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To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
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Subject:	COMMISSION STAFF WORKING DOCUMENT Subsidiarity Grid Accompanying the document 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

Delegations will find attached document SWD(2023) 34 final.

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COMMISSION STAFF WORKING DOCUMENT

Subsidiarity Grid

Accompanying the document

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

{COM(2023) 71 final} - {SEC(2023) 67 final} - {SWD(2023) 35 final} -
{SWD(2023) 36 final}

Subsidiarity Grid

1. Can the Union act? What is the legal basis and competence of the Unions' intended action?
1.1 Which article(s) of the Treaty are used to support the legislative proposal or policy initiative?
Article 153 of the Treaty on the Functioning of the European Union (TFEU), which empowers the European Union to support and complement the activities of the Member States as regards improvements, in particular of the working environment to protect workers' health and safety and to adopt, by means of directives, minimum requirements for gradual implementation, having regard to the conditions and technical rules obtaining in each of the Member States. Article 154 of the TFEU, which requests the Commission to initiate a two-stage consultation of the social partners at the EU level prior to submitting proposals in the social policy field.
1.2 Is the Union competence represented by this Treaty article exclusive, shared or supporting in nature?
In the case of social policy, the Union's competence is shared. Article 153(1)(a) of the TFEU states that the Union shall support and complement the activities of the Member States in the field of "*improvement in particular of the working environment to protect workers' health and safety*".
*Subsidiarity does not apply for policy areas where the Union has **exclusive** competence as defined in Article 3 TFEU[1]. It is the specific legal basis which determines whether the proposal falls under the subsidiarity control mechanism. Article 4 TFEU[2] sets out the areas where competence is shared between the Union and the Member States. Article 6 TFEU[3] sets out the areas for which the Unions has competence only to support the actions of the Member States.*
2. Subsidiarity Principle: Why should the EU act?
2.1 Does the proposal fulfil the procedural requirements of Protocol No. 2[4]: - Has there been a wide consultation before proposing the act? - Is there a detailed statement with qualitative and, where possible, quantitative indicators allowing an appraisal of whether the action can best be achieved at Union level?
As requested by the TFEU Article 154, a formal two-stage consultation of the social partners at EU level is required prior to submitting proposals in the social policy field. Such a two-stage consultation was performed in 2021. The Commission has also consulted the tripartite Advisory Committee on Safety and Health (ACSH) and its Working Party on Chemicals (WPC), both composed of representatives from Member States, representing national governments, workers' and employers' organisations. The ACSH has adopted an opinion on 24 November 2021. In addition to that, a call for evidence was published on the Europa website for feedback in February 2022. The explanatory memorandum and the impact assessment contain a section on the principle of subsidiarity. More information is available in question 2.2 below.
2.2 Does the explanatory memorandum (and any impact assessment) accompanying the Commission's proposal contain an adequate justification regarding the conformity with the

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12008E003&from=EN
[2] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12008E004&from=EN
[3] https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:12008E006:EN:HTML
[4] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12016E/PRO/02&from=EN

principle of subsidiarity?

Both the explanatory memorandum and the impact assessment accompanying the Commission's proposal contain an adequate justification regarding the conformity with the principle of subsidiarity.

As risks to workers' health and safety are broadly similar across the European Union, there is a clear role for the EU in supporting Member States to address such risks.

Data gathered in the preparatory work indicate that there are differences in the Member States regarding the setting of limit values both for lead and for diisocyanates, subjecting workers in the EU to different levels of protection.

Significant divergences between national limit values distort competition in the internal market. The costs of complying with lower national levels are generally higher and entail, therefore, a competitive advantage for enterprises operating in markets with no or less stringent national limit values.

For lead, companies based in Bulgaria, Czechia, Denmark, Latvia and Poland need to comply with an Occupational Exposure Limit (OEL) EL 3 times lower than the maximum OEL set at EU level (0.050 g/m^3 vs 0.150 g/m^3). 15 Member States have a Biological Limit Value (BLV) lower than the current EU BLV. Some Member States have a lower limit for women, this is age dependent or stated as women of childbearing age and typically ranges between 20-40 µg/100ml blood. The (OEL ranges from 0.050 mg/m^3 to 0.15 mg/m^3 (the current OEL under the Carcinogens, Mutagens and Reprotoxic Substances Directive[5] [CMRD]).

