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IMPACT ASSESSMENT REPORT

IMPACT ASSESSMENT

Accompanying the document

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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TABLE OF ACRONYMS

Acronym	Meaning or definition
AEL	Associated Emission Level
ASGM	Artisanal and Small-Scare Gold Mining
BAT	Best Available Techniques
BAU	Business As Usual
BREF	Best Available Techniques Reference Document
BRG	Better Regulation Guidelines
CAMEO	Crematoria Abatement of Mercury Emissions Organisation
CFL.i	Compact Fluorescent Lamp with integrated ballast
CFL.ni	Compact Fluorescent Lamp with non-integrated ballast
CJEU	Court of Justice of the EU
CLRTAP	Convention on Long-Range Transboundary of Air Pollution
COP	Convention of the Parties
DEFRA	Department of Environment, Food and Rural Affairs
DMFT	Decayed, Missing and Filled Teeth
EAC	Equivalent Annual Cost
EC	European Commission
EEA	European Environment Agency
EGD	European Green Deal
ELV	Emission Limit Value
EMEP	European Monitoring and Evaluation Programme
EPA	Environmental Protection Agency
EU / Union	European Union
HELCOM	Helsinki Baltic Marine Environment Protection Commission
Hg	Mercury
HID	High Intensity Discharge Lamps
IA	Impact Assessment

IED	Industrial Emissions Directive
HPS	High Pressure Sodium lamps
IQ	Intelligence Quotient
LED	Light-Emitting Diode
LFL	Linear Fluorescent Lamp
MAP	Mercury-Added Product
MCP	Medium Combustion Plant
Member States	Member States of the European Union (EU 27)
MIA	Minamata Initial Assessment
NEC	National Emissions Reduction Commitments
OSPAR	Convention for the Protection of the Marine Environment of the North-East Atlantic
OPC	Online Public Consultation
R&D	Research and Development
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RoHS	Restriction of Hazardous Substances
SCENIHR	Scientific Committee on Emerging and Newly Identified Health Risks
SCHER	Scientific Committee on Health and Environmental Risks
SDG	Sustainable Development Goal
SMEs	Small and Medium Size Enterprises
Third countries	Non-EU countries
TFEU	Treaty on the Functioning of the European Union
TSS	Targeted Stakeholder Consultation
UNEP	United Nations Environment Programme
UWWTP	Urban Wastewater Treatment Plants
WHO	World Health Organisation
ZPAP	Zero Pollution Action Plan

1. 1. INTRODUCTION: POLITICAL AND LEGAL CONTEXT

This initiative addresses three specific issues in accordance with Article 19(1) of ***Regulation (EU) 2017/852 on mercury*** (hereinafter, 'the Mercury Regulation')[1], i.e. (i) the feasibility to completely phase out dental amalgam in the Union; (ii) the potential need to regulate at EU level emissions of mercury and mercury compounds from crematoria; and (iii) the environmental benefits and feasibility to prohibit the manufacture, import and export of certain mercury-added products (hereinafter, 'MAPs')[2] already banned from being placed on the market. In light of the assessment carried out by the Commission and in accordance with Article 19(3) of this Regulation, the Commission intends to present a legislative proposal. This initiative is part of a wider EU and global policy and legal context.

1.1. 1.1. Policy context of the initiative

This initiative is firstly shaped by the 2019 ***European Green Deal (EGD)***[3] as well as by the 2020 EU ***Chemicals Strategy for Sustainability***[4] and the 2021 EU ***Zero Pollution Action Plan*** (ZPAP)[5] adopted under it.

Under those policy documents, the Commission calls for banning the most harmful chemicals in consumer products and has pledged to revise EU instruments to reduce air, water and soil pollution to levels no longer considered harmful to health and natural ecosystems, thus creating a toxic-free environment. The Commission has therefore committed to revise, for instance, the CLP Regulation[6] by introducing new hazard classes (including for bio-accumulative and toxic substances)[7] and the REACH Regulation[8] by updating registration requirements and adapting the processes for authorisation and

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1 Regulation (EU) 2017/852 of the European Parliament and of the Council of 17 May 2017 on mercury and repealing Regulation (EC) No 1102/2008 (OJ L 137, 24.5.2017).

2 'Mercury-added products' refers to products or product components containing mercury or mercury compounds that are intentionally added.

3 Communication from the Commission 'The European Green', COM(2019) 640 final, 11.12.2019.

4 Communication from the Commission 'Chemicals Strategy for Sustainability - *Towards a Toxic-Free Environment*', COM(2020) 667 final, 14.10.2020.

5 Communication from the Commission, 'Pathway to a Healthy Planet for All EU Action Plan*: 'Towards Zero Pollution for Air, Water and Soil'*, COM(2021) 400 final, 12.5.2021.

6 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).

7 Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, COM(2022) 748.

8 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).

restriction, hence increasing the protection of humans and the environment from the most harmful substances, including mercury. Hence, this initiative clearly fits into this context.

Another key policy objective of high significance for this initiative concerns the commitment by the EU under the EU Chemicals Strategy for Sustainability to '*lead by example, and, in line with international commitments, ensure that hazardous chemicals banned in the European Union are not produced for export, including by amending relevant legislation if and as needed',* hence reducing its external pollution footprint.

Secondly, this initiative contributes to the development of a new Union framework for sustainable products[9], which aims at complementing existing Union product ecodesign requirements[10]. It is expected that current requirements concerning, for instance, product energy efficiency, be supplemented by ecodesign rules on the presence of substances that inhibit circularity, such as mercury. Hence, whilst this initiative addresses, among others, the phasing-out of the manufacturing and international trade in some mercury-containing lamps, the proposed new ecodesign requirements aim at ensuring, simultaneously, a shift towards more durable and energy efficient products. Light-emitting diode (LED) lamps are more energy efficiency compared to mercury-containing lamps as LED bulbs waste very little energy on heat, concentrating electricity on the production of light.

The third main component of the EU policy context of this initiative is the 2005 ***Mercury Strategy***[11] as reviewed in 2010[12]. Considering the risk posed by mercury to both human health and the environment, the EU developed a dedicated strategy setting six general policy objectives and defining twenty actions on the reduction of mercury emissions, supply and demand and on the promotion of international action on mercury. Consequently, several non-regulatory and regulatory initiatives were undertaken by the EU, including the adoption of Regulation (EC) 1102/2008 on mercury exports and storage[13]**,** as the first EU legal instrument devoted to mercury. As an initial step, this Regulation addressed only a select number of issues, including the phase-out of the export of mercury and of several mercury compounds and the obligation to make certain mercury waste subject to final disposal. The 2010 reviewed Mercury Strategy called for further initiatives and actions concerning notably dental amalgam, other MAPs and EU's efforts to promote the development of an international legal framework on mercury. As a result, not only was a new legislative framework, i.e., the ***Mercury Regulation*** adopted in May 2017 addressing, *inter alia*, intentional uses of mercury in products, but the key role played by the EU together with other major economies in promoting the

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9 Proposal for a Regulation of the European Parliament and of the Council establishing a framework for setting ecodesign requirements for sustainable products and repealing Directive 2009/125/EC (COM(2022) 142 final, of 30.03.2022.

10 Directive 2009/125/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for the setting of ecodesign requirements for energy-related products (OJ L 285, 31.10.2009, p. 10).

11 Communication from the Commission '*Community Strategy Concerning Mercury'*, COM(2005) 20 final, 28.01.2005.

12 Communication from the Commission on the review of the Community Strategy Concerning Mercury, COM(2010) 723 final, 7.12.2010.

13 Regulation (EC) No 1102/2008 of the European Parliament and of the Council of 22 October 2008 on the banning of exports of metallic mercury and certain mercury compounds and mixtures and the safe storage of metallic mercury (OJ L 304, 14.11.2008).

development a multilateral environmental agreement resulted also in the adoption in 2013 of the ***Minamata Convention on Mercury*** *(hereinafter 'Minamata Convention')*[14].

The 2010 reviewed Mercury Strategy was subsequently endorsed by ***Council conclusions***[15] that called for phasing out all mercury uses, including MAPs as follows:

'*Mercury-added products, where viable alternatives exist, should be phased out as rapidly and as completely as possible, with the ultimate goal that all mercury-added products should be phased-out, taking into due account technical and economic circumstances and the needs for scientific research and development*.'

The global policy context of this initiative is first and foremost characterised by the aforementioned ***Minamata Convention***. This Convention, which has been ratified to date by the EU[16] and 138 countries, including all Member States and other major economies (e.g., US, China, Japan and Brazil), aims at protecting human health and the environment from anthropogenic emissions and releases of mercury and mercury compounds. To assist Parties in achieving this objective, the Minamata Convention addresses, amongst others, intentional uses of mercury in products, i.e., including in dental amalgam and other products such as lamps. As documented in this Impact Assessment Report (see sections addressing problem 3 and Annex 8), this initiative is developed on the basis of the existing and strong interplay between Union legislation on MAPs and the relevant Minamata Convention's provisions on products.

Additionally, this initiative contributes to the implementation within the EU of two ***Sustainable Development Goals*** (SDGs) i.e., good health and well-being ensuring healthy lives and promoting well-being for all at all ages (Goal 3) and responsible consumption and production ensuring sustainable consumption and production patterns (Goal 12)[17], as well as to the EU decarbonisation agenda[18] by promoting the substitution of mercury-containing lamps with more energy-efficient lighting alternatives, i.e. LED lamps (see Section 6.3.1 below).

1.2. 1.2. Legal context of the initiative

Whereas mercury and mercury compounds are addressed in numerous EU instruments, the Union legal context of this initiative is primarily concerned with the ***Mercury Regulation*** as the current dedicated EU legal instrument covering the entire life cycle of

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[14] The Minamata Convention that entered into force on 17 August 2017 is available here: https://www.mercuryconvention.org/sites/default/files/documents/information_document/Minamata-Convention-booklet-Sep2019-EN.pdf

[15] Council conclusions *Review of the Community Strategy concerning Mercury*, 3075th Environment Council meeting, 14 March 2011.

[16] Council Decision (EU) 2017/939 of 11 May 2017 on the conclusion on behalf of the European Union of the Minamata Convention on Mercury (OJ L 142, 2.6.2017, p. 4–39).

[17] Agenda 2030 for Sustainable Development: https://www.un.org/sustainabledevelopment/development-agenda/

[18] Communication from the Commission '*A clean planet for all a European strategic long-term vision for a prosperous, modern, competitive and climate neutral economy'*, COM/2018/773 final, of 28.11.2018.

mercury, from primary mining to its final disposal. This Regulation regulates, *inter alia*, the manufacture, import and export of MAPs and implements the Minamata Convention.

As mentioned above, whilst this initiative is specifically triggered by the review clause established in Article 19 of the Mercury Regulation, the Commission presented the outcome of this review in its ***Report on the use of mercury in dental amalgam and products*** adopted in August 2020 (hereinafter 'the Commission Review Report')[19]. A summary can be found in Annex 8. This impact assessment takes forward the results to inform on the possible revision of the Mercury Regulation as far as dental amalgam, other MAPs and mercury emissions from crematoria are concerned.

Regarding ***dental amalgam***, Article 10(2) of the Mercury Regulation sets an EU-wide prohibition to use dental amalgam since 1 July 2018 for dental treatment (i) of deciduous teeth and (ii) of vulnerable population (children below the age of 15, pregnant and breastfeeding women). Thanks to the ambition of the Union to achieve a mercury-free society both at EU and global level and to the key role played in this respect by the EU under the Minamata Convention, the fourth Conference of the Parties to that Convention (COP4) adopted in March 2022 Decision MC-4/3 amending Annex A (Part II) to the Convention by establishing therein a similar prohibition on the use of dental amalgam for vulnerable population.[20]

As far as ***mercury emissions from crematoria*** are concerned, EU law currently sets no legally binding requirements or standards. Such emissions are only addressed at international level in the form of non-legally binding recommendations on the use of Best Available Techniques (BAT) adopted under both OSPAR[21] and HELCOM[22] Regional Seas Conventions to which the EU and some Member States are Parties.

Concerning ***MAPs (other than dental amalgam)***, the legal context of this initiative consists of both EU and international law. Under Union legislation, the manufacture, placing on the market, import and export of MAPs, specifically mercury-containing lamps, is regulated by several instruments. On the one hand, the Mercury Regulation establishes an EU-wide prohibition since 1 January 2019 and 2021 on the manufacture, import and export of MAPs listed in its Annex II. This list includes batteries, pesticides, biocides and topical antiseptics and certain switches and relays, cosmetics, lamps (e.g., high pressure mercury vapour lamps for general lighting purposes) and non-electronic measuring devices (e.g., barometers and thermometers)[23] and mirrors the list of MAPs

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19 Report from the Commission to the European Parliament and the Council on the reviews required under Article 19(1) of Regulation 2017/852 on the use of mercury in dental amalgam and products, COM(2020) 378 final, 17.08.2020.

20 Decision MC-4/3: *Review and amendment of Annexes A and B to the Minamata Convention on Mercury*. It will enter into force on 28 September 2023. The text of the Decision is available at: https://www.mercuryconvention.org/en/meetings/cop4?document_types=307#cop-documents

21 OSPAR Recommendation 2003/4 on Controlling the Dispersal of Mercury from Crematoria, available at: https://www.ospar.org/convention/agreements/page5?t=32283.

22 HELCOM Recommendation 29/1 (2008) Reduction of emissions from crematoria, available at: https://helcom.fi/wp-content/uploads/2019/06/Rec-29-1.pdf.

23 The prohibition on the export of MAPs set out in the Mercury Regulation is also systematically thereafter implemented in Annex V (Part II) to Regulation (EU) No 649/2012 of the European

contained in Annex A (Part I) to the Minamata Convention subject to a similar prohibition at global level. On the other hand, restrictions on the placing on the market and import of those MAPs are also set out in other instruments, including REACH and the RoHS Directive[24].

De jure, MAPs that are already banned from being placed on the market and imported under REACH, the Cosmetics Regulation[25] and the Batteries Directive[26], are also listed in Annex II (Part A) to the Mercury Regulation, hence also subject to a manufacturing, export and import prohibition under that Regulation. Inversely, the alignment of the Mercury Regulation with the existing prohibition set out under the RoHS Directive to place on the market and import certain mercury-containing lamps is not yet complete as some of those lamps (see Table 3 below) are not to date referred to in the above-mentioned Annex II (Part A) and can therefore still be manufactured in the Union and exported from the EU.

By addressing the feasibility to further align EU law on mercury-containing lamps between the Mercury Regulation and the RoHS Directive, the Union must not only consider the difference in scope of application of both those instruments but must also take full account of the following developments that have taken place under the Minamata Convention.

Firstly, besides the establishment of a partial ban on the use of dental amalgam, aforementioned Decision MC-4/3 has also extended the list of prohibited MAPs referred to in Annex A (Part I) to that Convention. More specifically, Parties agreed to prohibit at global level the manufacturing, import and export, as from 1 January 2026, of seven additional MAPs including: (i) compact fluorescent lamps with an integrated ballast (CFL.i) for general lighting purposes that are ≤ 30 watts with a mercury content not exceeding 2.5 mg per lamp burner, (ii) cold cathode fluorescent lamps (CCFL) and external electrode fluorescent lamps (EEFL) of all lengths for electronic displays, that are not yet included in Annex A (Part I), (iii) melt pressure transducers, transmitters and pressure sensors, (iv) mercury vacuum pumps, (v) tire balancers and wheel weights, (vi) photographic film and paper and (vii) propellant for satellites and spacecraft.

Considering that such an extension of the list of prohibited MAPs under the Minamata Convention is in line with the formal proposal made by the Union ahead of COP4[27] and

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Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals (OJ L 201, 27.7.2012, p. 60).

24 Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011, p. 88–110).

25 Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59).

26 Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC (OJ L 266, 26.9.2006, p. 1).

27 Council Decision (EU) 2021/727 of 29 April 2021 on the submission, on behalf of the European Union, of proposals to amend Annexes A and B to the Minamata Convention on Mercury, regarding mercury-added products and manufacturing processes in which mercury or mercury compounds are used (OJ L 55 of 5.5.2021, p. 23).

with the relevant negotiating mandate provided by the Member States to the Commission[28], those MAPs will be added to Annex II (Part A) to the Mercury Regulation via a Delegated Act in accordance with Article 20 of this Regulation. In doing so, the addition of those MAPs is not subject to this impact assessment considering that the Union has, in this respect, no 'room for manoeuvre' within the meaning of the 'Better Regulation' toolbox[29] that complements the 2021 EU Better Regulation Guidelines[30].

Secondly, by means of Decision MC-4/3, Parties agreed also to consider at the fifth meeting of the Conference of the Parties to the Minamata Convention (COP5, November 2023) a further extension of the list of MAPs contained in Annex A (Part I) to the Convention. The potential supplementary MAPs include the following linear fluorescent lamps (LFLs) for general lighting purposes not already covered by the Convention: (i) halophosphate phosphor lamps and (ii) triband phosphor lamps < 60 watts. In particular, whilst Parties reached an agreement at COP4 on the principle of phasing-out those LFLs, consensus on the phase-out dates (1st January 2026, 2028 or 2031) is still to be reached and the outcome remains uncertain. As those LFLs are already prohibited from being placed on the market and imported since 24 February 2023 in accordance with the RoHS Directive, this initiative endeavours to address the manufacture and export of those lamps at EU level.

In conclusion, from the policy and legal context perspective, this initiative aims to contribute to increased coherence of the EU regulatory framework on MAPs and implement the international pillar of the ZPAP, reducing the EU pollution footprint in third countries and thereby safeguarding the EU's credibility ahead of future Minamata Conferences of the Parties, including at COP5.

2. 2. PROBLEM DEFINITION

Mercury is a highly toxic element and a major risk to the environment and human health. It is a potent neurotoxin inducing permanent brain and kidney damage in adults and affecting foetal and early childhood development. Hence, mercury has been classified under EU law as being toxic for reproduction, fatal if inhaled, causing damage to all organs through prolonged or repeated exposure and very toxic for aquatic life with long lasting adverse effects[31]. It is bio-accumulative and, via food-webs and transboundary transport of air pollution, travels around the globe. Mercury in the air deposits on land and water bodies. Due to its toxicity for aquatic life, mercury also classifies as a priority

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[28] Council Decision (EU) 2022/549 of 17 March 2022 on the position to be taken on behalf of the European Union at the second segment of the fourth meeting of the Conference of the Parties to the Minamata Convention on Mercury as regards the adoption of a Decision to amend Annexes A and B to that Convention (OJ L 107, 6.4.2022, p. 78).

[29] See Better regulation' toolbox (November 2021 edition), Tool #7 '*What is an Impact Assessment and when it is necessary*', available at: https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law/better-regulation-why-and-how/better-regulation-guidelines-and-toolbox_en

[30] Commission Staff Working Document '*Better Regulation Guidelines'*, SWD(2021) 305 final, 3.11.2021.

[31] *Supra* n° 6.

hazardous substance under Union water legislation, which implies that mercury releases into water bodies must cease at a certain point in time[32]. For this reason and considering the toxicity of mercury to human health, the EU has set maximum limit values for mercury content in fish for consumption (most large predatory fish)[33].

Mercury can be released to the environment by natural sources (earth's crust, volcanic emissions, geothermal activities, or forest fires) as well as **anthropogenic sources** resulting either from activities whereby **mercury is added intentionally** (dental amalgam and other MAPs) or where mercury is emitted non-intentionally as a side-product (coal-fired power plants, residential coal-burning for heating and cooking or waste incinerators)[34]. A general problem definition of mercury can be found in Annex 6.

At global level and based on the latest UNEP global mercury assessment[35], the largest anthropogenic mercury emissions to the environment occur from fossil fuel combustion (533 t/year), industrial processes (614 t/year) and artisanal small-scale gold mining (838 t/year). Annual world-wide emissions to air were estimated to amount to 2.200 t of which the EU(28) is responsible for 77.2 t i.e., 3.5% (2015). Regarding more specifically the use and disposal of MAPs, including dental amalgam and mercury-containing lamps, global emissions to water were estimated to amount to 99.4 t/year, i.e., about 17% of all mercury emissions (2015).

In the EU, the total quantity of anthropogenic mercury emissions has been steadily and significantly decreasing over the past 20 years, largely thanks to a dedicated Community strategy on Mercury (2005 and 2010) and related EU legislation (e.g., RoHS Directive), determined action at global level having led to the creation, in 2017, of the Minamata Convention, the decarbonisation agenda as well as the Mercury Regulation, which has prohibited since 2018 most intentional uses of mercury (including for manufacturing processes, artisanal and small-scale gold mining and dental amalgam for vulnerable populations).

The objective of this initiative is to address the continued **intentional use** of mercury in dentistry and products, as the **largest remaining intentional uses of mercury** in the EU, with a view to minimising the EU's contribution to the global build-up of mercury.

It is estimated that this initiative would cover between 52.9 and 87.9 t/year of mercury stemming from such MAPs. Such amounts can be broken down as follows:

- 40.4 t/year of mercury in dental amalgam for use in the EU

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[32] See Annex X to Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1).

[33] Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (OJ L 364, 20.12.2006, p. 5).

[34] WHO, 2017. Mercury and health (https://www.who.int/news-room/fact-sheets/detail/mercury-and-health)

[35] UNEP (2019) Global Mercury Assessment 2018, available at https://www.unep.org/explore-topics/chemicals-waste/what-we-do/mercury/global-mercury-assessment

- 13-38 t/year[36] of mercury in dental amalgam exported from the EU
- 0.5 t/year of mercury used for fluorescent lamps exported from the EU
- 1 t/year of mercury emissions from crematoria

This section describes the three elements linked to the review of the Mercury Regulation. Dental amalgam (use) is considered as Problem 1, emissions from crematoria as Problem 2 and MAPs (manufacture and export of dental amalgam and of certain mercury-containing lamps) are addressed under Problem 3. Each of the three problems is treated with its own set of policy options that respond directly to the identified problem drivers and specific objectives. The three problems are obviously interlinked as for example the phase-out of the use of dental amalgam in the EU will automatically lead to a reduction of mercury emissions from crematoria in the longer term.

2.1. 2.1. Problem 1 – Dental amalgam

The first problem concerns the risks for health and the environment associated with the use of dental amalgam.

Dental amalgam has been used as a dental filling material for centuries to fill dental cavities caused by tooth decay and to restore tooth surfaces. It is a product composed of metallic powders like copper, silver, tin, etc. mixed with mercury, where mercury represents 42% to 53% of the amalgam's mass[37,38,39].

