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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

(Text with EEA relevance)

{SEC(2025) 217 final} - {SWD(2025) 191 final} - {SWD(2025) 192 final} -
{SWD(2025) 193 final}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

In June 2021, the Commission presented the EU strategic framework on health and safety at work 2021-2027[1] ('EU OSH strategic framework'). This strategic framework aims to turn principle 10 of the European Pillar of Social Rights[2] on workers' right to a high level of protection of their health and safety at work into concrete actions. A key objective of the EU OSH strategic framework is preventing workplace accidents and illnesses, which can cause serious adverse health effects and fatalities for workers, resulting in an estimated annual loss of around 3.3% of gross domestic product in the EU.

Cancer remains the leading cause of work-related deaths in the EU. Every year, according to estimates, about 80 000 people in the EU lose their lives due to exposure to carcinogens at the place of work[3]. Exposure to reprotoxic substances in the workplace can also affect sexual function and fertility and harm the development of workers' offspring. Up to 1 274 reproductive ill-health cases in the EU could occur every year following exposure to reprotoxic substances that are not classified as carcinogenic or mutagenic[4]. This shows the need to further improve prevention of work-related diseases in the EU[5], which has consequences for workers and their families, businesses and public authorities.

The main legislative instrument to ensure workers' protection against these risks is the Carcinogens, Mutagens and Reprotoxic substances Directive ('CMRD'), an individual directive under the Occupational Safety and Health (OSH) Framework Directive[6]. The CMRD provides for measures to prevent and protect against risks linked to exposure to carcinogenic, mutagenic or reprotoxic substances at work and includes an obligation to set out limit values for all those carcinogens, mutagens or reprotoxic substances for which this is possible.

In 2017, the Commission's *ex post* evaluation of the European Union's occupational safety and health directives[7] ('REFIT OSH evaluation') concluded that the OSH directives, including the CMRD, remain highly relevant and effective. They contributed to the decrease in the incidence and number of accidents at work and illnesses. However, during this evaluation exercise, various stakeholders' groups raised the need to consider adopting limit values for more substances.

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[1] Communication from the Commission on EU strategic framework on health and safety at work 2021-2027 Occupational safety and health in a changing world of work, COM/2021/323 final.

[2] Interinstitutional Proclamation on the European Pillar of Social Rights, OJ C 428, 13.12.2017.

[3] EU-OSHA (2023), Occupational safety and health in Europe: state and trends 2023 – Summary, based on International Commission on Occupational Health's figures.

[4] European Commission, Directorate-General for Employment, Social Affairs and Inclusion, Cary, E., Holmes, P., Vencovsky, D. et al., *Study to collect recent information relevant to modernising EU Occupational Safety and Health chemicals legislation with a particular emphasis on reprotoxic chemicals with the view to analyse the health, socio-economic and environmental impacts in connection with possible amendments of Directive 2004/37/EC and Directive 98/24/EC – Final report. Report 1, Baseline assessment*, Publications Office, 2019, https://data.europa.eu/doi/10.2767/964906.

[5] COM/2021/323 final, op. cit., improving prevention of workplace accidents and illnesses is one of the three crosscutting key objectives identified in the EU OSH strategic framework.

[6] Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work, OJ L 183, 29.6.1989, p. 1-8.

[7] *Ex post* evaluation of the EU occupational safety and health directives (REFIT evaluation) – SWD (2017) 10 final.

Following this REFIT OSH evaluation, the Commission initiated a continuous update of the CMRD. The EU has adopted five revisions of the CMRD, addressing more than 40 key hazardous chemicals and helping save the lives of over 100 000 workers over the next 50 years.

This continuous revision process relies on an inclusive approach where the Commission involves scientists from the European Chemicals Agency's ('ECHA') risk assessment committee ('RAC'), Member States and social partners represented in the Advisory Committee on Safety and Health at Work[8] ('ACSH'), and social partners through the formal consultation provided by Article 154 of the Treaty on the Functioning of the European Union ('TFEU').

This legislative initiative is the sixth revision of the CMRD ('CMRD 6'). It proposes limit values and relevant notations for cobalt and its inorganic compounds in line with the European Parliament's and the Council's request through CMRD 4, polycyclic aromatic hydrocarbons and 1,4-dioxane. It also adds welding fumes to the 'List of substances, mixtures and processes' in Annex I to the CMRD. According to the evidence gathered in the impact assessment report supporting this initiative, more than 2.5 million workers[9] in the EU are exposed to these substances.

As part of the impact assessment supporting this initiative, the Commission also assessed the appropriateness of setting a limit value for isoprene. The evidence gathered shows that a limit value, even at a very low level, would bring costs but no benefit for workers. The absence of benefit is due to the current low levels of workers' exposure to isoprene in the EU.

This initiative also includes an amendment to correct the existing entry on mercury and divalent inorganic mercury compounds in Annex III to fully align the term used for this substance with the scope of the CMRD as defined in its Article 2.

CMRD 6 responds to requests made by the European Parliament and the Council as part of the fourth revision of the CMRD[10] ('CMRD 4') to achieve new or revised occupational exposure limits ('OELs') for at least 25 substances.

It is not possible to address all relevant hazardous substances through one single initiative, as the scientific assessment requires time and resources. Currently the RAC assesses five substances per year for updating the CMRD. As part of the REACH simplification the Commission could assess whether it is possible to increase this number.

This proposal therefore further strengthens the commitment undertaken by the Commission to continuously address dangerous chemicals as stated in the Staff Working Document on the list of substances to be scientifically assessed to achieve new or revised occupational exposure limit values for at least 25 substances, groups of substances or process-generated substances[11]. Accordingly, every year the Commission asks the ECHA/RAC to scientifically assess priority substances and groups of substances. In addition to the substances covered by this revision,

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[8] The ACSH is composed of three full members per Member States, representing national governments, trade unions and employers' organisations.

[9] Number of exposed workers per substance: 113,000 to cobalt and its inorganic compounds; 1,284,052 to PAHs; 31,150 to 1,4-dioxane; and 1,200,000 to welding fumes.

[10] Directive (EU) 2022/431 of 9 March 2022 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work, OJ L 88, 16.3.2022, p. 1-14.

[11] Commission Staff Working Document: List of substances to be scientifically assessed for the purposes of Article 18a, third paragraph, of Directive (EU) 2004/37/EC on presenting an action plan to achieve new or revised occupational exposure limit values for at least 25 substances, groups of substances or process-generated substances, SWD (2022) 438 final.

three more batches of substances are in different phases of scientific assessment by the ECHA/RAC. The next step after the scientific assessment is to launch the external study examining the impacts, the two-stage social partner consultation, the adoption of ACSH opinions and the impact assessment accompanying the possible future proposals.

- **Consistency with existing policy provisions in the policy area**

This initiative is in line with the European Pillar of Social Rights, particularly its principle 10 enshrining the workers' right to a healthy, safe and well-adapted work environment. Setting new limit values and enlarging the scope to new process-generated substances both contribute to a high level of protection of workers' health and safety.

By setting limit values for additional substances and adding welding fumes to the list of substances, mixtures and processes in Annex I to the CMRD, the CMRD 6 also contributes to improving prevention of workplace accidents and illnesses, a key objective of the EU OSH strategic framework and to ensuring high standards for health and safety as stated in the Commission work programme 2025[12].

