EUROPEAN COMMISSION

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REGULATORY SCRUTINY BOARD OPINION

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}
{SWD(2025) 191 final} {SWD(2025) 192 final} {SWD(2025) 193 final}

EUROPEAN COMMISSION
REGULATORY SCRUTINY BOARD

Brussels,
RSB

Opinion

Title: Impact assessment / Directive on the protection of workers from the risks related to exposure to carcinogens, mutagens or reprotoxic substances at work

Overall 2nd opinion: POSITIVE WITH RESERVATIONS

(A) Policy context

Every year, about 80,000 people in the EU lose their lives due to exposure to carcinogens at the place of work. The Directive on Carcinogens, Mutagens and Reprotoxic substances aims to mitigate these risks.

The sixth revision of the Directive sets exposure limits for four substances, groups of substances and process-generated substances ('substances'): cobalt and inorganic cobalt compounds, polycyclic aromatic hydrocarbons, 1,4-dioxane, isoprene and adds welding fumes to the Directive's scope.

(B) Summary of findings

The Board notes the changes to the report.

However, the report still contains serious shortcomings. The Board gives a positive opinion with reservations because it expects the DG to rectify the following aspects:

(1) The rationale for intervention regarding welding fumes is not demonstrated.
(2) The report does not sufficiently analyse the impacts of the transitional options. The comparison of options and the identification of the preferred options for each substance as well as the evidence base to justify the preferred option combination is not robust.
(3) The impacts on competitiveness and on consumers are not adequately analysed. The recording of stakeholder views in the report is partial.

Commission européenne/Europese Commissie, 1049 Bruxelles/Brussel, BELGIQUE/BELGIË - Tel. +32 22991111
regulatory-scrutiny-board@ec.europa.eu

(C) What to improve

(1) The problem analysis for welding fumes should set out a clear and unambiguous rationale for intervention in this area. It should clarify, with robust evidence, the existence and nature of the problem, in particular its driver(s), its scale and geographic distribution. The problem driver of insufficient of awareness of the possible dangers of welding fumes should be better explained and substantiated by robust evidence. The causal link between the lack of awareness and excessive exposure to welding fumes should be strengthened. If there are drivers other than awareness then they should be identified and included in the intervention logic where relevant.

(2) The specific objective regarding welding fumes should be less prescriptive and better linked with the causes of the problem. It should be clearly explained why non regulatory measures such as guidance in the first instance were deemed inappropriate given the lack of clarity on the scale and nature of the problem. The report (and Annex 10) should better explain and justify the limitations and inefficacity of the rejected soft law measures. It should elaborate in more detail how adding welding fumes to Annex I of the Directive would tackle the identified possible consequences on public health. The assumptions behind the intervention logic should be borne out and substantiated by evidence, in particular regarding current and expected use of risk management measures. Given that the Committee for Risk Assessment has not issued a scientific opinion on setting limit values the report should be clear on what basis action is now merited.

(3) The impact analysis of the welding fumes option and the transitional options should be further developed. The report should better explain the evidence underpinning the assessment of the benefits, in particular the evidence on the causal links between the intervention and the expected benefits. Given the current lack of substantiation of the assumptions, the report should undertake a sensitivity analysis of the key parameters of the benefit analysis for welding fumes to clarify the extent to which those assumptions drive the estimates of the total benefits. The report should also include a strategic autonomy impact analysis for welding fumes. It should clearly quantify the impacts of the transitional options as this is currently unclear, including obstacles as to why the methodology used for the other options cannot be applied. The report should ensure consistency between cost and benefit estimates between the main report and Annex 3.

(4) The report should significantly strenghten the analysis of the impacts on competitiveness and on consumers. It should substantiate the claim that for most businesses, including SMEs, the package of preferred options will not have any impact on their competitiveness. The report as well as Annex 5 should better explain why any negative impacts on competitiveness are expected to be mitigated by the transitional measures in the package of preferred options. The report should better analyse the capacity of companies to absorb significant compliance costs and the risk of passing these costs onto consumers. The assessment should include an analysis of likely market impacts, such as consumer prices and diversity of supply.