Whilst EU policy and law on mercury aims explicitly at eliminating mercury use and associated pollution, especially when mercury-free alternatives are feasible and available, dental amalgam still represents the **largest remaining intentional use of mercury in the EU**. This leads to adverse human health effects and mercury emissions, in particular during placement by dental practitioners and via excretion[40], cremation or burial of people fitted with dental amalgam[41]. The continued use of dental amalgam is therefore a practice that contributes to the continuous build-up of mercury in the environment and excessive and unsustainable amounts of mercury in fauna, flora and habitats.

Regarding the EU dimension of the problem, the mean total mercury used in dental amalgam in the EU is estimated to be **40.4 t in 2019** (18.6 t in teeth and 21.8 t as waste)

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[36] Due to the lack of credible export data the amount of mercury exported in the form of dental amalgam can only be roughly estimated, hence a range is presented

[37] See directions for use regarding dental amalgam product *Permite lojic+ & gs-80:* https://www.sdi.com.au/pdfs/instructions/pt-br/gs-80_sdi_instructions_pt-br.pdf

[38] See directions for use regarding dental amalgam product *Septalloy NG 70, Securalloy*: https://uploads-ssl.webflow.com/571024186d8e1cce4121d731/5be974bc16344085fcc0f4d6_S%2005%2086%20050%2005%2000_6amalgam-SP.pdf

[39] See directions for use regarding dental amalgam product *Dispersalloy:* http://www.dentsplyestore.com.au/www/770/files/dispersalloy_capsules_dfu.pdf

[40] The Contribution Of Dental Amalgam To Urinary Mercury Excretion In Children | Environmental Health Perspectives | Vol. 115, No. 10". 2022, https://ehp.niehs.nih.gov/doi/full/10.1289/ehp.10249 Accessed 31 Mar 2022.

[41] Alwyn Hart, Ammonia shadow of my former self: a review of potential groundwater chemical pollution from cemeteries, Land contamination & Reclamation, 13 (3), 2005

with the lower estimate being 31.6 t and the upper estimate being 50.3 t. The use of dental amalgam for the treatment of dental cavities varies across Member States (Table 1).

Whereas SE is to-date the only Member State having completely phased out the use of dental amalgam, many other Member States have made significant progress in phasing down its use. Yet, eight Member States (AT, HR, CZ, EL, MT, PL, SK, SI) in 2019 still conducted close to or over 50% of their dental treatments using dental amalgam, although several of them have since phased-out or announced their intention to progressively phase-out dental amalgam use before 2030. Yet, Table 1 below shows that, in the absence of EU regulatory intervention, dental amalgam would continue to be used, in some Member States with rather high quantities, well beyond 2025.

Table 1: Dental amalgam use per Member State (2019, 2025 and 2030)

	Amalgam use %	2019 (t)	Predicted 2025 (t)	Predicted 2030 (t)
AT	43%	1.291	0.893	0.579
BE	7%	0.427	0.285	0.150
BG	21%	0.379	0.225	0.146
HR	43%	0.110	0.000	0.000
CY	21%	0.008	0.005	0.004
CZ	43%	2.656	1.765	0.100
DK	1.7%	0.065	0.040	0.025
EE	2.5%	0.005	0.004	0.002
FI	1%	0.002	0.001	0.000
FR	25%	18.730	11.444	7.860
DE	6%	3.433	2.310	1.458
EL	43%	0.192	0.112	0.073
HU	7%	0.476	0.305	0.077
IE	20%	0.998	0.657	0.000
IT	2.5%	0.663	0.000	0.000
LV	21%	0.178	0.112	0.078
LT	4.6%	0.105	0.064	0.047
LU	21%	0.009	0.006	0.004
MT	43%	0.006	0.004	0.003
NL	0.5%	0.087	0.048	0.037
PL	43%	7.182	0.000	0.000
PT	10%	0.849	0.444	0.261
RO	7.5%	0.464	0.283	0.149
SK	50%	0.279	0.184	0.146
SI	70%	1.650	1.094	0.000
ES	1%	0.182	0.102	0.000
SE	0%	0.000	0.000	0.000
EU total		**40.4 t**	**20.4 t**	**11.2 t**

The continued use of dental amalgam notwithstanding the availability of mercury-free alternatives is mainly motivated by:

- lack of communication to and awareness of mercury-free alternatives among relevant patients,
- lack of training of dental practitioners to use such alternatives,
- higher costs incurred by patients in some EU Member States (e.g., DE, IT) when seeking the reimbursement of mercury-free versus mercury-added dental amalgam from national social security services or private insurances, creating an uneven level of health insurance coverage across the EU.

Additionally, limited continued use of dental amalgam across the EU results from the specific medical conditions of some patients (allergies to some components of the mercury-free amalgams, excessive saliva production, acute anxiety) for whom dental amalgam is the only appropriate dental treatment technique due to either its chemical properties or its reportedly faster application time.

In addition to the environment being directly affected by mercury emissions associated with the use of dental amalgam, specifically via emissions from crematoria, the main exposure to mercury in individuals with amalgam restorations occurs during placement or removal of the fillings[42], if not handled properly. Furthermore, low levels of exposure may also occur through the lifetime of a restoration.

In terms of evolution of the problem, the advantages that have historically been associated with the use of dental amalgam were that it was cheaper than its mercury-free counterpart and easier and quicker to place. However, the alternatives are now as cost-effective as dental amalgam and practitioners are increasingly replacing dental amalgam with these alternatives. It is therefore expected that the use of dental amalgam will decrease to **11.2 t by 2030** (with a lower estimate of 7.2 t and an upper estimate of 16.8 t). This is due to increased patient awareness with regards to mercury's negative health and environmental impacts and increased reliability of mercury-free alternatives and their aesthetic advantages. Nevertheless, the remaining amount will still represent the largest remaining intentional use of mercury in the EU and continue to circulate through environmental media (air, water and soil). Furthermore, with no policy intervention at EU level, a phase-out is predicted to take place at a much slower pace and at different times across the EU.

Problem drivers for Problem 1

Driver 1 – Market failure: Across the EU, whilst mercury-free alternatives have become as cost-effective as dental amalgam, an uneven level of health insurance coverage between dental amalgam and alternatives creates higher costs for patients choosing mercury-free alternatives. Furthermore, although the price of dental amalgam

[42] Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) '*The safety of dental amalgam and alternative dental restoration materials for patients and users'* (2008)

varies among Member States, its price often does not reflect the damage costs of mercury.

Driver 2 – Regulatory failure: The use of dental amalgam is only partially prohibited for vulnerable populations (i.e., children below the age of 15 years, pregnant and breastfeeding women) at EU level. The level to which this prohibition extends or will extend to other members of the population varies a lot between the EU Member States.

Driver 3 – Behavioural biases: In the EU, despite dental health improving over recent years, several problem drivers, including improper dental hygiene and poor eating habits continue to cause cavities, which require treatment and continue to do so as cavities cannot be eradicated completely. This is particularly important for vulnerable and socially excluded groups in society who experience significantly poorer oral health and access to dental services than the mainstream population[43].

2.2. 2.2. Problem 2 – Mercury emissions from crematoria

Crematoria continue to be an important source of mercury emissions in the EU[44,45]. These emissions originate mainly from mercury amalgam fillings in human remains.

In 2019, the EU had over **1.200 crematoria** (see Table 2 below and Annex 5) and experienced between 2010 and 2019 a **38% increase in annual cremation numbers** (from 1.5 million to over 2.1 million) (see Table 3).

Table 2: Number of crematoria by capacity band by Member State (2019)

Member State	Number of crematoria, 2019 (by capacity band)							
	<1,000	1,000 – 2,000	2,000 – 3,000	3,000 – 4,000	4,000 – 5,000	>5,000	Total	% change 2010 - 2019
AT	1	2	4	2	3	1	13	18%
BE	1	3	6	4	4	1	19	58%
BG	1	0	0	0	0	0	1	0%
CY	0	0	0	0	0	0	0	N/A
CZ	2	5	10	4	4	2	27	0%
DE	8	22	50	30	38	11	159	5%
DK	1	10	6	0	0	2	19	-38%
EE	2	0	0	0	0	0	2	0%
EL	1	0	0	0	0	0	1	N/A
ES	434	0	0	0	0	0	434	No 2010 data
FI	3	12	4	0	1	0	20	-9%
FR	88	71	21	3	1	1	185	23%
HR	0	0	0	0	0	1	1	0%

43 Watt RG, Venturelli R, Daly B. Understanding and tackling oral health inequalities in vulnerable adult populations: from the margins to the mainstream. Br Dent J. 2019 Jul;227(1):49-54. doi: 10.1038/s41415-019-0472-7. PMID: 31300784.

44 Supra No. 18

45 OSPAR Commission (2004). OSPAR Background Document on Mercury and Organic Mercury Compounds (2004 Update). https://www.ospar.org/documents?v=6904

Member State	Number of crematoria, 2019 (by capacity band)							
	<1,000	1,000 – 2,000	2,000 – 3,000	3,000 – 4,000	4,000 – 5,000	>5,000	Total	% change 2010 - 2019
HU	1	1	2	5	5	3	17	42%
IE	5	1	1	0	0	0	7	75%
IT	29	19	26	8	2	1	85	47%
LT	0	0	0	0	1	0	1	N/A
LU	0	0	1	0	0	0	1	0%
LV	0	0	0	1	0	0	1	0%
MT	0	0	0	0	0	0	0	N/A
NL	66	24	6	1	1	1	99	43%
PL	12	13	17	7	2	1	52	300%
PT	1	4	6	3	4	2	20	400%
RO	4	0	0	0	0	0	4	300%
SE	25	24	5	2	0	2	58	-12%
SI	0	0	0	0	0	2	2	0%
SK	0	0	0	0	1	2	3	0%
EU-27	**685**	**211**	**165**	**70**	**67**	**33**	**1,231**	

Crematoria numbers are estimated to steadily increase across the EU (to 1,482 crematoria in EU27 in 2030), based on an extrapolation of trends over the past 10 years and supported by feedback from stakeholders as part of the consultation activities.

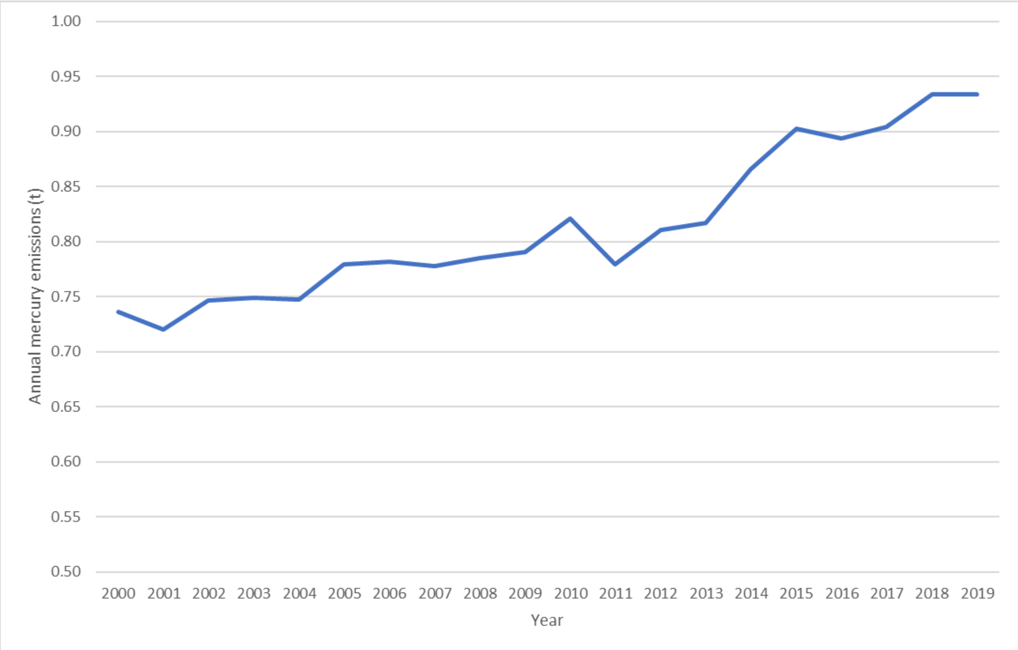
Table 3: Change in number of cremations (2010, 2019) per Member State

Member State	Number of cremations		
	2010	**2019**	**Change**
AT	25,553	41,869	64%
BE	51,062	67,794	33%
BG	364	519	43%
CY	0	0	0%
CZ	86,405	88,901	3%
DE	487,135	648,269	33%
DK	42,048	46,134	10%
EE	538	1,967	266%
EL	0	487	N/A
ES	174,649	185,332	6%
FI	21,103	30,956	47%
FR	165,907	239,283	44%
HR	39,258	38,647	-2%
HU	79,217	86,898	10%
IE	3,134	7,025	124%
IT	76,902	194,639	153%
LT	1,425	4,888	243%
LU	2,228	2,810	26%
LV	1,010	3,540	250%
MT	0	0	N/A
NL	77,471	101,687	31%
PL	34,063	132,746	290%
PT	56,632	64,259	13%

Member State	Number of cremations		
	2010	**2019**	**Change**
RO	857	1,248	46%
SE	69,548	73,631	6%
SI	14,569	17,506	20%
SK	4,810	17,248	259%
EU27	**1,517,897**	**2,100,301**	**38%**

Regarding mercury emissions from crematoria, this represents a **14% increase** (from 821 kg to 934 kg) as shown in Figure 1 based on Member State reporting under CLRTAP[46]. The wider public is impacted through exposure to mercury emissions from crematoria. Applying EEA damage cost functions for mercury[47] (which take into account mortality and IQ loss), the impacts of these emissions are valued at approximately €16 million[48] per year.

Figure 1: Annual crematoria mercury emissions to air for the EU 27 as reported by the Member States under CLRTAP (2000-2019)



Data from EMEP (2022)[49]

[46] It should be noted that these figures are based on Member State reporting under CLRTAP and more robust estimates of emissions have been developed for this study for the baseline which are described in Section 5.1.2.

[47] Damage costs express an impact value associated with a given volume of pollutant emission. EEA damage costs for mercury account for health impact including cardiovascular mortality and IQ loss.

[48] 2019 prices. Based on a marginal damage cost of €16,903 per kg. See: https://www.eionet.europa.eu/etcs/etc-atni/products/etc-atni-reports/etc-atni-report-04-2020-costs-of-air-pollution-from-european-industrial-facilities-200820132017/@@download/file/ETC-ATNI_2020-4_Task-1222_FINAL_v2_17-08-2021.pdf

[49] OSPAR Convention (2011). Implementation of OSPAR Recommendation 2003/4 on Controlling the Dispersal of Mercury from Crematoria: Second Overview assessment. https://www.ospar.org/documents?v=35427

Crematoria operators do not fall under the scope of application of the 2010/75/EU Industrial Emissions Directive[50]: hence, they are not subject to an obligation under EU law to make use of best available techniques (BAT).

The size of crematoria and businesses that operate crematoria varies significantly across the EU. For example, ES has the highest number of crematoria in Europe, but most crematoria are estimated to carry out less than 350 cremations a year[51]. In contrast, the average crematorium in HR carries out over 5,000 cremations per year. It is estimated that more than half of all crematoria in the EU are small (less than 1,000 cremations per year) as presented in Table 2 (see Annex 5 for number of crematoria and cremations per Member State).

Emissions of mercury from crematoria can be avoided through the application of abatement technologies. The most used technologies include Injection of Absorbent or Solid Bed Filtration using Absorbent. A list of Member States applying abatement technologies can be found in Annex 5. Uptake of emissions abatement technologies in crematoria is anticipated to increase in future years, at least in some Member States, although this is highly uncertain. In case of no EU-wide policy intervention, any prolonged use of dental amalgam will therefore entail continued mercury emissions from crematoria. The phase-out of dental amalgam would lead over time, taking into account legacy dental amalgam (the average life expectancy of a dental amalgam filling is 15 to 20 years), to a cessation of mercury emissions from crematoria and their associated environmental risks.

Problem drivers for Problem 2

The evidence points out to only two drivers for this problem as there is no indication for a market failure. The fact that environmental requirements are different in the various Member States might lead to marginally different costs for the cremation as usually, operators transfer these costs to the consumers via the application of an environmental levy. The cost of the cremation itself as a proportion of total funeral cost is low (around 10-20%) and the potential additional costs for abatement would not significantly change the overall cost.

However, the evidence points quite clearly towards no market distortion amongst Member States when it comes to cremation, not even in transboundary areas. In general, the cross-border transportation of deceased people occurs in cases of repatriation, where the main factor driving the transportation is social rather than financial (returning the body to hold a cremation or funeral where they or their loved ones live). As costs for repatriation are quoted to be in the order of thousands of euros, it is unlikely that small financial differences between cremation costs in neighbouring Member States are causing transboundary effects.

[50] Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (OJ L 334, 17.12.2010, p. 17–119).

[51] Analysis of the Funeral Market in Spain, Available at: https://news.wfuneralnet.com/en/funeral-market-spain/

Driver 1 – Regulatory failure: There is no provision in EU law requiring Member States to control mercury emissions from crematoria. At international level, recommendations for the use of abatement technologies using BAT have been adopted by both the OSPAR and HELCOM Commissions. These Recommendations are non-legally binding and only 15 Member States are signatories to the OSPAR and/or HELCOM Conventions. In this context, what is most apparent from available data is that the use of mercury emission abatement technologies across the EU varies significantly, with very high levels of uptake in some Member States (BE, DE, LU, NL, DK), and much lower uptake in others (PT, ES).

Driver 2 – Behavioural biases: Regarding mercury emissions from crematoria, the number of cremations conducted annually in the EU is increasing. Beyond the spike in numbers linked to the tragic loss of life due to the COVID-19 pandemic, the average increase, but also the variations in cremation rates across the EU is linked to social factors (i.e., costs of services, personal preferences for cremation over burial) and cultural preferences (i.e., religious practices).

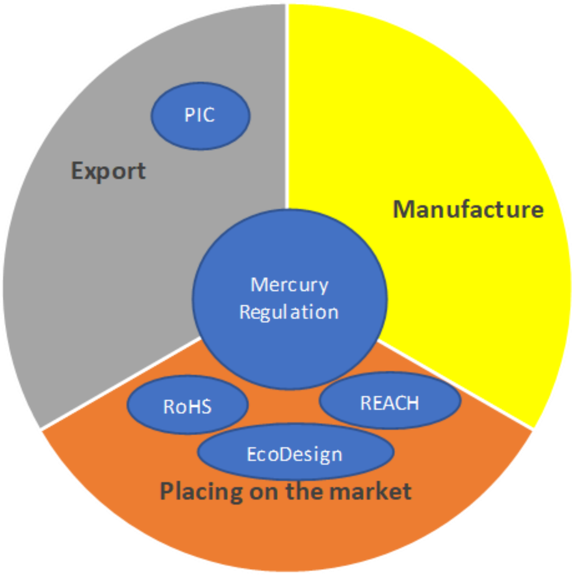
2.3. 2.3. Problem 3 – Manufacture of MAPs for export to third countries

The third problem that this initiative addresses are the adverse impacts of EU exported MAPs on third countries. For the purpose of this initiative, the expression ‘MAPs’ under problem 3 concerns dental amalgam and certain mercury-containing lamps (see also Section 1.2 and Annex 8).

Those exports highlight the current inconsistencies affecting Union law on MAPs. Various EU legal provisions have been developed and implemented to prohibit the placing on the EU market and import into the EU of MAPs, including under REACH, RoHS and Ecodesign[52]. The Mercury Regulation complements those provisions by additionally prohibiting the manufacture and export of those MAPs (see Figure 2). This, in turn, weakens the EU’s position and reputation as a leading player within the international community and jeopardising the objectives set out in the ZPAP on the reduction of the EU’s external pollution footprint. Furthermore, at an EU-level, such inconsistencies can cause regulatory uncertainty for industry.

[52] See Commission Regulation (EU) 2019/2020 of 1 October 2019 laying down ecodesign requirements for light sources and separate control gears pursuant to Directive 2009/125/EC of the European Parliament and of the Council and repealing Commission Regulations (EC) No 244/2009, (EC) No 245/2009 and (EU) No 1194/2012 (OJ L315 of 5.12.2019, p. 209.)

Figure 2: Interaction between EU legal instruments concerning the manufacture and trade of MAPs



As a result, **there are MAPs that are prohibited for placing on the EU market and import into the Union whilst still being manufactured in the Union for export to third countries.** An overview of relevant MAPs currently or soon no longer allowed to be placed on the EU market but allowed for manufacture and export can be found in Table 4 below.

Table 4: Mercury-containing lamps addressed by this impact assessment (as they are not or will soon no longer be allowed on the internal market but continue to be manufactured and exported)

Products
Compact fluorescent lamps (CLFs) for general lighting purposes not already covered by Annex II of the Mercury Regulation
Linear triband phosphor lamps for general lighting purposes not already covered in Annex II of the Mercury Regulation
Halophosphate phosphor lamps for general lighting purposes not already covered in Annex II of the Mercury Regulation
Non-linear tri-band phosphor lamps for general lighting purposes
High Pressure Sodium (vapour) lamps (HPS) for general lighting purposes not exceeding (per burner) in lamps with improved colour rendering index Ra: a) > 60: $P \leq 155$ W b) > 60: 155 W $< P \leq 405$ W c) > 60: $P > 405$ W

The continued export of concerned MAPs is a significant cause of mercury pollution, especially in third countries where EU-made products add to the national burden of hazardous products and increase the risk for local retailers, end-users, and inhabitants. In most low to medium-income third countries, few if any options exist for environmentally sound disposal of mercury-containing end-of-life products[53,54]. In the 2018 Global Mercury assessment[55], it was assumed that in many countries over 95% of MAPs were not separately collected and recycled but ended up in landfills and (much less frequently) in uncontrolled waste incinerators. This causes emissions to the environment and adverse health impacts for those populations that handle waste or live or work near disposal sites. Due to mercury's transboundary nature and accumulation in food chains, mercury that is released anywhere in the world[56] in turn poses a risk to European citizens.

Regarding the size of the identified problem, dental amalgam and mercury-containing lamps are the key MAPs in terms of volume, export values and mercury content. Accordingly, this initiative addresses those products specifically. Considering that a ban on the use of dental amalgam is assessed in this impact assessment (PO2a), problem area 3 also addresses the manufacture and export of dental amalgam in order to align the prohibition of manufacture and export with the ban on use.

Based on previous information on the relative ratio of EU demand, import, and export, it was estimated that with respect to mercury content, dental amalgam is the most relevant exported MAP (Table 5). **The amount of mercury in exported dental amalgam is in the order of 13 to 38 t in 2018.**

Table 5: Estimated mercury content in exported MAPs (only those for which quantitative data is available are listed)

Product	Mercury content in exported product per year
Dental amalgam (in capsules)	13 – 38 t (2019)
Hot cathode discharge lamps (CFLs, LFLs and other double-capped FLs)	0.46 t (2020)
High Pressure Sodium (vapour) lamps (HPS)	≈ 0.024 t (2020)

[53] UNEP (2017) Global Mercury Waste Assessment. 49 pp

[54] UNIDO (2019) No time to waste: International expert group meeting on the sustainable management of mercury waste. 56 pp.