- **Consistency with other EU policies**

Charter of Fundamental Rights of the EU

The objectives of the initiative are consistent with Article 2 (Right to life) and Article 31 (Right to fair and just working conditions) of the EU Charter of Fundamental Rights[13].

REACH Regulation

Among other things, the Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals[14] ('REACH Regulation') establishes two distinct EU regulatory approaches, namely restrictions and authorisations.

The REACH Regulation's provisions on the authorisation or restriction of cobalt and its inorganic compounds, polycyclic aromatic hydrocarbons (PAHs) and 1,4-dioxane are summarised in the table below. As process-generated substances, welding fumes are not covered by restrictions and authorisations under the REACH Regulation.

Substances	Restriction	Authorisation
Cobalt and inorganic cobalt compounds	No existing restrictions	No existing authorisations
PAHs	Existing restrictions on the use of certain mixtures and articles that	No existing authorisations

[12] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Commission work programme 2025, Moving forward together: A Bolder, Simpler, Faster Union, COM(2025) 45 final.
[13] OJ C 202, 7.6.2016, p. 389-405.
[14] OJ L 396, 30.12.2006, p. 1-849.

	may contain one or more PAH substances[15] Existing restriction on the use of creosote and creosote-related substances in wood treatment[16].	
1,4-dioxane	No existing restrictions	This is one of the substances of very high concern included in the candidate list for eventual inclusion in Annex XIV 'List of substances subject to authorisation'[17] according to Article 57(a) and (f) of the REACH Regulation, triggering substitution and information requirements.

None of the existing REACH restrictions set work-related limit values for cobalt and inorganic cobalt compounds, PAHs or 1,4-dioxane. Therefore, there is no overlap between this initiative and the existing restrictions under REACH.

Europe's Beating Cancer Plan

The aim of Europe's Beating Cancer Plan[18] is to tackle the entire disease pathway. It is structured around four key action areas where the EU can add the most value: (1) prevention; (2) early detection; (3) diagnosis and treatment; and (4) quality of life of cancer patients and survivors.

Occupational exposure to the four substances covered by this initiative can cause cancer. Setting limit values or including them in the CMRD will, therefore, help prevent cancer as stated in point 3.6 of Europe's Beating Cancer Plan, which refers to the CMRD, as a tool to prevent cancer and also contribute to the European Health Union.

Implementation and simplification

The Member States must transpose the amended provisions within the transposition deadline set in the directive. After this deadline, the Commission will assess compliance in two stages (transposition and conformity checks). It will also monitor the implementation of the Directive through the evaluation of the practical implementation of the proposed amendments

[15] Entry 50 of Annex XVII to REACH: Benzo[a]pyrene, Benzo[e]pyrene, Benzo[j]fluoranthene, Benzo[a]anthracene, Chrysene, Dibenzo[a,h]anthracene, Benzo[k]fluoranthene and Benzo[b]fluoranthene; Entry 50a of Annex XVII to REACH: Acenaphthene, Acenaphthylene, Anthracene, Benzo[a]anthracene, Benzo[a]pyrene, Benzo[def]chrysene, Benzo[b]fluoranthene, Benzo[e]acephenanthrylene, Benzo[e]pyrene, Benzo[ghi]perylene, Benzo[j]fluoranthene, Benzo[k]fluoranthene, Chrysene, Dibenzo[a,h]anthracene, Fluoranthene, Fluorene, Indeno[1,2,3cd]pyrene, Naphthalene, Phenanthrene, Pyrene.

[16] Entry 31 of Annex XVII to the REACH Regulation, available at: https://echa.europa.eu/documents/10162/a27e80a3-3798-3c76-01a0-32357cc09f6f.

[17] Decision of ECHA dated 23 June 2021 on the inclusion of substances of very high concern in the candidate list for eventual inclusion in Annex XIV, available at: ECHA decision on inclusion in Candidate List (europa.eu).

[18] Communication from the Commission to the European Parliament and the Council Europe's Beating Cancer Plan, COM/2021/44 final.

as part of the periodical evaluation to be carried out by the Commission under Article 17a of Directive 89/391/EEC.

The Senior Labour Inspectors Committee (SLIC) will inform the Commission of any practical problems related to the enforcement of this directive, including of difficulties linked to compliance with the binding limit values. The SLIC will also continue to assess the reported cases, exchange relevant information and good practices, and develop guidance and other supporting enforcement tools, if necessary.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

• Legal basis

Article 153 of the TFEU empowers the EU 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.

The CMRD was adopted based on Article 153(2)(b) of the TFEU with the aim of improving workers' health and safety. Article 16 of the CMRD provides for the adoption of limit values in accordance with the procedure laid down in Article 153(2) of the TFEU for all those carcinogens, mutagens or reprotoxic substances for which this is possible.

The objective of this proposal is to strengthen the level of workers' safety and health protection in line with Article 153(1)(a) of the TFEU, in the form of new limit values as well as notations in Annex III to the Directive and the inclusion of welding fumes in the list of substances, mixtures and processes in Annex I. Therefore, Article 153(2)(b) of the TFEU is the proper legal basis for the Commission's proposal to amend the CMRD.

Under Article 153(2) of the TFEU, the improvement of the working environment to protect workers' health and safety is an aspect of social policy where the EU shares competence with the Member States.

• Subsidiarity (for non-exclusive competence)

In the absence of EU values, Member States are free to adopt national limit values. Where they exist, the national limit values for the three 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 $\mu g/m^3$. Some Member States have therefore set limit values 50 times lower than others for the same substance. Five Member States have no limit values for cobalt[19].

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

[19] Italy, Luxembourg, Malta, Portugal and Slovenia.

Setting EU limit values also helps provide a level playing field for industry, as some employers' organisations emphasised in their response to the social partner consultation. The costs of complying with lower national limit values are generally higher and therefore give a competitive advantage to enterprises operating in markets with higher or non-existent 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 an enforceable exposure limit for all relevant carcinogens, mutagens and reprotoxic substances in all Member States and ensure a minimum level of protection for all workers. It will also reduce regulatory complexity resulting from rules that diverge greatly between Member States, helping to reduce the administrative burden of compliance for businesses operating across the single market. Furthermore, Member States will avoid the costs related to the administrative burden related to setting limit values following national processes.

The complexity and heterogeneity of the composition of welding fumes and the absence of harmonised classification in the CLP Regulation[20] contribute to a lack of clarity on their possible dangerousness for workers, and therefore a lack of appropriate risk management measures (RMMs) in the workplace. Classifying welding fumes at EU level would ensure more legal clarity, which would improve 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 to the CMRD, as clearly indicated in the two-stage consultation of social partners and the opinions of the tripartite ACSH.

- **Proportionality**

The proposal respects the principle of proportionality, as this initiative is limited to revising the annexes of the CMRD where necessary, based on the scientific and technical data available, as provided for by Article 16 of the CMRD. This initiative aims to take a step towards achieving the objectives set to improve health and safety of workers, while keeping costs to a level acceptable to businesses.