(5) The comparison of options and the identification of the preferred options needs to be revised. It should be clear how, methodologically, the report arrives at conclusions regarding the overall score for the different options for each substance. In that analysis any co-dependency between values of the variables under the different criteria ('effectiveness', 'efficiency', 'coherence' etc.) needs to be identified; and it needs to be ensured that any identical benefits, such as number of cancer and non-cancer cases avoided, are not counted twice. It should be clarified what the analytical consequences are of using ACSH recommendations both to define options and then to assess these options.

(6) Given the legal basis of the proposal, proportionality considerations need to be addressed. As the assessment estimated costs outweigh the monetised benefits for all the preferred options, except for welding fumes, the report needs to demonstrate what other

factors enter into the analysis in order to arrive at the conclusion that the preferred outcomes nevertheless conform to the principle of proportionality. If some specific benefits or costs are weighted more heavily than others this needs to be transparently stated in the analysis.
(7) The stakeholder views should be better analysed and presented systematically and clearly across different stakeholder groups. General categories such as 'relevant stakeholders' should be disaggregated into appropriate, individual groups. Annex 2 should summarise the findings coming from the 'consultation of other stakeholders', instead of only outlining the consultation method and strategy.

The Board notes the estimated costs and benefits of the preferred option(s) in this initiative, as summarised in the attached quantification tables.

(D) Conclusion

The DG must revise the report in accordance with the Board's findings before launching the interservice consultation.

Full title	Impact Assessment Report accompanying the Proposal for a Directive of the European Parliament and of the Council amending Directive 2004/37/EC of the European Parliament and of the Council on the protection of workers from the risks related to exposure to carcinogens, mutagens or reprotoxic substances at work
Reference number	PLAN/2022/1707
Submitted to RSB on	2 December 2024
Date of RSB meeting	"Written procedure"

ANNEX: Quantification tables extracted from the draft impact assessment report

The following tables contain information on the costs and benefits of the initiative on which the Board has given its opinion, as presented above.

If the draft report has been revised in line with the Board's recommendations, the content of these tables may be different from those in the final version of the impact assessment report, as published by the Commission.

I. Overview of Benefits (total for all provisions) – Preferred Option		
Description	***Amount***	***Comments***
Direct benefits		
Cost savings for workers and their families	Method 1: €1.16 billion Method 2: €600 million	More effective protection of their health, reducing suffering of workers and their families, increased length, quality and productivity of their working lives, avoiding ill-health.
Cost savings for businesses	€7 million	Cost savings made by businesses due to workers being less at risk of work-related illness, i.e.: higher labour productivity resulting from reductions in absenteeism and associated production losses, reduced administrative or legal costs relating to workers who are ill, reduced insurance premiums, reduced reputational risks and reduced sick leave payments. In addition, not quantified benefits include legal clarity, simplification in ensuring legal compliance and a more balanced level playing field for businesses across the EU.
Cost savings for public authorities	€26.65 million	Cost savings made by public authorities, i.e.: healthcare treatment costs, productivity loss due to mortality and lost earnings due to morbidity.
Indirect benefits		
Cost savings for public authorities	(up to) €3.75 million	Cost savings made by public authorities from not having to define their own national limit values, as a result of the introduction of an EU limit value. Defining a national limit value has associated costs for public authorities to carry out impact assessments and define a suitable level of avoided risk.

Note: estimates are rounded and relative to the baseline.

II. Overview of costs – Preferred option				
	Businesses		Administrations	
	One-off	Recurrent	One-off	Recurrent
Direct adjustment costs[174]	(At least) €511 million	(Less than) Method 1: €2.9 billion Method 2: €3 billion	€16 million	€46.5 million
Direct monitoring costs	€0	€456 million	€0	€390,000
Direct administrative costs	€0	€78.5 million	€0	€90,000
Transposition costs			(up to) €2.7 million	€0

Note: estimates are rounded and relative to the baseline.