[55] UNEP (2019) Global Mercury Assessment 2018

[56] EEA Report No 11/2018 Mercury in Europe's environment: A priority for European and global action, p.7

Regarding export value, lamps (CFLs, LFLs and other double-capped FLs, HPS) are much more important. According to published export data (EU PRODCOM[57] and UN COMTRADE[58]), in 2020 the EU **exported about 156 million hot cathode discharge lamps** (CFLs, LFLs and other double-capped FLs) with a **value of about €92 million**. This corresponds to a **mercury content in the order of 460 kg**.

Table 6: Estimated value of exported MAPs

Product	No. of exported MAPs (Mio. units)	Value of exported MAPs (Mio. €)
Hot cathode discharge lamps (CFLs, LFLs and other double-capped FLs)	156 (2020)	92 (2020)
Dental amalgam (in capsules)	≈ 21-64 (2019)	≈ 21-64 (2019)
High Pressure Sodium (vapour) lamps (HPS)	≈ 1	Not quantified

A significant share of these lamps exported from the EU are destined for countries with very low collection and recycling rates for electronic waste i.e., 0.4% in UAE[59] and 2.5% in the Russian Federation. Furthermore, as opposed to the EU which requires the installation of amalgam separators in dental practices, dental amalgam waste is often not collected separately in developing countries, but instead ends up in the normal waste stream[60,61,62]. Often, amalgam waste is disposed of in landfills without further treatment or incinerated together with other medical waste. It can therefore be assumed that most of the mercury waste from dental practices is released into the environment.

Following declining demand and global competition, many production lines in the Union for fluorescent lamps have already been closed in recent years. According to available information, the Impact Assessment identified only the four following factories in the EU that still produce fluorescent lamps for general lighting purposes[63]:

- Signify / Philips (PL)

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57 See EU PRODCOMM at https://ec.europa.eu/eurostat/web/main/home

58 See UN COMTRADE at https://comtradeplus.un.org/

59 See United Nations University, UNITAR, ITU, ISWA (2020) The global e-waste monitor 2020; United Nations University, UNITAR, ITU (2021) Regional e-waste monitor for the Arab states 2021; Saudi Daz Electronic and Solid Waste Recycling Factory (2022) What Is E-Waste? Available online at: https://www.dazrecycling.com.sa/e-waste/ (last accessed on 9 March 2022).

60 Singh, R.D.; Jurel, S.K.; Tripathi, S.; Agrawal, K.K.; Kumari, R. (2014) Mercury and Other Biomedical Waste Management Practices among Dental Practitioners in India. BioMed Res. Intl. 2014, ID 272750,

61 Daou, M., H.; Karam, R.; Khalil, S.; Mawla, D. (2015) Current status of dental waste management in Lebanon. Environm. Nanotechn. Monit. Man. 4, 1-5

62 Makanjuola, J.; O.; Ekowmenhenhen, U. I.; Enone, L.; L.; Umesi, D. C.; Ogundana, O. M.; Arotiba, G. T. Chioma, D. (2021) Mercury hygiene and biomedical waste management practices among dental health-care personnel in public hospitals in Lagos State, Nigeria. Afri Health Sci. 2021;21(1):457-69

63 CLASP (2022) Refurbishing Europe's Fluorescent Lamp Manufacturing Facilities. https://www.clasp.ngo/research/all/refurbishing-europes-fluorescent-lamp-manufacturing-facilities/

- Feilo Sylvania (DE)
- Tungsram, announced to be closed by the end of 2022 (HU)
- Ledvance / Osram (IT)

Available information shows that, until recently, there were 23 companies located within the EU that produced dental amalgam. 19 of them have stopped amalgam production in Europe or announced to do so by the end of 2024. The Impact Assessment identified only the following four EU companies producing encapsulated dental amalgam:

- Cavex (NL)
- Madespa S.A. (ES)
- Global Dental Trade (CZ)
- World Work Srl (IT)

Although a trend cannot be predicted for every single product type, a general trend of continuously decreasing EU export of MAPs can be observed. The increasing awareness about mercury-related risks, strengthened national and global legal regulation, and the availability of effective and affordable mercury-free alternatives are the main driving forces to further push MAPs out of the market. An increasing ambition towards eliminating MAPs at international level has led (at COP4) to decisions being adopted at global level. However, the continued level of ambition at future COPs, will still depend on Parties domestic regulatory regime and interests and thus remains uncertain.

In the absence of alignment between the Mercury Regulation and RoHS, inconsistencies within the EU acquis will lead to continued contribution by the Union to the availability of MAPs on the global market.

Problem drivers from Problem 3

Driver 1 – Market failure: Although for many MAPs the transition to mercury-free alternatives is technically feasible, the cost and availability of such alternatives influences the external market choice. Lower product prices that do not reflect environmental and human health costs and mask higher energy costs sustain demand for MAPs. European manufacturers of MAPs are sometimes reluctant to voluntarily leave the MAP market and forego revenues. In addition, the ongoing supply from EU manufacturers slows down the transition process and keeps mercury in circulation globally.

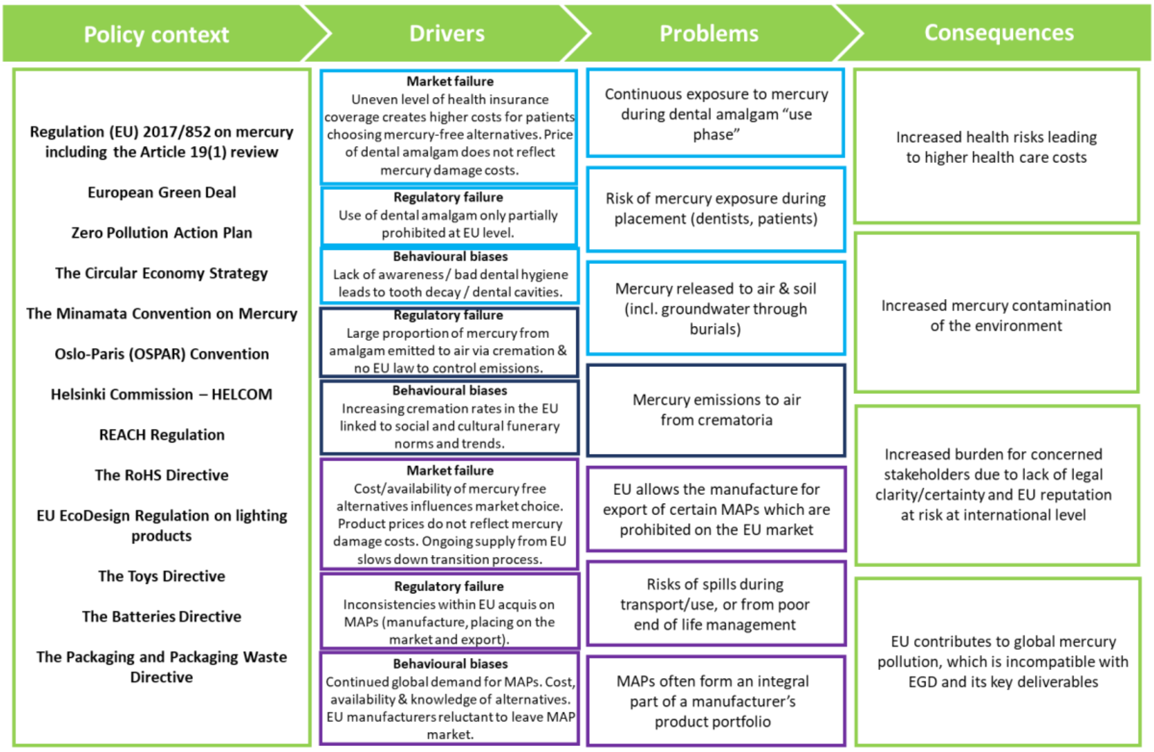
Driver 2 – Regulatory failure: Inconsistencies within EU law on MAPs (placing on the market and import prohibition vs. manufacture and export allowed) entitles the EU to manufacture and export certain MAPs, for which mercury-free alternatives exist. In doing so, the EU supplies the global market with mercury which in turn disincentives the shift towards mercury-free alternatives and harms the EU's reputation in the light of the EGD implementation.

Driver 3 – Behavioural biases: On one hand, there is still a global demand for MAPs affecting a complete transition to mercury-free alternative. Although the switch is usually economically attractive in the medium term, users shy away from the possible high short-term investment costs.

2.4. 2.4. Overview of problems and drivers

Figure 3 below represents the problem tree for the review of the Mercury Regulation.

Figure 3: The problem tree for the review of the Mercury Regulation



2.5. 2.5. Stakeholder views

Problem 1: Almost two-thirds of the consulted stakeholder believe that an EU-wide discontinuation of dental amalgam would require a general phase-out, while 28% believe a gradual phase-down to be chosen by each Member State according to national priorities and conditions would be appropriate. Citizens, civil society organisations, environmental non-governmental organisations (NGOs) and associations of environmental dental practitioners broadly support the elimination of dental amalgam from the market by 2025. Business associations and dental practitioners pointed out several conditions for an efficient phase-out: ensuring that the lower-income population has access to alternative solutions including a full range of dental hygiene prevention measures, promoting research and innovation in chemistry with the aim to find trustworthy and sustainable alternatives to dental amalgam and taking due account of specific medical needs of patients. A handful of organisations voiced concerns about an early phase-out, indicating that trends in oral health prevention and campaigning may suffice to naturally reduce dental amalgam use.

Problem 2: As regards mercury emissions from crematoria, there is a general understanding among stakeholders that they are directly linked to the continued use of dental amalgam and the majority of respondents to the online public consultation (OPC) and targeted survey supported EU-wide policy to control mercury emissions from crematoria. One environmental NGO strongly supported setting mercury emission limit values for all crematoria, while one business association recommended a flexible approach to addressing industrial emissions of mercury, i.e., to identify these specific activities in which mercury remains essential in the manufacturing process while promoting the use of BAT within the industrial sector to minimise them. As part of the targeted consultation, some stakeholders supported EU limits for all crematoria whereas other stakeholders expressed concerns about impacts on smaller crematoria if EU-wide limits were to be established and indicated that less stringent limits could be applied, or they could be excluded entirely.

Problem 3: Business associations, Member State authorities and NGOs agree that, within the context of the Minamata Convention, the EU has a responsibility to continue showing global leadership in phasing out anthropogenic sources of mercury. In this respect, restrictions on the manufacture and international trade of MAPs are a key element, in particular when alternatives are economically and technically feasible. All NGOs voiced a strong opinion that the EU should stop producing and exporting MAPs, which are already banned on the internal market, as this is a practice that directly contradicts the objectives of the EGD. Business associations supported globally harmonised actions but raised doubts about the effectiveness of unilateral EU measures, especially in foreign markets with persistent demand in and supply by third countries.

A full summary of stakeholder activities can be found in Annex 2.

3. 3. WHY SHOULD THE EU ACT?

3.1. 3.1. Legal basis

Articles 191 and 192 of the Treaty on the Functioning of the European Union (TFEU)[64] empower the EU to act *inter alia* to: preserve, protect and improve the quality of the environment; protect human health and promote measures at the international level to deal with regional or worldwide environmental problems.

3.2. 3.2. Subsidiarity: Necessity of EU action

This initiative stems directly from Article 19 of the Mercury Regulation. Paragraph 3 of this provision stipulates that the Commission shall, if appropriate, present a legislative proposal together with its report referred to in paragraph 1. In that respect, the Commission Review Report has concluded on the necessity of EU action to, *inter alia*, establish a complete EU phase-out of the use of dental amalgam and to align Union legislation on MAPs, for the purpose of protecting the environment and human health from mercury pollution (see Annex 6). This can be achieved by Member States, but by

[64] OJ C 326, 26/10/2012.

reason of the nature of the measures to be taken (i.e., uniform prohibition on the use of dental amalgam, alignment of EU law on MAPs), be better achieved at Union level.

3.3. 3.3. Subsidiarity: Added value of EU action

Mercury pollution is transboundary, travelling across national borders, both between Member States and across the frontiers of the EU. Hence appropriate and effective pollution control can be achieved more quickly and efficiently at Union level compared to Member States acting alone in an uncoordinated manner. Furthermore, as explained in sub-section 1.1 of this document, this initiative will contribute to the meeting of the objectives of the EGD and, in particular, of the ZPAP.

Additionally, action at Union level would allow establishing a more consistent and clearer legal framework by addressing all sides of the issue from manufacturing to export. Clear and precise EU-wide rules would enable concerned individuals and legal persons to ascertain the full extent of their rights and obligations.

The EU has always been an instrumental player at global level, advocating the gradual and rapid phase-out of all mercury production, use and trade. EU action, law and policy that is coherent with this policy will therefore strengthen the credibility of the EU and generate a positive impact on health and environment at international level and in third countries.

4. 4. OBJECTIVES: WHAT IS TO BE ACHIEVED?

4.1. 4.1. General objectives

The general objective of this initiative is to close remaining gaps in EU mercury legislation to further contribute to the objectives of (i) the Minamata Convention by protecting human health and the environment from mercury pollution, (ii) the G7 decarbonisation agenda by ensuring more energy efficient lighting products and (iii) the EGD aiming for a non-toxic environment and protecting natural ecosystems and public health from the adverse effects of mercury pollution at EU and global level.

4.2. 4.2. Specific objectives

The initiative aims to address the harmful impacts on health and the environment from mercury pollution currently not regulated or insufficiently regulated by the Mercury Regulation, to prevent, or at least minimise, the emissions of mercury and its compounds from dentistry, crematoria and the production and use of MAPs. There are three specific objectives logically linked to the two problem areas and their respective drivers:

Objective 1 (Dental amalgam use): Phase-out the use of dental amalgam in the EU whilst ensuring access of individuals to affordable mercury-free alternatives in relation to oral health and consumer rights, in order to eliminate exposure and risks associated with dental amalgam.

Objective 2 (crematoria emissions): Reduce emissions from crematoria to levels no longer considered harmful to human health and natural ecosystems, taking full account of the subsidiarity and proportionality principles.

Objective 3 (mercury-added products for export to third countries): Eliminate the manufacture and export of a variety of MAPs, with a view to reducing global mercury consumption and ensuring that the EU leads by example and align the EU acquis on the placing on the market, import, export and manufacturing of MAPs, thereby simplifying Union legislation and providing greater legal certainty for all stakeholders, including relevant industrial sectors.

5. 5. WHAT ARE THE AVAILABLE POLICY OPTIONS?

5.1. 5.1. What is the baseline from which options are assessed?

This section summarises the detailed description and discussion of the baseline provided in Annex 5. The baseline implies the continuation of the existing legal framework and scope. An assessment was made to evaluate whether and to what extent the baseline is dynamic for each of the three problem areas, taking full account of the increased awareness of mercury and its associated environmental and health risks. The key parameters of the baseline are depicted, by problem area, in the following sub-sections.

5.1.1. 5.1.1. Dental Amalgam

Decayed, Missing and Filled Teeth (DMFT) index

To develop a baseline for dental amalgam use in the EU, the DMFT epidemiologic index was used as the predominant population-based measure of caries experience worldwide. This index gives the sum of an individual's decayed, missing and filled permanent teeth for different age groups and for specific years (2000, 2005, 2015, and 2030). Thanks to this model (outlined in Annex 5), the state of dental health in the EU in 2019 was calculated and the DMFT index for all ages for all Member States was determined. To further develop the baseline, three sets of data were necessary to estimate the quantity of mercury used for the treatment of dental cavities:

Mercury content of dental amalgam capsules

Since 1 January 2019, dental amalgam is only allowed to be used in the EU in pre-dosed encapsulated from and the use of bulk mercury is prohibited. Dental amalgam capsules are round-ended plastic cylinder containing amalgam alloy and mercury. The content of mercury in dental amalgam capsules was identified for different types of capsules. The baseline assumes a total mercury content of amalgam capsules of **~590 ± 110 mg**.

Share of dental amalgam use

The share of dental amalgam use per Member State was approximated using a variety of data sources. The data clearly shows the difference in the share of dental amalgam use across Member States ranging from 0% to over 50%. The share of dental amalgam use per Member State is available in Annex 5 and includes baseline projections for 2030.

Share of dental amalgam capsules placed in the tooth

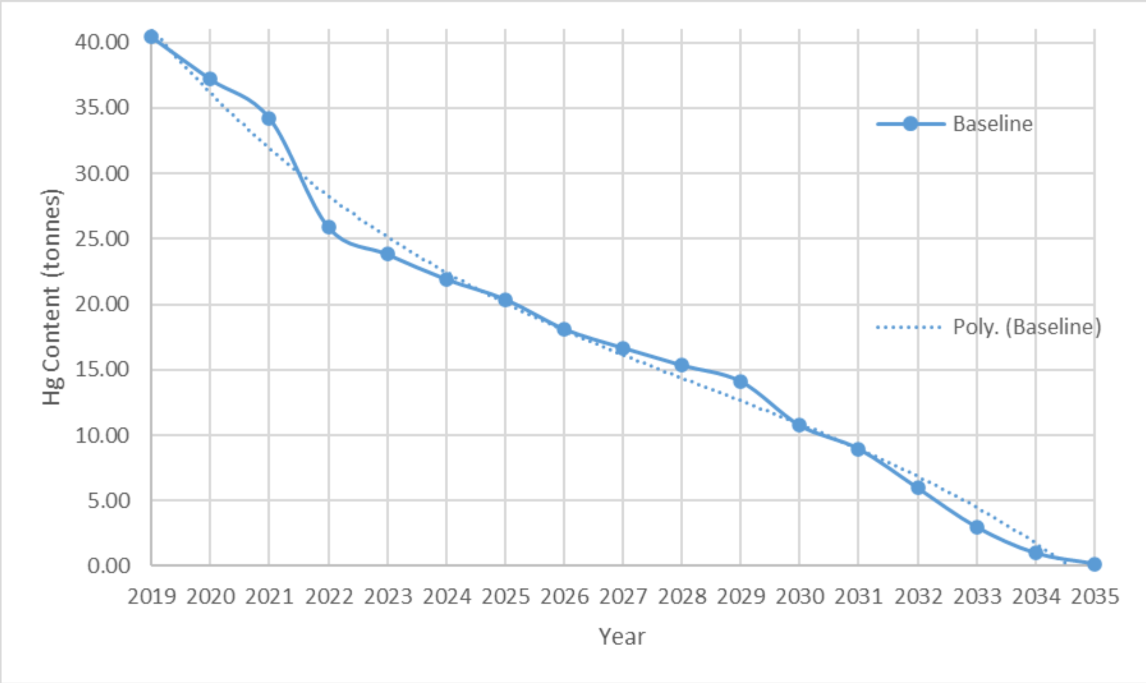
The share of dental amalgam capsule content put in patients' teeth was estimated to range from **26% to 66%**[65] which would represent a range of **125 mg to 462 mg per filling**.

Using the above information in combination with the population data from Eurostat for 2019 with projections to 2030 and the DMFT estimates for all Member States for 2019 and 2030, it was possible to estimate the quantities of mercury used in the EU due to dental amalgam use in 2019 and 2030.

The mean total mercury used in dental amalgam in the EU (Figure 4) is estimated to be **40.4 t in 2019** (of which 18.6 t are placed in teeth and 21.8 t are wasted) (with the lower estimate being 31.6 t and the upper estimate being 50.3 t). Mercury use is expected to decrease to **11.2 t by 2030** (with the lower estimate being 7.1 t and the upper estimate being 16.8 t). The use of dental amalgam is projected to be nearly totally phased out (reduced to 0.16 t) by 2035, subject to Member States continuing to reduce such use at a similar rate to the previous 10 years (which is not guaranteed). This reduction is mirrored by a decline in the number of manufacturers producing dental amalgam. In the EU, only four (out of nine) dental amalgam manufacturers (NL, ES, CZ, IT) remain to date, who also produce a variety of mercury-free dental filling materials.

Figure 4: Baseline projections for dental amalgam use (EU27)

[65] Drummond, James L. et al. "Mercury Generation Potential From Dental Waste Amalgam". Journal Of Dentistry, vol 31, no. 7, 2003, pp. 493-501. Elsevier BV, doi:10.1016/s0300-5712(03)00083-6. Accessed 29 Mar 2022.



The figures obtained for mercury use in dental amalgam in the different Member States in 2019, 2025 and 2030 can be found in Table 1 above (uncertainties and assumptions made during the quantification of mercury use in the EU are available in Annex 5).

Emissions from dental amalgam

Dental amalgam use (including wasted amalgam) in 2019 and 2030 (as part of the baseline) as well as their estimated emissions are presented in Table 7 below.

Table 7: Total dental amalgam inputs and outputs (2019 and 2030)

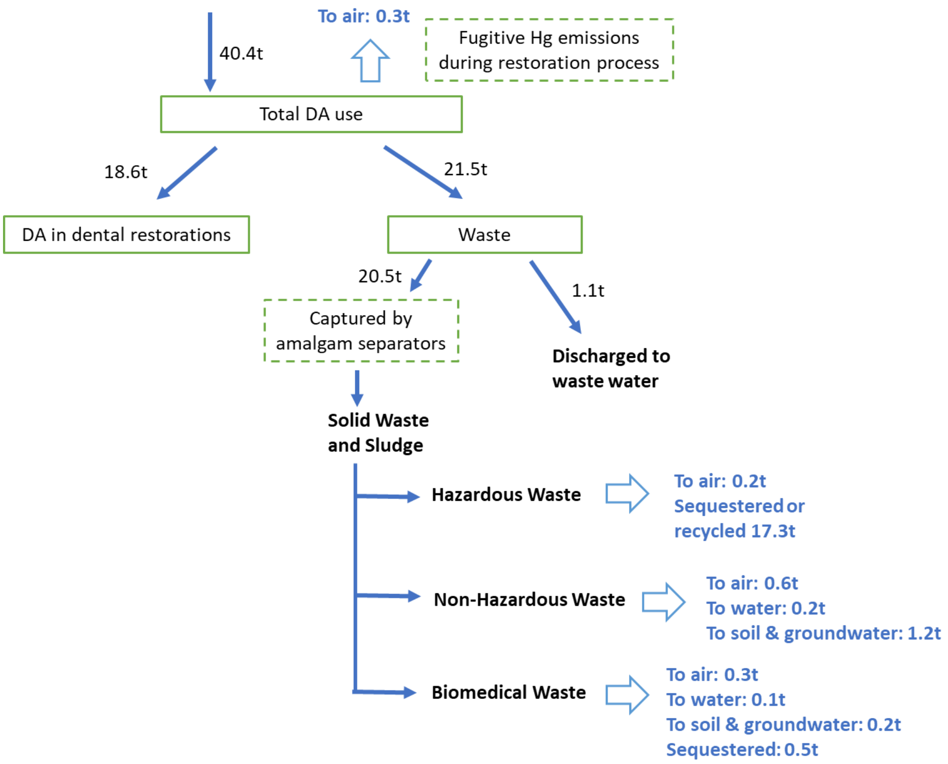
Fate of Dental Amalgam (DA)	T of Hg per year (2019)	T of Hg per year (2030)
TOTAL DA INPUTS		
Total DA	40.4	11.2
DA used in restorations	18.6	5.2
DA to waste	21.8	6.0
TOTAL DA OUTPUTS		
Emissions to air	1.3	0.4
Emissions to water[66]	0.3	0.1
Discharged to	1.1	0.3

[66] Refers to discharges direct to the aquatic environment.