As shown in the impact assessment supporting this initiative, the proposal also ensures a balanced approach, minimising economic disadvantages to businesses and business closures, while providing for adequate protection of workers at EU level and being consistent with the EU's key objectives, including EU strategic autonomy, Europe's Beating Cancer Plan, and the twin transition.

Socio-economic and feasibility factors have been taken into account after intensive discussions with all stakeholders within the ACSH. The proposal also has measures for mitigating burdens and supporting compliance, particularly transitional periods, which too have been discussed with the ACSH, but also a possible update of the existing Senior Labour Inspectors Committee's[21] (SLIC) Guidance for National Labour Inspectors on addressing

[20] 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.

[21] The SLIC has the mandate to give its opinion on all matters relating to the enforcement by the Member States of EU legislation on health and safety at work. It consists of representatives of the labour inspection services of the Member States, as mentioned in the Commission Decision of July 1995 setting up a Committee of Senior

health risks from Welding Fume[22], which would contribute to improving awareness of the possible dangerousness of welding fumes. These transitional measures contribute to the proportionality of this initiative by giving businesses more time to adapt, where necessary, while safeguarding the EU's strategic autonomy and its twin transition objective. They are expected to significantly mitigate the possible negative impacts on businesses.

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 the second stage of the consultation of the social partners, BusinessEurope and the European Trade Union Confederation supported the ACSH opinions, together with SMEunited, which however urged the Commission not to go beyond what was agreed by the ACSH. These social partners' views further support the proportionality of the preferred options.

Finally, this initiative also offers a certain margin of flexibility to Member States for the substances that are subject to the setting of limit values. Under 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).

- **Choice of instrument**

Article 153(2)(b) of the TFEU specifies that minimum requirements in the field of workers' health and safety protection may be adopted 'by means of directives'.

3. RESULTS OF *EX POST* EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

- ***Ex post* evaluations/fitness checks of existing legislation**

The REFIT OSH evaluation notes that chemicals classified as carcinogens and mutagens continue to be manufactured across the EU. Workers in manufacturing and downstream users are also exposed to them. The main conclusions of this evaluation indicate that the CMRD is considered highly relevant, to ensure workers' protection against carcinogens, mutagens and reprotoxic substances. Concerns raised by different stakeholders' groups in the evaluation process and in the national implementation reports show the need to consider adopting limit values for more substances. This would lead to better chemical risk management in the future and improve workers' health and safety protection.

- **Stakeholder consultations**

Two-stage consultation of social partners at EU level in accordance with Article 154 of the TFEU

The first stage of this consultation was launched on 16 February and ended on 31 March 2023. The first ad hoc meeting, corresponding to the first stage of the social partner consultation to gather their views on the proposal, was held online on 16 March 2023. Workers' organisations supported the list of substances prioritised for the planned initiative and stressed the need for considering the most stringent existing national limit values when

Labour Inspectors (95/319/EC). The Committee shall comprise on full member per Member State and one alternate member may be appointed for each full member.

[22] SLIC (2018), Guidance for National Labour Inspectors on addressing health risks from Welding Fume. Available at: https://circabc.europa.eu/ui/group/fea534f4-2590-4490-bca6-504782b47c79/library/2997b89a-1fbd-4f35-9874-9a9b5ea1a403?p=1&n=-1&sort=name_ASC

establishing EU-wide limit values. The European Trade Union Confederation also sent written comments per substance, in which they supported setting limit values for cobalt and its inorganic compounds, PAHs, 1,4-dioxane and isoprene, and the scope enlargement to welding fumes, including for the sake of legal clarity.

Employers' organisations highlighted the key role of the ACSH and its working party on chemicals in the process of developing legislative proposals and stressed the need for better protecting workers while preserving the competitiveness of EU-based companies.

In their written contribution, employers' representatives also highlighted that limit values always have a strong impact on SMEs. They insisted that due consideration be given to the socio-economic impact (including the impact on the green transition and on the competitiveness of the EU) of new limit values. They also supported the continuous revision of the CMRD and the enlargement of its scope, while advocating for implementing some new limit values with transitional periods.

The second stage of consulting the social partners was launched on 10 October 2023 and lasted until 21 November 2023, with an online meeting held on 7 November 2023. Social partners were consulted on objectives and avenues of EU action, possible legal instruments and willingness to enter into negotiations with a view to concluding an agreement under Article 155 of the TFEU. In addition to the contributions made during the meeting, the European Trade Union Confederation BusinessEurope and, SMEunited sent written replies.

More specifically, workers' organisations expressed support for reviewing the directive to achieve the best possible protection of workers and welcomed the tripartite opinions. They acknowledged that there will be costs for companies and agreed that there is a need to ensure the economical and industrial sustainability of the EU companies, avoid social dumping and ensure protection of the safety and health of all workers.

Employers' organisations confirmed what had been put forward by the ACSH, recognised the outcome of these opinions as a balanced compromise between all three interest groups, and asked that SMEs and the affected sectors be given sufficient time to adapt. Provision should be made for accompanying measures such as financial support and guidance to ensure that SMEs are able to adequately implement the new exposure levels.

As regards their willingness to enter negotiations to conclude a social partners' agreement, social partners reaffirmed their support for the current process to amend the CMRD, including the key role of the ACSH, and did not want to initiate a dialogue under Article 155 TFEU acknowledging that social dialogue on these substances already took place in the framework of the tripartite ACSH where an agreement has been reached covering all the substances identified in the revision.

More detailed information on the two-stage consultation of social partners is available in Annex II to the impact assessment accompanying this initiative.

Consultation of the Advisory Committee on Safety and Health at Work

The tripartite ACSH, composed of three full members per Member State, representing national governments, workers' and employers' organisations, assists the Commission in the preparation and implementation of decisions taken in the field of OSH. Taking into account the input from the ECHA and the scientific assessments from its RAC as well as socio-economic and feasibility data, it adopts opinions which the Commission then uses to prepare its proposals.

On 22 September 2023, the ACSH adopted five opinions to support this initiative. In its opinions on cobalt and its inorganic compounds[23], PAHs[24], 1,4-dioxane[25] and isoprene[26], the ACSH recommended limit values, and, where relevant, notations and transitional values. In its opinion on welding fumes[27], the ACSH recommended the inclusion of '*work involving exposure to fumes from welding processes containing substances that meet the criteria category 1A/1B set out in Annex I to the CLP Regulation*' in Annex I to the CMRD.

On 29 November 2023, the ACSH adopted an addendum[28] to its opinion on PAHs to clarify the list of sectors or processes that might have difficulties in complying with the OEL and might, therefore, need more time to comply with the limit value recommended.

This initiative follows the recommendations of the ACSH for cobalt and its inorganic compounds, PAHs, 1,4-dioxane and welding fumes. For isoprene, the Commission did not follow the recommendation of the ACSH to set an OEL. According to the impact assessment supporting this initiative, the evidence gathered indicates that workers are exposed to levels of isoprene which are lower than the health-based limit value derived from the RAC's opinion, suggesting that the current prevention of occupational exposure to isoprene is sufficient. Therefore, the Commission has decided not to set an OEL for isoprene also in order to avoid unnecessary costs for businesses.

Call for evidence and public consultation

There was no call for evidence and no public consultation for this initiative, because of the already extensive process of consulting the most relevant stakeholders for this initiative, particularly the two-stage consultation of social partners under the TFEU.

