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## COVER NOTE

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To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	SEC(2023) 395 final
Subject:	<b>REGULATORY SCRUTINY BOARD OPINION</b> Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EU) 2017/852 of the European Parliament and of the Council of 17 May 2017 on mercury as regards dental amalgam and other mercury-added products subject to manufacturing, import and export restrictions

Delegations will find attached document SEC(2023) 395 final.

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EUROPEAN COMMISSION

Brussels, 24.3.2023  
SEC(2023) 395 final

**REGULATORY SCRUTINY BOARD OPINION**

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EU) 2017/852 of the European Parliament and of the Council of 17 May 2017 on mercury as regards dental amalgam and other mercury-added products subject to manufacturing, import and export restrictions

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EUROPEAN COMMISSION  
Regulatory Scrutiny Board

Brussels,  
RSB/

## **Opinion**

**Title: Impact assessment / Revision of Regulation (EU) 2017/852 on mercury**

**Overall 2<sup>nd</sup> opinion: POSITIVE WITH RESERVATIONS**

### **(A) Policy context**

The Mercury Regulation is the main legal instrument regulating the use and the environmental impact of mercury pollution in the EU. It covers the entire life cycle of mercury from primary mining to its final disposal as waste. It sets specific provisions, inter alia, on dental amalgam and on the manufacture, use, import and export of Mercury-Added Products (MAPs). It is complemented by other EU legal instruments, such as the Restriction of Hazardous Substances Directive setting restrictions on the placing on the market and import of MAPs. In the international context, the Minamata Convention on Mercury sets rules aiming to protect human health and the environment from emissions and releases of mercury and mercury compounds.

The review clause set out in Article 19(1) of the Mercury Regulation requires an assessment of the feasibility to phase out mercury-containing dental amalgam, the potential need to regulate at EU level emissions of mercury from crematoria, and the benefits and feasibility to prohibit manufacture, import and export of certain MAPs. This impact assessment is based on the conclusions of the Commission Report on the Review of the Mercury Regulation and aims to inform on possible revision of the Mercury Regulation.

### **(B) Summary of findings**

**The Board notes the improvements 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 cost benefit analysis and comparison of options are not sufficiently clear and comprehensive.**
- (2) The analysis of the EU ban on the manufacture and export of Mercury-Added Products is not sufficiently balanced.**

### **(C) What to improve**

(1) The report should further improve the cost benefit analysis. The environmental impacts should be monetised (to the extent possible) and the results should be brought into the cost benefit analysis. The report should indicate the net impacts and the Benefit Cost Ratios of each of the sub-options related to establishing legally binding end date for the use of dental amalgam in the EU as well as of the preferred options package bringing together all monetised and non-monetised impacts. The cost benefit analysis should be presented in a more reader friendly manner by being clear on what metrics are used in the analysis and, where metrics differ or where multiple metrics are used, provide information on their comparability.

(2) The report should further improve comparison of options to better support the choice of decision makers. As it does not conclude on a preferred option for the problem concerning mercury emissions from crematoria, it should further elaborate on possible trade-offs between the options. It should systematically use the results of the cost benefit analysis of the sub-options related to establishing legally binding end date for the use of dental amalgam in the EU when comparing the options. A more consistent approach should be applied to presenting the estimates in the comparison of options by avoiding mixing figures calculated using different metrics.

(3) The report should be clearer on the likelihood that a ban on EU exports of MAPs will result in competing third-country producers filling the emerging gap (for lamps a substitution rate of 50 to 90% is assumed). It should include a more robust assessment informed by expert views and other available evidence regarding the risk that the substitute third country lamps will contain a higher amount of mercury and thus contribute to higher continued mercury pollution in third countries. Given this uncertainty and significant risks that the expected benefits may not materialise, the report should review the “extremely positive” score on environmental and “strongly positive” score on social impacts attributed to the EU export ban in the summary table. It should also clarify whether the phasing out of EU production and the resulting need to import amalgam for residual special medical needs may create any new EU dependencies.

(4) The report should further elaborate the analysis on the impact of the stricter options on the EU manufacturers of dental amalgam and MAPs, including on their competitiveness, as well as the possible impact on job losses. The report should clearly present the views of the cost-bearing stakeholders (EU manufacturers of dental amalgam and MAPs, small crematoria operators) with regard to the available options.

