EUROPEAN
COMMISSION

Brussels, 18.7.2025
SWD(2025) 191 final

COMMISSION STAFF WORKING DOCUMENT

Subsidiarity Grid

Accompanying the document

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

{COM(2025) 418 final} - {SEC(2025) 217 final} - {SWD(2025) 192 final} -
{SWD(2025) 193 final}

Subsidiarity Grid

- **As proposed by the Committee of the Regions with guidance in blue**
- **Obviously, the answers to the questions below, the explanatory memorandum and – if applicable – the impact assessment should be consistent. This may require some iterations.**
- **Please try to stay under 10 pages.**

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 2023. The Commission has also consulted the tripartite Advisory Committee on Safety and Health at Work (ACSH) and its Working Party on

[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

Chemicals (WPC), both composed of representatives from Member States, representing national governments, workers' and employers' organisations. The ACSH has adopted opinions on the 5 prioritised hazardous substances on 22 September 2023.

- 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 principle of subsidiarity?

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

In the absence of EU values, Member States are free to adopt national limit values. Where they exist, the national limit values for the 3 substances subject to the setting of a limit value as part of this initiative vary considerably between Member States. For instance, the national limit values for cobalt range from 10 to 500 µg/m3. Some Member States have therefore set limit values fifty times lower than others for the same substance. Five Member States have no limit values for cobalt[5].

Under such circumstances, minimum requirements for workers' health protection against the risks arising from exposure to these substances cannot be ensured for all EU workers in all Member States by actions taken by Member States alone.

In addition, setting EU limit values helps to provide a level playing field for industry as some employers' organisations stressed in their response to the social partner consultation. 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.

Setting EU limit values will not completely eliminate the differences between Member States since they can adopt more protective (lower) limits. However, it will reduce the scope for divergences and enhance certainty that there is a core definition and/or enforceable exposure limit for all concerned carcinogens and reprotoxic substances in all Member States. It will also reduce regulatory complexity resulting from highly diverging rules between Member States, contributing to reduce the administrative burden of compliance for businesses operating across the single market.

Regarding welding fumes, the complexity and heterogeneity of their composition, together with the absence of harmonised classification in the CLP Regulation[6], contribute to a lack of clarity on their possible dangerousness for workers, and therefore a lack of appropriate risk management measures at the workplace. Addressing this absence of classification for welding fumes at EU level would ensure more legal clarity, which would result in better implementation of the existing EU rules.

Governments', employers' and workers' representatives have expressed clear support for establishing limit values for the substances subject to this initiative, and for including welding fumes in Annex I of the Carcinogens, Mutagens and Reprotoxic substances Directive 2004/37/EC (CMRD), as it clearly results from the two-stage consultation of social partners and the opinions of the tripartite ACSH.

2.3 Based on the answers to the questions below, can the objectives of the proposed action be

[5] IT, LU, MT, PT, SI

[6] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, *OJ L 353, 31.12.2008, p. 1-1355*

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?
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 limit values. For instance, 9 Member States have currently no limit value for polycyclic aromatic hydrocarbons. 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 - assume burdens at EU level related to revision of the limit values or the list of process-generated substances 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. A consistent level of protection from the risks related to these substances is provided for by a framework of general principles to enable Member States to ensure the consistent application of the minimum requirements. The minimum requirements provided for in the CMRD 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 the prioritised substances can diverge from a Member State to another depending among others on whether national limit values have already been revised following scientific development or if welding fumes are already classified as process-generated substances. Furthermore, the existing national limit values are much higher than the limit values recommended by the European Chemicals Agency's Risk Assessment Committee, leading to likely insufficient protection of workers.

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

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

Although Member States may already have limit values for some of the substances addressed in this initiative, the problem is widespread across the European Union as risks to workers' health and safety are broadly similar. As explained above, the existing national limit values are much higher than the limit values recommended by the European Chemicals Agency's Risk Assessment Committee, leading to likely insufficient protection of workers.

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

The process of establishing limit values or modifying the list of process-generated substances is very complex and requires a high level of scientific expertise. This could partly explain why some Member States have no limit values yet for some of the substances addressed in this initiative or have not yet classified welding fumes as process-generated substances. An important advantage of addressing this issue at EU level is that it eliminates the need for Member States to conduct their own scientific analysis with likely substantial savings on administrative costs. Given the limited resources for occupational safety and health (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?

The tripartite ACSH, in September 2023, reached a consensus on the need to set binding limit values or introduce in the list of process-generated substances the substances prioritised as part of this initiative in view of better protecting workers' health and safety and thus reduce the probability for occupational diseases to happen.

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 the CMRD presents an EU added value in several aspects:

- Ensuring a similar and fair minimum level of workers' 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 3.3 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 limit values 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.
According to the impact assessment accompanying this initiative, the benefits related to avoided

costs of addressing exposure to the prioritised substances following national processes would represent up to €3.75 million.

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

The CMRD does not aim to replace national policies and rules but rather to set minimum requirements in order to protect workers at EU level. More stringent limit values 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 EU OSH Strategic Framework for 2021-2027.

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 limit values, or other protective measures.

