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NOTE

From:	General Secretariat of the Council
To:	Delegations
Subject:	Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Council Directive 98/24/EC and Directive 2004/37/EC of the European Parliament and of the Council as regards the limit values for lead and its inorganic compounds and diisocyanates

I. INTRODUCTION

1. On 13 February 2023, the Commission published its proposal for a directive amending Directive 98/24/EC and Directive 2004/37/EC of the European Parliament and of the Council as regards limit values for lead and its inorganic compounds and diisocyanates (doc. ST 6417/23) and transmitted it to the Council and to the European Parliament.
2. The proposal revises the current occupational exposure limit value (OEL) and biological limit value (BLV) for lead. It also seeks to introduce, for the first time, an OEL and a short-term limit value for diisocyanates.

3. The Council adopted a general approach on the proposal in June 2023. The general approach maintained the limit values proposed by the Commission but introduced several amendments. Most notably, it:
- introduced a transitional period for the biological limit value for lead;
 - introduced a provision aimed at protecting workers with historical exposure to lead, who, given the slow release of lead from the body, will not be able to adapt to the new, much lower limit value before the transposition period;
 - amended the provision on women of childbearing age in order to protect the offspring of this group of workers without creating legal uncertainty or barriers to their participation in the labour market;
 - introduced a non-threshold notation for lead because it is not scientifically possible to identify a safe level of exposure for lead and its inorganic compounds for the development effects of the offspring;
 - asked the Commission to prepare Union guidelines on health surveillance including biological monitoring, focusing on the implementation of provisions regarding blood lead level for workers with historical exposure and women of childbearing age.
4. The Committee on Employment and Social Affairs (EMPL Committee) of the European Parliament adopted its report on the proposal, including a decision to enter into trilogues, on 7 September 2023. The decision to enter into trilogues was confirmed by the plenary on 13 September 2023.
5. The first trilogue took place on 12 October 2023. It was an occasion for the co-legislators to present their mandates and exchange views on the entire list of open issues. While the co-legislators agreed on the core of the proposal (limit values for the two groups of substances), diverging positions were expressed on a number of other issues, particularly those regarding the Parliament's amendments which go beyond the Commission's proposal and are not accompanied by an Impact Assessment.

II. STATE OF PLAY

6. The European Parliament position seeks, among other things, to introduce a review clause for the limit values for lead, broaden the obligation of medical surveillance to all workers, mandate the Commission to develop guidance on data collection by Member States and introduce an exemption from limit values for lead for certain types of activities. The Parliament also addresses the issue of workers with historical exposure and women of childbearing age but adopts a different approach to the Council. The EP introduces an obligation for workers with historical exposure to stop working with lead if their BLV is over 30µg/100ml (the current value is 70 µg/100ml). As regards, women of childbearing age, the Parliament maintains the guidance value proposed by the Commission and seeks to mandate the Commission to assess and establish it as a binding BLV in a forthcoming revision. The Parliament also seeks to introduce a number of amendments that go beyond the Commission's proposal. This concerns a set of new priorities and additions, such as amendments concerning the definition of mutagen and reprotoxic substance, hazardous medicinal products and combined exposure. In addition, the Parliament proposes a set of new priorities and actions, such as amendments concerning cobalt and benzene, endocrine disruptors, carcinogenic occupations and additional substances.
7. The Council's mandate of June 2023 is limited to the Commission proposal and therefore does not include a position on any of the Parliament amendments that go beyond its scope.
8. The Parliament insisted on its report so it became clear that without a mandate of the Council on the EP proposals it will not be possible to continue negotiations or find an agreement on an overall package. Therefore, a revision of the Council mandate appears necessary to be able to pursue trilogues.
9. A first discussion on the EP proposed amendments took place at the Social Questions Working Party on 3 October, 2023. During that meeting delegations expressed their preliminary positions regarding the EP mandate. These preliminary positions are outlined under each thematic blow below.

III. OUTSTANDING ISSUES AND WAY FORWARD

Delegations will find below a set of questions/suggestions by the Presidency designed to provide further guidance for technical work and form the basis of a compromise package for further negotiations with the European Parliament, aiming at finding a swift agreement. Based on the answers received from delegations, the Presidency intends to ask Coreper for a revised negotiation mandate.

1. Diisocyanates review of OELs

The Parliament seeks to mandate the Commission to, no later than 2029, launch a revision process for the limit values for diisocyanates and submit necessary amendments to this Directive, where appropriate.

The Presidency asks delegations:

- a) Can you support the EP amendment ?