(5) With a view to assessing all relevant policy choices, the report should consider presenting an alternative option regarding the mandatory abatement of mercury emissions by including a variant with a capacity threshold set at 3000 (and above). This seems justified given the expected additional environmental benefits and the fact that the related Benefit Cost Ratio is close to the included variant with a threshold of 4000 (and above), in particular, if a dental amalgam phase-out in 2025 is assumed.

(6) The report should further elaborate on the reasons for the estimated substantial remaining use of dental amalgam in certain Member States, in particular in view of available cost-effective alternatives.

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.**

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

Full title	Revision of Regulation (EU) 2017/852 on mercury
Reference number	PLAN/2020/9940
Submitted to RSB on	27 February 2023
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.*

### **Policy Option 2a – Dental amalgam phase-out in 2025**

<b><i>I. Overview of Benefits (total for all provisions) – PO2a</i></b>		
<b><i>Description</i></b>	<b><i>Amount</i></b>	<b><i>Comments</i></b>
<b><i>Direct benefits</i></b>		
Establish a 2025 legally binding end-date for the use of dental amalgam in the EU	Estimated cumulative reductions in direct mercury releases by 2030 of 3.1 t to air, 3.4 t to soil, 0.6 t to waterbodies, 2.6 t to wastewater, and 42.1 t sequestered or recycled	Indirect emissions to soil and water bodies not feasible to quantify. Benefits of reduced mercury releases to the environment can only be valued for emissions to air but no other environmental media. Therefore, monetised benefits are significantly underestimated.
Reduced mercury exposure to dental practitioners and patients	In the absence of PO2a, the expected amount of mercury put into teeth will be about 9.3 t in 2025.	Significant reductions in mercury vapour exposure for dental practitioners.
Reduction in hazardous waste generation	In the absence of PO2a, the expected amount of mercury wasted and collected in amalgam separators will be about 11 t in 2025.	Significant reductions in hazardous waste generation.
<b><i>Indirect benefits</i></b>		
Compliance cost reductions	Reduced costs associated with dental amalgam waste (collected by authorised waste management establishments or undertakings) borne by dentists.	Not possible to robustly quantify. These benefits would be realised once all legacy amalgam restorations have been disposed of. The majority of amalgam in the population would be replaced / disposed of within around 15 years.
Reduced mercury emissions from crematoria	PO2a will lead to reductions in mercury emissions from crematoria of 54 kg (by 2030)  <i>Note: Discarded PO2b would lead to 31 kg (by 2030) and PO2c would lead to 3 kg (by 2030).</i>	
Public health & safety and health systems	For PO2a, human health benefits valued at €900,000 as a result of reduced mercury emissions from crematoria in 2030.	Reductions in mercury emissions to air will result in reduced human exposure to atmospheric mercury. This will deliver human health benefits. These have been valued by applying EEA damage costs to predicted mercury emission reductions. Benefits of reductions in mercury exposure for dental practitioners and patients cannot be robustly quantified or monetised so health benefits are underestimated.

<i>II. Overview of costs – PO2a</i>							
		Citizens/Consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
<b>Compliance costs</b>	Direct costs	0	The recurrent costs will depend on the reimbursement of dental treatment by state social security and private medical insurance.	Not possible to accurately quantify the cost impacts resulting from pressure on manufacturers of amalgam fillings and dentists using amalgam products.		0	0
	Indirect costs	Increased costs of dental treatment estimated at €208 million in the first year of phase-out (in 2025).	0	0	Short-term and/or limited increase in dentist fees, most likely to be passed on to state or private health insurance.	0	Not possible to accurately quantify the cost impacts resulting from increased pressure on the state health insurance systems across the EU.
<b>Admin costs</b>	Direct costs	0	0	0	0	0	0
	Indirect costs	0	0	0	0	0	0

### Policy Option 3 – EU guidance on emissions abatement in crematoria

<i>I. Overview of Benefits (total for all provisions) – PO3</i>		
<i>Description</i>	<i>Amount</i>	<i>Comments</i>
<i>Direct benefits</i>		
EU guidance on emissions abatement in crematoria	N/A	A consequence of PO3 is a possible reduction in mercury emissions to air. This has indirect benefits in terms of environmental quality and human health.
<i>Indirect benefits</i>		
Quality of natural resources	Mercury emissions reductions of 17kg (6-29kg). Mercury emissions reductions of 14kg (3-27kg) when combined with a 2025 phase-out (PO2a)	Any reduction in mercury emissions will result in reduced deposition of atmospheric mercury to soil and waterbodies. It is not possible to robustly quantify the reduced deposition or to put an economic value on it.
Public health & safety and health systems	Human health benefits valued at €300,000 (€100,000-€600,000) as a result of reductions in emissions of mercury, PM <sub>2.5</sub> , lead, cadmium, arsenic, chromium, nickel and dioxins and furans. Human health benefits valued at €300,000 (€100,000-€500,000) as a result of reductions in	Reductions in mercury emissions to air will result in reduced human exposure to atmospheric mercury. This will deliver human health benefits. These have been valued by applying EEA damage costs to predicted mercury emission reductions.

