: welding fumes.

According to the evidence gathered[4], more than 2.6 million workers in the EU are exposed to one of these 5 substances. In case of no action at EU level, it would result in more than 29,000 lung cancer cases and 27,000 non cancer cases[5] over the next 40 years.

Workers, businesses and Member States are particularly impacted by the insufficient prevention of occupational exposure to cobalt and its inorganic compounds, PAHs, 1,4-dioxane and welding fumes. Conversely, the evidence gathered indicates that workers are exposed to levels of isoprene which are lower than the health-based limit value[6] derived by the European Chemicals Agency's ('ECHA') Risk Assessment Committee ('RAC') in its opinion[7], suggesting that the current prevention of occupational exposure to isoprene is sufficient.

1.2. What is the initiative expected to achieve?

[1] Communication from the Commission on EU strategic framework on health and safety at work 2021-2027 Occupational safety and health in a changing world of work, COM/2021/323 final
[2] Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work, *OJ L 158, 30.4.2004, p. 50-76*
[3] COM/2021/323 final, op. cit.
[4] RPA (2024), *Study on collecting the most recent information on substances to analyse health, socio-economic and environmental impacts in connection with possible amendments of Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens, mutagens or reprotoxic substances at work*.
[5] 4,365 restrictive lung diseases, 14,152 upper airway irritations, 38 developmental toxicity cases, 3,157 cases of male infertility, 633 liver effects cases, 497 kidney effects cases and 4,381 cases of effects in nasal cavity
[6] Level of exposure that is considered to be safe (health-based) for a chemical substance in the air of a workplace.
[7] RAC (2022), Opinion on scientific evaluation of occupational exposure limits for isoprene, available at: 11c4dd13-2117-8cd1-83d6-44fc9e591b8f (europa.eu)

This initiative aims to comply with the legal obligations laid down in Article 16 of the CMRD related to the setting of limit values, and to prevent work-related deaths and diseases, in line with the second key objective of the EU OSH strategic framework. This initiative will pursue the following specific objectives:

- To further improve workers' protection from exposure to cobalt and its inorganic compounds, PAHs and 1,4-dioxane in the EU through the adoption by employers of appropriate risk management measures;
- To increase the clarity and effectiveness of the CMRD by keeping it up to date with the latest scientific data allowing the establishment of limit values;
- To facilitate implementation, and contribute towards a better level playing field for economic operators by adopting minimum requirements at the EU level that apply to all businesses, irrespective of their location; and
- To bring more clarity on the scope of the CMRD with regard to welding fumes so that businesses perform the mandatory risk assessment and apply, if workers are likely to be exposed to carcinogens, mutagens or reprotoxicants according to the risk assessment, all requirements.

1.3. What is the added value of action at EU level?

By acting at EU level, this initiative will:

- *improve clarity and enforcement:* establishing limit values for additional substances or groups of substances will provide common reference points that are used as a practical tool by employers, workers and enforcers to assess compliance with the general requirements, in particular in those Member States with no existing limit values. Adding welding fumes in Annex I of the CMRD will also contribute to address the lack of clarity on the possible dangerousness of these fumes for workers, and therefore the lack of appropriate risk management measures ('RMMs').

- *ensure a similar minimum level of protection across the EU:* the national limit values for cobalt and its inorganic compounds, PAHs and 1,4-dioxane vary considerably between Member States, where they exist. For instance, the national limit values for cobalt range from 10 to 500 µg/m³ for those Member States that have them. In the absence of any action at the EU level, very different levels of workers' protection are likely to persist.

- *Contribute to a more levelled playing field:* the costs of complying with lower national levels are generally higher and entail, therefore, a competitive advantage for enterprises operating in markets with no or less stringent national limit values. Setting EU limit values helps to provide a level playing field for industry by reducing the scope for divergences and enhancing certainty that there is a core definition or enforceable limit value in all Member States. It will also reduce regulatory complexity resulting from highly diverging rules between Member States, contributing to reduce the administrative burden of compliance for businesses operating across the single market.

- *Reduce burdens related to derivation of limit values:* the process of establishing limit values is very complex and requires a high level of scientific expertise, as well as an impact assessment and discussions with the stakeholders (depending on national practices). An important advantage of setting OELs at EU level is that it eliminates the need for Member States to conduct their own analysis, including scientific assessment, with likely substantial savings on administrative costs.

2. POLICY OPTIONS

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

2.1.1. Substances prioritised for the setting of limit values

For each substance subject to the setting of limit values (cobalt and its inorganic compounds, PAHs and 1,4-dioxane), which have currently no binding limit value at EU level[8], several policy options for limit values were identified. These policy options always include the limit values derived by RAC (scientific experts), when they exist, and those recommended by the tripartite ACSH (stakeholders).

In addition, other relevant reference points are chosen as policy options to ensure a wide range of levels for assessment. These additional policy options were mainly based on the new methodology establishing risk-based limit values for non-threshold carcinogens[9] and the existing national limit values.

With regard to isoprene, the evidence gathered indicates the current and future levels of workers' exposure are already lower than the health-based limit value derived by RAC in its opinion. Despite the unanimous support of representatives from businesses, workers and Member States within the ACSH for setting a limit value for isoprene, an action at EU level does not seem necessary for improving workers' protection. Therefore, no policy option was considered for this specific substance.