2. Lead: transitional period, historical exposure to lead, women of childbearing age, medical surveillance and guidelines

The Presidency considers that these matters represent the core of the Council's General Approach. Following the discussions in the Working Group on 3 October, the Presidency concludes that the vast majority of delegations are in favour of maintaining the General Approach. Against this background, the Presidency asks delegations:

- a) Which EP amendments can you support on these matters?
- b) Can you support the introduction of an obligation of medical surveillance if a blood-lead level greater than 4,5 µg Pb/100 ml blood is measured in an individual worker?

3. **Lead: review clause, data collection, exemption for certain activities**

Introducing a review clause for lead limit values is one of the key demands for the EP. The Parliament also wishes to introduce a recital on the collection of data on work-related health problems due to lead exposure. The Presidency asks delegations:

- a) Can you accept to introduce a review clause for the lead limit values with a realistic timeframe?
- b) Can you accept a recital on the importance of data collection, which does not add new obligations on Member States?

As for the exemption, the EP asks the Commission, by 1 year after the entry into force of this Directive, to consider targeted and limited exemptions for cultural and heritage-related work activities to existing OEL and BLV and take appropriate action. At the Working Party meeting, an overwhelming majority of delegations were against such exemptions. Against this background, the Presidency asks delegations:

- c) Can you support the EP amendment asking for exemption for certain activities?

4. **European Parliament's proposals: new additions**

- a) **Definition of “mutagen” and “reprotoxic substance”**
- b) **Hazardous medicinal products (HMPs)**
- c) **Combined exposure**

The EP amendments concern new additions, some of which enlarge the scope of the Commission's proposal. At the Working Party meeting, delegations generally expressed caution regarding these issues.

The Parliament proposes to clarify that the definition of “mutagens” and “reprotoxic substances” includes the list referred to in Annex I. Delegations have expressed their openness to these amendments, with the possibility of making some technical adjustments. Against this background, the Presidency asks delegations:

- a) Can you support the Parliament's proposals on the definition of "mutagen" and "reprotoxic substance"?

The Parliament proposes to add a definition of hazardous medicinal products (HMPs) and to include them in Annex I of the CMRD. The EP insists these amendments are necessary to address the current situation of uncertainty in the healthcare sector. At the Working Party meeting, it was recalled that Article 18a of the last revision of CMRD already mandates the Commission to develop a definition and establish an indicative list of hazardous medicinal products or the substances contained therein. Some delegations cautioned that accepting EP amendments might create legal uncertainty, given that a list of products is still not established. As a matter of compromise, in technical discussions, the Parliament has offered to include in Annex I a reference to "HMPs which are carcinogenic, mutagenic or reprotoxic". The Presidency believes that adding such a definition would create uncertainty and run counter to the joint institutional statement accompanying the last revision of CMRD, which makes it clear that such HMPs are covered. In addition, since the list of such HMPs is not yet know, this solution would not help improve the situation of those handling these products. Against this background, the Presidency asks delegations:

- b) Can you accept to add in Annex I a reference to "HMPs which are carcinogenic, mutagenic or reprotoxic"?
- c) Can you support introducing a recital which would highlight the obligation of employers to carry out a risk assessment in relation to HMPs which may be carcinogenic, mutagenic or reprotoxic (and therefore under the scope of this Directive)?

Regarding combined exposure, delegations warned about the lack of scientific consensus or impact assessment.

- d) Can you accept asking the Commission to develop guidelines on combined exposure, based on scientific knowledge, in a realistic timeframe?

5. European Parliament's proposals: new priorities and actions

- a) **Cobalt and benzene**
- b) **Endocrine disruptors**
- c) **Carcinogenic occupations**
- d) **Additional substances**

These EP proposals concern new mandates for the Commission. At the last Working Party meeting, delegations generally expressed concern that these proposals circumvent the well-established tripartite process for setting limit values and supported the prioritisation of harmful substances through the ACSH.

As regards **cobalt and benzene**, the EP seeks to mandate the Commission to review the limit values for cobalt by the end of this year, and to revise the limit value for benzene by 2030. The ACSH has already adopted an opinion on cobalt. In its opinion on benzene, the ACSH suggests a revision by the end of 2030. Bearing in mind this background, the Presidency asks the delegations:

- a) Can you support the EP proposals on cobalt and benzene, with a realistic timeline?