	emissions of mercury, PM <sub>2.5</sub> , lead, cadmium, arsenic, chromium, nickel and dioxins and furans, when combined with a 2025 phase-out (PO2a).	
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<b>II. Overview of costs – PO3</b>							
		Citizens/Consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
<b>Compliance costs</b>	Direct costs	0	0	€10.3 million	€320,000 per year	0	0
	Indirect costs	Costs to operators are passed on to consumers. Not quantified.	0	0	0	0	0
<b>Admin costs</b>	Direct costs	0	0	0	0	Limited cost to institutions to develop guidance	0
	Indirect costs	0	0	0	0	0	0

#### Policy Option 4a – Mandatory abatement of mercury emissions at all crematoria

<b>I. Overview of Benefits (total for all provisions) – PO4a</b>		
<i>Description</i>	<i>Amount</i>	<i>Comments</i>
<b>Direct benefits</b>		
Mandatory abatement of mercury emissions at all crematoria	N/A	A consequence of PO4a is a reduction in mercury emissions to air. This has indirect benefits in terms of environmental quality and human health.
<b>Indirect benefits</b>		
Quality of natural resources	Mercury emissions reductions of 314kg (105-542kg). Mercury emissions reductions of 269kg (50-496kg) when combined with a 2025 phase-out (PO2a)	Any reduction in mercury emissions will result in reduced deposition of atmospheric mercury to soil and waterbodies. It is not possible to robustly quantify the reduced deposition or to put an economic value on it.
Public health & safety and health systems	Human health benefits valued at €6.1 million (€2.2 million-€10.4 million) as a result of reductions in emissions of mercury, PM <sub>2.5</sub> , lead, cadmium, arsenic, chromium, nickel and dioxins and furans.  Human health benefits valued at €5.4 million (€1.3 million-€9.6 million) as a result of reductions in emissions of mercury, PM <sub>2.5</sub> , lead, cadmium, arsenic, chromium, nickel and dioxins and furans, when combined with a 2025 phase-out (PO2a).	Reductions in mercury emissions to air will result in reduced human exposure to atmospheric mercury. This will deliver human health benefits. These have been valued by applying EEA damage costs to predicted mercury emission reductions.



<i>II. Overview of costs – PO4a</i>							
		Citizens/Consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
<b>Compliance costs</b>	Direct costs	0	0	€182 million	€5.7 million per year	0	0
	Indirect costs	Costs to operators are passed on to consumers. Not quantified.	0	0	0	0	0
<b>Admin costs</b>	Direct costs	0	0	0	€400,000	0	€500,000
	Indirect costs	0	0	0	0	0	0

### Policy Option 4b – Mandatory abatement of mercury emissions at large crematoria

<i>I. Overview of Benefits (total for all provisions) – PO4b</i>		
<i>Description</i>	<i>Amount</i>	<i>Comments</i>
<i>Direct benefits</i>		
Mandatory abatement of mercury emissions at large crematoria	N/A	A consequence of PO4b is a reduction in mercury emissions to air. This has indirect benefits in terms of environmental quality and human health.
<i>Indirect benefits</i>		
Quality of natural resources	Mercury emissions reductions of 141kg (70-210kg).  Mercury emissions reductions of 113kg (33-182kg) when combined with a 2025 phase-out (PO2a)	Any reduction in mercury emissions will result in reduced deposition of atmospheric mercury to soil and waterbodies. It is not possible to robustly quantify the reduced deposition or to put an economic value on it.
Public health & safety and health systems	Human health benefits valued at €2.7 million (€1.3 million-€3.9 million) as a result of reductions in emissions of mercury, PM <sub>2.5</sub> , lead, cadmium, arsenic, chromium, nickel and dioxins and furans.  Human health benefits valued at €2.2 million (€0.7 million-€3.5 million) as a result of reductions in emissions of mercury, PM <sub>2.5</sub> , lead, cadmium, arsenic, chromium, nickel and dioxins and furans, when combined with a 2025 phase-out (PO2a).	Reductions in mercury emissions to air will result in reduced human exposure to atmospheric mercury. This will deliver human health benefits. These have been valued by applying EEA damage costs to predicted mercury emission reductions.

