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From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	22 September 2020
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union

Subject:	REGULATORY SCRUTINY BOARD OPINION: Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work
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Delegations will find attached document SEC(2020) 302 final.

Encl.: SEC(2020) 302 final



EUROPEAN COMMISSION

Brussels, 29.5.2020
SEC(2020) 302 final

REGULATORY SCRUTINY BOARD OPINION

**Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE
COUNCIL amending Directive 2004/37/EC on the protection of workers from the risks
related to exposure to carcinogens or mutagens at work**

{COM(2020)571 final}
{SWD(2020) 183 final}
{SWD(2020) 184 final }



EUROPEAN COMMISSION
Regulatory Scrutiny Board

Brussels,
RSB/

Opinion

Title: Impact assessment/ Protection of workers from the risk related to exposure to carcinogens or mutagens at work.

Overall opinion: POSITIVE WITH RESERVATIONS

(A) Policy context

Workplace exposure to certain chemicals may cause cancer. In 2004, the EU adopted the Carcinogens and Mutagens Directive (CMD). It aims to eliminate or limit workers' exposure to cancer-causing chemicals. Its instruments include setting maximum exposure levels for workers. Limits are put in place and updated as additional scientific information becomes available.

Over the past four years, the Commission has proposed three revisions of the Directive. These revisions targeted 26 substances, to improve the working conditions of 40 million workers. This report presents the fourth amendment of the directive. It proposes exposure limits for three additional substances: acrylonitrile, nickel compounds and benzene, affecting an estimated 1.1 million workers in the EU.

(B) Summary of findings

The Board notes the useful additional information provided in advance of the meeting and commitments to make changes to the report. The Board also notes that the draft report is concise and clear despite its technical scope.

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 is not sufficiently clear how the situation would evolve without new exposure limits. It does not factor in trends in actual exposure and the impacts of the Directive's requirement that employers minimise workers' exposure.
- (2) The report does not sufficiently analyse the impacts of the various transitional periods, which it introduces only at the stage of comparing options.
- (3) The report does not sufficiently explain the criteria for selecting the preferred options. The relative weight of consultative processes vs. cost benefit analysis is not clear.
- (4) The report does not sufficiently assess the proportionality of the preferred

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

options.

(C) What to improve

- (1) The report could explain how the Occupational Safety and Health evaluation and the conclusions of the REACH REFIT evaluation have fed into this impact assessment. Where relevant, it should explicitly refer to evaluation findings in the problem definition.
- (2) The baseline should explain why it expects downward trends in exposure to the substances to stop. It should analyse to what extent these trends are due to technical progress through the normal replacement of equipment. The baseline should clarify the assumptions for exposure levels to nickel compounds. The baseline should also explain why it assumes that the application and enforcement of the minimisation obligation will not reduce exposure.
- (3) The report should clearly distinguish between the problems for Acrylonitrile and Nickel compounds (for which EU OELs do not exist) and Benzene (which has an EU OEL). For benzene, the report should better explain how the existing OEL has worked and why there is a need to revise it. Similarly, the report should distinguish arguments on subsidiarity that apply to the new OELs (acrylonitrile, nickel compounds) and revised ones (benzene).
- (4) The report should justify the choice of durations and starting points of the proposed transitional periods for each substance when describing the options. It should clarify whether it proposes transitional periods to synchronise with equipment renewal cycles.
- (5) The cost analysis should better reflect what investments are regular equipment renewal, which is part of the baseline, as opposed to additional investment to comply with the new OELs.
- (6) The report should clarify the criteria it applied in selecting the preferred options. It should explain how the outcome of the consultative process was weighed against the results of the cost-benefit analysis.
- (7) Given the outcome of the quantitative cost-benefit analysis (i.e., negative net benefit ratio), the report should further discuss why the preferred options are considered proportionate. It should explain the stakeholders' arguments in this regard.

The Board notes the estimated costs and benefits of the preferred options 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.

If there are any changes in the choice or design of the preferred options in the final version of the report, the DG may need to further adjust the attached quantification tables to reflect this.

Full title	Proposal for a European Parliament and Council Directive amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work
Reference number	PLAN/2019/5411
Submitted to RSB on	23 April 2020
Date of RSB meeting	27 May 2020

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.

Acrylonitrile

The table below summarises the benefits as calculated on the basis of Method 1, which relies on Willingness to Pay (WTP) values for avoiding a case of mortality and morbidity. A low-high range has been provided that represents the lowest and highest values estimated based on the different Method 1 approaches and assumptions. Estimates on the basis of Method 2, which relies on monetised Disability Adjusted Life Years (DALYs), are of a similar order of magnitude at OEL levels of 1 mg/m³ inhalable.