For diisocyanates, as there is no EU limit value, differences are even larger. Three EU Member States have a general OEL and 18 have different OELs for some, but not all, diisocyanates. As regards the Short Term Exposure Level (STEL), 17 Member States have a STEL, of which only 5 have a general level; the others are for specific diisocyanates substances. This makes presenting a general range challenging. However, where they exist, OELs range from 3 µg NCO/m^3 to 500 µg NCO/m^3 with a median value of 17.4 µg NCO/m^3. For the STEL, the range is from 10 to 82 µg NCO/m^3.

Updating the CMRD for lead and the Chemical Agents Directive[6] (CAD) for diisocyanates is an effective way to ensure that preventive measures would be updated accordingly in all Member States, providing a uniform level of minimum requirements designed to guarantee a better standard of health and safety and thus minimising the disparities in health and safety protection levels of workers between Member States.

Moreover, a revision of those directives can only be done by action at EU level. Such revision is necessary in view of the development of scientific knowledge in this area. The fact that 15 EU Member States have already reduced their exposure limit values for lead and that 18 have introduced limit values for diisocyanates demonstrates this need. The need for revision has also been recognised by the tripartite ACSH.

The revision of the limit values under the CMRD and the CAD at the EU level will lead to a greater harmonisation of limit values across the EU. Companies willing to operate in different EU Member States can further benefit from a streamlining of the applicable limit values, potentially providing for savings as common solutions can be adopted across facilities, as opposed to having to design site-specific solutions to meet different requirements.

Furthermore, the revision of limit values is very complex and requires a high level of scientific expertise. An important advantage of the revision of the limit values at EU level is that it eliminates the need for Member States to conduct their own scientific analysis, with likely substantial savings on

[6] Directive 98/24/EC

administrative costs. These resources saved could instead be dedicated to further improving occupational safety and health (OSH) policies in each Member State.

2.3 Based on the answers to the questions below, can the objectives of the proposed action be achieved sufficiently by the Member States acting alone (necessity for EU action)?

Risks to workers' health and safety are broadly similar across the European Union. National actions alone lead to insufficient and divergent levels of protection of workers' health, as well as to an uneven playing field for businesses.

(a) Are there significant/appreciable transnational/cross-border aspects to the problems being tackled? Have these been quantified?

As explained in point 2.2, risks to workers' health and safety are broadly similar across the European Union. However, data gathered in the preparatory work indicates differences in the Member States regarding the OEL and BLV for lead and the OEL and STEL for diisocyanates.

It is estimated that currently between 50 000 and 150 000 workers are exposed to lead. Determining a precise number for lead is difficult because workers in sectors such as demolition, waste management, and those using articles of lead metal may only occasionally be exposed to lead, but sometimes at relatively high levels. Approximately 4.2 million workers are exposed to diisocyanates.

Moreover, diisocyanates are found in insulation materials in construction, and this sector is characterised by a considerable level of cross-border work.

Therefore, such differences in limit values result in high disparities in the levels of protection of workers' health in the different Members States.

(b) Would national action or the absence of the EU level action conflict with core objectives of the Treaty[7] or significantly damage the interests of other Member States?

National actions alone lead to high disparities between the existing national limit values, with the consequences in point 2.3 (a) above. EU level action would not conflict with core objectives of the Treaty or significantly damage the interests of other Member States. On the contrary, it would enable among others to:

- ensure a similar and fair minimum level of protection across the European Union;
- contribute to a level playing field;
- improve clarity and enforcement of the CMRD and the CAD;
- assume burdens at EU level related to revision of the limit values by eliminating the need for Member States to individually conduct their own scientific analyses.

(c) To what extent do Member States have the ability or possibility to enact appropriate measures?