- **Collection and use of expertise**

The continuous revision of the CMRD is based on a well-established procedure involving scientific expertise. A sound scientific basis is indispensable in underpinning any OSH actions, particularly in relation to dangerous substances. In this regard, the Commission sought advice from the ECHA and its RAC.

The RAC develops high-quality comparative analytical knowledge and ensures that Commission proposals, decisions and policy on the protection of workers' health and safety are based on sound scientific evidence. Members of the RAC are highly qualified, specialised, independent experts selected based on objective criteria. They provide the Commission with opinions that are used to develop EU policy on workers' protection.

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[23] ACSH (2023), Opinion on an EU binding Occupational Exposure Limit Value (BOEL) and notations for cobalt and its inorganic compounds, Doc. 005/23, available at: ACSH Adopted opinion Cobalt and inorganic compounds 22.09.23-EN.pdf (europa.eu).

[24] ACSH (2023), Opinion on an EU binding Occupational Exposure Limit Value (BOEL) for Polycyclic Aromatic Hydrocarbons (PAHs), Doc. 003/23, available at: ACSH Adopted opinion PAHs 22.09.23-EN.pdf (europa.eu).

[25] ACSH (2023), Opinion on an EU binding Occupational Exposure Limit Value (BOEL), Short-Term Exposure Limit (STEL), Biological Limit Value (BLV) and skin notation for 1.4-dioxane, Doc. 007/23, available at: ACSH Adopted opinion 1_4-dioxane 22.09.23-EN.pdf (europa.eu).

[26] ACSH (2023), Opinion on an EU binding Occupational Exposure Limit Value (BOEL), for isoprene, Doc. 004/23, available at: ACSH Adopted opinion Isoprene 22.09.23-EN.pdf (europa.eu).

[27] ACSH (2023), Opinion on introducing work involving exposure to fumes from welding processes containing substances that meet the criteria for CMR category 1A/1B set out in Annex I to the CLP Regulation, Doc. 006/23, available at: ACSH Adopted opinion Welding fumes 22.09.23-EN.pdf (europa.eu).

[28] ACSH (2023), Addendum to the ACSH opinion 003/23 on an EU binding Occupational Exposure Limit Value (BOEL) for Polycyclic Aromatic Hydrocarbons (PAHs), Doc. 003/23/2, available at: Addendum to ACSH opinion PAHs-EN.pdf (europa.eu).

For this initiative, the ECHA provided a scoping study on welding fumes[29] and the RAC adopted four scientific opinions[30] evaluating the latest scientific data and proposing limit values and relevant notations for the protection of workers from chemical risks on cobalt and its inorganic compounds, PAHs, 1,4-dioxane and isoprene.

- **Impact assessment**

This proposal is supported by an impact assessment report, which was presented to and reviewed by the Regulatory Scrutiny Board on 29 May 2024, which gave it a negative opinion dated 31 May 2024. The board's comments were addressed in a revised version of the report. This version was resubmitted to the board on 2 December 2024, which then gave it a positive opinion with reservations on 19 December 2024.

The following options for different limit values for each of the three carcinogens or reprotoxic substances were assessed: (1) a baseline scenario of no further EU action for each substance subject to this initiative; and (2) options for limit values (including some accompanied by transitional values) at the level proposed by the ACSH and at additional reference points (including limit values derived by the RAC).

Based on this impact assessment, the limit values and approach recommended by the ACSH have been chosen as the preferred options for cobalt and inorganic cobalt compounds, PAHs, 1,4-dioxane and welding fumes. In the absence of health benefits resulting from the different policy options for isoprene, as workers' exposure is already lower than the health-based value derived by the RAC, the baseline scenario was preferred. The package of preferred options includes transitional values for cobalt and its inorganic compounds and for PAHs.

For cobalt and inorganic cobalt compounds, the ACSH's opinion recommended transitional limit values of 20 µg/m³[31] / 4,2 µg/m³[32] for six years. These transitional values apply to all sectors, giving businesses more time to plan their investments and allowing them to spread the substantial one-off investments (about 70% of the total investments in additional RMMs) over more years. This transitional value was strongly recommended by the social partners and Member States within the ACSH and should help mitigate the negative impacts of compliance costs for businesses.

For PAHs, the transitional value of 140 ng/m³ (double the preferred option) would apply for six years and would be limited to nine sectors: (1) steel and iron foundries, which includes ferroalloy manufacturers, (2) aluminium manufacturers, (3) carbon and graphite electrode manufacturers, (4) coking plants, (5) coal tar distillation, (6) refractory products manufacturers, (7) welding of train tracks, (8) other non-ferrous metallurgical processes, and (9) casting of metals. Among the total number of companies with workers exposed to PAHs, companies in these nine sectors are expected to face higher costs and/or are at risk of discontinuation. This transitional value gives companies more time to plan their investments and allows them to spread the substantial one-off investments over more years, reducing the negative economic impacts and the number of discontinuations.

[29] ECHA (2022), Scoping Study report for evaluation of limit values for welding fumes and fumes from other processes that generate fume in a similar way at the workplace, available at: report_welding_fumes_en.pdf (europa.eu).
[30] Available at: RAC opinions on scientific evaluations of OELs - ECHA (europa.eu).
[31] Inhalable fraction.
[32] Respirable fraction.

The package of preferred options is assessed to entail the following impacts (more detailed information is available in the impact assessment accompanying this initiative):

Overall impacts on workers

Overall, the preferred options are expected to prevent 1 676 lung cancer cases and 18 912 non-cancer cases[33] over 40 years. These ill-health cases prevented would represent savings to governments and businesses totalling up to EUR 1.16 billion[34]. The benefits of the preferred options would, however, also be accompanied by some negative economic impacts for businesses, including closures. Without any transitional periods for cobalt and its inorganic compounds and PAHs, it was estimated that about 4 000 workers[35] would lose their jobs. However, both policy options for those two groups of chemicals have a transitional value which is expected to reduce the negative economic impacts and the estimated number of closures by giving more time to businesses to plan their investments or develop RMMs which allow compliance with the preferred options. In the absence of data, the impacts of the transitional measures for cobalt and inorganic cobalt compounds and PAHs could not be reflected in the overall impacts on workers.

Overall impacts on businesses, including SMEs

As shown in the impact assessment supporting this initiative, the total adjustment costs incurred by the preferred options over 40 years would amount to EUR 3.3 billion. In the absence of evidence, it is not possible to break down adjustment costs into investments in additional RMMs and discontinuations costs. However, it is expected that the transitional periods for cobalt and its inorganic compounds and for PAHs will decrease economic costs and result in less discontinuations compared to a scenario with the same limit values without any transitional periods, for which 209 discontinuations were estimated. As 95% of businesses expected to discontinue in the absence of transitional periods were SMEs, the inclusion of transitional measures would mainly benefit them.

Businesses will also need to bear monitoring and administrative costs amounting in total to about EUR 535 million over 40 years. Overall, the total costs for businesses arising from the preferred options are expected to amount to approximately EUR 3.8 billion over the same period.