Table: Overview of benefits for acrylonitrile

I. Overview of Benefits (total for all provisions), € over 60 years – Preferred Option		
Description	Amount	Comments
Direct benefits		
Avoided cancer cases	€7,100 - €97,000	Benefits are shared between: <ul style="list-style-type: none">- Workers: having less costs of informal care- Business: 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.- Public sector: 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. In addition, not quantified benefits include clarity regarding the acceptable levels of exposure, facilitates the work of inspectors by providing a helpful tool for compliance checks. Furthermore, the existence of an EU OELV eliminates the need for national public authorities to independently evaluate each carcinogen, removing an inefficiency of repetition of identical tasks.
Avoided non-cancer cases	€8,400 - €47,000	
Indirect benefits		
Avoided cancer cases	€500 - €6,400	Benefits to society: less loss of productivity
Avoided non-cancer cases	€0 - €0	
Intangible benefits		
Avoided cancer cases	€420,000 - €5,700,000	The main intangible benefits are to workers and families: More effective protection of their health, reducing suffering of workers and their families, increased length, quality and productivity of their working lives, avoiding premature deaths.
Avoided non-cancer cases	€22,000 - €120,000	

Note: Estimates are relative to the baseline as a whole (i.e. the impact of individual actions/obligations of the preferred option are aggregated together).

Table: Overview of costs for acrylonitrile

II. Overview of costs, € million over 60 years – Preferred option							
		Citizens/Consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
Preferred option	Direct costs	Negligible	Negligible	€30	-€2	1.35	N/A
	Indirect costs	Negligible	Negligible	N/A	N/A	N/A	N/A

Note: Estimates are relative to the baseline as a whole (i.e. the impact of individual actions/obligations of the preferred option are aggregated together).

Nickel compounds

The table below summarises the benefits as calculated on the basis of Method 2, which relies on monetised Disability Adjusted Life Years (DALYs). Estimates on the basis of Method 1, which relies on Willingness to Pay (WTP) values for avoiding a case of mortality and morbidity, are approximately 70-80% of those under Method 1.

Table: Overview of benefits for nickel compounds

I. Overview of Benefits (total for all provisions), € million over 60 years – Preferred Option (without transition measures)		
Description	Amount	Comments
Direct benefits		
Avoided cancer cases	€1	Benefits are shared between: <ul style="list-style-type: none">- Workers: having less costs of informal care- Business: 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.- Public sector: 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. In addition, not quantified benefits include clarity regarding the acceptable levels of exposure, facilitates the work of inspectors by providing a helpful tool for compliance checks. Furthermore, the existence of an EU OELV eliminates the need for national public authorities to independently evaluate each carcinogen, removing an inefficiency of repetition of identical tasks.
Avoided non-cancer cases	€5	
Indirect benefits		
Avoided cancer cases	€0	Benefits to society: less loss of productivity
Avoided non-cancer cases	€0	
Intangible benefits		
Avoided cancer cases	€37	The main intangible benefits are to workers and families: More

Avoided non-cancer cases	€48	effective protection of their health, reducing suffering of workers and their families, increased length, quality and productivity of their working lives, avoiding premature deaths.
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Note: Estimates are relative to the baseline as a whole (i.e. the impact of individual actions/obligations of the preferred option are aggregated together).

Table: Overview of costs for nickel compounds

II. Overview of costs, € million over 60 years – Preferred option (without transition measures)							
		Citizens/Consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
Preferred option	Direct costs	Negligible	Negligible	€4,300	€2,300	0.73	N/A
	Indirect costs	Negligible	Negligible	N/A	N/A	N/A	N/A

Note: Estimates are relative to the baseline as a whole (i.e. the impact of individual actions/obligations of the preferred option are aggregated together).

Benzene

The table below summarise the benefits as calculated on the bases of Method 1, which relies on Willingness to Pay (WTP) values for morbidity. Estimates on the basis of Method 2, which relies on monetised Disability Adjusted Life Years (DALYs), were about 60% of the values calculated with Method 1.

Table: Overview of benefits for benzene

I. Overview of Benefits (total for all provisions), € million over 60 years – Preferred Option (without transition measures)		
Description	Amount	Comments
Direct benefits		
Avoided cancer cases	€9	Benefits are shared between: <ul style="list-style-type: none">- Workers: having less costs of informal care- Business: 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.- Public sector: 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. In addition, not quantified benefits include clarity regarding the acceptable levels of exposure, facilitates the work of inspectors by providing a helpful tool for compliance checks. Furthermore, the existence of an EU OELV eliminates the need for national public authorities to independently evaluate each carcinogen, removing an inefficiency of repetition of identical tasks.
Avoided non-cancer cases	€2	
Indirect benefits		
Avoided cancer cases	€0	Benefits to society: less loss of productivity
Avoided non-cancer cases	€1	

Intangible benefits		
Avoided cancer cases	€196	The main intangible benefits are to workers and families: More effective protection of their health, reducing suffering of workers and their families, increased length, quality and productivity of their working lives, avoiding premature deaths.
Avoided non-cancer cases	€0	

Note: Estimates are relative to the baseline as a whole (i.e. the impact of individual actions/obligations of the preferred option are aggregated together).

Table: Overview of costs for benzene

II. Overview of costs, € million over 60 years – Preferred option (without transition measures)							
		Citizens/Consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
Preferred option	Direct costs	Negligible	Negligible	€2,461	€5,149	0.3	N/A
	Indirect costs	Negligible	Negligible	N/A	N/A	N/A	N/A

Note: Estimates are relative to the baseline as a whole (i.e. the impact of individual actions/obligations of the preferred option are aggregated together).