As regards **endocrine disruptors**, the Parliament wants the Commission to assess the feasibility of including these substances within the scope of this Directive. The delegations questioned the pertinence of including endocrine disruptors within the scope of the CMRD because many health effects caused by these substances are not associated with cancer or reprotoxic effects. In addition, some delegations believe that these substances pose a larger risk to public health so they should be dealt with under a different legal basis. Still, in technical discussions, the Parliament insisted that this is one of its priorities. Against this background, the Presidency asks delegations:

- b) Can you accept asking the Commission to assess the feasibility of including endocrine disruptors within the scope of the CMRD, within a realistic timeframe?

As regards **carcinogenic occupations**, the Parliament wants to mandate the Commission to develop a definition of carcinogenic occupations. At the Working Party meeting, the delegations did not support the idea of developing a definition or list of carcinogenic occupations or including such occupations in the scope of this Directive. They argued that such a concept does not fit within the architecture of OSH legislation which is centred around risk assessment and obligations on the employer. In addition, delegations cautioned against unclear consequences of such an amendment and possible stigmatisation of these professions. Against this background, the Presidency asks delegations:

- c) Can you accept the EP amendments on carcinogenic occupations?

Finally, the EP seeks to mandate the Commission to revise its action plan for introducing limit values for **additional substances** in order to include lithium, lithium compounds, methyl hydrazine, 1,3-propanesultone, welding fumes and leather dust and to submit, where appropriate, a legislative proposal within 2 years.

- d) Can you accept to mandate the Commission to revise its action plan for achieving new limit values by including an additional 5 substances (not identified by name)?

6. Sustainable transition, circular economy, informal economy and SMEs

The EP introduces several recitals asking the MS to monitor and report the effects of the Directive on SMEs, highlighting the situation of workers in circular economy, exploring the interconnection of this Directive and the goal of sustainable transition, and stressing the need for ensuring OSH standards for workers in the informal economy.

At the Working Party meeting, delegations have questioned the added value of these amendments and cautioned that they may be out of scope of this Directive.

Against this background, the Presidency asks delegations:

- a) Can you support a compromise that would remain within the scope of this legal instrument and would not create new obligations on Member States?

IV. NEXT STEPS

Delegations are asked to provide **written answers to the above questions by 31 October** to be discussed at the **next Working Party meeting on 6 November**. The Presidency intends to use the feedback received from delegations to prepare a proposal for a revised mandate to be sought in Coreper, in view of continuing trilogues.

In the **Annex** to this Document, delegations will find a **summary of all questions asked in the note**.

1. Diisocyanates review of OELs

- b) Can you support the EP amendment ?

2. Lead: transitional period, historical exposure to lead, women of childbearing age, medical surveillance and guidelines

- a) Which EP amendments can you support on these matters?
- b) Can you support the introduction of an obligation of medical surveillance if a blood-lead level greater than 4,5 µg Pb/100 ml blood is measured in individual workers?

3. Lead: review clause, data collection, exemption for certain activities

- a) Can you accept to introduce a review clause for the lead limit values with a realistic timeframe?
- b) Can you accept a recital on the importance of data collection, which does not add new obligations on Member States?
- c) Can you support the EP amendment asking for exemption for certain activities?

4. European Parliament's proposals: new additions

- a) **Definition of “mutagen” and “reprotoxic substance”**
- b) **Hazardous medicinal products (HMPs)**
- c) **Combined exposure**
- d) Can you support the Parliament's proposals on the definition of “mutagen” and “reprotoxic substance”?
- e) Can you accept to add in Annex I a reference to “HMPs which are carcinogenic, mutagenic or reprotoxic”?

- f) Can you support introducing a recital which would highlight the obligation of employers to carry out a risk assessment in relation to HMPs which may be carcinogenic, mutagenic or reprotoxic (and therefore under the scope of this Directive)?
- g) Can you accept asking the Commission to develop guidelines on combined exposure, based on scientific knowledge, in a realistic timeframe?

5. European Parliament's proposals: new priorities and actions

- a) **Cobalt and benzene**
- b) **Endocrine disruptors**
- c) **Carcinogenic occupations**
- d) **Additional substances**

- a) Can you support the EP proposals on cobalt and benzene, with a realistic timeline?
- b) Can you accept asking the Commission to assess the feasibility of including endocrine disruptors within the scope of the CMRD, within a realistic timeframe?
- c) Can you accept the EP amendments on carcinogenic occupations?
- d) Can you accept to mandate the Commission to revise its action plan for achieving new limit values by including an additional 5 substances (not identified by name)?

6. Sustainable transition, circular economy, informal economy and SMEs

- a) Can you support a compromise that would remain within the scope of this legal instrument and would not create new obligations on Member States?