<b>II. Overview of costs – PO4b</b>							
		Citizens/Consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
<b>Compliance costs</b>	Direct costs	0	0	€14.9 million	€460,000 per year	0	0
	Indirect costs	Costs to operators are passed on to consumers. Not quantified.	0	0	0	0	0
<b>Admin costs</b>	Direct costs	0	0	0	€23,000	0	€28,000
	Indirect costs	0	0	0	0	0	0

**Policy Options 6a and 6b – EU ban on the manufacture and export of dental amalgam by 2025 and MAPs by 2026/2028**

<b>I. Overview of Benefits (total for all provisions) – PO6a and PO6b</b>		
<i>Description</i>	<i>Amount</i>	<i>Comments</i>
<b>Direct benefits</b>		
EU ban on the manufacture and export of dental amalgam by 2025 (PO6a) and MAPs by 2026/2028 (PO6b)	PO6a will lead to a decrease of demand for mercury for dental amalgam in the order of 30 to 180 t between 2025 and 2030 PO6b will lead to decreased demand for mercury for MAP production of 0.8 to 1.5 t between 2026 and 2030	A direct consequence of decreased demand for MAP production is a significant decrease of mercury in exported products.
<b>Indirect benefits</b>		
Quality of natural resources	PO6a will lead to a reduction of mercury in exported dental amalgam in the order of 30 to 180 t between 2025 and 2030. PO6b will lead to a reduction of mercury in exported MAPs of 0.8 to 1.5 t and consequently a reduction of mercury into general waste streams of 0.7 to 1.3 t. In importing third countries, the net reduction may be smaller or even negative (increase of total mercury content) due to possible substitution by MAP imports from non-EU countries: -0.3 to +1.1 t (PO6b).	In importing third countries: PO6a would lead to positive net impact depending on the level of substituting imports from non-EU countries PO6b would lead to a positive net impact if an EU ban is closely followed by a global ban.
Public health & safety and health systems	Lower risk of exposure to mercury due to contact with waste or contaminated land, if non-EU MAP substitution is minimal.	Reduced input into the general waste stream will lessen the risk of exposure to mercury for the population living close to waste disposal sites or directly involved in waste management (in importing third countries).
Conduct of business	PO6a will lead to a higher demand for mercury-free filling materials PO6b will lead to a significant increase in sales of LED lamps, luminaires and lighting systems (but lower increase than in policy option PO5)	Dental amalgam no longer provided by EU manufacturers may partially be substituted by products (incl. amalgam) from non-EU manufacturers Possible risk of short-term negative impact due to non-EU substituting MAP imports, limiting demand for mercury-free alternatives

<b>II. Overview of costs –PO6a and PO6b</b>							
		Citizens/Consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
<b>PO6a Export ban 2025 (Dental amalgam)</b>	Direct costs	0	0	Loss of revenues: €50 to €300 million (retail value, revenue considerably smaller) (2025 – 2030)	0	0	0
	Indirect costs	0	Dental amalgam: possible short- term increased costs for dental restorations in third countries due to decreased supply.	0	0	0	0
<b>PO6b Export ban 2026/ 2028 (MAPs)</b>	Direct costs	0	0	Loss of revenues: €97 to €190 million (2026-2030)	0	0	0
	Indirect costs	0	Dental amalgam: possible short- term increased costs for dental restorations in third countries due to decreased supply.	0	0	0	0



Brussels,  
RSB

### **Opinion**

**Title: ENV Impact assessment / Revision of Regulation (EU) 2017/852 on mercury**

**Overall opinion: NEGATIVE**

#### **(A) Policy context**

The Mercury Regulation is the main legal instrument regulating the use and the environmental impact of mercury pollution in the EU. It covers the entire life cycle of mercury from primary mining to its final disposal as waste. It sets specific provisions, inter alia, on dental amalgam and on the manufacture, use, import and export of Mercury-Added Products (MAPs). It is complemented by other EU legal instruments, such as the Restriction of Hazardous Substances Directive setting restrictions on the placing on the market and import of MAPs. In the international context, the Minamata Convention on Mercury sets rules aiming to protect human health and the environment from emissions and releases of mercury and mercury compounds.