Fate of Dental Amalgam (DA)	T of Hg per year (2019)	T of Hg per year (2030)
wastewater[67]		
Emissions to soil	1.4	0.4
Sequestered or recycled	17.8	4.9

Any mercury used in dental amalgam will, in the short, medium or long-term, enter the environment via various pathways (see Figure 5).

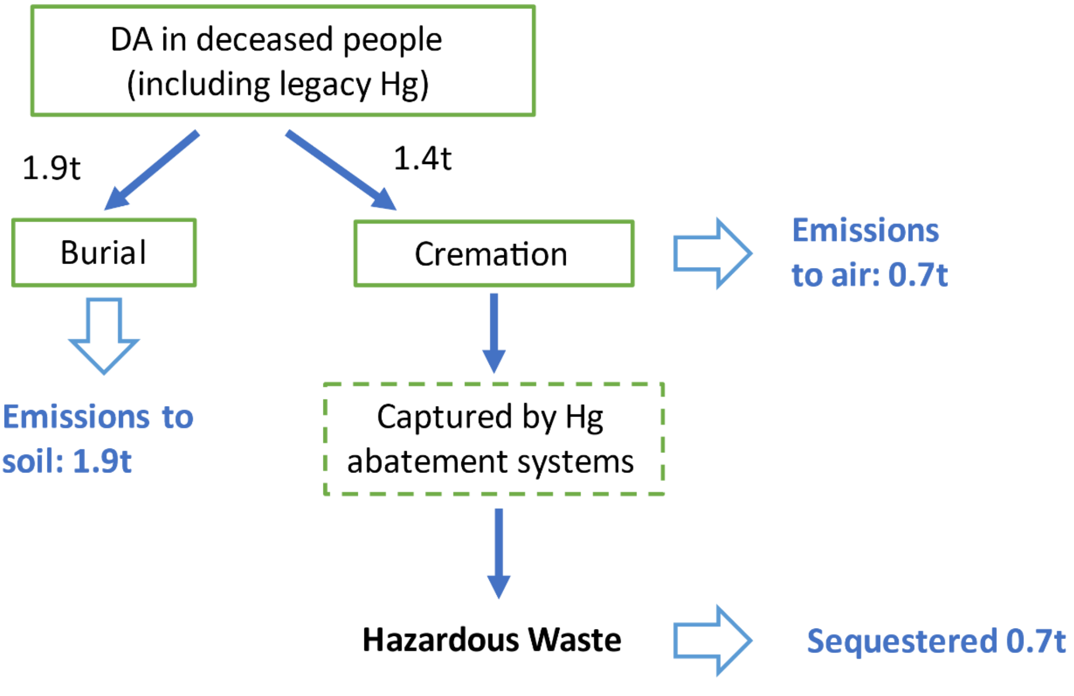
Figure 5: Fate of mercury and flows into the environment resulting from dental amalgam use (2019)



[67] Refers to discharges to wastewater streams, ultimately reaching wastewater treatment plants.

Additionally, the releases of mercury to the environment in 2019 as a result of dental amalgam in deceased people' mouths are displayed in Figure 6. These emissions are displayed separately from the releases from dental use, as the former account for legacy mercury (i.e., mercury in dental amalgam restorations fitted in patients' teeth in 2019 as well as previous years), while the latter only account for releases in 2019 (i.e., mercury used in restorations fitted in patients' teeth in 2019 only).

Figure 6: Fate of mercury and flows into the environment resulting from dental amalgam in deceased people (2019)

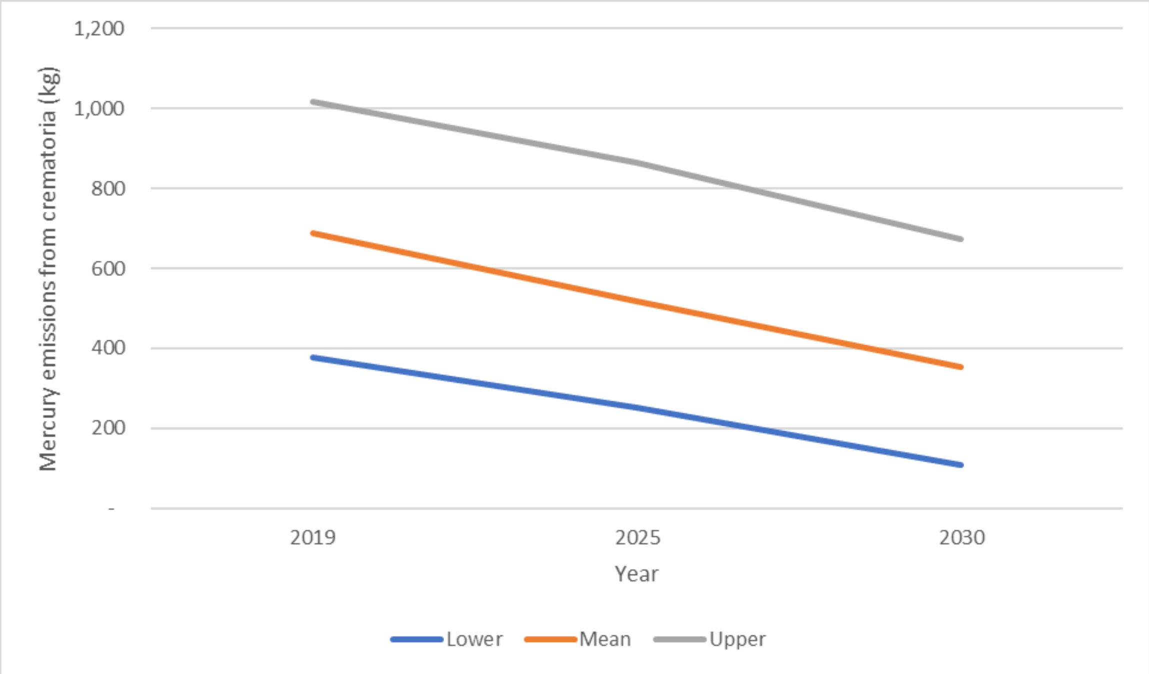


The three phase-out scenarios assessed within this Policy Option would reduce these environmental releases to zero as the underlying source, continued dental amalgam use, is eliminated, except in the few cases where such a use will remain justified to address specific medical conditions.

5.1.2. 5.1.2. Emissions from crematoria

Estimated emissions for individual Member States in 2019 and in 2030 are presented in Annex 5. Total mercury emissions are estimated at **0.69 t in 2019**. Emissions in **2030 are estimated at 0.36 t**. All Member States are predicted to see a decline in emissions over this period as a result of declining use of dental amalgam in the baseline. Figure 7 displays the predicted evolution of mercury emissions from crematoria under the baseline scenario.

Figure 7: Baseline projections for mercury emissions from crematoria (EU27)



These figures (for 2019) are lower than those reported by the Member States under the CLRTAP as set out in Section 2.2 and Figure 1. It is likely that the emissions inventory data reported under the CLRTAP are largely derived using a top-down approach based on a simplified approach. In defining the baseline for this assessment, a bottom-up approach to quantifying emissions has been adopted which is considered more representative. This involved exploring trends and activity levels in the underlying drivers in order to build up to an estimate of crematoria emissions as well as considering existing controls already applied in some Member States.

In constructing a baseline, four underlying drivers were considered separately before they were drawn together to estimate crematoria emissions. The framework for combining these separate factors into a quantified reference scenario of mercury emissions from crematoria is set out in Annex 5. In addition, for the analysis of impacts of different policy options, a dynamic baseline has been developed with or without a phase-out of dental amalgam (being considered as part of Problem 1).

Note: All impacts of Policy Options addressing mercury emissions from crematoria in subsequent sections are assessed relative to a baseline assuming no phase-out of dental amalgam. However, such a phase-out would have significant impacts on the effectiveness and efficiency of PO3 and PO4a and b, i.e., considering that the average lifetime of dental amalgam fillings is 15 to 20 years, a phase-out in 2025 would mean that most dental amalgam will be removed from people's mouths by 2045, hence decreasing the amount of mercury reaching crematoria. The combined impact of PO3 or PO4a and b and a phase-out of dental amalgam are therefore considered in the assessment (Section 6) and comparison of options (Section 7).

Annual cremation rates per Member State

Data for each Member State were obtained from the Cremation Society for the period 2010 to 2019 where available. These were used to extrapolate historical trends to a future baseline year of 2030 using a linear regression (see Annex 5). The projected cremation rates from 2019 to 2030 show an overall increased trend across the EU with some Member States expected to experience a significant rise in cremation rates e.g., Germany's cremation rates rising to above 97% in 2030 and Poland's cremation rate doubling to reach 61% in 2030. Targeted stakeholder feedback also confirmed an overall increasing trend in numbers of cremations.

Complete data are available only up to the year 2019 and therefore do not reflect the very sad and sudden increase in mortality rates brought about by the COVID-19 pandemic. Limited data on 2020 cremation rates in some Member States were accessed during targeted stakeholder consultation.[68] Although most cremation rates had increased in 2020 in comparison to 2019 rates, the amount by which they increased varied greatly, and some Member States even saw modest decreases in cremation rates (NL and SE). Large increases between 2010 and 2019 were seen in BE (58% increase), IE (75% increase) and IT (47% increase). Most other Member States for which data is available saw an increase closer to 5-7% from 2019 rates. However, it is expected that as the pandemic diminishes, cremation rates will return to pre-pandemic trends. Consequently, future projections are based solely on pre-pandemic trends.

Total corpse mercury content

The mercury content for corpses in different age bands was calculated for each Member State. This was based on (i) the mean number of decayed, missing and filled teeth (DMFT) for each age group; (ii) the relative share of amalgam use in dental restorations and (iii) the typical mercury content of a dental amalgam filling. Details on this methodology are set out in Annex 5, which links the baseline for crematoria with the one on dental amalgam.

Uptake of emissions abatement technologies

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[68] 2020 cremation rates for BG, CZ, DE, DK, EL, FI, HU, IE, LT, NL, PT, SE and SL were provided via direct correspondence with the International Cremation Federation on 25th July 2022.

Historical data on uptake of emissions abatement systems at crematoria are limited and it was not possible to obtain any further information through the stakeholder survey; it was therefore not possible to robustly project uptake trends into the future. It was therefore assumed that, under a business-as-usual baseline scenario, future uptake of abatement systems would remain at the same level as current levels (presented in Annex 5).

Mercury removal efficiency of abatement systems

For this assessment, it has been assumed that 100% of mercury reaching crematoria in corpses is emitted to air during cremation. This assumption is considered an accurate approximation of operating conditions[69]. Data collated from the literature on mercury removal efficiencies for the most widely used abatement technologies are presented in Annex 5.

Where no further country-specific removal efficiency could be obtained, an upper value of 99.9% was assumed along with a lower value of 90% and a central value of 95%. This is based on reported removal efficiencies for carbon injection and solid bed filtration, the most widely used abatement technologies.

5.1.3. 5.1.3. Mercury-added products for export to third countries

Based on the problem description, three groups of MAPs have been selected as they constitute the vast majority of MAPs both in number and value currently being manufactured and exported from the EU.

- Dental amalgam
- CFLs for general lighting purposes
- Double capped hot cathode fluorescent lamps for general lighting purposes (mainly LFLs)

The baseline scenario aims to provide a reference point against which the potential impacts of an EU-wide manufacture and export prohibition can be assessed. This requires a reasonable estimation of the current manufacture in the Union and export from the EU of MAPs. Third countries' legal regimes, national programmes and initiatives that will lead to a change in demand of products exported from the EU were analysed and taken into account.

A baseline scenario was developed, which assumes:

- No further legal actions in the EU beyond those already agreed or planned to take place,

[69] Piagno and Afshari (2020). Mercury from crematoriums: human health risk assessment and estimate of total emissions in British Columbia. https://doi.org/10.17269%2Fs41997-020-00327-0

- The impact of national measures in importing third countries in response to restrictions already laid down in EU law.

The baseline does not include the additional mercury-containing lamps (triband phosphor lamps and halophosphate lamps), for which Parties decided to defer to COP5 the possible decisions on their phase-out dates (2025, 2027 or 2030), since it entails a relatively high level of uncertainty in terms of outcome. COP Decisions to determine if, when and to what extent a specific MAP will be restricted under the Minamata Convention are not in the hands of the EU alone. In practice, consensus needs to be reached among all 139 Parties whose national interests in this matter may vary significantly and where major economies can show strong resistance.

For the baseline scenario, future exports of relevant MAPs in terms of number, value, and mercury content were estimated based on identified current and past trends.
Predicted export volumes for 2025 and 2030

Regarding dental amalgam and considering the expectations expressed in a WHO study[70] (75% of participants foresaw a phase-out by 2030) and data on declining use in the USA and Canada, it is expected that the demand for EU-made encapsulated amalgam will decrease and that exports will **decrease by 25% to 75% of the current levels by 2030**. The already large uncertainty concerning current dental amalgam exports only allows a rough calculation of the order of future export volumes. The mercury content of these exports is estimated to range from 13-55 million capsules with a total **mercury content of 7-32 t in 2025** and 5-48 million capsules with a total mercury content of **3-28 t in 2030**.

Regarding other MAPs (more specifically, mercury-containing lamps), the projected exports (in terms of units) for the baseline is summarised in Annex 5. For the baseline, it is expected that, **by 2025, export volumes for all CFLs and LFLs would fall to around 83-141 million units**. **By 2030, the numbers would fall to between 49 and 83 million units**. The calculated decrease is stronger for CFL lamps. In comparison to 2020, exports are predicted to **decrease by 47-68%.**

The value of all above-mentioned exported lamps decreases from €92.2 million (2020) to approx. €59 million by 2025 and to approx. €29 million by 2030.

Due to an increased shift towards LED lamps, in the EU, there are only four remaining manufacturers (the two largest are located in DE and PL) that continue to produce mercury-containing lamps, although even their production lines are increasingly focused on the production of LEDs. One of the four plants (located in HU) has already announced its closure by the end of 2022. The amount of mercury exported via CFLs and LFLs is estimated at **450-501 kg in 2020**[71]. This quantity would decrease to about **245-414 kg by**

[70] WHO (2021) Report of the informal global WHO consultation with policymakers in dental public health, 2021: monitoring country progress in phasing down the use of dental amalgam

[71] This value was calculated on basis on of available information on the mercury content per lamp in 2022. The actual value in 2020 was probably higher.

2025 and to about **146-246 kg by 2030**. The wide range follows from the uncertainty of the average mercury content of the exported lamps.

5.2. 5.2. Description of the policy options

The policy options have been developed from the list of potential policy measures, which were identified based on the findings of Commission Review Report and input from Member States and stakeholders. These measures were screened to identify those that should be retained for further analysis.

The screening process resulted in a list of 13 measures retained for impact assessment, including three for dental amalgam, six for crematoria emissions and four for MAPs. After impact assessing all policy options, six were retained (two for dental amalgam, two for crematoria emissions and two for MAPs). Whilst most are relatively independent from each other, some of them contribute to several specific objectives. Others are mainly relevant for a single objective. Annex 7 contains the list of measures which were screened out, as well as the rationale for not retaining them.

Problem 1: Health and environmental risks associated with the use of dental amalgam

Policy Options for Problem 1 are mapped below in Figure 8.

Policy Option 1 (PO1) – Dental health communication campaigns: It may provide for several information campaigns to improve the knowledge and understanding of patients and healthcare practitioners, such as:

- A patient awareness campaign on the current knowledge of the risks associated with amalgam and the indications for the removal of old amalgam
- A campaign to evaluate current professional practices in relation to monitoring of urinary mercury in health professionals
- The continuation of training for future practitioners on the risks associated with removal of dental amalgam and related waste management beyond 2030

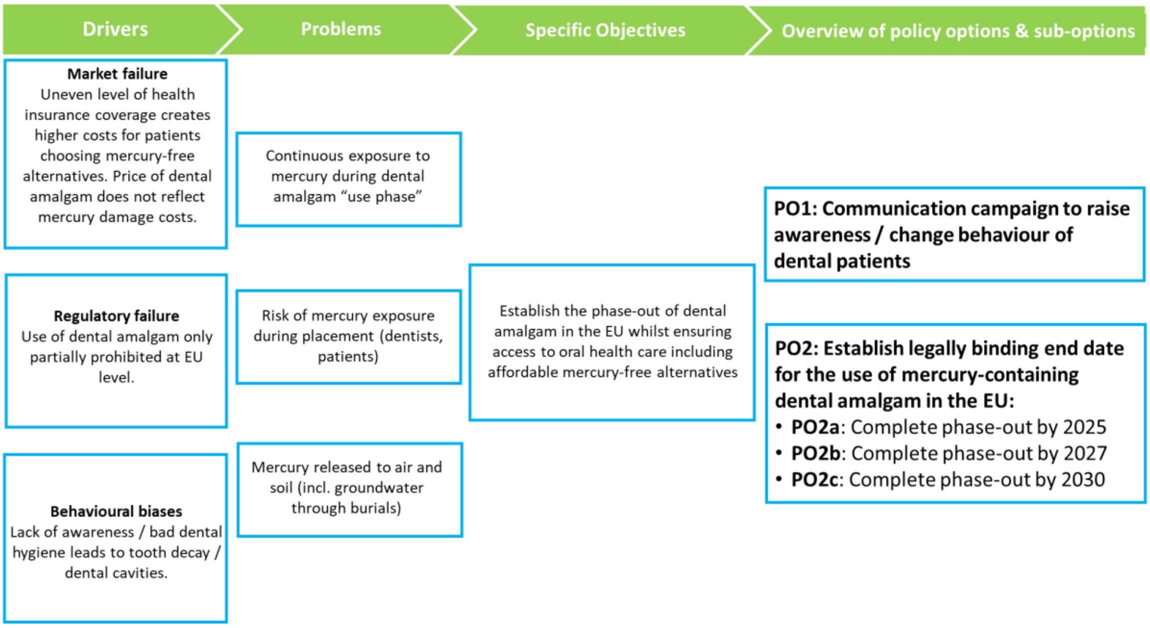
Policy Option 2 (PO2) – Establish a legally binding end date for the use of dental amalgam in the EU: This option foresees an amendment of the Mercury Regulation establishing a legally binding phase-out of dental amalgam use in the EU. The exact impacts of PO2 would depend on the timelines of the EU-wide ban, and the following scenarios have been assessed:

- **PO2a**: a phase-out with a 2025 deadline
- **PO2b**: a phase-out with a 2027 deadline
- **PO2c**: a phase-out with a 2030 deadline

Note: This Policy Option would not affect the existing derogation set out under Article 10(2) of the Mercury Regulation allowing continued use of dental amalgam in the very few cases where the dental practitioner deems it strictly necessary to treat specific medical conditions (e.g., allergies). Considering that this option would prohibit the use

(PO2) and manufacture and export of dental amalgam (PO6 below) in the Union, dental amalgam required to address those limited specific cases would either be imported and/or sourced from existing stocks in the EU.

Figure 8: Mapping of policy options addressing the continued use of dental amalgam



Problem 2: Health and environmental risks associated with mercury emissions from crematoria

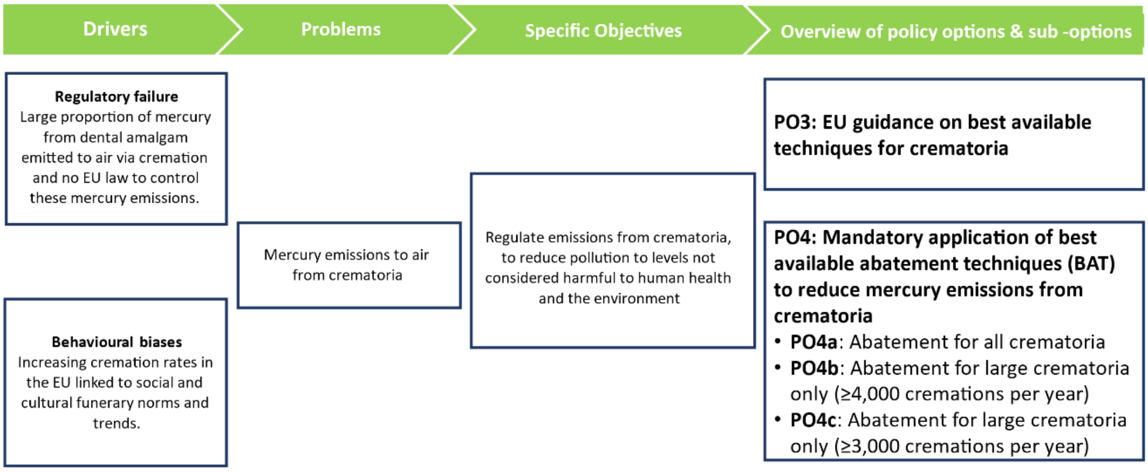
Policy Options for Problem 2 are mapped below in Figure 9.

Policy Option 3 (PO3) – Guidance on abatement technology: It provides for EU guidance on abatement technology for controlling mercury emissions from crematoria, including adsorption techniques. Such guidance could describe various available abatement techniques and the costs associated with installing, operating and maintaining these, taking into account the existing OSPAR and HELCOM recommendations.

Policy Option 4 (PO4) - Mandatory abatement of mercury emissions: provides for EU-wide mandatory application of abatement technology using BAT**.** A number of routes to delivering PO4 have been assessed[72]:

- **PO4a** – Abatement for all crematoria: assumed to deliver a 100% uptake in emissions abatement systems in all crematoria across the EU.
- **PO4b** – Abatement for large crematoria: only crematoria above a certain number of cremations per year would be required to install abatement. The threshold is set at ≥4,000 based on Table 9 (below) that shows that below this threshold the benefits to cost-ratio falls rapidly under breakeven point.
- **PO4c** – Abatement for large crematoria: only crematoria above a certain number of cremations per year would be required to install abatement. The threshold is set at ≥ 3,000 based on Table 9 (below).

