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To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	SEC(2023) 67 final
Subject:	REGULATORY SCRUTINY BOARD OPINION Impact assessment / EMPL - Protection of workers health from risks related to exposure to lead and di-isocyanates

Delegations will find attached document SEC(2023) 67 final SEC(2023) 67 final.

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EUROPEAN COMMISSION

Brussels, 16.12.2022
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REGULATORY SCRUTINY BOARD OPINION

Impact assessment / EMPL - Protection of workers health from risks related to exposure to lead and di-isocyanates

{COM(2023) 71 final}
{SWD(2023) 34 final}
{SWD(2023) 35 final}
{SWD(2023) 36 final}

EUROPEAN COMMISSION
Regulatory Scrutiny Board

Brussels,
RSB/

Opinion

Title: Impact assessment / EMPL - Protection of workers health from risks related to exposure to lead and di-isocyanates

Overall opinion: POSITIVE WITH RESERVATIONS

(A) Policy context

Lead and di-isocyanates represent a risk to workers' health potentially causing reproductive health problems and asthma respectively. The Directive on the protection of workers from risks related to chemical agents at work (Directive 1998/24/EC) limits the workers' exposure to lead to maximum 0.15 mg/m3 (occupational exposure limit, OEL) and 70 µg/100 ml blood (biological limit value, BLV). Di-isocyanates do not have a safe exposure limit and currently, there is no binding limit at EU level.

The risk of workers' exposure to lead is mostly related to its industrial production and use, lead-acid battery production, renovation work and recycling. The risk of workers' exposure to di-isocyanates is mostly related to the manufacturing of polyurethane, used mainly in construction, vehicle repairs, textiles, furniture, and manufacture of motor vehicles, domestic appliances and computers.

The initiative aims to lower the biological limit value and the occupational exposure limit for lead and to introduce exposure levels for di-isocyanates.

(B) Summary of findings

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

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

(1) The report does not fully address the coherence with other initiatives. It does not sufficiently assess how the problem will evolve as a consequence of the expected industry changes. It does not factor into the dynamic baseline all relevant information for the two substances.

(2) The cost benefit analysis is not sufficiently explained.

(3) For both substances, the report does not sufficiently justify the choice of the preferred options and their proportionality.

This opinion concerns a draft impact assessment which may differ from the final version.

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(C) What to improve

(1) The report should address upfront the coherence of the initiative with the REACH Restriction Regulation (Regulation (EU) 2020/1149) on di-isocyanates and the need to act now given their similar objectives and the REACH Restriction Regulation's imminent entry into force in 2023. It should be clear about the relevance of the 2017 ex-post evaluation of the EU Occupational Safety and Health Directives including the Chemical Agents Directive and Carcinogens and Mutagens Directive. For lead, the initiative's potential contribution to the Europe's Beating Cancer plan should be qualified based on current scientific knowledge.

(2) The report should better present the dynamic baseline. It should be more transparent on the data used for lead regarding exposed workers and concentrations and clarify the baseline assumption that exposure concentrations in lead will remain stable. It should better describe how the main markets using the two substances will be impacted by the EU Green Deal and the consequent electrification of transport, phasing out of internal combustion engines, and overall use of greener and safer materials. For di-isocyanates the report should provide evidence supporting a growing demand. The report should explain to what extent the trend to automate industrial processes and its consequence of reducing the exposure of workers would affect the estimated future disease burden and how these trends have been factored in the dynamic baseline.

(3) The report should explain why the option of a phasing out of the use of lead is not considered given that lead is already banned in some Member States and alternatives exist.

(4) The report should better describe all relevant (quantified and not-quantified) costs and benefits and classify them correctly for the purpose of the One In, One Out approach. It should better explain why the benefits for the two options on di-isocyanates (including the preferred one) are not estimated. It should better justify the absence of enforcement and notification costs. The report should provide further details on the methodological limitations and uncertainties and explain how they affect the calculations. In particular, it should provide further details on how the number of companies discontinuing activities is estimated. It should also consider, at least qualitatively, the transfer of jobs to companies offering alternative solutions.

(5) The report should better justify the choice of the preferred option for both substances and significantly strengthen their proportionality assessments given that the costs outweigh the benefits for the preferred option on lead and the preferred option on di-isocyanates imposes the high costs without any quantified benefits. The report should bring together all quantified and non-quantified costs and benefits and demonstrate that the initiative meets the objectives at least cost.

(6) The report should specify how and by when the initiative will be evaluated. The indicators and proposed monitoring of all specific objectives should be included in the report.

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

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

(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 1998/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work and Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens, mutagens and reprotoxic substances
Reference number	PLAN/2020/7869
Submitted to RSB on	14 September 2022
Date of RSB meeting	12 October 2022

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.

1. SUMMARY OF COSTS AND BENEFITS FOR LEAD

I. Overview of Benefits (total for all provisions) – Preferred Option		
Description	***Amount***	***Comments***
Direct benefits		
Savings for companies	€5 million	Reduced absenteeism, productivity losses and insurance 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.
Savings for public sector	€100 million	Having reduced health care costs. Avoidance of loss of productivity and mitigation of financial loss of national social security systems, reducing the costs of healthcare and the loss of tax revenue due to morbidity and mortality.
Savings for workers & families	€160 – 250 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 (including their offspring), less costs of informal care.

II. Overview of costs – Preferred option					
		Businesses		**Administrations**	
		One-off	**Recurrent**	**One-off**	**Recurrent**
	Compliance costs	€565 million	€180 million	€500,000	€0
	Monitoring costs	€0	€0	€0	€0
	Administrative costs	€0	€0	€0	€0

Costs related to the 'one in, one out' approach					
Total	Direct adjustment costs	€565 million	€180 million		
	Indirect adjustment costs	€0	€0		
	Administrative costs (for offsetting)	€0	€0		

2. SUMMARY OF COSTS AND BENEFITS FOR DI-ISOCYANATES

I. Overview of Benefits (total for all provisions) – Preferred Option		
Description	***Amount***	***Comments***
	Direct benefits	
Savings for companies	€0	Reduced absenteeism, productivity losses and insurance 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.
Savings for public sector	€0	Having reduced health care costs. Avoidance of loss of productivity and mitigation of financial loss of national social security systems, reducing the costs of healthcare and the loss of tax revenue due to morbidity and mortality.
Savings for workers & families	€0	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, less costs of informal care.

II. Overview of costs – Preferred option					
		Businesses		**Administrations**	
		One-off	**Recurrent**	**One-off**	**Recurrent**
	Compliance costs	€14.8 million	-€4.4 million	€970,000	€0
	Monitoring costs	€0	€11 000 million	€0	€0
	Administrative costs	€0	€2 400 million	€0	€0

Costs related to the 'one in, one out' approach					
Total	Direct adjustment costs	€14.8 million	€11 000 million		
	Indirect adjustment costs	€0	€0		
	Administrative costs (for offsetting)[1]	€0	€0		

[1] The costs that relate to the inspection on behalf of public authorities and are therefore not subject to offsetting in the context of the 'one in, one out' approach in line with Better Regulation Tool #58 'EU Standard Cost Model'.