



EUROPEAN COMMISSION

*Brussels, 26.1.2021  
C(2021) 499 final*

*Dear President,*

*The Commission would like to thank the Senato della Repubblica for its Opinion on the 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 {COM(2020) 571 final}.*

*Fighting against occupational cancer is a priority for the Commission and the adoption of this proposal by the European Parliament and the Council will improve the health and safety of more than 1 million workers in the European Union. This legislative proposal is the first initiative of the Commission's commitment to fight cancer under the upcoming Europe's Beating Cancer Plan.*

*Cancer is still the main cause of work-related deaths in the European Union. According to the European Agency for Safety and Health at Work, 52% of annual occupational deaths in the European Union are currently attributed to cancer. In this context, the Commission initiated a continuous amendment process of the Directive 2004/37/EC, with the aim to improve constantly the protection of workers from cancer-causing chemicals.*

*The proposed Directive is the fourth legislative amendment and sets binding occupational exposure limit values for three priority carcinogens. The first three amendments of the Directive 2004/37/EC addressed 26 substances. The limit values set at the European level reduce the exposure of workers to carcinogens at their workplaces, as well as work related ill-health and suffering of workers and their families.*

*At the same time, the proposal aims to increase the effectiveness of the EU framework by updating it on the basis of most recent available scientific expertise, and to achieve a more balanced protection of workers across the EU against carcinogens while ensuring more clarity and level playing field for economic operators.*

*Ms Maria Elisabetta ALBERTI CASELLATI  
President of the  
Senato della Repubblica  
Piazza Madama, 1  
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*The Commission is pleased that the Senato della Repubblica shares the view that action at the EU level as envisaged in the proposal is required to achieve the objectives of this proposal, and welcomes the conclusion that the proposal complies with the principle of subsidiarity.*

*The Commission takes seriously the concerns expressed by the Senato della Repubblica as regards the respect of the principle of proportionality, the compliance with the provisions of the legal basis, and the lack of data in the impact assessment concerning the repercussions of the ecological transitions from fossil to green energies. However, the Commission is of the opinion that its legal proposal is in line with the principle of proportionality and with Article 153 of the Treaty on the Functioning of the European Union, as also explained in the explanatory memorandum accompanying the proposal. Furthermore, the Commission confirms that the ecological transition evoked in the Opinion of the Senato della Repubblica has duly been taken into account in the impact assessment which also accompanies the proposal.*

*The Commission also notes the suggestion of the Senato della Repubblica to enable Member States to adopt forms of compensation, especially for small businesses. In this regard, the Commission would like to draw your attention to the fact that the Opinion has been forwarded to the relevant Commission services and will feed into further work in this area.*

*The action against cancer caused by occupational exposure is a common concern for the Commission and the Member States. In this context, the Commission welcomes Italy's integrated and proactive approach aiming at the protection of workers exposed to carcinogens, and in particular, those initiatives that facilitate compliance with the national legislation transposing the Directive on the protection of workers from the risks related to exposure to carcinogens or mutagens at work.*

*In response to the more technical issues raised in the Opinion, the Commission would like to refer to the attached annex.*

*The Commission hopes that the clarifications provided in this reply address the issues raised by the Senato della Repubblica and looks forward to continuing the political dialogue in the future.*

*Yours faithfully,*

*Maroš Šefčovič  
Vice-President*

*Nicolas Schmit  
Member of the Commission*

## Annex

*The Commission has carefully considered the issues raised by the Senato della Repubblica in its Opinion and would like to offer the following observations.*

*As far as the issue of the principle of proportionality and Article 153 of TFEU are concerned, and more especially the impacts on small companies, the Commission specified in its impact assessment accompanying the legislative proposal that small and medium-sized enterprises (SMEs) might face higher costs of finance to invest in the necessary risk management measures compared to large companies. However, as explained in the impact assessment, in most cases, costs incurred by SMEs dealing with acrylonitrile and benzene would be not significant. At the same time, it is acknowledged that some SMEs concerned with the use of nickel compounds and operating in the oil refineries, welding and metals sectors might face more difficulties to comply with the measures laid down in the proposal. Taking into account these impacts on SMEs, the Commission included transitional measures to enable them, but also other companies, to anticipate the changes, gradually introduce improvements and plan the necessary investments. The aim is always to guarantee the same level of minimum requirements at the EU level to workers of all enterprises independently of their size.*

*In addition to the estimates in the impact assessment, the occupational exposure limit values and transitional measures proposed in the legislative proposal are based on the recommendations of the tripartite Advisory Committee on Safety and Health at Work, composed of employers', workers' and governments' representatives, which are the key stakeholders in the area of occupational safety and health. Setting measures unanimously recommended by the three interest groups ensures a balanced approach between adequate protection of workers at the EU level and prevention of closures and other severe disadvantages for the industries, including SMEs.*

*Furthermore, as mentioned in the recital 4 of the legislative proposal, compliance with occupational exposure limit values is without prejudice to other employers' obligations pursuant to Directive 2004/37/EC. These obligations include, as far as it is technically possible, the replacement of the carcinogen or mutagen by a substance, mixture or process that is not dangerous or is less dangerous to workers' health, the use of a closed system or other measures aiming to reduce the level of workers' exposure. The introduction of an occupational exposure limit value would only have a significant impact on companies that have not yet made the investments to comply with these obligations.*

*Concerning the impact assessment, and more specifically the repercussions of the ecological transitions from fossil to green energies, the Commission specifies that this has been taken into account when setting the future trend on the number of workers exposed to benzene. As mentioned in section 6.3 of the impact assessment, the 2% annual decrease is explained by an estimated decrease in the use of petrol due to the gradual change to electric vehicles.*