Figure 9: Mapping of policy options addressing mercury emissions from crematoria



Problem 3: Health and environmental risks associated with MAPs manufactured in and exported from the EU

Policy Options for Problem 3 are mapped below in

[72] Best Available Technique (BAT)/Associated Emission Levels (AELs), Mercury benchmarks / reduction targets, Burden-sharing agreements, National mercury reduction commitments.

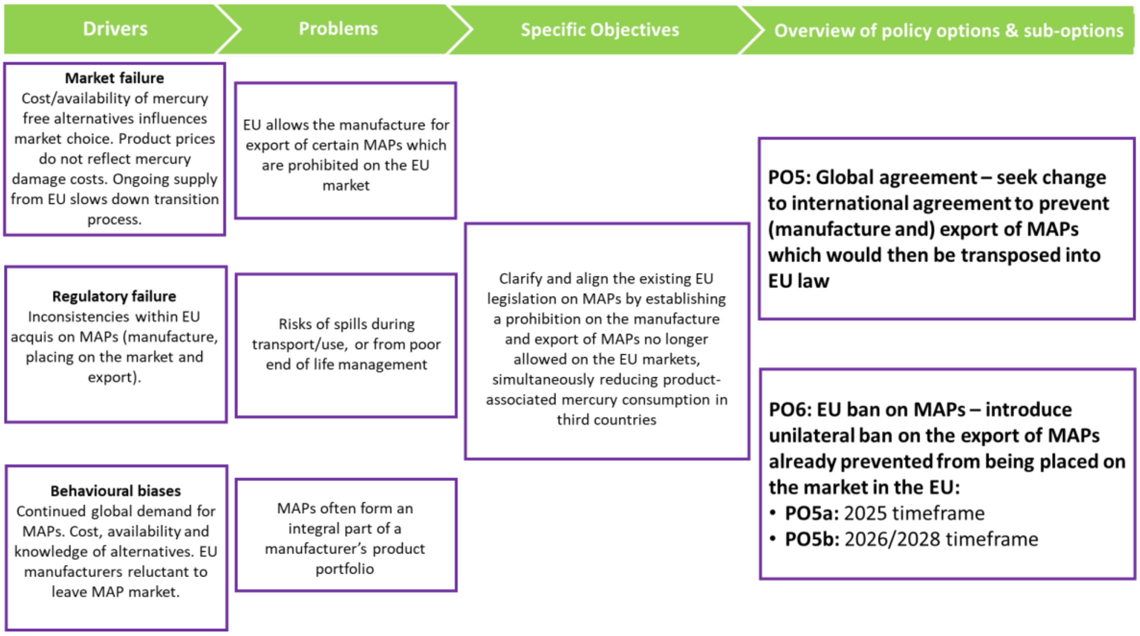
Figure 10 10.

Policy Option 5 (PO5) - Global agreement: It addresses the continued manufacture in and export from the EU of dental amalgam and concerned mercury-containing lamps by seeking international agreement, under the Minamata Convention, to prohibit it. The EU would need to negotiate and achieve global agreement on amendments to Annex A of the Convention, which lists MAPs and sets deadlines after which the manufacture, export and import of the concerned MAPs is no longer allowed. Implementation of such a global agreement into EU law could then be done by amending the Mercury Regulation via Delegated Acts (in line with its Article 20).

Policy Option 6 (PO6): EU ban on MAPs: It assesses the possibility of introducing an EU-wide ban on manufacturing and exporting dental amalgam and concerned mercury-containing lamps. Two timeframes were considered by which such EU-wide ban could enter into force:

- **PO6a**: 2025
- **PO6b**: 2026/2028 based on the earliest phase-out dates retained for negotiations at the next Conference of the Parties to the Minamata Convention (COP5) (further described in Annex 8, 2026 for halophosphate LFLs and 2028 for all other considered lamp types)

Figure 10: Mapping of policy options addressing the manufacture and export of MAPs



6. 6. WHAT ARE THE IMPACTS OF THE POLICY OPTIONS?

This section presents an assessment of the impacts of all options against the baseline. As options and sub-options are packages of measures, the impact assessment builds on the assessment of the impacts of the individual measures, which is available in Annex 8.

6.1. 6.1. Problem 1 – dental amalgam use

6.1.1. 6.1.1. Analysis of Policy Option 1 – Dental health communication campaigns

Economic impacts

The impact of the measures taken by Member States under PO1 is expected to be positive regarding employment. Jobs may first be created for organising awareness-raising activities, although these jobs may use the existing personnel or temporary ones created only for a short period. Jobs may also be created to train dentists in mercury-free restoration techniques. Finally, as this option is expected to foster innovation in mercury-free filling materials, it may also generate new employment opportunities in R&D activities within the dental industry.

Environmental impacts

The non-mandatory nature of this option makes it difficult to quantify the potential human health impacts. Any reduction in the use of dental amalgam would result in direct health benefits from reduced patient exposure to mercury. It would also result in reduced emissions of mercury to the environment from both direct (dental practices) and indirect sources (including crematoria emissions) and would reduce public environmental exposure to mercury. The voluntary character of the option however means that there is no certainty regarding environmental and health benefits.

Social impacts

The impact of health improvement campaigns cannot be measured in absolute magnitude but on the degree of their effectiveness. For such campaigns, studies have highlighted various aspects of socio-economic inequality, which will impact their effectiveness, including coverage of state social security, patient income disparities, and dependence on public versus private dental insurance.

Stakeholder views

About 89% of the stakeholders who responded to the OPC, including almost all companies and business associations, believe that dental health in the EU could still be improved. Such improvement can be achieved by a continuous/further expansion of prevention measures at the national level, in which communication campaigns play a significant role. Stakeholders also believed corresponding developments can already be seen in Member States that have increased their focus on prevention.

6.1.2. 6.1.2. Analysis of Policy Option 2 – Establish a legally binding end date for the use of dental amalgam in the EU

Economic impacts

Conduct of business: Considering that six out of the nine manufacturers have already (or will soon) discontinue the production of dental amalgam, the impact of a dental amalgam phase-out would be limited to those few remaining manufacturers (SME's). For some of these remaining manufacturers, existing certificates issued under the previous Medical Device Directive 93/42/EEC[73] were due to expire on 31 December 2028 in accordance with the new Medical Device Regulation EU 2017/745[74]. No information on whether any of these manufacturers have sought to apply for new certificates under this Regulation has been identified.

The extent of potential adverse effects on those manufacturers will therefore depend on the share of dental amalgam in their overall production and the capacity to switch production lines to mercury-free alternatives. Although the four remaining EU dental amalgam manufacturers are considered SMEs, available information suggests that they

[73] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1).

[74] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

do not rely solely on the production of dental amalgam but also produce mercury-free alternatives and other medical devices. Although information is limited for this sector, the small number of remaining EU manufacturers and their capacity to shift to other product lines implies a limited economic impact of a manufacture and export ban. Companies with a high share of mercury-free materials in their production will gain an even more significant competitive advantage.

Although dental practices are considered micro-enterprises, the associated costs of a phase-out of the use of dental amalgam are considered negligible for dentists as the costs are passed on to patients (or in some Member States, the re-imbursement schemes). Costs incurred by dentists due to the maintenance of amalgam separators and the collection and treatment of amalgam waste as hazardous waste will not change as legacy dental amalgam will need to be treated. In the short-term, a phase-out scenario may put pressure on the few remaining dentists who have limited experience in carrying out mercury-free restorations. On the other hand, a phase-out will generate a competitive advantage for dentists already fully skilled in mercury-free restoration techniques.

Consumers and households: Currently, the use of dental amalgam affects EU citizens mainly through their tax contributions to the costs of managing mercury-contaminated urban wastewater and municipal waste (usually included in local taxes). If the installation of separators has not already led to sufficiently low levels of mercury in sewage sludge, an amalgam phase-out would ultimately (in the long-term) result in an even lower input of mercury into the wastewater system. Overall, this will have a positive economic impact on municipalities and taxpayers, as it will reduce the environmental costs associated with managing mercury pollution from dental amalgam.

Dental restoration costs borne by the patients depend on four main factors, i.e. (i) the cost of the filling material (negligible difference between dental amalgam and alternatives), (ii) reimbursement by the social security and/or private medical insurance, (iii) the longevity of restorations and (iv) labour cost for the treatment. The difference in cost of restorations can vary across the EU (see Table 8 although the data is from 2018 and cost differentials are expected to have further narrowed as more Member States phase out dental amalgam use and experience with use of alternatives increases). In DK (a Member State with long-term experience with dental amalgam phase-out), dental amalgam use decreased to 1.7% by 2017, and the cost difference associated with this shift to mercury-free alternatives has been estimated to be about €6 per treatment. This figure is therefore considered most representative of the cost differential if a full EU phase-out were to be applied.

Table 8: Price difference between dental amalgam and its alternatives per Member State

Country	Price per restoration (dental amalgam) (EUR)	Price per restoration (alternatives) (EUR)	Price difference (EUR)
AT	97.5	97.5	0
BE	52.5	52.5	0
BG	13.0	13.1	0.1
CY	60.0	60.0	0
CZ	19.2	19.3	0.1

Country	Price per restoration (dental amalgam) (EUR)	Price per restoration (alternatives) (EUR)	Price difference (EUR)
DE	48.2	75.0	26.8
DK	54.2	60.6	6.4
EE	28.3	28.5	0.2
ES	46.1	46.1	0
FI	50.0	50.0	0
FR	40.0	40.0	0
EL	50	60	10
HR	23.0	23.2	0.2
HU	20.4	20.6	0.2
IE	50.0	51.5	1.5
IT	125.0	175.0	50
LT	19.9	20.0	0.1
LU	58.0	71.0	13
LV	15.0	25.0	10
MT	70.0	70.0	0
NL	45.0	67.3	22.3
PL	19.0	19.1	0.1
PT	33.7	33.7	0
RO	13.9	14.0	0.1
SE	N/A	105.0	N/A
SI	26.0	48.5	22.5
SK	22.7	22.9	0.2
UK	42.7	45.8	3.1
EU 28	40.8	50.5	9.7

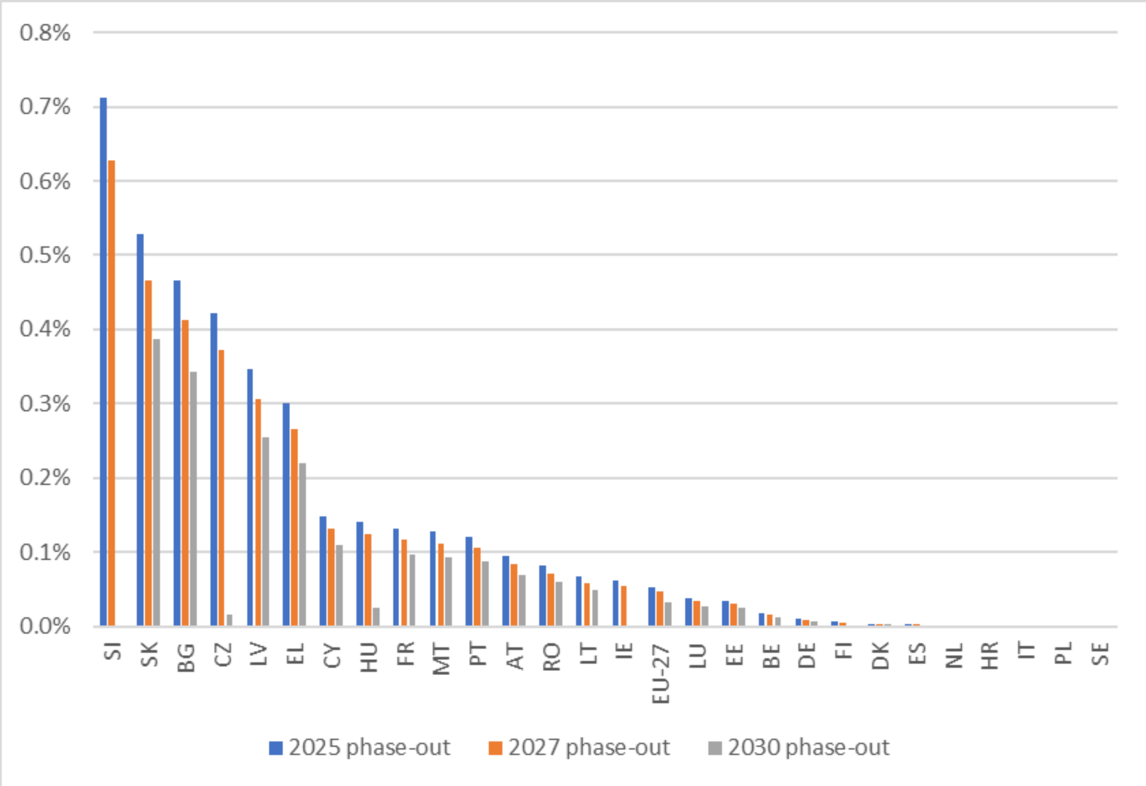
Based on this information, the additional annual costs to EU consumers (i.e., national care health systems) using alternatives in the first year of the phase-out of dental amalgam (i.e., 2025, 2027 or 2030) are estimated as follows:

- €208 million in 2025 (with a phase-out in 2025 i.e., PO2a)
- €170 million in 2027 (with a phase-out in 2027 i.e., PO2b)
- €114 million in 2030 (with a phase-out in 2030 i.e., PO2c)

The cost of a dental amalgam phase-out per Member State is available in Annex 7. Considering the difference in the use of dental amalgam across the EU, the distribution of these costs will affect Member States differently. However, the economic impact of a phase-out of the use of dental amalgam is expected to be minimal compared to Member States national healthcare budgets.

Figure 11 illustrates that the greatest burden of a dental amalgam phase-out on the national healthcare budget may be incurred by SI, SK, BU, and the CZ (between 0.4% and 0.7% of their national healthcare budgets). This is based on the assumption that all costs associated with a shift towards mercury-free alternatives are covered by national insurance schemes. However, it is likely that this will not be the case for all Member States where costs may be shared over national or private insurance schemes or transferred to patients (see Figure 12).

Figure 11: Cost to Member States associated with dental amalgam phase-out (2025, 2027 and 2030), expressed as a % of national healthcare budgets



Environmental impacts

A phase-out of dental amalgam would lead to a sudden drop to zero of its use in the deadline year. Small amounts of mercury may however still be used to treat patients with specific medical conditions.

The cumulative reductions in mercury used in dental restorations up until the year 2035 are given below for each of the three phase-out scenarios:

- **PO2a (2025 phase-out)**: a reduction in mercury use of 114.4 t by 2035
- **PO2b (2027 phase-out)**: a reduction in mercury use of 75.9 t by 2035
- **PO2c (2030 phase-out)**: a reduction in mercury use of 29.8 t by 2035

Previous assessments estimated the total mass of mercury in people's mouths in the EU-27 (excluding Croatia but including the UK) at over 1,000 t[75]. The total population

[75] European Commission (2012). Study on the potential for reducing mercury pollution from dental amalgam and batteries: Final report. https://ec.europa.eu/environment/chemicals/mercury/pdf/mercury_dental_report.pdf

mercury load will be declining as a result of existing actions taken by the Member States to eliminate or reduce the use of dental amalgam. The phase-out scenarios would facilitate a quicker reduction in the population mercury load, although it is not possible to reliably quantify this change in reduction.

The cumulative reductions in environmental releases of mercury up until the year 2030 resulting from the phase-out scenarios, considering the mass flows set out in Figure 5, are displayed in Table 9.

Table 9: Cumulative reductions in environmental mercury releases resulting from phase-out scenarios

Fate of Dental Amalgam (DA)	T of Hg (PO2a 2025 phase-out)	T of Hg (PO2b 2027 phase-out)	T of Hg (PO2c 2030 phase-out)
Emissions to air[76]	3.1	1.3	0.4
Emissions to water[77]	0.6	0.3	0.1
Discharged to wastewater[78]	2.6	1.1	0.3
Emissions to soil	3.4	1.4	0.4
Sequestered or recycled	42.1	17.9	4.9
Total	51.7	22	6.1

In addition, a phase-out of dental amalgam would result in indirect environmental benefits through reduced mercury emissions from crematoria, although the continued arrival of mercury to crematoria in ‘legacy’ restorations means that emissions reductions would be delayed and would not follow dental amalgam use in immediately dropping to zero. Relative to a baseline assuming no EU-level phase-out of dental amalgam, the PO2 scenarios are anticipated to have the following impacts in terms of mercury emissions from crematoria in 2030 (relative to baseline emissions of 355 kg). The below figures represent a snapshot of changes in emissions in 2030, and not cumulative emissions savings over a set period of time. They take account of emissions from ‘legacy’ amalgam in old dental restorations, hence continued crematoria emissions even after the phase-out of dental amalgam. The figures highlight that an earlier dental amalgam phase-out would deliver much greater crematoria emissions reductions sooner (both in 2030 and cumulatively from the date of a ban).

- **PO2a (2025 phase-out)**: a reduction in mercury emissions of 54 kg
- **PO2b (2027 phase-out)**: a reduction in mercury emissions of 31 kg
- **PO2c (2030 phase-out)**: a reduction in mercury emissions of 3 kg

Social impacts

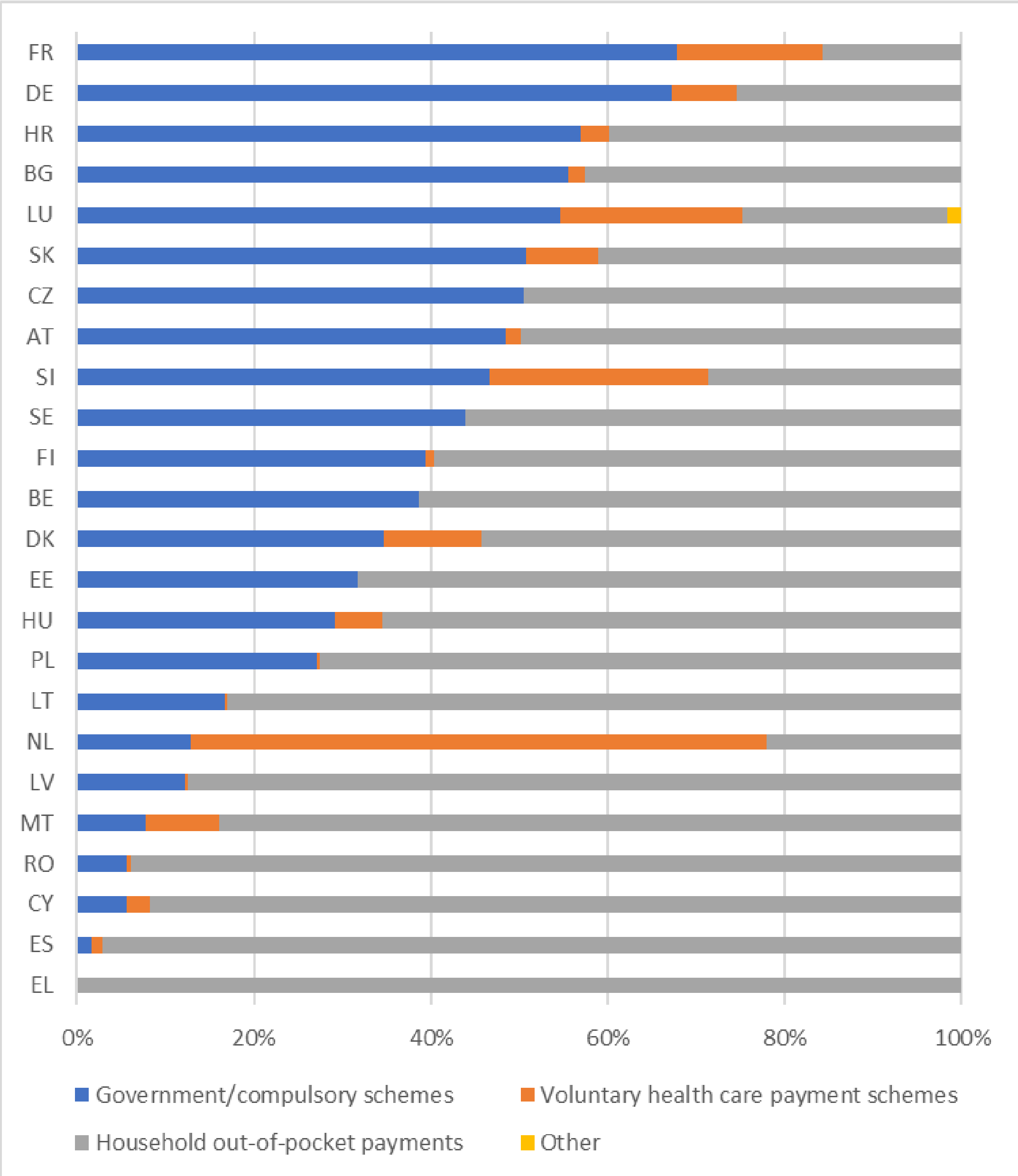
[76] Includes emission from crematoria.
[77] Refers to direct discharges to the aquatic environment.
[78] Refers to discharges to wastewater streams, ultimately reaching wastewater treatment plants.

It is expected that new jobs will be created to train the dentists who did not receive training for using alternatives or haven't practiced it much, some of which will need to improve their skills or acquire new skills in mercury-free restoration techniques within a short timeframe. New jobs would also be expected to support R&D activities in the dental fillings industry due to the need for companies to maintain a high level of innovation in mercury-free materials.

A phase-out of dental amalgam is expected to have both direct and indirect health benefits for EU society. Benefits will be observed for the general population as mercury exposure reduction will likely lead to lower mercury levels in the blood, especially for practitioners, and reduction of associated health risks. In particular, the greatest direct benefits will be for dental practitioners as they are directly exposed to mercury vapours. These benefits are expected to be higher under PO2a as the exposure will cease sooner. The reduction of releases to water (e.g., via deposition from the atmosphere and emissions from crematoria) is likely to reduce mercury content in the marine food chain and, ultimately in fish, which is directly linked to human exposure to mercury.

Figure 12 provides an overview of the existing financing structures in the dental sectors of a number of Member States, which will likely influence the way in which the costs of switching to mercury-free alternatives will be distributed. FR and DE have the greatest share of public expenditure in their total dental expenditure (>60%), followed by HR, BG, LU and SK. Dental care expenditure in EL, ES and CY is dominated by private financing, while voluntary health insurance schemes make up the majority (>60%) of expenditure in the NL. The distribution of costs for dental amalgam and mercury-free alternatives per Member State is available in Annex 7.