Although the total costs for businesses are significant compared to the baseline, they would be spread over a high number of businesses. Consequently, most businesses would face costs less (and often far less) than 1% of their turnover. Nevertheless, businesses operating in some sectors with workers exposed to cobalt and PAHs, particularly SMEs, would face higher costs compared to their turnover. The impact of these high costs is expected to be mitigated by the transitional values, which would enable employers to make the necessary investments in additional RMMs and to develop new technical tools to ensure compliance. In this regard, existing EU programmes, such as Horizon Europe, could help to develop innovative solutions to protect workers' health.

Businesses will also benefit from the package of preferred options. Workers being less at risk of occupational illness means lower costs arising from reduced productivity, costs of

[33] 2 842 restrictive lung disease, 7 363 upper airway irritation, 38 developmental toxicity, 3 157 male infertility, 497 kidney effects, 633 liver effects and 4 382 local irritation in the nasal cavity.

[34] Application of willingness-to-pay values to each case (= method 1). Willingness-to-pay values measure an individual's willingness to pay to avoid a case of a disease.

[35] In the absence of data for welding fumes, the impact on employment could not be quantified.

replacement, rehabilitation costs and medical costs, etc. In total, businesses are expected to avoid costs totalling EUR 7 million.

The transitional measures will benefit SMEs more than large companies, as SMEs have a higher ratio of compliance costs to turnover or gross operating product. SMEs will have more time to plan their investments, which should also reduce the number of discontinuations compared to the same package of options without transitional periods. The impact on SMEs, although higher than on larger companies, should therefore remain limited. Furthermore, existing guidance and tools, such as the European Agency for Safety and Health at Work's (EU-OSHA) Online interactive Risk Assessment[36], can help businesses and SMEs in particular SMEs, to comply with OSH regulatory requirements, including those arising from this legislative proposal, directly contributing to the 'digital by default' principle.

Overall impacts on public authorities

Overall, the package of preferred options would cost all public authorities about EUR 66 million over 40 years. Over 95% of this relates to the adjustment, monitoring and administrative costs for the preferred option for PAHs. These costs aim to ensure that firefighters' exposure does not exceed the level provided for in this legislative proposal. On average, this would cost about EUR 80 000 per public authority[37] over 40 years. The remaining 5% relates to transposition costs. Member State would need to dedicate up to EUR 100 000 (corresponding to the highest transposition costs for welding fumes[38]) for transposing the new rules.

The package of preferred options would also bring benefits amounting to about EUR 30.4 million for public authorities, including cost savings (e.g. healthcare cost savings due to fewer cancer and non-cancer cases) of EUR 26.65 million. The remaining benefits relate to avoided costs of up to EUR 3.75 million for setting limit values following national processes.

The net costs over 40 years for public authorities would therefore amount to about EUR 35.5 million, of which about EUR 15 million would be one-off costs[39]. However, the transitional value for PAHs would give public authorities more time to bear most of these one-off costs.

Overall impacts on the green and digital transitions

The package of preferred options would result in an increasing use of some enclosed processes, leading to less of some hazardous substances being released into the environment. However, this direct impact on the environment is expected to be negligible.

[36] The EU-OSHA created this set of tools, available at Online interactive Risk Assessment, in 2009 to provide easy-to-use tools to guide micro and small organisations through the risk assessment process.

[37] In this case, public authority means firefighting organisations. According to the evidence gathered for the impact assessment, it is assumed that 758 firefighting organisations are active across in the EU (mostly at province level).

[38] As mentioned in the impact assessment, public authorities will need to transpose in their national legislations the package of preferred options as soon as the latter is stricter than existing national rules. Since Member States are expected to carry out the transposition in one go, the transposition costs for each substance will not be cumulative. Since no Member State currently has a national legislation which is in full compliance with the package of preferred options, it is reasonable to assume that Member State will need to dedicate up to €100,000 (corresponding to the highest transposition costs for welding fumes) for the transposition of the new rules.

[39] This would include for example risk management measures such as installations of closed systems to comply with the new limit value.

The package of preferred options might have some negative indirect impacts on the green transition or on the digital transition due to discontinuations in key sectors such as coking plants, other non-ferrous metallurgy, coal tar distillation and graphite and carbon electrode manufacture. Indeed, these sectors play an important role in for the development of the circular economy, the manufacture of green infrastructures and the manufacture of semiconductors. However, the risk of discontinuing is expected to be mitigated by the transitional measures planned in the package of preferred options, in particular by the transitional period for PAHs. Therefore, the overall indirect impact on the green transition should be limited.

Given the expected low impacts on the environment, the 'do no significant harm' principle assessment and climate consistency check were not conducted for the impact assessment accompanying this initiative.

Overall impacts on EU Open Strategic Autonomy

This package could result in some coking plants discontinuing. As a result, those sectors dependent on the production of coking plants (e.g. coal tar) might need to import their products from outside the EU, which would hinder the EU's open strategic autonomy in its objective of green and digital transition as coal tar is essential in the production of batteries storing energy produced by wind turbines, semiconductors and electric vehicles. However, this negative impact should be mitigated by the transitional measures for PAHs contained in the package of preferred options, which is expected to reduce the number of possible discontinuations in the coking sector.

Overall impacts on relevant sustainable development goals

By improving the prevention of work-related diseases, the CMRD 6 will also contribute to the United Nations 2030 Agenda for Sustainable Development[40], in particular sustainable development goal 3[41] ('Ensuring healthy lives and promote well-being for all at all ages') and goal 8[42] ('Promote sustained, inclusive and sustainable economic growth, full and productive employment and decent work for all').

- **Regulatory fitness and simplification**

Impact on EU competitiveness

Coking plants, manufacturers of refractory products, manufacturers of graphite and carbon electrode, steel and iron foundries and ferroalloy companies, businesses operating in other non-ferrous metallurgy sector and coal fired power plants would need to make investments in additional RMMs from the very beginning which would represent more than 10% of their gross operating surplus. As most of these companies (except for graphite and electrode manufacturers) are SMEs, they have less capacity to absorb these compliance costs. It cannot be excluded that some businesses would discontinue, which would negatively impact the availability of products, the diversity of supply, and would push prices up for consumers. However, introducing transitional periods for cobalt and its inorganic compounds and PAHs is expected to limit the number of discontinuations and give more time to businesses, particularly SMEs, to plan and make the necessary investments in additional RMMs.

[40] United Nations resolution entitled 'Transforming our World: the 2030 Agenda for Sustainable Development, adopted at the UN Sustainable Development Summit on 25 September 2015 in New York.

[41] In particular, target 3.4 ('by 2030, reducing by one third premature mortality from non-communicable diseases through prevention') and target 3.9 ('by 2030, substantially reducing the number of deaths and illnesses from hazardous chemicals').

[42] In particular, target 8.8 ('promoting safe and securing working environments for all workers').

Therefore, the impact on prices and diversity of supply/availability of products for consumers of the products produced by these businesses is expected to be mitigated but not totally excluded.

