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DIRECTORATE-GENERAL FOR EMPLOYMENT, SOCIAL AFFAIRS AND INCLUSION

Employment
Health and Safety

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Cantoni Susanna, President
Consulta Interassociativa Italiana
per la Prevenzione
Via San Barnaba 8
20122 Milano - Italy

Dear Ms Cantoni,

I would like first to thank you for your interest in the Commission's legislative proposal amending for the fourth time the Carcinogens and Mutagens Directive 2004/37/EC.

Since 2017, the European Union adopted three Directives amending the Carcinogens and Mutagens Directive, addressing 26 substances. The fourth proposal for an update of Directive 2004/37/EC is the first initiative of the Commission's commitment to fight cancer under Europe's Beating Cancer Plan. It will improve the protection of more than 1 million workers who are exposed to acrylonitrile, nickel compounds and benzene.

When proposing new or revised occupational exposure limits under the Carcinogens and Mutagens Directive, the Commission follows a comprehensive process. This procedure includes among others the consultation of the European Chemicals Agency's Risk Assessment Committee, the Social Partners and the tripartite Advisory Committee on Safety and Health at Work¹. In addition, the Commission carries out an impact assessment to evaluate the economic, social and environmental impacts of several policy options. This comprehensive procedure enables to propose limit values and other relevant provisions such as notations and transitional periods established through a thorough scientific, technical and socioeconomic discussion.

I would like to mention that pursuant to the Treaty on the Functioning of the European Union, the European Union can adopt minimum requirements in the area of occupational safety and health. Therefore, the Member States can maintain or adopt more stringent limit values in their national legislations.

¹ The Advisory Committee for Safety and Health at Work (ACSH) is tripartite body which assists the Commission in the preparation, implementation and evaluation of activities in the field of occupational safety and health (OSH) and facilitates cooperation between national administrations, trade unions and employers' organisations.

Occupational exposure limit values are important components of the general arrangements for the protection of workers established by Directive 2004/37/EC. However, compliance with them is without prejudice to other employers' obligations pursuant to the Carcinogens and Mutagens Directive, in particular the reduction of the use of carcinogens and mutagens at the workplace, the prevention or reduction of workers' exposure to carcinogens or mutagens and the measures that should be implemented to that effect. Those measures should include, in so far as is technically possible, the replacement of the carcinogen or mutagen with a substance, mixture or process which is not dangerous or is less dangerous to workers' health, the use of a closed system and other measures aiming to reduce the level of workers' exposure.

I would also like to stress that the Carcinogens and Mutagens Directive does not only protect workers from the chemicals for which an occupational limit value is set in its Annex III. The Directive 2004/37/EC covers all the carcinogens or mutagens (substance or mixture) which meet the criteria for classification as a category 1A or 1B set out in Annex I to the Classification, Labelling and Packaging (CLP) Regulation 1272/2008. The Carcinogens and Mutagens Directive also applies to the substances, mixtures or processes referred in its Annex I, as well as to substances or mixtures released by a process referred in the same Annex.

Furthermore, other pieces of legislation in the area of occupational safety and health also ensure the protection of workers from the exposure to hazardous chemicals. In particular, the Chemical Agents Directive 98/24/EC lays down minimum requirements for the protection of workers from chemical agents, including the reprotoxic substances, that are present at the workplace or as a result of any work activity involving chemical agents.

In your letter, you refer to the possible inclusion of the reprotoxic substances and the hazardous medicinal products in the scope of the Carcinogens and Mutagens Directive. As requested by the European Parliament and the Council in the context of previous revisions of the Directive 2004/37/EC, the Commission commissioned two studies supporting its assessment on the need to include reprotoxic substances and the hazardous medicinal products in Directive 2004/37/EC. The study on reprotoxic substances is already finalised and was transmitted to the tripartite Working Party on Chemicals², in line with the co-legislators' request to consult management and labour. The study on hazardous medicinal products is now being finalised and will also be sent to the Working Party on Chemicals.

The Commission is now waiting for the opinions of the Working Party on Chemicals on the reprotoxic substances and the hazardous medicinal products before continuing its internal procedure mentioned in the third paragraph of this letter. In the meantime, the Commission services started the preparatory work with the aim to set a stricter binding limit value for lead and its compounds – the major reprotoxic substance – under the Chemical Agents Directive.

Yours faithfully,

² The Working Party on Chemicals is a working party of the Advisory Committee on Safety and Health at Work.

Charlotte GREVFORS ERNOULT
Head of Unit

c.c.:

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