Figure 12: Government, voluntary and out-of-pocket spending for dental care as % of total dental outpatient curative care expenditure



Data from the OECD Health Statistics 2022 database. Data for 2020, except for Denmark and the Netherlands (2021 data), and Malta (2019 data). No data for Portugal, Italy or Ireland.

Stakeholder views

Overall, 58% of the consulted stakeholders believe a phase-out could be achieved by 2025 and 22% indicated a phase-out being achievable by 2030, while 20% think that a phase-out is not needed, or the proposed years are not appropriate. Among companies or business associations, 65% and 20% respectively believed that a phase-out was achievable by 2025 and 2030 respectively. Of both EU and non-EU citizens' responses, 50% and 29% respectively believed a phase-out could be achieved by 2025 and 2030 respectively. Four responses were received from public authorities, two of which responded by indicating 2025 with the other two supporting a 2030 phase-out. From Civil Society stakeholders, 62% and 10% were in favour of a 2025 or 2030 phase-out of dental amalgam respectively.

6.2. 6.2. Problem 2 – Emissions of mercury from crematoria

6.2.1. 6.2.1. Analysis of Policy Option 3 – Publication of EU guidance on emissions abatement in crematoria

Economic impacts

*Operating costs and the conduct of business***:** The introduction of EU guidance on emissions abatement in crematoria, is not anticipated to have a significant impact on abatement uptake in the absence of supporting legislation. Nonetheless, crematoria operators choosing to implement the non-legally binding guidance on information for abatement would face additional operational and capital costs. These vary according to the cremation capacity of the installation.

- For **PO3** a 5% increase in abatement uptake (compared to baseline levels) is assumed to occur, with no impact assumed to occur in Member States where guidance or legislation is already in effect. Costs to operators in 2030 relative to a baseline assuming no phase-out of dental amalgam are estimated as total one-off capital costs of €10.3 million and annual operating costs of €0.32 million (equivalent annual costs of €1.08 million).

Administrative burden on businesses and public authorities: The cremation sector is not anticipated to incur any administrative burdens from the introduction of sector-specific guidance. EU institutions producing the guidance and Member States' competent authorities disseminating these are likely to face some level of cost (albeit relatively limited) in doing so; this would vary depending on the scope of the guidance.

*Position of SMEs***:** Although more than half of EU crematoria are considered SMEs, the associated costs of application of BAT are considered to be passed on to consumers. According to available information this is done in most Member States by using environmental premiums/fees. Given the voluntary nature of the option, it is not anticipated that issuing EU guidance will present significant impacts for SMEs.

*Consumers and households***:** Given the voluntary uptake of the guidance, it is difficult to estimate the additional costs by consumers and households, albeit it can be assumed the associated costs of application of BAT would be passed on to them.

Table 10: PO3 cost-benefit summary table (assuming 5% increase in abatement uptake)

2030 Cremation capacity

	<1,000	1,000 - 2,000	2,000 - 3,000	3,000 - 4,000	4,000 - 5,000	>5,000	Total
Total emission reductions (kg)	1,0	1,6	4,0	2,7	2,7	5,1	17,1
Capital costs (€, one-off)	6.465.662	1.020.366	1.279.049	596.503	515.258	412.179	10.289.017
Operating costs (€, annual)	201.154	31.745	39.793	18.558	16.030	12.823	320.103
Capital and operational costs (€, EAC)	681.444	107.541	134.805	62.868	54.305	43.441	1.084.404
Admin burdens (€, operators and authorities)	Assumed to be zero for PO3						
Total annual benefits (€, central)	26.795	33.114	76.565	51.546	51.967	96.277	336.265
Costs per kg mercury abated	682.997	65.879	33.864	23.491	20.045	8.577	63.560
Net costs / benefits	654.649	74.427	58.239	11.322	2.338	-52.836	748.139
Benefit-cost ratios	**0,04**	**0,31**	**0,57**	**0,82**	**0,96**	**2,22**	**0,31**

Environmental impacts

Quality of natural resources: PO3 is estimated to result in a reduction in mercury emissions in 2030 of around 17 kg (compared to 2030 baseline emissions of 355 kg). Any reduction in mercury emissions would result in an improvement in the quality of natural resources. Most directly, it would result in improved air quality, which would indirectly result in reduced mercury deposition to soil and waterbodies. In turn, the improved environmental quality would result in further indirect human health benefits; seafood is the primary source of human exposure to mercury, and reduced presence of mercury in environmental media would lead to reduced mercury in seafood consumed by populations.

Social impacts

Public health & safety and health systems: Mercury exposure is linked with health outcomes including cardiovascular mortality, IQ loss in younger age groups, and anemia. Based on EEA damage costs, the health benefits of the mercury emission reductions outlined in the previous section for 2030 are estimated at around €0.30 million, if applied across all crematoria, with the greatest benefit gained through emission reductions among crematoria operating at capacities of above 5,000 cremations annually.

Abatement technology used to reduce mercury emissions also capture a number of other pollutants. In light of this, human health benefits would also be experienced through reductions in $PM_{2.5}$ emissions and other pollutants (including lead, cadmium, arsenic, chromium, nickel and dioxins and furans) estimated at €36,000 (2030).

Stakeholder views

Whilst no explicit feedback was received from stakeholders on a possible option involving the development of EU guidance, the majority of respondents to the OPC and targeted survey supported EU-wide policy to control mercury emissions from crematoria although this related more to the establishment of specific limits and application of BAT.

6.2.2. 6.2.2. Analysis of Policy Option 4 – Mandatory application of emissions abatement in crematoria

Economic impacts

Operating costs and the conduct of business: Mandatory application of best available mercury emission abatement techniques would entail additional capital costs to crematoria operators from installing abatement systems, and additional operational costs from their continued maintenance and use. These vary according to the cremation capacity of the installation. Additional costs to operators in 2030 relative to a baseline assuming no phase-out of dental amalgam are estimated as follows:

- Where **PO4a** is expected to deliver a 100% uptake of emissions abatement across all crematoria in the EU, it is estimated to result in total one-off capital costs of €182 million, and annual operating costs of €6 million
- **PO4b** is expected to deliver a 100% uptake of emissions abatement across crematoria operating at a capacity of ≥ 4000 cremations per year and is estimated to result in total one-off capital costs of €15 million and annual operating costs of €0.46 million (see Table 11).
- **PO4c** is expected to deliver a 100% uptake of emissions abatement across crematoria operating at a capacity of ≥ 3000 cremations per year and is estimated to result in total one-off capital costs of €25 million and annual operating costs of €0.78 million (see Table 11).

Table 11: PO4 cost-benefit summary table

	2030 Cremation capacity						
	<1,000	**1,000 - 2,000**	**2,000 - 3,000**	**3,000 - 4,000**	**4,000 - 5,000**	**>5,000**	**Total**
Total emission reductions (kg)	16,8	31,3	75,4	49,3	47,4	93,9	314,1
Capital costs (€, one-off)	118.677.895	14.954.038	23.816.566	10.039.199	8.396.870	6.481.619	182.366.188
Operating costs (€, annual)	3.692.201	465.237	740.960	312.331	261.236	201.650	5.673.615
Capital and operational costs (€, EAC)	12.507.980	1.576.071	2.510.132	1.058.075	884.983	683.126	19.220.367
Admin burdens (€, operators and authorities)	564.276	123.601	115.909	44.193	27.425	23.293	898.698
Total annual benefits (€, central)	465.515	618.902	1.450.451	944.566	902.607	1.765.889	6.147.930
Costs per kg mercury abated	776.883	54.321	34.840	22.357	19.257	7.525	61.201
Net costs / benefits	12.606.741	1.080.771	1.175.590	157.702	9.801	-1.059.470	13.971.135

Benefit-cost ratios	0,04	0.36	0.55	0.86	0.99	2.50	0.31

The greatest costs are incurred among low-capacity crematoria, (below 1,000 cremations per year), where the cost per unit of mercury emissions abated is highest. By implementing PO4b with an activity threshold exempting installations below a capacity of 4000 cremations per year, the capital and operating costs to business can be significantly reduced. By implementing PO4c, the capital and operating costs can only be slightly reduced.

A phase-out of dental amalgam (PO2a) in 2025 will lead to a significant reduction in mercury emissions from crematoria, decreasing the cost-benefit ratio of PO4 to 0.27 (see Table 12). The long-term positive economic effect stemming from a dental amalgam phase-out will ultimately result in the non-necessity to install mercury abatement techniques in new EU crematoria (as only small quantities of dental amalgam would still be used within the EU). These benefits will materialize following a delay due to legacy dental amalgam (the lag in dental restorations reaching crematoria).

By combining a dental amalgam phase-out (in 2025) with mandatory abatement of mercury emissions from crematoria:

- **PO4a** is expected to result in total one-off capital costs of €182 million, and annual operating costs of €6 million
- **PO4b** is expected to be cost-beneficial in crematoria operating at a capacity of ≥ 4000 cremations per year and is estimated to result in total one-off capital costs of €15 million and annual operating costs of €0.46 million (see Table 12), covering crematoria in 17 Member States (100 crematoria).
- **PO4c** is expected to be only marginally cost-beneficial in crematoria operating at a capacity of ≥ 3000 cremations per year and is estimated to result in total one-off capital costs of €25 million and annual operating costs of €0.78 million (see Table 12), covering crematoria in 18 Member States (170 crematoria).

Table 12: PO4 cost-benefit summary table assuming a dental amalgam phase-out in 2025

2030 Cremation capacity							
	<1,000	1,000 – 2,000	2,000 – 3,000	3,000 – 4,000	4,000 – 5,000	>5,000	Total
Total emission reductions (kg)	15,7	29,2	68,2	43,0	37,8	75,0	268,9
Capital costs (€, one-off)	118.677.895	14.954.038	23.816.566	10.039.199	8.396.870	6.481.619	182.366.188
Operating costs (€, annual)	3.692.201	465.237	740.960	312.331	261.236	201.650	5.673.615
Capital and operational costs (€, EAC)	12.507.980	1.576.071	2.510.132	1.058.075	884.983	683.126	19.220.367
Admin burdens (€, operators and authorities)	564.276	123.601	115.909	44.193	27.425	23.293	898.698
Total annual benefits (€, central)	444.895	581.988	1.324.683	834.310	733.157	1.433.862	5.352.895
Costs per kg mercury abated	835.032	58.225	38.490	25.612	24.168	9.417	71.485

Net costs / benefits	12.627.361	1.117.684	1.301.358	267.958	179.252	-727.443	14.766.170
Benefit-cost ratios	**0,03**	**0,34**	**0,50**	**0,76**	**0,80**	**2,03**	**0,27**

*Position of SMEs***:** Implementing the measure with no, or a low, activity threshold would incur substantial costs to smaller installations. Some stakeholders indicated that there is potential movement away from significant public sector involvement in operation of crematoria to greater involvement from private enterprises. Limited data are available on the structure of the sector across the EU, but there are likely to be SMEs involved, especially in Member States dominated by smaller crematoria (including ES and FR). The implementation of no activity threshold is likely to have greater implications for SMEs within the sector, who would bear higher costs. However, according to available information, these costs are passed on (in full or in part) to consumers by using environmental premiums/fees and thus impacts on crematoria are expected to be limited.

Administrative burden on businesses and public authorities: In addition to the costs of implementing and operating mercury emissions abatement systems at their installations, crematoria operators would face added administrative burdens. This would arise from the need to submit information on their abatement systems and any periodic emissions monitoring and reporting to Member States' competent authorities, who would also encounter a new administrative burden in processing such information. It is assumed that costs to both operators and authorities would be comparable to administrative burdens incurred by the smallest medium combustion plants (1-5 MWth) under Directive (EU) 2015/2193 on medium combustion plants[79]. Administrative costs are estimated to amount to €400,000 to operators and €500,000 to authorities for PO4a (all crematoria), €23.000 to operators and €28.000 to authorities for PO4b (crematoria greater than 4,000 cremations per year) and €42.000 to operators and €53.000 to authorities for PO4c (crematoria greater than 3,000 cremations per year) in 2030.

Consumers and households: Crematoria operators implementing abatement technologies are likely to pass some or all of the capital and operational costs on to consumers, who would ultimately pay more for the same services. The degree to which costs would be passed on is not known.

Environmental impacts

*Quality of natural resources***:** PO4a is anticipated to result in emissions abatement uptake of 100% across EU crematoria, mercury emissions reductions are estimated at 314 kg (compared to a baseline of 355 kg), assuming no activity threshold (PO4a), 141 kg (compared to a baseline of 355 kg) with an activity threshold of 4,000 cremations per

[79] Directive (EU) 2015/2193 of the European Parliament and of the Council of 25 November 2015 on the limitation of emissions of certain pollutants into the air from medium combustion plants *(*OJ L 313, 28.11.2015, p. 1–19).

year (PO4b) and 191 kg (compared to a baseline of 355 kg) with an activity threshold of 3,000 cremations per year (PO4c).

If PO4 is combined with a dental amalgam phase-out in 2025 (PO2a), its efficiency would decrease. It is anticipated that resulting emission reductions would be 269 kg (compared to a baseline of 301 kg) assuming no activities threshold (PO4a), 113 kg (compared to a baseline of 301 kg) with an activity threshold of 4,000 cremations per year (PO4b) and 156 kg (compared to a baseline of 301 kg) with an activity threshold of 3,000 cremations per year (PO4c).

Any reduction in mercury emissions would result in an improvement in the quality of natural resources through improved air quality and subsequently reduced deposition to soil and waterbodies. Reduced emissions to air from crematoria can be quantified and valued using damage cost functions. For other releases / sources (e.g., to water) there is no robust way of quantifying and valuing such changes in releases. Following decreasing mercury use in dentistry, extra operational costs will decrease with time, albeit slowly due to the lifetime of dental amalgam restorations and time it takes for it to be removed from circulation e.g., during replacement of restorations.

Social impacts

Public health & safety and health systems: Mercury exposure is linked with health outcomes including cardiovascular mortality, IQ loss in younger age groups, and anemia. Based on EEA damage costs, the health benefits of the mercury emissions reductions outlined in the previous section for 2030 are estimated at around €6 million, for PO4a, with the greatest benefit gained through emissions reductions among crematoria operating at capacities of above 4,000 cremations annually (PO4b) estimated at €2 million and €3 million for PO4c (3,000 cremations annually and above).

Abatement technology used to reduce mercury emissions also capture a number of other pollutants. In light of this, human health benefits would also be experienced through reductions in $PM_{2.5}$ emissions and other pollutants (including lead, cadmium, arsenic, chromium, nickel and dioxins and furans) estimated at €0.62 million (PO4a, 2030), €0.18 million (PO4b, 2030) or €0.26 million (PO4c, 2030).

Stakeholder views

Overall, 86% (115/133) of respondents to the OPC believed that there should be an EU wide policy to limit mercury emissions from crematoria. This picture was consistent across all stakeholder groups that responded to the OPC (i.e., civil society, EU & non-EU citizens, companies & business associations and public authorities). As part of the targeted consultation, some stakeholders supported EU limits for all crematoria whereas other stakeholders expressed concerns about impacts on smaller crematoria if EU-wide limits were to be established and indicated that less stringent limits could be applied, or they could be excluded entirely. Some of the experts consulted indicated that crematoria should be treated similarly to other emission points, such as through Best Available Techniques (BAT) and associated emission levels (similar to the Industrial Emissions Directive) whereas others felt that the use of minimum emission limit values and a simpler regulatory approach would be more appropriate (e.g., similar to the Medium Combustion Plant Directive).

6.3. 6.3. Problem 3 – Mercury-added products for export to third countries

6.3.1. 6.3.1. Analysis of Policy Option 5 – Global agreement to ban the manufacture and trade of mercury-containing lamps

Economic impacts

Conduct of business: Under a global ban scenario, EU exports of FLs would stepwise decrease to zero between 2026 and 2030. The accumulated number of exported FLs would be 167 million to 308 million units in comparison to 412 million to 693 million in the baseline scenario. The calculated accumulated loss of export value would be €97 to €190 million between 2025 and 2030. Jobs in the order of 500 may be affected by an export ban. Demand for lighting products in general will not be affected by a global ban of mercury-containing lamps but instead is expected to increase (by about 4% annually). Thus, manufacturers have opportunities to compensate for losses in the conventional lighting sector, e.g., by selling LED lamps/luminaries and smart lighting systems. For other lamp types, the impact is considered small (about €25 million per year, or less than 10% of annual export volume) because many applications still fall under exemptions within the EU. The economic impact for other MAPs e.g., certain types of rheometers, electrodes, seam-welding machines could not be quantified but is considered small in comparison to lamps.

Position of SMEs: In the case of FLs, SMEs would not be affected by an export ban since both remaining EU manufacturers belong to large company groups**.** This does not necessarily apply to SMEs that are producing other lamp types (HID lamps, other low pressure discharge lamps for special purposes). Manufacturers of aforementioned other MAPs are typically SMEs, but the impacts are considered minor as MAPs are only a small part of their portfolio.

Administrative burden on businesses and public authorities: The administrative impact of a ban is considered small to negligible as the cessation of manufacture and exports is not related to specific administrative burdens.

Environmental impacts

A global ban on FLs for general lighting purposes would primarily result in less mercury being needed within the EU to produce discharge lamps. To the same extent, the mercury content of exported lamps would decrease. With a ban taking effect in two steps by in 2026 and 2028, this would affect a quantity of 0.9 to 1.5 t of mercury in the period 2026-2030. Stopping the export could prevent some 0.8 to 1.3 t from entering the general waste stream and contributing to a contamination of soil and emissions to air in third countries, as currently only about 15% of lamps are recycled.

The magnitude of energy savings due to the switch from FLs to LEDs was estimated to be in the order of 10 to 28 TWh. Considering a carbon intensity of electricity of about 475 g CO_2/ kWh, this would result in a lifetime saving of about 5 to 13 Mt CO_2, constituting an important contribution to the fight against climate change and to the objectives under the EU decarbonisation agenda.

Social impacts

For citizens in importing third countries, the phase-out of mercury-containing fluorescent lamps would eliminate the most important source of product-related mercury exposure. New input of mercury into general waste would be avoided, so that populations working with waste (e.g., waste pickers) or living near waste dump sites have a lower risk of getting in contact with mercury. Social impacts in the EU are considered negligible.

Stakeholder views

During the stakeholder consultation, both NGOs and business associations supported a global agreement as it would effectively reduce access to and supply of MAPs, reduce mercury demand and at the same time contribute to energy savings. At the same time, it provides equal conditions for all market participants. However, industry stressed the necessity of a gradual and manageable transition to LED-based lighting in order to avoid disruptions of the supply chain and to improve the availability of compatible LED plug-and play solutions.

6.3.2. 6.3.2. Analysis of Policy Option 6 – EU ban on the manufacture and export of MAPs

Economic impacts

Conduct of business:

- **PO6a** would ensure that all exports of would end from 2025, so that 412 million to 693 million ***FLs*** would no longer be exported. Their accumulated export value in the period 2025 to 2030 is €191 to €347 million. Jobs in the order of 500 may be affected by an export ban. If it is assumed that around 8% of the current HID lamp exports would be affected by an export ban, about 6 million units of HID lamps could no longer be exported within 2025 to 2030. Their value is at approximately €55 million. For ***dental amalgam***, an export ban would affect predicted sales with a total retail value of about €50 to €300 million in the period 2025-2030. Because of the costs in the intermediate trade, the manufacturers' sales value is considerably smaller. The number of affected jobs is considered to be significantly below 200.
- **PO6b** would ensure that all exports would end with a later ban on 1st January 2026 (halophosphate LFLs) and 1st January 2028 (all other considered lamp types), so that 167 million to 308 million FL units could still be exported until

then, and the foregone revenue would decrease to €97 to €190 million, the majority of which (78%) can be attributed to double-capped FLs. For dental amalgam sales with a retail value of €30 to €200 million in the period 2027 to 2030 would be affected. The number of affected jobs is considered to be slightly below the values of option PO6a as exports and thus employment linked to these exports are expected to decrease even without a ban.

The ability to compensate losses in FL sales by increased LED sales would depend on the extent these markets switch to LED solutions. Stakeholders agreed that a significant part of the FL market currently supplied by EU exports will shift to FLs manufactured in third countries (especially mainstream lamp types). However, there are different opinions on the extent of this shift and how long it will last. In this assessment, they are expressed by assuming that the substitution rate is 50-90% of EU exports (see Annex 07).

The effect on employment for FL production would be similar to **PO5** (global ban). The major difference between **PO5 and PO6 (a** and **b)** would be that FL exports from third countries may persist under **PO6** until a global ban comes into force and/or the full transition to LED.

All four identified manufacturers that have not yet ceased dental amalgam production belong to SMEs. Two of these companies specialize to a large extent in dental amalgam. Depending on the relevance of the amalgam business, an export ban could result in a reduction in sales if not replaced by the export of mercury-free filling materials or other dental products to third countries.

Administrative burden on businesses and public authorities: The administrative impact of a ban is considered small to negligible as the cessation of manufacture and exports is not related to specific administrative burdens.

Environmental impacts

An EU export ban from 2025 would avoid the use of about 1.21 t to 2.17 t of mercury in European lamp products between 2025 and 2030. About 85% of this amount or 1 t to 1.9 t would not enter the general waste stream in importing countries. With an export ban from 2026/2028, the mercury content in exports would decrease by 0.8 t to 1.5 t and the mercury input into general waste by 0.7 t to 1.3 t. However, this is countered by the amount of mercury contained in FLs that are imported instead of European lamps. The assessment considers a level of substituting imports in the range of 50% to 90%. In addition, non-European FLs have a significantly higher average mercury content. While the difference for CFL.ni lamps is often only small and amounts to only a few tenths of a milligram, the difference is higher for the economically more important FL lamps and there especially for halophosphate lamps (3 to 5 mg per lamp).

For the scenario of an export ban from 2025, the substitute FLs would have a mercury content that is 0.53 t lower but can also be 1.59 t higher. The low values of this range are only realised when low substitution rates and low mercury contents in substituting imports coincide. The range is smaller if an export ban is considered from 2026/2028 (-0.32 t to 1.12 t). For HID lamps the environmental impact is expected to be limited.

An EU decision by the EU is not detached from further negotiations at the international level. If an EU export ban and a global ban coincide in 2026/2028, the effect is equally positive as if there had only been a global ban (-1.50 t to -0.97 t). Should the global ban occur two years later (2028/2030), the net effect is still positive (-0.57 t to -0.24 t), as substitute imports could only occur for a maximum period of two years.

In the case of an export ban in 2025, the mercury content of exported dental amalgam would decrease by approximately 30 t to 180 t in the years 2025 to 2030. A later phase-out (2027) would result in a decrease of 20 t – 120 t. The reduced exports, if not substituted by dental amalgam supply from other third countries would result in reduced mercury releases to air and soil in the same order of magnitude.

