Council of the European Union

Brussels, 30 November 2023
(OR. en)

16071/23

Interinstitutional File:
2023/0033(COD)

LIMITE

SOC 831
EMPL 596
SAN 705
IA 328
CODEC 2300

NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee
No. Cion doc.:	6417/23 - COM(2023) 71 final
Subject:	Proposal for a Directive of the European Parliament and of the Council amending Council Directive 981241EC and Directive 20041371EC of the European Parliament and of the Council as regards the limit values for lead and its inorganic compounds and diisocyanates - Analysis of the final compromise text with a view to agreement

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[1] 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.

[1] Doc. 6417/23

3. The draft Directive is based on Article 153(2)(b) in conjunction with Article 153(1)(a) of the Treaty on the Functioning of the European Union (TFEU). The ordinary legislative procedure is applicable.

4. The European Economic and Social Committee delivered its opinion on the proposal on 22 March 2023[2]. The Committee of the Regions decided at its meeting on 20 April 2023 not to issue an opinion[3].

5. 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, a provision on workers with historical exposure to lead and an amendment to the provision on medical surveillance concerning women of childbearing age. In addition, the general approach introduced a non-threshold notation for lead and asked the Commission to prepare Union guidelines on health surveillance including biological monitoring.

6. 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.

7. Following the first trilogue on 12 October 2023, at its meeting of 10 November, Coreper gave guidance on the outstanding issues in order to enable the Spanish Presidency to continue negotiations with the Parliament.

8. At the second trilogue, on 14 November, 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.

[2] Doc. 8667/23
[3] Doc. 10062/23

II. ELEMENTS OF THE PROVISIONAL AGREEMENT

1. Transitional period for the biological limit value for lead

The transitional period for the BLV for lead has been one of the central elements of the negotiation. The Parliament was keen on removing this provision introduced by the Council's General Approach. However, the Coreper meeting of 10 November showed that this was a red line for certain Member States. Since a compromise was necessary to secure a deal, the provisional agreement contains a minor adjustment to the Council's general approach. The duration and the scope of the transitional period have been maintained, while the transitional limit value has been only slightly reduced from 35 to 30 µg/100 ml blood. The value of 30 µg/100 ml blood corresponds to the lowest observed adverse effect level (LOAEL) for clastogenic effects (DNA mutation)

2. Workers with historical exposure to lead

Both the Parliament and the Council had introduced specific provisions for those workers who, given the slow release of lead from the body, would not be able to adapt to the new, much lower limit value before the transposition period. The provisional agreement maintains the Council's general approach, with the necessary adjustment in line with the change to the transitional limit value.

3. Review clause for limit values for lead

As one of the biggest priorities of the Parliament, the provisional agreement asks the Commission to assess the limit values for lead in the context of the next evaluation of the implementation of the Directive (which is a regular process occurring every 5 years pursuant to Article 17a of Directive 89/391/EEC) and to propose legislative amendments, where appropriate.

4. Medical surveillance and women of childbearing age

The Council's general approach on medical surveillance has been maintained. Therefore, the provisional agreement stipulates that medical surveillance is to be carried out for women of childbearing age whose blood lead levels exceed 4,5 µg Pb/100 ml blood or the national reference value of the general population. The aim of this provision is to protect the offspring of this group of workers without creating barriers to their participation in the labour market.

As a matter of compromise necessary to reach a deal, the provisional agreement reintroduces the footnote regarding women of childbearing age in Annex II of the Commission's proposal linked to the biological limit value. The footnote reproduces an extract of a recommendation by the scientific Risk Assessment Committee. It is not binding.

5. Guidelines

The Council's general approach was maintained on this issue.

6. Endocrine disruptors

This issue was one of the priorities for the Parliament. As a matter of compromise, the provisional agreement introduces a provision stating that, within two years from the adoption of the Directive, the Commission shall initiate a scientific assessment of endocrine disruptors that can affect workers' health and safety, with a view to evaluate the appropriateness of including them within the scope of the Directive on Carcinogens, Mutagens and Reprotoxic Substances and, where appropriate, submit a legislative proposal.

The Commission is therefore not obliged to submit a legislative proposal on this issue, but only to start a scientific assessment.

7. HMPs, carcinogenic occupations, lead data collection

On these issues, the provisional agreement contains recitals which do not alter the basic Directive or introduce new obligations for the Member States.

8. Combined exposure

The potential usefulness of Commission guidelines for situations of exposure to a combination of harmful substances was acknowledged by delegations, although some cautioned about the lack of scientific consensus on the issue. Therefore, the provisional agreement asks the Commission to initiate an assessment of the effects of exposure to a combination of substances, with a view to prepare Union guidelines on how to address this matter where appropriate.

9. Diisocyanates

The Parliament wanted to task the Commission with launching a revision process for the limit values for diisocyanates no later than 31 December 2029. The provisional agreement does not introduce such an operative provision. Instead, it includes a recital which recalls that ACSH has recommended a review of the limit values for diisocyanates starting in 2029 and reaffirms the Commission's right of legislative initiative.

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.