The CMRD aims to protect workers from the health and safety risks related to exposure to carcinogens, mutagens or substances toxic to reproduction at work. The CAD aims to protect workers from risks to their safety and health arising, or likely to arise, from the effects of chemical agents that are present at the workplace.

A consistent level of protection from the risks related to carcinogens, mutagens and reprotoxic substances, and to chemical agents respectively is provided for by a framework of general principles to enable Member States to ensure the consistent application of the minimum requirements. The

[7] https://europa.eu/european-union/about-eu/eu-in-brief_en

minimum requirements provided for in the Directives aim to protect workers at Union level. More stringent binding limit values or other protective measures can be set by Member States.

(d) How does the problem and its causes (e.g., negative externalities, spill-over effects) vary across the national, regional and local levels of the EU?

Risks to workers' health and safety are broadly similar across the European Union.

However, in the absence of EU action, the level of workers' protection from exposure to lead can diverge from a Member State to another depending among others on whether national OELs and BLVs have already been revised following scientific development. For instance, 15 Member States have a BLV lower than the EU level (Bulgaria, Croatia, Czechia, Denmark, Finland, France, Germany, Hungary, Italy, Latvia, the Netherlands, Poland, Slovakia, Slovenia and Sweden). Some Member States also have lower, age-dependant limits for women.

As for diisocyanates, despite the lack of EU limit values, three EU Member States have a general OEL and 18 have different OELs and STELS for some, but not all, different diisocyanates. 17 have a STEL.

(e) Is the problem widespread across the EU or limited to a few Member States?

Although the current levels of protection diverge considerably, the problem is widespread across the European Union as risks to workers' health and safety are broadly similar.

A wide variety of sectors working with lead are particularly represented in France, Germany, Italy, Poland and Spain, in which the existing limit value is higher than the Commission proposal. Therefore, these Member States are expected to be more affected by a lowering of the limit values, although all will be impacted. 2.4 million companies across most Member States are concerned by the proposal on diisocyanates.

(f) Are Member States overstretched in achieving the objectives of the planned measure?

The process of establishing limit values is very complex and requires a high level of scientific expertise. This could partly explain why some Member States have not yet lowered their OELs and BLVs for lead (from the values set at EU level in 1982) or have not introduced limit values for diisocyanates. An important advantage of setting limit values at EU level is that it eliminates the need for Member States to conduct their own scientific analyses, with likely substantial savings on administrative costs. Given the limited resources for OSH at national level, this could release funds to be redirected into other OSH priorities.

(g) How do the views/preferred courses of action of national, regional and local authorities differ across the EU?

Acknowledging the development of the scientific knowledge, 15 EU Member States have already reduced their BLV for lead, 21 have introduced an OEL for diisocyanates and 17 a STEL.

The tripartite ACSH (composed of representatives of National Authorities, Employers and Workers´ organisations in each Member State), in November 2021, reached a consensus on the need to substantially revise downwards the existing binding OEL and BLV for lead and to introduce an OEL and STEL for diisocyanates to better protect workers' health and safety and thus reduce the probability for occupational diseases to happen.[8]

[8] DOC.008 21. ACSH Opinion on an EU Binding Occupational Exposure Limit Value for Asbestos under the Asbestos at Work Directive 2009/148/EC. Adopted on 24/11/2021

2.4 Based on the answer to the questions below, can the objectives of the proposed action be better achieved at Union level by reason of scale or effects of that action (EU added value)?

Acting at the EU level would enable among others to ensure a fair similar minimum level of protection across the European Union, contribute to a level playing field and improve clarity and enforcement. Revising the limit values at the EU level would also enable to eliminate the need for Member States to conduct their own scientific analyses with likely substantial savings on administrative costs.

(a) Are there clear benefits from EU level action?

Amending Directive 98/24/EC and 2004/37/EC presents an EU added value in several aspects:

- Ensuring a similar and fair minimum level of protection across the European Union;
- Contributing to a level playing field;
- Assuming burdens at EU level related to revision of limit values.

More information can be found in point 3.2 of the Impact Assessment.