III. Application of the 'one in, one out' approach – Preferred option(s)			
[million€]	**One-off** (annualised total net present value over the relevant period)	**Recurrent** (nominal values per year)	**Total**
Businesses			
New administrative burdens (INs)	€0	€78.5 million	€78.5 million
Removed administrative burdens (OUTs)	€0	€0	€0
Net administrative burdens*	€0	€78.5 million	€78.5 million
Adjustment costs**	(At least) €511 million	(Less than) Method 1: €2.9 billion Method 2: €3 billion	
Citizens			
New administrative burdens (INs)	€0	€0	€0
Removed administrative burdens (OUTs)	€0	€0	€0
Net administrative burdens*	€0	€0	€0
Adjustment costs**	€0	€0	
Total administrative burdens***	**€0**	**€78.5 million**	**€78.5 million**

(*) Net administrative burdens = INs – OUTs;
(**) Adjustment costs falling under the scope of the OIOO approach are the same as reported in Table 2 above. Non-annualised values;
(***) Total administrative burdens = Net administrative burdens for businesses + net administrative burdens for citizens.

Brussels,
RSB

Opinion

Title: Impact assessment / Protection of workers from risks related to exposure to carcinogens at work

Overall opinion: NEGATIVE

(A) Policy context

Every year, about 80,000 people in the EU lose their lives due to exposure to carcinogens at the place of work. The Directive on Carcinogens, Mutagens and Reprotoxic substances aims to mitigate these risks.

The sixth revision of the Directive sets exposure limits for four substances, groups of substances and process-generated substances ('substances'): cobalt and inorganic cobalt compounds, polycyclic aromatic hydrocarbons, 1,4-dioxane, isoprene and adds welding fumes to the Directive's scope.

(B) Key issues

The Board notes the additional information provided and commitments to make changes to the report.

However, the Board gives a negative opinion because the report contains the following serious shortcomings that the lead Service must address:

(1) The analysis does not sufficiently elaborate and present the evidence related to the magnitude of the problem, especially related to welding fumes and isoprene. The dynamic baseline analysis is not sufficiently clear on how the problems and their drivers would develop in the future.

(2) The report does not adequately identify, assess and compare the options, particularly in relation to the transitional measures. It does not explain clearly enough why it considers only one option on welding fumes.

(3) The analysis of impacts lacks clarity on the robustness of the evidence base. The impacts on consumers, Member States, competitiveness and SMEs, are not brought out clear enough.

(4) The choice of the preferred options and preferred package of options is not sufficiently clear on the analysis of the three comparison criteria and the applied scoring. The proportionality of the preferred package of measures is not sufficiently analysed and demonstrated. The coherence with recent initiatives on EU strategic autonomy is not sufficiently demonstrated.

(C) What to improve

(1) The policy context should better explain the choice, (including the criteria applied and the main arguments used for each substance by the different actors involved) of the five substances out of the list of 28 substances to be scientifically assessed. Those explanations should enable to better understand the choices in particular for substances with limited health impact. The problem analysis should better justify the grounds for EU action, taking into account the scale of the problem related to each substance. It should better assess the magnitude of the problem by presenting the available evidence, especially in relation to health dangers coming from isoprene and welding fumes. Based on robust evidence, the problem drivers should cover, in more detail, issues related to existing employers' practices, such as limited or uneven take up of risk management measures, or most modern technology. The conclusion on the lack of awareness of workers and employers regarding the dangerousness of welding fumes should be also based on robust evidence.

(2) The problem analysis should better investigate how the problems would evolve under the dynamic baseline, considering other related initiatives at EU and national level as well as existing obligations and exposure limits. The baseline scenario should reflect whether there is expected technology progress which could reduce the health dangers and the current and future worker safety and automation trends in production in the industries affected, making good use of foresight insights as well as information and awareness measures taken by the competent authorities.

(3) The objectives section should better present what the initiative aims to achieve to have a clearer and more measurable view of what success would look like. It therefore should better structure the specific objectives, present them in more SMART terms and link them clearly to the problem drivers to be tackled. The report should present a more complete illustration of the intervention logic, linking the problems, their drivers, the policy objectives, and the policy options.