The package of preferred options might also negatively impact the capacity of some businesses to innovate. Although for most businesses, compliance costs represent less than 10% (or even less than 1% for most sectors) of their R&D expenditures, the share is higher for SMEs operating in the following sectors: coking plants (costs to businesses represent up to 160% of R&D expenditures), soil remediation (up to 155%), welding of train tracks (up to 120-135%) and other non-ferrous metallurgy (up to 53%). Again, the transitional measures provided for in the package of preferred options is expected to mitigate this negative impact by giving businesses more time to plan their investments. Therefore, the impact on R&D expenditures should be negligible, except for the sectors mentioned above, which might face more difficulties maintaining their investments and for which the transitional measures will play an important role.

Sectors such as steel and iron foundries, ferroalloys, aluminium manufacturers, other metallurgy, casting of metals, and graphite and carbon electrode manufacturers already experience pressure from cheaper imports, particularly from Asian countries. Therefore, additional operational costs arising from compliance costs could negatively impact their international competitiveness against cheaper imports from outside the EU. As mentioned above, some businesses (particularly coking plants) will probably discontinue as a result of the package of preferred options.

Depending on the number of discontinuations, downstream users dependent on the production of coking plants could become more dependent on imports from outside of the EU. This is particularly the case for companies producing batteries storing energy produced by wind turbines, semiconductors, and electric vehicles. All these negative impacts are expected to be mitigated by the presence of transitional measures which should reduce the number of discontinuations and give businesses more time to make the necessary investments. Overall, the impact on international competitiveness should be negligible, except for those sectors mentioned above, in particular coking plants. Transitional measures are therefore important to mitigate these negative impacts, although the evidence gathered does not allow for a precise quantification of these effects.

The package of preferred options should contribute to create a more level-laying field for businesses within the internal market and improve workforce retention by providing a more protective workplace. These factors might enhance competitiveness, particularly strengthening the competitive position of EU firms with respect to non-EU competitors.

A more detailed analysis of the impact on competitiveness is provided in the impact assessment accompanying this legislative proposal.

- **Fundamental rights**

Article 31 of the EU Charter of Fundamental Rights states that workers have the right to fair and just working conditions that respect their health, safety and dignity. This is further developed in the European Pillar of Social Rights which aims to build a fairer and more inclusive European Union. This initiative will further improve the protection of workers from the health risks posed by exposure to hazardous substances, preventing ill-health. Therefore, it will also positively impact this fundamental right.

4. BUDGETARY IMPLICATIONS

The proposal does not require additional budget and staff resources for the EU budget or bodies set up by the EU. This initiative has no financial and digital implications and therefore the legal, financial, digital statement (LFDS) is not provided.

5. OTHER ELEMENTS

- **Implementation plans and monitoring, evaluation and reporting arrangements**

The number of cases of occupational ill-health in the EU and the reduction of costs of occupational ill-health (e.g. loss of productivity) for businesses and social security systems in the EU are core indicators when monitoring the impacts of this Directive.

The monitoring of the first indicator refers to:

(a) the available data collected by Eurostat (and other relevant information sources such as the European Agency for Safety and Health at Work's OSH Barometer, European Foundation for the Improvement of Living and Working Conditions (Eurofound), International Labour Organisation, World Health Organisation);

(b) data notified by employers to the competent national authorities in accordance with Article 14(8) of the Directive and which may be accessed by the Commission in accordance with Article 18 of the Directive; and

(c) data submitted by Member States in their national implementation reports in accordance with Article 17a of Directive 89/391/EEC.

The second indicator is monitored by comparing the expected figures for economic loss and healthcare costs caused by occupational ill-health with the actual figures collected for these after the adoption of the amended directive.

Other indicators for monitoring the operational objective of better implementation of the Directive in the Member States include:

- information on adequate implementation of the Directive provided by ACSH working parties and interest groups and by the Senior Labour Inspectors Committee (SLIC);
- guidelines developed by the Member States, awareness-raising campaigns, training courses and other related activities reported by Member States through the Questionnaire on the practical implementation of the OSH Directives under the 5-yearly country report in accordance with Article 17a of Directive 89/391/EEC and information from the ACSH and the SLIC;
- number or proportion of companies encouraging good practices that prevent cases of ill-health associated with the use of CMR substances which could be monitored through data comparison from EU-OSHA’s European Survey of Enterprises on New and Emerging Risks, Eurofound’s European Working Conditions Survey, and information from the SLIC.

Transposition and conformity checks will be carried out in a two-stage compliance assessment of the transposition of the established limit values and other related provisions. The practical implementation of the proposed amendments will be evaluated as part of the periodical evaluation to be carried out by the Commission under Article 17a of Directive 89/391/EEC.

The application and enforcement will be monitored by national authorities, particularly the national labour inspectorates.

At EU level, the SLIC will continue to inform the Commission of any practical problems related to the enforcement of Directive 2004/37/EC, including difficulties linked to compliance with binding limit values. The SLIC will also continue to assess the reported cases, exchange information and good practice in this regard and, if necessary, develop guidance and other supporting enforcement tools.

- **Explanatory documents (for directives)**

Member States must send the Commission the text of national provisions transposing the Directive together with a correlation table between those provisions and the Directive. Unambiguous information on the transposition of the new provisions is needed to ensure compliance with the minimum requirements established by the proposal. The estimated additional administrative burden of providing explanatory documents is not disproportionate (it is one-off and should not require many organisations to be involved). These explanatory documents can be drafted more efficiently by the Member States. Accordingly, it is suggested that Member States undertake to notify the Commission of their transposition measures by providing one or more documents explaining the relationship between the components of the Directive and the corresponding parts of national transposition instruments.

- **Detailed explanation of the specific provisions of the proposal**

Article 1

Article 1 provides for the amendment of the Carcinogens, Mutagens and Reprotoxic substances Directive 2004/37/EC (CMRD), specifically Annex I (List of substances, mixtures and processes that fall under the definition of a carcinogen and mutagen in line with Article 2, points (a)(ii) and (b)(ii) of the Directive), Annex III (Limit values and other directly related provisions) and Annex IIIa (Biological limit values and health surveillance measures).

To better protect workers through occupational exposure limit values and biological limit values, these limit values must be revised and/or established in the most efficient manner whenever this becomes necessary in light of the latest scientific data and technical and scientific progress.

Article 1 provides for the amendments of Annex I, Annex III and Annex IIIa. Welding fumes are included in the list of substances, mixtures and processes in Annex I. Occupational exposure limit values and relevant notations for cobalt and its inorganic compounds, polycyclic aromatic hydrocarbons and 1,4-dioxane are proposed in Annex III. A biological limit value (BLV) for 1,4-dioxane, which must not exceed 45 mg (2-Hydroxyethoxy)acetic (HEAA) in urine/g creatinine, is proposed in Annex IIIa.

Article 1 states that Directive 2004/37/EC is amended in accordance with its Annex. Two new substances are added to Annex III, expanding the list of binding EU limit values, supplemented by a dermal and respiratory sensitisation notation for cobalt and inorganic cobalt compounds, and a skin notation for 1,4-dioxane. An existing entry in Annex III, namely ‘polycyclic aromatic hydrocarbon mixtures, particularly those containing benzo[a]pyrene, which are carcinogens, mutagens or reprotoxicants within the meaning of this Directive’, has been updated with the introduction of an occupational exposure limit, while its skin notation has been kept. Transitional measures for cobalt and its inorganic compounds,

and polycyclic aromatic hydrocarbon mixtures (PAHs) have been provided for in the last column of the table. It is proposed that the term used for the agent 'mercury and divalent inorganic mercury compounds including mercuric oxide and mercuric chloride (measured as mercury)' is replaced by 'mercury and divalent inorganic mercury compounds falling within the scope of Directive 2004/37/EC (measured as mercury)', clarifying that the limit value applies only to mercury and divalent inorganic mercury compounds that fall under the scope of the CMRD.