Social impacts

An EU ban on the manufacture and export of MAPs will contribute to a decrease of mercury input into the society, thus reducing the risk of exposure and contamination. However, should third country markets replace EU made MAPs by imported MAPs from other countries, this could lead to continued mercury pollution. However, such negative impacts are limited to a couple of years until the predicted general decrease of FL sales compensates a possible short-term effects or measures.

In case of an EU ban on dental amalgam export, access of practitioners in third countries could become more difficult in the short-term. However, in the context of the Minamata Convention, the African Region has already highlighted its capacity to “leap-frog” dental amalgam and provide patients with mercury-free alternatives. Consequently, an EU export ban of dental amalgam may incentivize the accelerated transition from dental amalgam to mercury-free alternatives in third countries in the long-term, depending on their health systems and self-defined priorities.

Stakeholder views

NGO’s supported unilateral measures and expected an overall positive environmental impact caused by reduced supply from the EU in combination with national measures that follow the EU example. They preferred an early phase-out of exports as it would avoid a higher amount of mercury used in lamps. On the other hand, businesses expressed concerns that cutting supply to the global market from the EU could be compensated to a large extend by increased imports from third countries. In case of lamps, they expect a neutral or even negative effect because persistent demand could be met by imports of lamps (e.g., from Asia) with a higher mercury content. Businesses expressed caution over unilateral measures and preferred a global agreement on MAPs. In addition, businesses stressed the need for sufficient transition periods as short-term phase-outs pose serious challenges for users who may need to make significant investments to replace existing luminaires. Also, time is needed to re-export legally imported lamps that are currently in European distribution centers. Concerning dental amalgam, only one amalgam manufacturer submitted an opinion, stressing that European exports mainly go to low-income countries where many clinics don’t have the technical equipment for mercury-free fillings.

7. 7. HOW DO THE OPTIONS COMPARE?

The legal basis for this initiative is Article 19 of the Mercury Regulation, which requires the Commission to address three distinct issues, different in nature addressing the largest remaining intentional use of mercury in the EU (problem area 1), mercury emissions to air (problem area 2) and the alignment of EU law on MAPs (problem area 3).

Regardless of differences in scope and objectives, this initiative seeks to provide for a single policy package with an overall objective towards a non-toxic environment. In doing so, for the purpose of developing an effective, efficient and proportionate policy package, this initiative makes comparisons across problem areas, where feasible.

This section highlights the key aspects of the impact assessment relevant for supporting decision-making on the choice of options and sub-options to include in the preferred package. It identifies which sub-options have a favourable cost-benefit profile. Furthermore, where sub-options include alternatives, their impacts are compared (Table 13, Table 14 and Table 15).

Problem area 1 - Dental amalgam: Comparison between PO1 and PO2

Regarding **PO1**, as a ‘soft’ policy option, the assessment of the economic, environmental and social impacts of the implementation of communication campaigns shows that it would not deliver strong positive outcomes across the EU. Whilst the foreseen impacts are likely to be minimal in terms of costs, they would yield only limited environmental and social benefits. Due to uncertainties regarding the type, extent, content and potential overlaps with existing national campaigns, it not possible to robustly quantity the impacts of PO1.

Concerning **PO2,** as a ‘hard’ policy option, the assessment of the economic, environmental and social impacts of the implementation of a legally binding phase-out on the use of dental amalgam shows that significant environmental and human health benefits are associated with that option compared to PO1. Yet, due to the very nature of PO2 as a legally binding measure and its associated implementation (compulsory substitution of dental amalgam with mercury-free alternatives), that option incurs more costs compared to PO1.

The extent to which PO2 yields environmental and human health benefits depends on the date when the obligation to phase-out the use of dental amalgam enters into force. In particular, the cumulative reductions of mercury emissions by 2030 are significantly higher with an early phase-out date: 51.7 t for **PO2a** (2025), 21.9 t for **PO2b** (2027) and 6.0 t for **PO2c** (2030) (see Table 9). In parallel, human health benefits as a result of reduced mercury emissions to air from crematoria will also be significantly higher with an earlier phase-out date (2025), valued at €900,000 in 2030 compared to €50,000 with a 2030 phase-out date.

Problem area 2 – Emissions from crematoria: Comparison between PO3 and PO4

As PO2 addresses the reduction of mercury use at source resulting *de facto* in significantly reduced mercury emissions from crematoria, it decreases the effectiveness and cost-benefit ratio of PO3 and PO4. Hence, with PO2 in place, operators of crematoria will only have to abate mercury emissions from legacy dental amalgam.

Regarding **PO3,** as a 'soft' policy option, the assessment of the economic, environmental and social impacts of the development of a non-legally binding guidance on abatement technologies to control and reduce mercury emissions from crematoria shows some environmental and human health benefits. Estimated mercury emissions reductions of 17 kg in 2030 have been estimated assuming no phase-out of dental amalgam, delivering human health benefits valued at just over €300,000. Costs to operators in 2030 assuming no phase-out of dental amalgam are estimated as total one-off capital costs of €10.3 million and annual operating costs of €0.32 million.

Concerning **PO4a, PO4b or PO4c**, as a 'hard' policy option, the assessment of the economic, environmental and social impacts of an EU-wide obligation to install mercury emission abatement technologies in crematoria shows higher environmental and human health benefits compared to PO3, but significantly higher associated costs.

Under **PO4a**, estimated mercury emissions reductions amount to 314 kg in 2030, delivering human health benefits valued at €6.1 million. However, when combined with PO2a, estimated emissions reductions amount to 269 kg in 2030, delivering human health benefits valued at €5.3 million. **PO4a** is expected to deliver a 100% uptake of emissions abatement across all crematoria in the EU and is estimated to result in total one-off capital costs of €182 million, and annual operating costs of €6 million.

Under **PO4b**, estimated mercury emissions reductions amount to 141 kg in 2030, delivering human health benefits valued at €2.7 million. However, when combined with PO2a, emissions reductions amount to 113 kg in 2030, delivering human health benefits valued at €2.2 million. **PO4b** is expected to deliver a 100% uptake of emissions abatement across crematoria operating at a capacity of ≥ 4000 cremations per year and is estimated to result in total capital costs of €15 million and annual operating costs of €0.46 million.

Under **PO4c,** estimated mercury emissions reductions amount to 191 kg in 2030, delivering human health benefits valued at €3.4 million. However, when combined with PO2a, emissions reductions amount to 156 kg in 2030, delivering human health benefits valued at €2.7 million. **PO4c** is expected to deliver 100% uptake of emissions abatement across all crematoria operating at a capacity of ≥ 3000 cremations per year and is estimated to result in total capital costs of €25 million and annual operating costs of €0.78 million.

Problem area 3 – Mercury-added products: Comparison between PO5 and PO6

Regarding **PO5,** as an option based on potential developments at international level, the assessment of the economic, environmental and social impact shows that the estimated decreased demand for mercury in the EU to be used for producing the concerned **mercury-containing lamps** (relevant LFLs) amount to 0.8-1.5 t (2026-2030) and the cumulative foregone revenues to EU businesses amount to €144 million (€97-190 million) (2026-2030). PO5 is characterised by a high level of uncertainty as Parties to the Minamata Convention may fail to reach an agreement at COP5 or at subsequent COPs on the phase-out dates for relevant MAPs[80].

Concerning **PO6,** as an option based on a unilateral prohibition, the assessment of the economic, environmental and social impact shows that the decreased demand for mercury in the EU to be used for producing the concerned **mercury-containing lamps** (relevant LFLs, CFLs and HPS) amounts to 1.2-2.2 t (export ban in 2025 under **PO6a**) and to 0.8-1.5 t (export ban in 2026/2028 under **PO6b**). Both PO6a and PO6b would lead to cumulative foregone revenues to EU businesses amounting to €191-347 million (PO6a; 2025-2030) or to € 144 million (PO6b; 2026-2030).

The assessment of the economic, environmental and social impact shows that **PO6a** applied only to **dental amalgam** would reduce the EU export of mercury in the range of 13-38 t and affect predicted sales with a total retail value of about €50 to €300 million in the period 2025-2030.

It is to be noted that both **PO5** and **PO6b** are assumed to result in similar environmental benefits and foregone revenues, should the international community agree, based on Minamata Decision MC-4/6, on the most ambitious proposed phase-out date (2026) to be considered by Parties to the Minamata Convention at COP5. However, considering the uncertainty linked to PO5, PO6b provides for certainty across the EU on the applicable regulatory regime to MAPs.

Colour coding is used to summarise the assessment of impacts referring to the direction (positive or negative) and magnitude (small or large) of any expected impacts (see Table 13).

Table 13: Coding used to present expected impacts

XXX	XX	X	O	✓	✓✓	✓✓✓
Extremely negative	Strongly negative	Weakly negative	Zero i.e., no or limited impact	Weakly positive	Strongly positive	Extremely positive

The coding provided in the summary tables below for each policy option are based on the detailed assessment of impacts (see Annex 8) for each measure and option. Quantitative information on the likely impacts of each option was not always available and, where it was, it was not always comparable across options e.g., compliance costs compared to potential loss of revenue. Therefore, expert judgement has been applied for the overall coding and comparison.

80 For reminder, the phase-out of dental amalgam for all members of the population at global level is not currently envisaged by Parties to the Minamata Convention, hence PO5 does not address the manufacture and export of dental amalgam.

Table 14: Summary of impacts for PO1 to PO4 (Problems 1 and 2)

Policy option	Main impacts			Benefits	Costs	Admin burden	Key aspects
	Econ.	Env.	Social.				
PO1 Communication campaign	O / X	O / ✓	O / ✓	• Benefits not feasible to quantify due to high uncertainties and overlaps with existing dental health campaigns. • Increased employment in organizing awareness-raising activities, training dentists in mercury-free restoration, and R&D of mercury-free alternatives. • Potential resulting reductions in mercury emissions to air, soil, and water.	• Limited costs anticipated for developing and running communication campaigns (existing campaigns already in place for improving dental hygiene). • Potential loss of business to amalgam producers depending on several factors (e.g., content and extent of the campaign).	Limited	Many MSs already implement such communication campaigns so limited additional impacts anticipated from further awareness raising campaigns.
PO2 Establish legally binding end date for use dental amalgam	X	✓✓✓	✓	Cumulative reductions in mercury used in dental restorations of: • **PO2a** (2025 phase-out): 114.4 t by 2035 • **PO2b** (2027 phase-out): 75.9 t by 2035 • **PO2c** (2030 phase-out): 29.8 t by 2035 Estimated cumulative reductions in direct mercury emissions from dental amalgam phase-out by 2030 of: • **PO2a:** 3.1 t to air, 3.4 t to soil, 0.6 t	• Loss of business to manufacturers of amalgam fillings, dentists using amalgam products estimated to be limited. • Anticipated that they would quickly adapt in case of a phase-out in light of on-going decreasing trend in dental amalgam use. Estimated increased	• Business 0 • Public authorities <1	Scale and timing of impacts depend on sub-options PO2a, PO2b and PO2c. Unlike for the reductions of mercury emissions from crematoria, it has not been possible to value/monetize robustly the benefits associated with PO2. Therefore, the valued benefits are significantly underestimated, and it is not feasible or appropriate to present a cost-benefit ratio as for PO3 and PO4.

Policy option	Main impacts			Benefits	Costs	Admin burden	Key aspects
	Econ.	Env.	Social.				
				to waterbodies, and 2.6 t to wastewater. • **PO2b:** 1.3 t to air, 1.4 t to soil, 0.3 t to waterbodies, and 1.1 t to wastewater • **PO2c**: 0.4 t to air, 0.4 t to soil, 0.1 t to waterbodies, and 0.3 t to wastewater. Estimated reductions in mercury emissions from crematoria by 2030 of: • **PO2a:** 54 kg • **PO2b:** 31 kg • **PO2c**: 3 kg. Human health benefits from reductions in mercury emissions from crematoria valued at: • **PO2a:** €900,000 • **PO2b:** €500,000 • **PO2c**: €50,000 Anticipated social benefits resulting from PO2 combine: i. improved health thanks to reduced mercury pollution exposure, ii. positive impacts of improved	short-term costs of dental treatment (for citizens, social security and./or private healthcare depending on systems in place in each MS) as a result of use of mercury-free alternatives: • **PO2a:** €208 million • **PO2b:** €170 million • **PO2c**: €114 million		.

Policy option	Main impacts			Benefits	Costs	Admin burden	Key aspects
	Econ.	Env.	Social.				
				dental aesthetics, especially for modest income households, iii. R&I promotion potentially leading to slight increases in employment, but also slight increases of expenses for national healthcare systems			
PO3 Issue guidance on emissions abatement in crematoria	X	✓	✓	• **PO3:** estimated mercury emissions reductions of 17 kg in 2030, delivering human health benefits valued at €300,000. Associated **cost-benefit ratio: 0.31** (when benefits from other pollutant reductions, described below, are also accounted for)**.** • **PO3 combined with PO2a:** estimated emissions reductions of 14 kg in 2030, delivering human health benefits valued at €280,000. Associated **cost-benefit ratio: 0.27** (when benefits from other pollutant reductions, described below, are also accounted for)**.** • **PO3**: estimated reductions in emissions of $PM_{2.5}$ and other pollutants delivering human health benefits valued at €36,000.	• Total capital and operational costs of €1.1 million (EAC) in 2030 (with or without PO2).	• Business 0 • Public authorities – limited costs for EU institutions to prepare guidance	Non-legally binding guidance will be helpful for those MSs that do not currently address mercury emissions from crematoria.
PO4a Mandatory application of best	XXX	✓✓	✓✓	• **PO4a**: estimated mercury emissions reductions of 314 kg in	• Total capital and operational costs of	• Business €400,000	The mandatory application of BAT for crematoria in the EU

Policy option	Main impacts			Benefits	Costs	Admin burden	Key aspects
	Econ.	Env.	Social.				
available abatement techniques for all crematoria				2030, delivering human health benefits valued at €5.5 million. Associated **cost-benefit ratio: 0.31** (when benefits from other pollutant reductions, described below, are also accounted for). • **PO4a combined with PO2a**: estimated emissions reductions of 269 kg in 2030, delivering human health benefits valued at €4.7 million. Associated **cost-benefit ratio: 0.27** (when benefits from other pollutant reductions, described below, are also accounted for). • **PO4a**: estimated reductions in emissions of $PM_{2.5}$ and other pollutants delivering human health benefits valued at €621,000.	€19.2 million (EAC) in 2030.	• Public authorities €500,000	will require the development and implementation of associated requirements, including in terms of permit/registration, monitoring, reporting, inspections etc.
PO4b Mandatory application of best available abatement techniques only for crematoria above 4000 cremations per year	X	✓	✓	• **PO4b**: estimated mercury emissions reductions of 141 kg in 2030, delivering human health benefits valued at €2.5 million. Associated **cost-benefit ratio: 1.65** (when benefits from other pollutant reductions, described below, are also accounted for). • **PO4b combined with PO2a**: estimated emissions reductions of	• Total capital and operational costs of €1.6 million (EAC) in 2030.	• Business €23,000 • Public authorities €28,000	The mandatory application of BAT for crematoria in the EU will require the development and implementation of associated requirements, including in terms of permit/registration, monitoring, reporting, inspections etc.

Policy option	Main impacts			Benefits	Costs	Admin burden	Key aspects
	Econ.	Env.	Social.				
				113 kg in 2030, delivering human health benefits valued at €2.0 million. Associated **cost-benefit ratio: 1.34** (when benefits from other pollutant reductions, described below, are also accounted for)**.** • **PO4b**: estimated reductions in emissions of $PM_{2.5}$ and other pollutants delivering human health benefits valued at €183,000.			
PO4c Mandatory application of best available abatement techniques only for crematoria above 3000 cremations per year	X	✓	✓	• **PO4c:** estimated mercury emissions reductions of 191 kg in 2030, delivering human health benefits valued at €3.4 million. Associated cost-benefit ratio: **1.33** (when benefits from other pollutant reductions, described below, are also accounted for). • **PO4c combined with PO2a:** estimated emissions reductions of 155 kg in 2030, delivering human health benefits valued at €3 million. Associated cost-benefit ratio: **1.10** (when benefits from other pollutant reductions, described below, are also accounted for). • **PO4c:** estimated reductions in	• Total capital and operations costs of €2.6 million (EAC) in 2030.	• Business €42,000 • Public authorities €53,000	The mandatory application of BAT for crematoria in the EU will require the development and implementation of associated requirements, including in terms of permit/registration, monitoring, reporting, inspections etc.

Policy option	Main impacts			Benefits	Costs	Admin burden	Key aspects
	Econ.	Env.	Social.				
				emissions of $PM_{2.5}$ and other pollutants delivering human health benefits valued at €260,000.			

Table 15: Summary of impacts for PO5 and PO6 (Problem 3)

Policy option	Main impacts			Benefits	Compliance costs	Admin costs €million/y	Key aspects
	Econ.	Env.	Social.				
PO5 Seek change to international agreement	X	✓✓✓	✓✓	• Decreased demand for mercury for mercury-containing lamps production in the order of 0.8-1.5 t (2026-2030) • Decreased demand for mercury for dental amalgam production in the order of 30-180 t (2025-2030).	• Foregone revenues to EU businesses of €144 million (€97-190 million) (2026-2030) for mercury-containing lamps. • Foregone revenues to EU businesses of €50-300 million for dental amalgam (2025-2030)	• Business 0 • Public authorities 0	On the one hand, the analysis has quantified the potential reduction in demand for mercury for production of MAPs. Yet, on the other hand and unlike for PO3 and PO4, it has not been feasible to further quantify or value the benefits (e.g. impacts for the environment and human health) due to the significant uncertainties associated with the fate of such MAPs in third countries. Overall, a positive environmental impact is expected but this strongly depends on willingness of Parties to the Minamata Convention to agree on a global ban at COP5 or at subsequent COPs.
PO6 EU export ban	XX	✓✓	X / ✓	Decreased demand for mercury for mercury-containing lamps production of: • **PO6a:** 1.2-2.2 t • **PO6b:** 0.8-1.5 t Lower release of mercury to general waste and resulting reduced human exposure.	Foregone revenues to EU businesses of: • **PO6a:** €191-347 million (2025-2030) • **PO6b:** €97-190 million (2026-2030)	• Business 0 • Public authorities 0	As set out above for PO5, whilst the analysis has quantified the potential reduction in demand for mercury for production of MAPs, it has not been feasible to further quantify or value the benefits (e.g., impacts for the environment and human health) due to the significant uncertainties associated with the fate of such MAPs in third countries. The ultimate benefits will depend upon the resources and regulatory measures for such MAPs in third

							countries. As a result, it has not been feasible to present a cost benefit ratio similar to PO3 and PO4. Overall impacts will depend on rate of FL substitution in importing third countries and mercury content of lamps produced outside the EU. Economic operators may better adapt the longer the transition phase, i.e. if more time is given between the adoption of the manufacture and export ban decision and its entry into force.

8. 8. PREFERRED OPTION

Table 16 summarises the broad rationale for selecting or discarding (sub-)options. Retained (sub-) options appear in bold. The preferred Policy Option for problem area 2 will require a political choice.

Table 16: (Sub-) options included in and discarded from the preferred policy package

POLICY OPTION	BROAD RATIONALE FOR RETAINING OR DISCARDING THE OPTION/SUB-OPTION
1 – Reducing the health and environmental risks associated with mercury exposure during the use and disposal of mercury containing dental amalgam.	
PO1: Communication campaign to raise awareness and change behaviour of dental patients *(discarded)*	Several such campaigns are already organised by MSs and the consultation responses show that most people are aware of impacts of mercury and availability of alternatives. Whereas some sectoral stakeholders consider the above-mentioned initiatives of high relevance, in terms of pollution control, they are not expected to have much impact.
PO2: Establish legally binding end date for the use of mercury-containing dental amalgam in the EU. **Sub-option phase-out by 2025 (retained)** *Sub-options phase-out by 2027 or 2030 (discarded)*	A number of MSs have already phased out dental amalgam use or are planning to in the coming years demonstrating that it is technically feasible to do so. Although the baseline shows significant reductions in usage for all MSs over the assessment period, an EU wide phase-out of the use of dental amalgam would ensure a uniform phase-out across all MSs and place the EU in a first-move leadership role in relation to future international negotiations within the context of the Minamata Convention. 2025 is the preferred option for phase-out as it would lead to the greatest environmental and health benefits and is considered feasible to implement within this time frame.
2 – Reducing the health and environmental risks associated with mercury emissions from crematoria.	
PO3: EU guidance on BAT for crematoria	Non-legally binding EU guidance on abatement technology for mercury emissions from crematoria should provide a valuable reference guide for the MSs to be able to implement controls at national (or local or regional) level. This should be of most value to those MSs that do not currently regulate mercury emissions from crematoria and choose to do so voluntarily e.g., for a crematorium located near residential areas or for pollution control of other substances. Documents on BAT have been developed by the European Commission for other sectors under, in particular, the Industrial Emissions Directive[81] and the Mining Waste Directive[82]. A supporting voluntary agreement with the sector has been discarded as it is not considered feasible to broker such an agreement at EU level and should be left to the MSs to determine how best to engage with the sector.

[81] Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (OJ L 334, 17.12.2010, p. 17–119).

[82] Directive 2006/21/EC of the European Parliament and of the Council of 15 March 2006 on the management of waste from extractive industries and amending Directive 2004/35/EC (OJ L 102, 11.4.2006, p. 15–34).