(4) The report should clearly present upfront and subsequently fully analyse and compare all the relevant options, including the transitional options. It should better link the individual options and the corresponding risk management measures. It should explain how adding welding fumes to Annex I of the Directive is an effective way to tackle the corresponding health issues arising from certain types of welding fumes, better ensure effective implementation of preventive measures and thus deliver the expected health benefits. The rationale behind proposing at this point only a single option for welding fumes and not presenting options setting differentiated limit values should be better explained. The report should better elaborate on the discarded options (including in the main report), in particular why non-regulatory options were discarded, such as guidance and awareness rising activities. It should also clarify why it presents options for isoprene in the absence of any clear evidence on the existence of a problem.

(5) The report should present a clearer and more developed analysis of impacts on competitiveness and SMEs. It should better assess the impacts on competitiveness, for example by being more nuanced on how the estimated level of compliance costs affects cost competitiveness and by avoiding relativising negative impacts against external circumstances and thus ignoring potential cumulative cost effects. Costs should be assessed not only in relation to turnover, but also to rates of profitability if available. The report should present in a more balanced manner the expected impacts on SMEs (including on competitiveness) by providing a comprehensive four-step of SME test. The competitiveness check in Annex 5 should fully reflect the competitiveness analysis developed in the main report.

(6) The report should clearly assess the impact of the proposed measures on the EU's strategic autonomy in critical raw materials (e.g., cobalt), steel and substances vital to the digital and green transitions (graphite, graphene etc). It should assess the risk that the proposed measures will either lead to discontinuation of EU production thereby creating a strategic dependence or to offshoring of production leading to de-skilling of the EU workforce.

(7) The report should further develop the analysis of distributional effects. It should provide a more developed analysis of the impacts on consumers to justify the conclusion that the impact on consumers should be limited or even negligible for all substances. In this respect, it should provide evidence on the capacity of companies to absorb significant compliance costs and on the likelihood that the costs may be passed on to consumers. It should include the analysis on the likely impact on consumer prices and a range of goods offered on the market. The report should also further develop the analysis of the impacts, in particular of business discontinuation, on Member States.

(8) More generally, the impact analysis should bring out clearer the evidence underpinning the cost and benefit estimates. It should better present the costs and benefits for each option, including transitional options, and should include a summary of this analysis in an overview table. The report should be clearer on how robust the estimates are, what the related uncertainties are, and how they are perceived by affected stakeholders. It should more explicitly explain how industry evidence has been taken into account in the analysis and why there are significant differences in the estimates of costs by the industry and in the report.

(9) The comparison of options by substance should be presented immediately after their assessment. When subsequently identifying the preferred package of options, the report should provide clear comparison criteria and explain their interaction, relative weighting and co-dependency. It should also explain how the scoring of options (numbers of pluses and minuses) was carried out and reflects the collected evidence on impacts. On this basis, the report should better demonstrate the proportionality of the preferred policy package, in particular regarding cobalt and polycyclic aromatic hydrocarbons (PAHs). The coherence with other initiatives aimed to build EU strategic autonomy, such as Critical Raw Materials and Chips should be better reflected. The coherence of the options with underlying legal frameworks, including provisions on SMEs should be assessed.

(10) The report should better analyse and present various stakeholder views, with clear differentiation between different affected groups. This should apply to stakeholder views on the magnitude of the problem, feasibility and usefulness of the options, and significance of the impacts. The report should clearly present the numbers and distribution of stakeholders who provided their views and analyse the representativeness of stakeholder feedback. The analysis should make more evident what various stakeholders think about the preferred policy package.

(11) The evaluation arrangements in the report need clarification, in particular regarding the timing of the evaluation. Monitoring and evaluation section should present what the success will look like and propose a set of SMART indicators capturing the whole intervention logic (e.g. take up of risk management measures by businesses).

Some more technical comments have been sent directly to the author Service DG.

(D) Conclusion **The lead Service(s) must revise the report in accordance with the Board's findings and resubmit it for a final RSB opinion.**	
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