(b) Are there economies of scale? Can the objectives be met more efficiently at EU level (larger benefits per unit cost)? Will the functioning of the internal market be improved?

The process of establishing limit values is very complex and requires a high level of scientific expertise. An important advantage of setting OELs at EU level is that it eliminates the need for Member States to conduct their own scientific analyses. These economies of scale should lead to likely substantial savings on administrative costs. Given the limited resources for OSH at national level, this could release funds to be redirected into other OSH priorities.

(c) What are the benefits in replacing different national policies and rules with a more homogenous policy approach?

Directives 98/24/EC and 2004/37/EC do not aim to replace national policies and rules but rather to set minimum requirements in order to protect workers at EU level. More stringent binding OELs or other protective measures can be set by Member States.

However, the minimum requirements provided for in the Directives aim, among others, to ensure a similar minimum level of protection across the European Union while contributing to a level playing field and a better functioning of the internal market.

(d) Do the benefits of EU-level action outweigh the loss of competence of the Member States and the local and regional authorities (beyond the costs and benefits of acting at national, regional and local levels)?

The fight against occupational diseases remains a high priority in the area of OSH at EU-level.

The Commission announced in the European Pillar of Social Rights Action Plan the intention to ensure a healthy, safe and well adapted work environment, which was confirmed with the adoption of the OSH Strategic Framework for 2021-2027. Also, the 2020 Chemicals Strategy for Sustainability recognises the need to strengthen the protection of workers and identifies lead and diisocyanates among the priority chemicals to act upon.

Therefore, acting at the EU level will enable to support all the Member States in addressing occupational diseases arising from exposure to chemicals at work. In addition to that, Member States can continue to set additional or more stringent binding OELs, or other protective measures.

(e) Will there be improved legal clarity for those having to implement the legislation?

The revision of the limit values under the CMRD and the CAD at the EU level will lead to a greater harmonisation of limit values across Europe, with expected improvements in the level playing field for enterprises, particularly those operating in different Member States.

The revision of the CAD to remove the reference to lead, and the simultaneous revision of the CMRD to update the OEL and BLV for lead will substantially improve legal clarity, as provisions on lead will only be included in one legal instrument, therefore eliminating the risk of contradictions and discrepancies between the two, and clearly outlining employers' responsibilities and the protective measures to follow.

3. Proportionality: How the EU should act

3.1 Does the explanatory memorandum (and any impact assessment) accompanying the Commission's proposal contain an adequate justification regarding the proportionality of the proposal and a statement allowing appraisal of the compliance of the proposal with the principle of proportionality?

Both the explanatory memorandum and the impact assessment accompanying the Commission's proposal contain such a justification.

This proposal makes a step forward to achieve the objectives set to improve living and working conditions of workers.

With regard to the revision of the limit values proposed, socio-economic and technical feasibility factors have been taken into account after intensive discussions with all stakeholders (representatives of workers' organisations, representatives of employers' organisations, and representatives of governments).

The costs of the proposed option for lead would amount to EUR 30 000 per company over 40 years, which represents less than 1% of companies' turnover. For diisocyanates, a company would have to spend EUR 6 000 over 40 years, which would not represent a significant share of their turnover either. Besides, the values are endorsed by employers, meaning that despite the costs, businesses consider it a proportionate option.

In accordance with Article 153(4) of the TFEU, the provisions in this proposal do not prevent any Member State from maintaining or introducing more stringent protective measures compatible with the Treaties, in the form for example of lower limit values. Article 153(3) of the TFEU gives Member States the possibility to entrust management and labour, at their joint request, with the implementation of directives adopted pursuant to Article 153(2) of the TFEU, thus respecting well established national arrangements for regulation in this area.

It follows that in line with the principle of proportionality, as set out in Article 5(4) of the TFEU, this proposal does not go beyond what is necessary in order to achieve its objectives, namely, the improvement of the health and safety of workers pursuant to Article 153 TFEU.

3.2 Based on the answers to the questions below and information available from any impact assessment, the explanatory memorandum or other sources, is the proposed action an appropriate way to achieve the intended objectives?

