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From:	General Secretariat of the Council
To:	Delegations
Subject:	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 - Analysis of the final compromise text with a view to agreement

I. INTRODUCTION

1. On 18 July 2025, the Commission submitted to the Council and the European Parliament (EP) a 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 IIIa¹. This is the sixth amendment of Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens, mutagens or reprotoxic substances at work.
2. The proposal aims to improve the protection of workers from dangerous chemicals at the workplace, inter alia by setting exposure limits for cobalt and its inorganic compounds, for polycyclic aromatic hydrocarbons (PAHs) and for 1,4-dioxane, and by adding welding fumes to the list of substances, mixtures and processes in Annex I to the Directive.

¹ Doc. 11823/25 + ADD1

3. The Council adopted a general approach on the proposal on 1 December 2025. The general approach maintained the core of the Commission proposal and introduced several mostly minor amendments. These include an addition of an occupational exposure limit value for isoprene, as recommended by the Risk Assessment Committee (RAC) and the Advisory Committee on Safety and Health (ACSH); a recital on residual risk drawing attention to the fact that setting occupational exposure limit values (OELs) does not completely eliminate risks to the health and safety of workers; a recital on the importance of developing further guidance on welding fumes; and an update of the definitions to reflect the inclusion of a potentially reprotoxic substance (welding fumes) in Annex I.
4. The Committee on Employment and Social Affairs (EMPL Committee) of the EP adopted its report on the proposal, including a decision to enter into trilogues, on 15 April 2026. The decision to enter into trilogues was confirmed by the EP plenary on 29 April 2026.
5. The first trilogue took place on 7 May 2026. The co-legislators presented their mandates and tasked the technical experts with holding in-depth discussions on all the open issues.
6. On 19 June, Coreper approved a revised mandate in order to enable the Cyprus Presidency to secure an agreement with the Parliament.
7. At the second trilogue, on 23 June, the negotiating teams of the Council and the Parliament reached a provisional agreement resulting in the final compromise text as set out in the Addendum to this note. The main elements of the agreement are outlined below.

II. ELEMENTS OF THE PROVISIONAL AGREEMENT

1. Polycyclic aromatic hydrocarbons (PAHs)

In its mandate, the Parliament proposed to prolong the transitional period for the new occupational exposure limit value for PAHs from 6 to 10 years and to broaden the scope of sectors benefitting from the transitional period to all carbon and graphite manufacturers. The Parliament insisted that these amendments were central to its mandate and necessary in order to allow employers to make the needed investments and ensure effective compliance across the EU. While Member States considered the proposed 10-year transitional period to be unjustifiably long, they showed openness for a limited prolongation as well as for broadening of the scope of sectors. Therefore, in line with the revised mandate of 19 June, the provisional agreement contains a minimal prolongation of the transitional period to 7 years and a broadening of the scope of sectors from manufacturers of carbon and graphite electrodes to all carbon and graphite manufacturers.

2. Personal protective equipment

The Parliament treated its amendments on this issue as a priority, arguing that it was necessary to clarify the role of personal equipment in achieving compliance with the occupational exposure limit value. While Member States had reservations about the wording of the Parliament's amendments, they showed willingness to clarify the existing rules. In line with the revised mandate, the provisional agreement contains a provision requiring regular breaks for workers using personal protective equipment as well as a provision clarifying the applicable rules regarding the use of personal protective equipment in relation to existing legislation, including Directive 2004/37/EC, and in particular to the hierarchy of control measures set out in its Article 5. The latter provision does not interfere with the existing hierarchy of control measures but rather explicitly clarifies that personal protective equipment is to be used as a measure of "last resort".

3. Definitions (carcinogens, mutagens, reprotoxic substance), isoprene, 1,4 dioxane

On these issues, the provisional agreement reflects the Council's general approach. As regards the definitions, the Council's general approach concerning references to Annex I has been maintained, with some lawyer-linguistic adjustments to the structure of the relevant amending provisions. On isoprene, which constitutes the main addition in the Council's general approach, the co-legislators' mandates were fully aligned from the outset. Regarding 1,4 dioxane, the phrase "in accordance with national law or practice", which was strongly advocated by some Member States has been maintained with a minor lawyer-linguistic adjustment.

4. Welding fumes

The provisional agreement retains the Council's general approach regarding the need for additional guidance and includes, as a matter of compromise with the Parliament, an operative provision requiring the Commission to assess whether to set additional limit values for substances contained in welding fumes. The wording of the latter provision has been modified so as not to contain a deadline or refer to setting a limit value for welding fumes in general, which was originally proposed the Parliament but considered unfeasible by Member States.

5. Hazardous medicinal products (HMPs)

In its mandate, the Parliament proposed to include a definition of HMPs and add "work involving HMPs" to Annex I, which most Member States firmly opposed. As a compromise, the provisional agreement contains two recitals: one specifically clarifying that HMPs which contain carcinogenic, mutagenic or reprotoxic substances fall within the scope of Directive 2004/37/EC, and another mentioning HMPs by recalling the existing operative provision from Article 11 regarding training for workers.

6. Firefighters and combined exposure

To respond to the Parliament's concerns regarding the risks inherent to the work of firefighters and emergency services personnel while ensuring consistency with existing tools and guidance, the provisional agreement contains a recital which highlights that it is important for EU-OSHA to consider developing a specific Online interactive Risk Assessment tool (OiRA) tailored for the needs of that sector. As regards combined exposure, the provisional agreement contains a recital asking the Commission to take into consideration the relevant specificities of these services when preparing Union guidelines on the effects of exposure to a combination of substances. This compromise is set against the backdrop of the ongoing work on the aforementioned guidelines pursuant to the previous revision of Directive 2004/37.

7. Data collection and SMEs

On these issues, the provisional agreement contains a recital specifying that it could be appropriate for the Commission to consider developing recommendations for data collection by the Member States, as well as a recital highlighting the specific situation and needs of SMEs and microenterprises. The latter recital implies no obligation on Member States to monitor and report the effects of the implementation of the Directive on SMEs, which was proposed by the Parliament in its mandate but strongly opposed by Member States.

III. CONCLUSION

1. The Permanent Representatives Committee is therefore invited to:
 - (a) confirm agreement on the final compromise text as set out in the addendum to this note with a view to reaching an agreement at first reading with the European Parliament;
 - (b) authorise the Chair of the Permanent Representatives Committee to send a letter to inform the Chair of the European Parliament's EMPL Committee that, should the European Parliament adopt its position at first reading on the text of the proposal in the exact form as set out in the addendum to this note, and subject to revision of that text by the lawyer-linguists of both institutions, the Council will approve the European Parliament's position and the act will be adopted in the wording which corresponds to the European Parliament's position.
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