2.1.2. Welding fumes, process-generated substance subject to inclusion in Annex I of the CMRD

The evidence gathered[10] indicates that some employers are not aware that their welding processes may release fumes containing carcinogens, mutagens or reprotoxic substances. These employers may therefore ignore to what extent exposure to welding fumes is dangerous for their workers. For that reason, the policy option considered for welding fumes is their

[8] 1,4-dioxane has a limit value of 73 mg/m3 set in the Chemical Agents Directive. However, this limit value is indicative, not binding. Following the recent EU reclassification of 1,4-dioxane as carcinogen, it now falls under the scope of the CMRD and requires the setting of a binding limit value.
[9] DG EMPL (2023), Methodology establishing risk-based limit values for non-threshold carcinogens, for the purposes of Article 1 (18a) of Directive 2004/37/EC, available at: https://ec.europa.eu/social/BlobServlet?docId=27151&langId=en
[10] RPA (2024), op. cit.

inclusion in Annex I to the CMRD in order to improve legal clarity and raise awareness of the possible dangerousness of welding fumes.

2.1.3. Preferred choices

Based on a thorough impact assessment, limit values recommended by the ACSH have been retained as preferred options for cobalt and inorganic cobalt compounds, PAHs, 1,4-dioxane and welding fumes, as they represent the best balance in terms of effectiveness, efficiency, and coherence.

2.2. Who supports which choice?

Within the framework of the formal two-stage consultation, social partners supported the list of priority substances to be addressed in the 6th revision of the CMRD. Governments, employers and workers' representatives within the ACSH support the preferred options for cobalt and its inorganic compounds, PAHs, 1,4-dioxane and welding fumes, including the transitional periods proposed to mitigate technical or economic challenges for employers regarding cobalt and its inorganic compounds, and PAHs.

3. IMPACTS OF THE PREFERRED OPTION

3.1. What are the benefits of the preferred options?

With regard to workers, the preferred options for the 4 substances are expected to prevent about 1,700 lung cancer cases and 19,000 non-cancer cases over the next 40 years. These avoided ill-health cases represent savings amounting to up to €1.16 billion[11].

The preferred options would also result in benefits for businesses in terms of reduction of absenteeism, productivity losses and insurance payments for about €7 million over the next 40 years. The estimated benefits for businesses do not include some positive impacts such as the improved legal clarity. Furthermore, the preferred options would also bring benefits to public authorities in terms of costs savings related to healthcare expenditures amounting to €26.65 million and avoided costs of setting limit values following national processes, which would represent up to €3.75 million.

3.2. What are the costs of the preferred options?

The total adjustment costs for businesses incurred by the preferred options over 40 years would amount up to €3.3 billion. In the absence of evidence, it is not possible to break adjustment costs into investments in additional RMMs (1st year and recurrent) and discontinuations costs. However, it is expected that the transitional period provided by the package of preferred options for cobalt and its inorganic compounds and PAHs will result in less discontinuations compared to a scenario with the same limit values without any transitional periods, for which 209 discontinuations were estimated. Therefore, the discontinuation costs should be much less than the €2.6 billion expected without transitional

[11] Application of WTP (willingness to pay) values to each case (= method 1).

period. In addition, businesses will also need to support monitoring and administrative costs amounting for about €535 million over 40 years. Overall, the total costs for businesses arising from the preferred options amount to approximatively €3.8 billion during the same period. For most of businesses, these costs would represent less (and often far less) than 1% of their turnover. It is worth noting that the estimates related to the number of discontinuations are likely to be overestimated.

Overall, the package of preferred options would cost to public authorities about €66 million over 40 years, of which more than 95% are related to the adjustment, monitoring and administrative costs related to the protection of firefighters against exposure to PAHs. The remaining 5% relates to transposition costs.

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

The share of compliance costs compared to turnover or gross operating product is higher for SMEs than large companies operating in the same sector. Therefore, SMEs are likely to be more impacted by the package of preferred options compared to larger enterprises.

Furthermore, SMEs are more likely to experience discontinuations than larger companies. Therefore, the transitional measures provided by in the package of preferred options will benefit more to SMEs than large companies. SMEs will have more time to plan their investments, which should also reduce the number of discontinuations compared to the same package of options without transitional periods.

The impact on SMEs, although higher than on larger companies, should therefore remain limited. The transitional measures contribute to avoid imposing financial constraints in a way which would hold back the creation and development of SMEs.

3.4. Will there be significant impacts on national budgets and administration?

Overall, public authorities are expected to spend €66 million over 40 years (approx. €1.65 million per year). At the level of Member States, these costs are likely to have limited impacts on national budgets and administration. Furthermore, these costs will be mitigated by the benefits arising from the preferred options (around €30 million), in particular related to the healthcare cost savings.

3.5. Will there be other significant impacts?

The package of preferred options might have some negative indirect impacts on the green transition or the digital transition due to discontinuations in key sectors, such as coking plants, other non-ferrous metallurgy, coal tar distillation and graphite and carbon electrode manufacture. These sectors play a key role for the development of the circular economy, the manufacture of green infrastructures and the manufacture of semiconductors. However, the risk of discontinuing is expected to be mitigated by the transitional measures provided in the package of preferred options, in particular the transitional period for PAHs. Therefore, the overall indirect impact on the green and the digital transition should be limited.

4. FOLLOW-UP

4.1. When will the policy be reviewed?

The effectiveness of the proposed CMRD revision would be measured in the framework of the evaluation of the EU Occupational Health and Safety Directives as foreseen in the Article 17a of the Directive 89/391/EEC[12].

[12] Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work, *OJ L 183, 29.6.1989, p. 1-8*