The European Pillar of Social Rights[9], jointly proclaimed by the European Parliament, the Council and the Commission at the Social Summit for Fair Jobs and Growth on 17 November 2017, enshrines workers' right to healthy, safe, and well-adapted work environment, including protection from harmful substances, which covers lead and diisocyanates.

Therefore, it is appropriate to act at the EU level in order to ensure to the workers the right to a high level of protection of their health and safety at work, and to support and complement the activities of the Member States in this regard, pursuant to Article 153 of the TFEU.

It is all the more appropriate as the CMRD and CAD are already in force, and this proposal is limited to revising the limit values of two of the substances covered by those directives on the basis of the latest scientific and technical data available.

(a) Is the initiative limited to those aspects that Member States cannot achieve satisfactorily on their own, and where the Union can do better?

This initiative aims at ensuring a balanced approach, i.e., to prevent companies from facing severe economic disadvantages while providing an adequate protection to workers at EU level. It is considered balanced and justified in light of the accrued and longer-term benefits in terms of reducing health risks arising from workers' exposure to asbestos and saving lives, without putting disproportionate burdens on economic operations in the concerned sectors, including on micro, small and medium-sized enterprises.

(b) Is the form of Union action (choice of instrument) justified, as simple as possible, and coherent with the satisfactory achievement of, and ensuring compliance with the objectives pursued (e.g. choice between regulation, (framework) directive, recommendation, or alternative regulatory methods such as co-legislation, etc.)?

Article 153(2)(b) of the TFEU allows minimum requirements in the field of workers' health and safety protection to be adopted 'by means of directives'. In addition, Directives 98/24/EC and 2004/37/EC are already in force, and this proposal is limited to revising the limit values of lead and diisocyanates on the basis of the scientific data available.

(c) Does the Union action leave as much scope for national decision as possible while achieving satisfactorily the objectives set? (e.g. is it possible to limit the European action to minimum standards or use a less stringent policy instrument of approach?)

Article 153(2)(b) of the TFEU only allows minimum requirements in the field of workers' health and safety protection to be adopted 'by means of directives'. These minimum requirements are proposed by the European Commission after consultation of representatives of workers' organisations, representatives of employers' organisations, and representatives of governments. The provisions in this initiative do not prevent any Member State from maintaining or introducing more stringent protective measures compatible with the Treaties.

(d) Does the initiative create financial or administrative cost for the Union, national governments, regional or local authorities, economic operators or citizens? Are these costs commensurate with the objective to be achieved?

Actions to adjust working practices (risk management measures, health surveillance, monitoring and

[9] Available at: https://ec.europa.eu/commission/priorities/deeper-and-fairer-economic-and-monetary-union/european-pillar-social-rights_en

training) to comply with the new values will result in increased costs for companies. The estimated cost of the preferred options is overall bearable for businesses. For lead, the costs would amount to EUR 30 000 per company over 40 years (less than 1% of their turnover). For diisocyanates, a company would have to spend EUR 6 000 over 40 years, which would not represent a significant share of their turnover either. Since these are sectors with a high degree of competition, impacts on consumers are expected to be limited.

Additional administrative and enforcement costs that might be incurred by enforcing authorities are not expected to be significant. The reduction of ill-health cases will contribute to mitigating financial losses as burdens to social security and health care systems are reduced. The estimated savings for public authorities for lead are around EUR 100 million over 40 years, which outweighs the one-off costs (EUR 500 000). For diisocyanates, public administrations in the EU will have to incur one-off costs of around EUR 970 000, also expected to be balanced by the benefits (EUR 1 750 000).

In addition to that, this initiative should result in benefits in terms of avoided cases of occupational diseases and related monetised health benefits including intangible costs such as the reduced quality of life, the suffering of the workers and their families, etc.

(e) While respecting the Union law, have special circumstances applying in individual Member States been taken into account?

As mentioned above, the European Commission consulted the tripartite ACSH, composed of three full members per Member State, representing national governments, trade unions and employers' organisations. This broad representation enables to take into account special circumstances applying in individual Member States.