



Council of the
European Union

Brussels, 7 November 2023
(OR. en)

14814/23

LIMITE

SOC 729
EMPL 520
SAN 625
IA 279
CODEC 1999

**Interinstitutional File:
2023/0033(COD)**

NOTE

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| From: | General Secretariat of the Council |
| To: | Permanent Representatives Committee |
| Subject: | Proposal for a Directive of the European Parliament and of the Council amending Council Directive 98/24/EC and Directive 2004/1371/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), the positions were far apart primarily because many of the European Parliament's proposed amendments go beyond the scope of the Commission's proposal and are therefore not covered by the Council's general approach.

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, as well as to mandate the Commission to develop guidance on data collection by Member States and consider introducing 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. In the first trilogue and in subsequent contacts with the Presidency, the Parliament insisted on its report. Therefore, it became clear that the Presidency would have to seek guidance and flexibility from Member States in order to continue negotiations and find an agreement on an overall package.

9. The Presidency has consulted delegations on the issues covered by the EP mandate. Discussions on the amendments proposed by the EP took place at the Social Questions Working Party meetings on 3 October and 6 November 2023. The feedback received from the delegations is summarised under thematic headings below.
10. Following the above-mentioned Working Party meetings, the Presidency addresses a call for guidance to Coreper in order to be able to pursue trilogues. The intention of the Presidency is to pursue a political agreement with the European Parliament on the main political lines in a compromise package.

III. GUIDANCE FOR TRILOGUE PREPARATION

Based on the positions expressed by delegations at the above-mentioned Working Party meetings, the Presidency has identified some areas of flexibility and possible ways forward, as outlined below.

1. **Lead: transitional period, workers with historical exposure to lead, women of childbearing age, medical surveillance, guidelines, review clause, data collection and exemption for certain activities**

The Presidency considers that some of these matters represent the core of the proposal and therefore also of the Council's General Approach. Indeed, these issues are closely interlinked, complex and important for both co-legislators. The Parliament has stressed that it cannot accept the transitional period for the biological limit value introduced by the Council's general approach. As a matter of compromise, the Parliament suggested removing the transitional period for BLV but keeping the Council's general approach regarding workers with historical exposure to lead. Introducing a review clause for limit values for lead is one of the key demands for the EP and it appears crucial for reaching an agreement. As regards data collection and exemption for certain activities, the Parliament has expressed some potential flexibility.

At the Working Group meetings on 3 October and 6 November and in the written comments received, most delegations expressed their wish to maintain the general approach on the core issues of medical surveillance, women of childbearing age and workers with historical exposure. As regards the transitional period, some delegations showed flexibility regarding the Parliament's compromise proposal, while others were cautious. On the review clause and data collection, at the Working Party meeting on 6 November, delegations supported compromise solutions proposed by the Presidency and have shown some openness provided that, respectively, a realistic timeframe is foreseen and no new obligations on the Member States are added. Meanwhile, most delegations were categorically opposed to the Parliament's amendment regarding the exemption for certain activities. However some linked the possible exemptions for certain sectors and activities with the Parliament's compromise proposal concerning the transitional period for the biological limit value.

Against this background, the Presidency proposes to:

- **defend** the Council's general approach on medical surveillance, women of childbearing age and workers with historical exposure;
- **consider** some flexibility of the transitional period, if necessary for the sake of reaching an overall balanced agreement.
- **stress** the importance of reviewing the limit values for lead in line with scientific knowledge;
- **introduce** a recital on the importance of data collection, which does not add new obligations on Member States;
- **reject** the EP amendment asking for exemption for certain activities.

2. European Parliament's proposals: new additions

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

The EP amendments concern new additions, some of which seek to enlarge the scope of the Commission's proposal. The Parliament has particularly highlighted HMPs and combined exposure as important issues which it wants to include in this revision. HMPs are a long-standing demand of the Parliament which was already addressed in the last revision of the Carcinogens and Mutagens Directive. However, the EP believes the problems on the ground still persist. As regards combined exposure, the Parliament has shown some flexibility, but continues to insist on addressing the issue in this revision.

Regarding the definition of “mutagens” and “reprotoxic substances”, delegations generally viewed the EP amendment as a potential improvement and expressed their flexibility towards it with the condition of introducing some technical adjustments. Regarding hazardous medicinal products (HMPs), some delegations cautioned that adding HMPs to Annex I might create legal uncertainty, given that a list of products is still not available. Since this issue is one of the priorities for the Parliament, the Presidency asks for some flexibility in looking for solutions which would help address the EP's concerns without creating legal uncertainty. Regarding combined exposure, delegations expressed openness to the compromise proposed by the Presidency, as outlined below.

Against this background, the Presidency proposes to:

- **introduce** the definition of “mutagens” and “reprotoxic substances”, provided that the necessary technical adjustments are made in order to ensure scientific consistency and legal clarity;

- **introduce** a recital which would highlight the obligation of employers to implement all the provisions of the Carcinogens, Mutagens and Reprotoxic Substances Directive, including risk assessment, when their employees are exposed to HMPs;
- **highlight** the need to address the effects of exposure to a combination of substances.

3. European Parliament's proposals

- **Cobalt and benzene**
- **Endocrine disruptors**
- **Carcinogenic occupations**
- **Additional substances**
- **Diisocyanates: review of OELs**

These EP amendments concern new mandates for the Commission.

At the Working Party meetings, 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 tripartite Advisory Committee on Safety and Health. Delegations cautioned against setting deadlines for a review of the limit values for cobalt and benzene. They cautioned that the inclusion of endocrine disruptors in CMRD may not be pertinent and that the introduction of carcinogenic occupations could alter the existing architecture of Directives in the area of occupational safety and health. As regards additional substances, delegations expressed a certain flexibility, but cautioned that it would affect the prioritisation of other harmful substances.

Against this background, the Presidency proposes to:

- **reject** the Parliament's proposals on cobalt and benzene;

- **stress** the importance of assessing the need to include endocrine disruptors within the scope of the CMRD;
- **reject** the Parliament's amendments on carcinogenic occupations and **introduce** a recital that highlights the situation of firefighters;
- **highlight** the importance of evaluating the need to include new substances within the CMRD, and establish new limit values where appropriate.
- show **openness** to a possible compromise on diisocyanates if necessary for the sake of reaching an overall balanced agreement;

4. 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 proposes to:

- **introduce** a compromise recital that would remain within the scope of this legal instrument and would not create new obligations on Member States.

IV. NEXT STEPS

11. Delegations are asked to share their assessment of these areas of flexibility and possible ways forward as identified by the Presidency. The feedback of delegations will help the Presidency to decide how to pursue the negotiations with the European Parliament.