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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/EC on the protection of workers from the risks related to  
exposure to carcinogens or mutagens at work.**

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## Executive Summary Sheet

Impact assessment on Proposal for a Directive amending Directive 2004/37/EC on the protection of workers from the risk related to exposure to carcinogens or mutagens at work.

### A. Need for action

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

The exposure of workers to carcinogens and mutagens represents a significant risk to workers' health. According to EU-OSHA<sup>1</sup>, 52% of annual occupational deaths in the EU are attributed to cancer. For this reason, the Commission continues its process of updating the Carcinogens and Mutagens Directive (CMD)<sup>2</sup> by proposing this fourth batch of additional Occupational Exposure Limits (OELs). This is in line with the CMD, which requires that OELs must be set for all those carcinogens and mutagens for which this is possible in the light of the available information.

More than 1 million EU workers are currently exposed to the three substances addressed in this initiative, namely acrylonitrile, nickel compounds and benzene. In case of no action at the EU level, the occupational exposure to these three substances would lead to almost 2000 cancer and other work-related illness cases over the next 60 years.

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

The main general objective of this initiative is to further strengthen the workers' right to a high level of protection of their health and safety at work and to prevent death caused by work-related cancer and other health problems caused by these three substances. In order to support this general objective, this initiative will pursue three specific objectives:

- Further improving protection from occupational exposure to carcinogens and mutagens in the EU;
- Increasing the effectiveness of the EU legal framework by updating it on the basis of scientific expertise;
- Ensuring more clarity, facilitating implementation and contributing towards a better level playing field for economic operators by adopting minimum requirements at the EU level.

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

Establishing new or revised OELs in the CMD will enable to ensure a similar minimum level of protection for workers across the EU. Indeed, in the absence of EU wide OELs, as in the case of nickel compounds and acrylonitrile, some Member States have not set any national OELs or have adopted very different levels, leading to high disparities in terms of protection of workers from the exposure to these substances. With regard to benzene, even if an EU OEL exists, workers' protection varies as some Member States have adopted a lower national OEL.

In addition to this similar minimum level of protection across the EU, this initiative will also improve clarity and enforcement, contribute to a better level playing field for the economic actors in the sectors using those substances and avoid any work duplication by eliminating the need for Member States to conduct their own scientific analysis to establish OELs.

### B. Solutions

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

Several options have been discarded as they were considered disproportionate or less effective in reaching the objectives of this initiative. Among these options are the ban on the use of the carcinogenic chemical agents at work, market-based instruments (subsidies, tax breaks, etc.), industry self-regulation and guidance documents.

Setting new or revised EU wide OELs in the CMD have been retained as the most appropriate option. Several OELs scenarios have been assessed, including OELs agreed by the tripartite Advisory Committee on Safety and

<sup>1</sup> EU-OSHA (2017), An international comparison of the cost of work-related accidents and illnesses, available at: <https://osha.europa.eu/en/publications/international-comparison-cost-work-related-accidents-and-illnesses/view>

<sup>2</sup> 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. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32004L0037>

Health at Work (ACSH), which take into account scientific recommendations as well as socio-economic and feasibility issues. The ACSH is composed of representatives of Governments, Employers and Workers. In addition to OELs agreed by the ACSH, lower and higher limit value scenarios have been considered for each substance.

Based on a thorough impact assessment, OELs recommended by the ACSH have been retained as the preferred options as they represent the best scenarios in terms of effectiveness, efficiency and coherence. These retained options are also considered complementary with the existing REACH measures for each substance.

#### **Who supports which option?**

Within the framework of the formal two-stage consultation, Social Partners support the list of substances to be addressed in the fourth amendment of the CMD.

Governments, Employers and Workers' representatives within the ACSH support all the preferred options, including the transitional periods proposed to mitigate technical or economic challenges for employers concerning the three substances.

### **C. Impacts of the preferred option**

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

The main benefits arising from the preferred options for the three substances consist in contributing to the protection of more than 1,000,000 workers by preventing more than 1700 cases of work-related illness over the next 60 years, including cancer. This reduction of occupational diseases will lead among others to less suffering of workers and their families and greater length, quality and productivity of their working lives.

The preferred options will also bring benefits to business by reducing absenteeism, productivity losses and insurance payments for an estimated amount of €7 million over the next 60 years. The estimated benefits for business does not integrate some advantages like the improved legal clarity. Public authorities will also benefit from these preferred options as it will lead among others to decreased health care costs. The benefits for public authorities have been estimated to €5 million over the next 60 years.

In addition to these economic and social benefits, the preferred option for benzene will lead to reducing fugitive or diffuse emissions in some sectors, which will have positive impacts on environment. The preferred options for acrylonitrile and nickel compounds should have no or very limited positive environmental impacts.

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

Companies will have to make investments in order to comply with the preferred options as well as spend additional resources to monitor the exposure, which will entail operating costs. It is estimated that these expenses could reach €14 billion over the next 60 years. However, these costs should be sustainable for the majority of businesses compared to their turnover. Furthermore, transitional measures have been included in the preferred options package in order to mitigate challenges for employers but also to avoid job losses.

Although companies may decide to pass on cost increases in some very specific cases, there will be no or very limited impacts in terms of prices for consumers.

Public authorities will have to invest money when transposing these preferred options in their own legislation. It is estimated that transposition costs could reach €2.5 million.

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

The package of preferred options will entail operating costs for companies, which will have to put in place additional protective measures, irrespective of their size. However, compared to the annual turnover, these investments are expected to be sustainable for the three substances.

While companies using acrylonitrile are mainly large companies, SMEs represent a large proportion of the relevant industries dealing with nickel compounds and benzene. For all the substances considered in this initiative, the required investments for SMEs will represent a small share of the SMEs' turnover over the next 60 years. Only a very few number of SMEs concerned by the use of nickel compounds might face some difficulties to comply with the preferred option. For that reason, transitional periods aiming to mitigate the challenges have been included in the package of preferred options for all the substances.

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

Additional administrative and enforcement costs might be incurred by enforcing authorities. However, it is not expected for the costs to be significant. The retained option should also contribute to mitigate financial loss of Member State social security and health care systems by preventing ill-health. The benefits for public authorities (almost €5 million) are expected to be higher than the costs (almost €2.5 million).

**Will there be other significant impacts?**

The package of preferred options will limit the scope for divergences between the Members States, which will contribute to a level-playing field and improve further the functioning of the internal market. These preferred options will also have a positive impact on fundamental rights, especially with regard to the article 2 (Right to life) and 31 (Right to fair and just working conditions which respect his/her health, safety and dignity) of the Charter of Fundamental Rights of the European Union.

**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 Directives as foreseen in the Article 17a of the Directive 89/391/EEC. It is suggested to make use of the next relevant evaluation exercise, after the end of the transposition period.