The review clause set out in Article 19(1) of the Mercury Regulation requires an assessment of the feasibility to phase out mercury-containing dental amalgam, the potential need to regulate at EU level emissions of mercury from crematoria, and the benefits and feasibility to prohibit manufacture, import and export of certain MAPs. This impact assessment is based on the conclusions of the Commission Report on the Review of the Mercury Regulation and aims to inform on possible revision of the Mercury Regulation.

#### **(B) Summary of findings**

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 significant shortcomings:

- (1) The report is not sufficiently clear on the scale and the drivers of the problems. It does not sufficiently describe the dynamic baseline.
- (2) The report does not present a clear, comprehensive and analytically coherent cost benefit analysis.
- (3) The report does not provide a clear and comprehensive comparison of options. It is not clear how the choice of the preferred options is supported by the analysis.



### **(C) What to improve**

(1) The report should clarify and further elaborate on the scope and scale of the problems. It should be clear that the term Mercury Added Products also covers dental amalgam. It should specify the amount of mercury addressed by the initiative as compared to the total amount of mercury released from or used in other human activities. It should present the breakdown of amounts between dental amalgam (for use in the EU and for exports), crematoria emissions and the different MAP categories. The report should elaborate on the scale and reasons for the continued use of dental amalgam in certain Member States, in particular considering the availability of safer alternatives and the phase-out in some Member States. It should explain in detail the underlying reasons and whether those are due to technical constraints, cost, or other factors. The report should discuss to what extent, the differing regulations and standards in Member States lead to market fragmentation, affect the functioning of the single market and contribute to the problem.

(2) The report should better describe the dynamic baseline. It should further justify the assumptions on the uptake of emissions abatement technologies in view of the recent and parallel initiatives towards zero pollution, as well as in view of potential accelerated deployment of mercury vapour capture in crematoria thanks to more affordable solutions. With regard to MAPs, the report should clarify if the envisaged prohibition of additional MAPs under the Minamata Convention is included in the baseline. It should explain if the baseline considers the accelerated shift towards alternatives to mercury-containing lamps using LED technology. It should also explain why the option related to seeking prohibition under the Minamata Convention is not considered part of the dynamic baseline. It should also consider to what extent non-legislative guidance type options form part of the dynamic baseline.

(3) The report should present a clear, comprehensive and analytically coherent cost benefit analysis. It should systematically present the available data and estimates for each option and sub-option in a transparent and comparable manner. It should provide an overview of the costs and benefits, the net impacts and Benefit Cost Ratio of each option describing all quantitative and qualitative information. It should be clearer on what metrics are used in the analysis and, where metrics differ or where multiple metrics are used, provide information on their comparability.

(4) The report should further develop the impact analysis. The environmental and health impacts should be monetised to the extent possible. Where quantitative evidence is lacking, the report should provide the qualitative analysis emphasising uncertainties and limitations. It should assess in greater detail the impact on the EU manufacturers of amalgam and MAPs, in particular on SMEs, including on their international competitiveness. The report should be clearer on the risk of substitution of banned EU exports with third country products and should inform whether the remaining third country producers can be expected to follow similar sustainability standards as EU business. It should clarify the source of amalgam for residual special medical needs in case such exemption is foreseen when phasing-out of the EU production. It should also better explain the impact from the communication campaigns and how the voluntary character of the option on guidance for crematoria on BATs is reflected in the analysis.

(5) The report should further develop an assessment of the effectiveness, efficiency and coherence of each option, as well as provide a detailed and clear comparison of the alternative options using the results of the cost benefit analysis.



(6) The report should further substantiate the choice of the preferred options. It should clearly explain how the analysis feeds into the choice of the preferred options. In particular, the report should better justify why the non-legally binding guidance is preferred over the mandatory application of BAT, based on the comparison of their effectiveness, efficiency and coherence. It should also explain why the majority view of consulted experts was not followed. The report should explain if the effectiveness assessment of the different options for reducing emissions from crematoria reflect the legacy of mercury-containing dental amalgam in the population before phasing out and the related long-term latency effect. The report should also present the total costs and benefits and cost-effectiveness of the preferred option(s).

(7) The report should systematically refer to the views of stakeholders, including diverging views, in particular with regard to the options, impact and comparison sections.

*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 and resubmit it for a final RSB opinion.**

Full title	Revision of Regulation (EU) 2017/852 on mercury
Reference number	PLAN/2020/9940
Submitted to RSB on	15 November 2022
Date of RSB meeting	14 December 2022