Article 2 to 4

Articles 2 to 4 contain the provisions on transposition into the Member States' national law. Article 3 states the date of entry into force of the Directive.

Annex

The term 'limit value' used in the Annex is defined in Article 2(c) of the Directive. Limit values address the inhalation route of exposure, describing a maximum airborne concentration level for a given chemical agent above which workers should not be exposed, on average, during a fixed time period.

A 'skin notation' identifies the possibility of significant uptake through the skin. It is assigned for those chemical agents where the European Chemicals Agency's Risk Assessment Committee (RAC) has assessed that dermal absorption could contribute to the total body burden and consequently to possible health effects, namely for 1,4-dioxane and PAHs. This notation is therefore kept for PAHs and introduced for 1,4-dioxane. A notation for 'dermal sensitisation' is assigned for chemical agents for which the RAC has assessed that exposure is liable to cause adverse skin reactions, namely cobalt and its inorganic compounds. A notation for 'respiratory sensitisation' is assigned for one chemical agent for which the RAC has assessed that exposure by inhalation can cause adverse reactions in the respiratory tract, namely cobalt and its inorganic compounds. Employers must take these notations into account when performing risk assessments and implementing preventive and protective measures for a particular carcinogen, mutagen or reprotoxic substance in accordance with the Directive.

2025/0232 (COD)

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

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 153(2), point (b), in conjunction with Article 153(1), point (a), thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee[43],

After consulting the Committee of the Regions[44],

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) To improve the protection of workers against risks from exposure to carcinogens, mutagens or reprotoxic substances at the place of work and ensure the same minimum level of protection across the Union, regular updates of Directive 2004/37/EC of the European Parliament and the Council[45] are necessary. Occupational exposure limit values should be established or revised in light of available information, including up-to-date scientific evidence and technical data, and should be based on a thorough assessment of the socio-economic impact and feasibility factors. That information should, if possible, include opinions of the Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA) established by Regulation (EC) No 1907/2006 of the European Parliament and of the

[43] OJ C […], […], p. […].
[44] OJ C […], […], p. […].
[45] Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens, mutagens or reprotoxic substances at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (codified version), (OJ L 158, 30.4.2004, p. 50).

Council[46] and opinions of the Advisory Committee on Safety and Health at Work (ACSH)[47].

(2) Directive 2004/37/EC covers substances or mixtures which meet the criteria for classification as a category 1A or 1B carcinogen, mutagen or reprotoxic set out in Annex I to Regulation (EC) No 1272/2008 of the European Parliament and of the Council[48] as well as substances, mixtures or processes referred to in Annex I to that Directive. Robust scientific evidence is to be provided for any new addition to the list of substances, mixtures and processes referred to in that Annex I to demonstrate that these substances, mixtures and processes fall under the scope of Directive 2004/37/EC, based on available valid scientific sources such as the ECHA, the International Agency for Research on Cancer (IARC) and national bodies, paying particular attention to peer-reviewed published literature on that substance.

(3) The IARC classified welding fumes as 'carcinogenic to humans' (Group 1 of the IARC classification). According to the ECHA scoping study[49], welding fumes are complex and may include carcinogens, mutagens or reprotoxic substances, such as chromium(VI) compounds, nickel compounds, cadmium and its inorganic compounds. The complexity and heterogeneity of welding fumes, together with the absence of harmonised classification in the Regulation (EC) 1272/2008, 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 that absence of classification for welding fumes at Union level would ensure more legal clarity in terms of the application of Directive 2004/37EC. It is therefore appropriate, in line with the opinion of the ACSH[50], to include in Annex I to Directive 2004/37/EC work involving exposure to fumes from welding processes containing substances that meet the criteria for a substance or mixture which meets the criteria for classification as a category 1A or 1B carcinogen, mutagen or reprotoxic set out in Annex I to Regulation (EC) No 1272/2008.

(4) Cobalt metal and several cobalt compounds meet the criteria for classification as carcinogenic and reprotoxicant (category 1B) in accordance with Regulation (EC) No 1272/2008 and are therefore carcinogens or reprotoxics within the meaning of Directive 2004/37/EC. Workers are often exposed to a mixture of cobalt compounds and occupational exposure limit values should be applied to all cobalt inorganic

[46] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1, ELI: http://data.europa.eu/eli/reg/2006/1907/oj).

[47] Council Decision of 22 July 2003 setting up an Advisory Committee on Safety and Health at Work (OJ C 218, 13.9.2003, p. 1).

[48] 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).

[49] ECHA (2022), Scoping Study report for evaluation of limit values for welding fumes and fumes from other processes that generate fume in a similar way at the workplace, available at: report_welding_fumes_en.pdf (europa.eu)

[50] ACSH (2023), Opinion on introducing work involving exposure to fumes from welding processes containing substances that meet the criteria for CMR category 1A/1B set out in Annex I to the CLP Regulation, Doc. 006/23, available at: ACSH Adopted opinion Welding fumes 22.09.23-EN.pdf (europa.eu)

compounds. It is therefore appropriate, based on available information, including scientific and technical data, to establish a limit value for cobalt and its inorganic compounds in Directive 2004/37/EC.

(5) The Advisory Committee on Safety and Health at Work (ACSH) set up by Council Decision of 22 July 2003[51], based on the RAC opinion[52], agreed that exposure to cobalt and its inorganic compounds in the workplace may also result in dermal sensitisation and sensitisation of the respiratory tract. It is therefore appropriate to establish limit values for both the inhalable and respirable fractions of cobalt and its inorganic compounds within the scope of Directive 2004/37/EC and to assign to it a notation for dermal and respiratory sensitisation.

(6) For cobalt and its inorganic compounds, it is foreseeable that it will be difficult to comply with a limit value of 0,01 mg/m³ for the inhalable fraction and 0,0025 mg/m³ for the respirable fraction in the short term. It is therefore appropriate to introduce a transitional period of six years after entry into force of this Directive, during which the limit values of 0,02 mg/m³ (inhalable fraction) and 0,0042 mg/m³ (respirable fraction) should apply.

(7) Certain polycyclic aromatic hydrocarbons (PAHs) mixtures, particularly those containing benzo[a]pyrene, meet the criteria for classification as carcinogenic, mutagenic or reprotoxicant (category 1A or 1B) in accordance with Regulation (EC) No 1272/2008 and therefore fall under the scope of Directive 2004/37/EC. The RAC[53] has identified the possibility of significant uptake through the skin for those mixtures and the ACSH has agreed on the importance of introducing an occupational exposure limit value for all PAH mixtures falling under the scope of Directive 2004/37/EC, measured as benzo(a)pyrene, and to maintain a skin notation already contained in Annex III.