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

Establishing limit values for cobalt and inorganic cobalt compounds, polycyclic aromatic hydrocarbons and 1,4-dioxane will provide common reference points that are used as a practical tool by employers, workers and enforcers to assess compliance with the general requirements, in particular in those Member States with no existing limit values.

The complexity and heterogeneity of the composition of welding fumes, together with the absence of harmonised classification for welding fumes in the CLP Regulation, contribute to a lack of clarity on the possible dangerousness of welding fumes for workers, and therefore a lack of appropriate RMMs. Addressing this absence of classification for welding fumes at EU level would ensure more legal clarity, which would result in better implementation of the existing rules.

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?

The proposal respects the principle of proportionality, as this initiative is limited to revising the annexes to the CMRD, where necessary, on the basis of the scientific and technical data available, as provided for by Article 16 of the CMRD. This initiative aims to make a step forward to achieve the objectives set to improve health and safety of workers, while imposing costs that are considered by businesses as acceptable and bearable.

As shown in the impact assessment supporting this initiative, the proposal also ensures a balanced

approach, i.e. to prevent as much as possible industries from closures or severe economic disadvantages while providing for an adequate protection of the workers at the EU level and being coherent with the key objectives of the EU, including Europe's Beating Cancer Plan, the twin transition, and the EU strategic autonomy.

Socio-economic and feasibility factors have been taken into account after intensive discussions with all stakeholders within the ACSH. It also includes measures for mitigating burdens and supporting compliance (including transitional periods) which have also been discussed with the ACSH. These transitional measures contribute to the proportionality of this initiative by ensuring a more appropriate temporal margin for businesses to adapt, where necessary, while safeguarding the EU's twin transition objective and strategic autonomy. It is expected to significantly mitigate the possible negative impacts on businesses and on the key objectives of the EU.

Despite their high costs, the measures provided by this initiative have the support of the key stakeholders in the area of OSH, namely the employers, workers and national governments represented within the ACSH. In addition, and as part of the 2nd stage consultation of social partners, BusinessEurope and ETUC supported the ACSH opinions while SMEunited calls on the Commission not to go beyond what was agreed by the ACSH. These social partners' views further support the proportionality of the package of preferred options.

Finally, this initiative also offers a certain margin of flexibility to Member States as regards the substances that are subject to the setting of limit values. In accordance with Article 153(4) of the TFEU, setting limit values at EU level does not prevent Member States from maintaining or introducing more stringent protective measures (i.e. lower limit values).

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[8], 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 carcinogens. However, a lack of EU action will most likely mean that there will remain Member States where no limit values exist for certain carcinogens or reprotoxics or where those values are too high to ensure adequate worker protection.

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 given the fact that the CMRD already exists, and this initiative is limited to amend its Annexes I, III and IIIa on the basis of 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?

The proposal is limited to revising the annexes of the CMRD, where necessary, on the basis of the scientific and technical data available, as provided for by Article 16 of the CMRD. This initiative aims to make a step forward to achieve the objectives set to improve health and safety of workers, while imposing costs that are considered by businesses as acceptable and bearable. This initiative does not prevent any Member State from maintaining or introducing more stringent protective measures

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

compatible with the Treaties.

(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 to that, the CMRD already exists, and this initiative is limited to the amendment of Annexes I, III and IIIa to the Directive on the basis of scientific and technical data available, as provided by Article 16 (1) of Directive 2004/37/EC.

(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 or 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?

The general objective of this initiative is to ensure to workers the right to a high level of protection of their health and safety at work. This objective is in line with the European Pillar of Social Rights, which enshrines workers' rights to healthy, safe and well-adapted work environment, and with Europe's Beating Cancer Plan. Overall, this initiative is expected to prevent 1,676 lung cancer cases and 18,912 non-cancer disease cases over the next 40 years.

More stringent policy options would have allowed to make even greater progress in the fight against occupational cancer and other work-related illnesses. However, these policy options would have had significant consequences on businesses, leading to a high number of discontinuations and job losses and a substantial loss of competitiveness for European companies operating in certain sectors. They would have negatively impacted the Open Strategic Autonomy of the EU, as well as its transition towards a greener and more digital European Union. This is in line with what employers' organisations raised as part of the 2nd phase of the social partners consultation, namely that this initiative could have more far-reaching consequences for the European industry, including in terms of strategic autonomy, relocation of production sites outside of the EU, etc. In this regard, SMEunited called the Commission not to go beyond what was agreed by the ACSH, and by extension beyond the package of preferred options (except for isoprene). For its part, Business Europe supported the ACSH opinions.

On the other side, some less stringent policy options (including the baseline scenario) would be less costly for businesses than the package of preferred options. However, the positive effect of these options on workers' health would be more limited and would not consequently contribute to the general objective in a satisfactory manner.

Finally, the introduction of transitional measures for cobalt and its inorganic compounds and for

polycyclic aromatic hydrocarbons is expected to significantly mitigate the possible negative impacts on businesses and on the key objectives of the EU. Therefore, the costs arising from this initiative are considered as commensurate with the key objective to be achieved.
(e) While respecting the Union law, have special circumstances applying in individual Member States been taken into account?
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.