(8) For PAHs mixtures, it is foreseeable that it will be difficult for some sectors to comply with a limit value of 0,00007 mg/m³ (measured as benzo(a)pyrene) in the short term. It is therefore appropriate to introduce a transitional period of six years after entry into force of this Directive, during which the limit value of 0,00014 mg/m³ (measured as benzo(a)pyrene) should apply. That transitional period should be limited to the following sectors: (a) steel and iron foundries, which includes ferroalloy manufacturers; (b) aluminium manufacturers; (c) carbon and graphite electrode manufacturers; (d) coking plants; (e) coal tar distillation; (f) refractory products manufacturers; (g) welding of train tracks; (h) other non-ferrous metallurgical processes; and (i) casting of metals.

(9) 1,4-dioxane meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and is therefore a carcinogen within the meaning of Directive 2004/37/EC. It is therefore appropriate, based on the available information, including scientific and technical data, including the RAC[54] and ACSH opinions, to establish a long- and short-term occupational exposure limit value of 7,3 mg/m³ (2 ppm) and 73 mg/m³ (20 ppm), respectively, supplemented by a skin notation and a biological limit value of 45 mg HEAA in urine/g creatinine, at the end of exposure or shift.

[51] OJ C 218, 13.9.2003, p. 1.
[52] https://echa.europa.eu/oels-activity-list/-/substance-rev/69405
[53] https://echa.europa.eu/oels-activity-list/-/substance-rev/63901
[54] https://echa.europa.eu/oels-activity-list/-/substance-rev/61801

(10) The Commission has carried out a two-stage consultation of social partners in accordance with Article 154 of the Treaty on the Functioning of the European Union. It has also consulted the ACSH, which has adopted opinions for all substances subject to this Directive and recommended one or several binding limit values for each of them, and notations and transitional values for some of them, where appropriate. Transitional values should allow employers make the necessary investments in additional risk management measures and develop technical means of ensuring compliance. In this regard, existing Union programmes, such as Horizon Europe, could help to develop innovative solutions to protect workers' health.

(11) It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making[55]. When establishing or revising limit values, the Commission should consult the RAC and the ACSH to ensure that they are evidence-based, proportionate and measurable.

(12) Since the objective of this Directive, namely to protect workers from exposure to carcinogens, mutagens and reprotoxic substances at work, cannot be sufficiently achieved by the Member States acting alone but can rather, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary to achieve that objective. Directive 2004/37/EC should therefore be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 2004/37/EC is amended as follows:

Annexes I, III and IIIa to Directive 2004/37/EC are amended in accordance with the Annex to this Directive.

Article 2

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by […] [The time limit for transposition will be as short as possible and, generally, will not exceed two years] at the latest. They shall immediately inform the Commission thereof.

When Member States adopt those measures, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

[55] OJ L 123, 12.5.2016, p. 1.

Member States shall communicate to the Commission the text of the main measures of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*

EUROPEAN
COMMISSION

Brussels, 18.7.2025
COM(2025) 418 final

ANNEX

ANNEX

to the

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

{SEC(2025) 217 final} - {SWD(2025) 191 final} - {SWD(2025) 192 final} -
{SWD(2025) 193 final}

ANNEX

ANNEX

Annexes I, III and IIIa to Directive 2004/37/EC are amended as follows:

(1) in Annex I, the following point 9 is added:

‘9. Work involving exposure to fumes from welding processes containing substances that meet the criteria for a substance or mixture which meets the criteria for classification as a category 1A or 1B carcinogen, mutagen or reprotoxic set out in Annex I to Regulation (EC) No 1272/2008[1];

(2) in Annex III, point A is amended as follows:

(a) in the Table the row related to polycyclic aromatic hydrocarbons mixtures, particularly those containing benzo[a]pyrene, which are carcinogens within the meaning of this Directive, is replaced by the following:

‘

Name of agent	EC No (1)	CAS No (2)	Limit values						Notation	Transitional measures
			8 hours (3)			Short-term (4)				
			mg/m3 (5)	ppm (6)	f/ml (7)	mg/m3	ppm	f/ml		
Polycyclic aromatic hydrocarbons mixtures, particularly those containing benzo[a]pyrene, which are carcinogens, mutagens or reprotoxicants within the meaning of this Directive			0,00007(*2)						Skin (10)	***Limit value 0,00014(*2) until …[OJ: six years after the date of entry into force of the amending Directive] limited to the following sectors: (1) steel and iron foundries, which includes ferroalloy manufacturers, (2) aluminium manufacturers, (3) carbon and graphite electrode manufacturers, (4) coking plants, (5) coal tar distillation, (6)***

[1] Exposure shall not exceed the limit value of a carcinogen, mutagen or a reprotoxic substance as set out in Annex III when those substances are released during the welding process.

										refractory products manufacturers, (7) welding of train tracks, (8) other non-ferrous metallurgical processes, and (9) casting of metals.

’

(b) in the Table, the row related to mercury and divalent inorganic mercury compounds including mercuric oxide and mercuric chloride (measured as mercury) is replaced by the following:

‘

Name of agent	EC No ([1])	CAS No ([2])	Limit values						Notation	Transitional measures
			8 hours ([3])			Short-term ([4])				
			mg/m^3 ([5])	ppm ([6])	f/ml ([7])	mg/m^3	ppm	f/ml		
Mercury and divalent inorganic mercury compounds that fall under the scope of this Directive (measured as mercury)			0,02		–	–	–	–		

’;

(c) in the table the following rows are added

‘

Name of agent	EC No ([1])	CAS No ([2])	Limit values						Notation	Transitional measures
			8 hours ([3])			Short-term ([4])				
			mg/m^3 ([5])	ppm ([6])	f/ml ([7])	mg/m^3	ppm	f/ml		
Cobalt and inorganic cobalt compounds			0,01([11]) 0,0025([9])		–	–	–	–	dermal and respiratory sensitisation ([13])	***Limit value of 0,02([11]) and 0,0042([9]) until …[OJ: six years after the date of entry into force of the amending Directive]***

1,4-dioxane			7,3	2		73	20		Skin ([10])	

’;

(d) in the footnotes after the Table, the following footnote (*2) is added:

‘(*2) Measured as benzo[a]pyrene.’;

([1]) EC No, i.e. Einecs, ELINCS or NLP, is the official number of the substance within the European Union, as defined in Section 1.1.1.2 in Annex VI, Part 1, to Regulation (EC) No 1272/2008.

([2]) CAS No: Chemical Abstract Service Registry Number.

([3]) Measured or calculated for a reference period of eight hours time-weighted average (TWA).

([4]) Short-term exposure limit (STEL). A limit value above which exposure should not occur and which is for a 15-minute period unless otherwise specified.

([5]) mg/m^3 = milligrams per cubic metre of air at 20 °C and 101,3 kPa (760 mm mercury pressure).

([6]) ppm = parts per million by volume in air (ml/m^3).

([7]) f/ml = fibres per millilitre.

([9]) Respirable fraction.

([10]) Substantial contribution to the total body burden via dermal exposure possible.

([11]) Inhalable fraction.

([13]) The substance can cause sensitisation of the skin and of the respiratory tract.

(3) in Annex IIIa, the following point is added:

‘1,4-dioxane

2. The binding biological limit value is 45 mg HEAA*in urine/g creatinine.’

*(2-Hydroxyethoxy)acetic acid’.