PO4: Mandatory application of best available abatement techniques to reduce mercury emissions from crematoria. *Sub-option: for all crematoria* *Sub-option: only for crematoria with capacity ≥ 4000* *Sub-option: only for crematoria with capacity ≥ 3000*	Whilst mandatory application of abatement technology would guarantee a uniform application of abatement across the EU, the potential costs relative to benefits are high, particularly for the smaller, more numerous crematoria, many of which are SMEs. In addition, if dental amalgam is phased out in 2025 (PO2a) then emissions from crematoria will be even lower by 2030 so the cost effectiveness of this option reduces. When the obligation to operate crematoria with abatement techniques applies only to larger crematoria (more than 4000 cremations/year), the cost-benefit ratio becomes slightly positive. This would capture around 30% of mercury emissions from all EU crematoria of all sizes while keeping the administrative costs for the authorities and the economic costs for the operators reasonable. However, only a few Member States would be concerned (in particular DE, HU), i.e., this raises questions about the EU added value. When the obligation to operate crematoria with abatement techniques applies to crematoria with a capacity ≥ 3000 cremations per year, the cost-benefit ratio is reduced.
3 – Reducing the health and environmental risks associated with mercury contained in products intended for export from the EU (but banned in the EU).	
PO5: Seek change to international agreement to prevent (manufacture and) export of mercury containing products which would then be transposed into EU law (retained)	This option is considered an effective approach to achieve a maximum reduction of product-related mercury use and emissions. If agreed upon by Parties to the Minamata Convention, it provides for an international phase-out of MAPs. The instrument would close most, if not all, loopholes for third country manufacturers (other than an EU ban). Due to its consensual character, interests and priorities of third countries, especially developing countries are explicitly considered. However, the outcome of international negotiations on the prohibition of additional MAPs is undoubtedly uncertain regarding both its content and timing.
PO6: Introduce an EU ban on the export of mercury containing products already prevented from being placed on the market in the EU **Sub-option by 2025 (retained for dental amalgam)** **Sub-option by 2026/28 (retained for relevant mercury-containing lamps**	An EU ban would allow the EU to take immediate action and to further decrease export of MAPs independently form the outcome of future negotiations at the international level (Minamata Convention). Thereby, the EU could lower its external pollution footprint. Such an action is a political signal to other countries that may wish to follow this path and prohibit the sale/export of MAPs as well. However, the EU cannot restrict the import to third countries of MAPs produced outside the EU. Part of EU-made products may be substituted by products with a possibly higher mercury level. The risk for net negative impacts decreases if more time is planned between adoption of the initiative and entry into force of a manufacture and export ban. This would also give third countries more time to adjust their national legislation. If closely followed by a global ban (PO5) no negative impacts are to be expected. This is the reason why a ban on the manufacture and export of FLs in 2026/2028 is preferred whereas a similar prohibition on the manufacture and export of dental amalgam in 2025 is preferred.

Overall, the preferred policy package would likely generate significant and positive environmental impacts and incur limited negative economic impacts. Where it has not been possible to systematically quantify and monetise all impacts for all measures, quantification has been supplemented with qualitative data based on expert judgement.

8.1.1 Preferred Policy Option for Problem 1

The preferred policy option for Problem Area 1 tackles the issue of continued dental amalgam use at source through the earliest possible phase-out (2025) (**PO2a**). An EU wide phase-out of the use of dental amalgam would ensure a uniform phase-out across all Member States and place the EU in a first-mover leadership role in relation to future international negotiations within the Minamata Convention. Absence of such action could result in global criticism and risks reduced credibility of the EGD and EU Chemicals policy at global level.

Whilst this will lead to some additional costs due to the current cost difference between dental amalgam and mercury-free alternatives, many Member States are already planning phase-outs so additional impacts of EU action are relatively limited. These additional costs decline over time as the cost difference between dental amalgam and mercury-free alternatives is expected to narrow with greater demand and innovation. The year 2025 is the preferred option for a phase-out as it would lead to the greatest environmental and health benefits and is considered feasible to implement within a short timeframe (as demonstrated by some Member States already having phased out, or planning to phase out, dental amalgam use by then).

The phase-out of dental amalgam use in the EU will lead to significant benefits for the environment and health. In addition, it will lead to reductions in mercury emissions from crematoria, which will continue to steadily decline over time.

8.1.2 Preferred Policy Option for Problem 2

The policy options concerning mercury emissions from crematoria will require a political choice. The outcome of this choice will have environmental and economic impacts. There are advantages and disadvantages associated with each policy option identified for Problem 2.

Regarding **PO4a** or **PO4b**, on the one hand, it would ensure the implementation of a uniform and legally certain obligation to install mercury emission abatement technologies in crematoria across the EU at a time where cremation rates are increasing. On the other hand, whereas for PO4a, in practice, all EU crematoria (25 Member States) would be covered under PO4a, this proves not to be cost-beneficial with a very low cost-benefit ratio of 0.31. Furthermore, PO4a would prove to place considerable economic pressure on SMEs operating crematoria with low capacity (noting that the sector is dominated by SMEs) as well as significant administrative burden on operators and competent authorities (e.g., compliance and enforcement). Whilst a slightly positive cost-benefit ratio (between 1.34 or 1.65, depending on the implementation of PO2a) can be achieved under PO4b, the legal obligation would apply in practice to very few crematoria (around 100 out of 1.200) located mainly in two Member States (DE, HU) and abate less than 40% of mercury emissions from EU crematoria. Under PO4c, a cost-benefit ratio between 1.10 or 1.33 (depending on the implementation of PO2a) can be achieved, but the legal application would only apply, in practice, to an additional 70 crematoria compared to PO4b. Hence, above-mentioned disadvantages may put into question in particular the proportionality principle, especially when considering a dental amalgam phase-out (PO2a).

An alternative to PO4 is **PO3** whereby the European Commission develops a non-legally binding guidance on BAT for the abatement of mercury emissions from crematoria. The advantage of PO3 provides room for manoeuvre for operators to make an informed choice on whether economic and administrative burden is feasible, dependent on their capacity.
In choosing the preferred option, account should be taken also of the time needed to implement abatement technology in crematoria across the EU (typically, around 2-3 years for developing appropriate BATs and then at least 1-2 years for Member States to implement them).

8.1.3 PREFERRED POLICY OPTION FOR PROBLEM 3

The preferred policy options for Problem Area 3 includes both the introduction in the Mercury Regulation of an EU-wide prohibition of the manufacture and export of mercury-containing lamps which are already prohibited from being placed on the internal market, by 2026 and 2028 and a manufacture and export ban of dental amalgam aligned with the phase-out of its use in 2025 (**PO6b**) as well as the promotion of a ban under the Minamata Convention **(PO5)**. It is to be noted that this manufacture and export ban, once implemented into the Mercury Regulation by this initiative, will also be transposed into Annex V (Part 2) to the PIC Regulation, as has been done with the full list of MAPs under Annex II to the Mercury Regulation.

An EU ban **(PO6)** would allow the EU to take immediate action and to further decrease export of MAPs independently from the unpredictable outcome of future negotiations at the international level (Minamata Convention). Such an action is a signal to third countries that may wish to follow this approach and prohibit the sale/export of MAPs as well. It also sets an example for future negotiations under the Convention. Furthermore, such action would ensure upholding the EU's credibility vis-à-vis the objectives set out in the EGD and EU Chemicals Strategy for Sustainability.

However, recognising the risk of substitution of products that can no longer be exported from the EU but still sourced from elsewhere in the world, the preferred option also includes a concerted push to reach a global agreement (at international level) on a ban of such products (**PO5**). A global ban of such products is considered the most effective approach to achieve the maximum reduction of product-related mercury use and emissions. If agreed upon by Parties to the Minamata Convention, it provides for a uniform phase-out of MAPs at global level.

The main overlap between the three problem areas and policy options relates to dental amalgam which is currently manufactured within the EU, and both used in the EU as well as manufactured and exported. The preferred policy option is coherent in that a phase-out of dental amalgam use in the EU would apply from 2025, simultaneously to a ban on the manufacture and export to non-EU countries.

8.1.4 OVERALL PREFERRED POLICY PACKAGE

Overall, the **combined preferred options** would lead to the following impacts in the EU:

- **PO2a** resulting in a cumulative reduction in mercury used in dental restorations in the EU of 114 t by 2035 (following a 2025 phase-out) and additional costs of using alternatives of €208 million in 2025 declining over time.

- **PO3** (in combination with PO2a) resulting in estimated mercury emissions reductions of 14.5 kg in 2030, delivering human health benefits valued at €280,000 with costs to operators in 2030 estimated as total one-off capital costs of €10.3 million and annual operating costs of €0.32 million.

  Alternatively, **PO4b** (in combination with PO2a) resulting in estimated mercury emissions reductions of 167 kg (i.e., foregone emissions of 54 kg stemming from a 2025 phase-out of dental amalgam and 113 kg from controls on crematoria greater than 4,000 cremations per year) in 2030, delivering human health benefits valued at €2.2 million, and is estimated to result in total one-off capital costs of €15 million and annual operating costs of €0.46 million.

- **PO6b** resulting in a reduction in demand for mercury for mercury-containing lamps production in the order 0.8-1.5 t (export ban in 2026/2028). This would be associated with potential foregone revenues to businesses €97-190 million (2026-2030; 2026/2028 export ban). In addition, **PO6a (2025)** resulting in a reduction of mercury use for the production and export of dental amalgam in the order 30-180 t (export ban in 2025). This would be associated with potential foregone revenues to EU businesses €50-300 million (2025-2030).

8.2.1. REFIT

In line with the Commission's commitment to better regulation, this proposal has been prepared inclusively (3), based on full transparency (3) and continuous engagement with stakeholders (3) with due regard to avoiding unnecessary burdens (2). It is based on the best available evidence (1), referenced in the document, and expert knowledge (1) taking into account the external feedback (1).

The Mercury Regulation does not currently impose reporting (and associated reporting costs) on operators of crematoria, dental practitioners or MAPs producers. Member State Authorities report on the implementation of the Regulation, and the approximate annual administrative burden of this overall reporting is moderate (30 000 – 100 000 EUR/p.a. for the whole EU) and is based on data that should already be available to authorities.

PO2a (phase-out of dental amalgam from 2025) would impact on dentists (all of whom are likely to be SMEs) across the EU as they would no longer be able to offer restorations using dental amalgam. However, impacts are expected to be minimal as there has already been a steady transition towards phase out happening in recent years and any additional costs associated with offering alternatives would be expected to be passed through to the consumer (and/or covered by social security systems and/or private healthcare).

For crematoria, whilst there is uncertainty over how many SMEs are operating in the sector this is expected to be high (aside from those that are publicly run most of the rest are expected to be SMEs.

PO3 would be entirely voluntary and therefore no impacts on SMEs are expected. It would be up to the individual Member States and/or operators to decide whether or not to implement controls.

PO4a (mandatory application of BAT for all crematoria) would cover all crematoria and therefore impacts on SMEs could potentially be significant. However, all additional compliance costs associated with installing mercury controls would be expected to be passed through to the consumer in terms of fees for cremations, as they are already done in many countries where abatement is already required. A mandatory option would also entail some administrative burden for operators (and public authorities) for ensuring and demonstrating compliance e.g. reporting on results of emissions monitoring. However, it is assumed that these would also be passed through to consumers alongside costs for installing and running abatement controls.

PO4b (mandatory application of BAT for large crematoria only) would only cover the largest crematoria (above 4,000 cremations per year) thus excluding the smaller crematoria from any impacts (compared to PO4a this would reduce the number of crematoria potentially impacted from 1,500 to just under 130 crematoria). For those crematoria that are covered by PO4b, impacts could potentially be significant. However, all additional compliance costs associated with installing mercury controls would be expected to be passed through to the consumer in terms of fees for cremations, as they are already done in many countries where abatement is already required. A mandatory option would also entail some administrative burden for operators (and public authorities) for ensuring and demonstrating compliance e.g., reporting on results of emissions monitoring. However, it is assumed that these would also be passed through to consumers alongside costs for installing and running abatement controls.

PO4c (mandatory application of BAT for crematoria operating above ≥ 3000 cremations per year) would cover 170 out of 1200 crematoria, thus excluding the smaller crematoria from any impacts (compared to PO4a). For those crematoria that are covered by PO4c, impacts could potentially be significant. However, all additional compliance costs associated with installing mercury controls would be expected to be passed through to the consumer in terms of fees for cremations, as they are already done in many countries where abatement is already required. Like for PO4b, a mandatory option would also entail some administrative burden for operators (and public authorities) for ensuring and demonstrating compliance e.g., reporting on results of emissions monitoring.

For PO5, a global agreement would have an impact for some SMEs that are manufacturing certain types of MAPs, namely some lamp types other than FLs for general lighting purposes. As only about 8% of current HID exports would be affected by a ban the relative impact would be limited.

For PO6a and PO6b, a unilateral MAP export ban would have similar effects as PO5. In addition, a ban on the export of dental amalgam (only after a phase-out within the EU) would effectively end the production of amalgam by the four remaining EU producers, eliminating a large part of their current business. However, this would lead to a decrease of amalgam use in the EU in the order of 13 to 38 t.

This limits the potential for future streamlining, nevertheless the combination of measures designed to reduce the environmental footprint of European MAPs and aligning EU acquis on the placing on the market, import, export and manufacturing of MAPs will offer more legal certainty on the applicable rules (see Annex 9) for manufacturers and exporters and therefore ensure costs savings (2).

A revision of the Mercury Regulation will allow provisions that have become obsolete to be eliminated which would simplify its implementation (2).

8.1. 8.2.2 One-in-one-out

The proposed options will not bring about new administrative burdens to citizens, and the additional burden to businesses will be limited. The administrative impact of the amalgam phase-out (PO2a) and of measures addressing MAPs (PO5 and PO6) will bring limited cost savings – these could not be calculated in an exact manner as the current Mercury Regulation does not impose direct reporting obligations to business operators (dental practitioners, crematoria operators or MAP producers), Member States report on mercury emissions in a highly aggregated way.

PO3 would not introduce any new administrative burdens for businesses, citizens or Member State public authorities as the measure would be voluntary and up to the Member States themselves (and/or operators) to decide whether to implement controls for crematoria using the developed guidance as a framework for any requirements.

Should PO4a,PO4b or PO4c be retained as the preferred policy option, this would introduce new administrative burdens to both crematoria operators and Member State competent authorities, arising from the enforcement of the policy option.

For PO4a, in addition to the costs of implementing and operating mercury emissions abatement systems at their installations, crematoria operators would face added administrative burdens. This would arise from the need to submit information on their abatement systems and any periodic emissions monitoring and reporting to Member States' competent authorities, who would also encounter a new administrative burden in processing such information. It has been assumed that costs to both operators and authorities would be comparable to administrative burdens incurred by the smallest medium combustion plants (1-5 MWth) under Directive (EU) 2015/2193 on medium combustion plants[83]. Administrative costs are estimated to amount to €400,000 to operators and €500,000 to authorities for PO4a (all crematoria) in 2030.

For PO4b, in addition to the costs of implementing and operating mercury emissions abatement systems at their installations, large crematoria operators would face added administrative burdens. This would arise from the need to submit information on their abatement systems and any periodic emissions monitoring and reporting to Member States' competent authorities, who would also encounter a new administrative burden in processing such information. It is assumed that costs to both operators and authorities would be comparable to administrative burdens incurred by the smallest medium combustion plants (1-5 MWth) under Directive (EU) 2015/2193 on medium combustion plants[84]. Administrative

[83] Directive (EU) 2015/2193 of the European Parliament and of the Council of 25 November 2015 on the limitation of emissions of certain pollutants into the air from medium combustion plants *(*OJ L 313, 28.11.2015, p. 1–19).

[84] Directive (EU) 2015/2193 of the European Parliament and of the Council of 25 November 2015 on the limitation of emissions of certain pollutants into the air from medium combustion plants *(*OJ L 313, 28.11.2015, p. 1–19).

costs are estimated to amount to €23.000 to operators and €28.000 to authorities for PO4b in 2030. For PO4c, administrative costs are estimated to amount to €42,000 to operators and €53,000 to authorities in 2030.

8.2.3. PREFERRED INSTRUMENT

Based on the analysis of the problems, the most appropriate instrument to address them is a revision of the current Mercury Regulation.

9. 9. HOW WILL ACTUAL IMPACTS BE MONITORED AND EVALUATED?

9.1. 9.1. Identification of monitoring needs

Monitoring the implementation of a phase-out of the use of dental amalgam (PO2) will imply an obligation on Member States to undertake market surveillance and compliance checking in accordance with Regulation (EU) 2019/1020[85]. Under a voluntary application of abatement technology (PO3), no further monitoring obligations will be imposed at EU level, leaving the implementation of mercury emission abatement technology and associated monitoring to Member State competent authorities. However, in case of mandatory application of abatement technology for crematoria (PO4), EU law would have to provide for monitoring, reporting obligations for operators of crematoria and administrative (information processing, inspections etc.) obligations for competent authorities. Similarly, regarding the prohibition to manufacture and export of MAPs (i.e., CFLs and LFLs), the extension of Annex II to the Mercury Regulation will not lead to an ad-hoc EU obligation to monitor implementation (PO5 and PO6). Any relevant information can be provided to the Commission via Member State reports on the implementation of the Mercury Regulation (under Article 18). Jointly with the ongoing decarbonisation efforts, this initiative should translate into a progressively decreased presence of mercury in air, water and soil, to be tracked under the bi-yearly Zero Pollution Monitoring and Outlook Report.

9.2. 9.2. Identification of key indicators

The key indicator for dental amalgam could be the amount of dental amalgam used in the EU. The key indicator for crematoria could be the uptake of mercury abatement techniques in crematoria. For MAPs, no indicators are deemed necessary with a ban on their manufacture and export.

[85] Regulation (EU) 2019/1020 of the European Parliament and of the Council of 20 June 2019 on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) 765/2008 and (EU) 305/2011 (OJ L169, 25.6.2019, p.1.).

Annex 1: Procedural Information

10. 1. LEAD DG, DECIDE PLANNING/CWP REFERENCES

The preparation of this file was led by DG Environment (ENV) and comprises a review of Regulation (EU) 2017/852 on mercury, in accordance with its Article 19(1).
The Mercury Regulation is the most important legal instrument in regulating the environmental impacts of mercury pollution by addressing the entire life cycle of mercury. Article 19(1) of the Mercury Regulation requires the Commission to review the following aspects:

(a) The need for the Union to regulation emissions of mercury and mercury compounds from crematoria;

(b) The feasibility of a phase out of the se of dental amalgam in the long term, and preferably by 2030, taking into account the national plans referred to in Article 10(3) and whilst fully respecting Member State' competence for the organisation and delivery of health services and medical care; and

(c) The environmental benefits and the feasibility of a further alignment of Annex II with relevant Union legislation regulating the placing on the market of mercury-added products.

The overall "Mercury Regulation Review" takes into account the feasibility assessment of phasing out dental amalgam (2020) [1] and the study supporting the revision of Regulation (EU) 2017/852 on mercury[2] in order to update the instrument to be able to deliver the aims and targets of the wide-ranging and overarching policy aims as described in Section 2.

The DECIDE/Agenda Planning is the following:

Mercury – Review of EU law: Revision of Regulation (EU) 2017/852 on mercury, and repealing Regulation (EC) No 1102/2008	PLAN/2020/9940

11. ORGANISATION AND TIMING

The Mercury Regulation Review initiative feeds into objectives set out in the European Green Deal[3], the Zero Pollution Action Plan[4] and the EU Chemicals Strategy for Sustainability[5]. The **Inception Impact Assessment Roadmap** was published on 5 March 2021 with a feedback period until 2 April 2021.

1 Deloitte, Ineris, Wood (2020), Assessment of the feasibility of phasing-out dental amalgam – Final report
2 Regulation (EU) 2017/852 of the European Parliament and of the Council of 17 May 2017 on mercury and repealing Regulation (EC) No 1102/2008 (OJ L137, 24.5.2017 p. 1).
3 Communication from the Commission 'The European Green', COM(2019) 640 final, 11.12.2019.
4 Communication from the Commission, 'Pathway to a Healthy Planet for All EU Action Plan*: 'Towards Zero Pollution for Air, Water and Soil*' COM(2021) 400 final, 12.5.2021.
5 Communication from the Commission 'Chemicals Strategy for Sustainability - *Towards a Toxic-Free Environment*', COM(2020) 667 final, 14.10.2020.

The Inter Service Steering Group (ISSG) for the Impact Assessment was set up by DG Environment. It included the following DGs and services: ENER (Energy), GROW (Internal Market, Industry, Entrepreneurship and SMEs), JRC (Joint Research Centre), RTD (Research and Innovation), SANTE (Health and Food Safety), SJ (Legal Service) as well as TRADE (Trade). Meetings were organised between January 2021 and October 2022.

The ISSG discussed the Inception Impact Assessment as well as the Terms of Reference (ToR) for the support contract, assisting the Commission with the Impact Assessment. The ISSG meetings have discussed the main milestones in the process, in particular evidence gathering, coherence with other (ongoing draft) legislative initiatives, the consultation strategy and main stakeholder consultation activities. The ISSG has been consulted regarding, and has given input to, key deliverables from the support study and the draft Impact Assessment report prior to its submission to the Regulatory Scrutiny Board (RSB).

12. CONSULTATION OF THE RSB

An informal upstream meeting with the RSB took place on 11 January 2021.

After final discussion with the ISSG, a draft of the Impact Assessment was submitted to the RSB on 14 November 2022 and discussed at a meeting with the RSB on 14 December 2022.

Following the negative opinion of the RSB, changes were made to the Impact Assessment in order to reflect the recommendations of the Board.

After another consultation of the ISSG, the Impact Assessment was re-submitted to the RSB on 17 February 2023.

Following the positive opinion of the RSB (24 March 2023), additional changes were made to the Impact Assessment in order to reflect the recommendations of the Board.

Table 1 presents an overview of the RSB’s comments and how these have been addressed.

Table 1: How the RSB comments have been addressed

General RSB comments	How addressed
Main findings	
1. The report is not sufficiently clear on the scale and the drivers of the problems. It does not sufficiently describe the dynamic baseline.	• Supplementary information on dental amalgam and mercury emissions from crematoria have been added across the whole report. • Using additional work commissioned to the consultant, the information describes in more granular detail the current baseline situation in the EU and in each Member State (p. 13 and 14), as well as the drivers and scale of issues associated with a phase-out of the use of dental amalgam (p. 15), mercury emissions from crematoria (p. 19) and restriction of mercury-added

	products (MAPs) (pp. 23 and 24).
2. The report does not present a clear, comprehensive and analytically coherent cost benefit analysis.	• The report provides a clearer and a more comprehensive and analytically coherent picture of the costs and benefits of each Policy Option (Section 7), using additional more granular Member State level information.
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.	• The Policy Options were restructured, separating the options related to crematoria from the options related to dental amalgam. Several options were screened out (Annex 7). • The link between impacts of a dental amalgam phase-out and costs of crematoria emissions abatement is clearly described in Sections 6.21, 6.2.2 and 7. • An overview of costs and benefits (qualitative and/or quantitative where it is not feasible to quantify impacts) is presented in a tabular format (Table 12 and 13) describing all available quantitative and qualitative information in Sections 7 (and Annex 3).

Specific RSB comments	**How addressed**
Way 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	• Section 2 was amended to improve the description of the scope and size of the problem and includes a breakdown of amounts of mercury addressed by the initiative (p. 11). • Section 1 provides a clear definition of the term mercury-added products (MAP), describing the type of products addressed, and making clear that dental amalgam is included in the definition of MAPs (p. 5 and 22). • Section 2.1 describes the reasons for which some Member States continue the use of dental amalgam and presents (in a tabular format Table 1 on pp. 13-14) the current and projected dental amalgam use per Member State. • Section 6.1.2 presents the price difference between dental amalgam and

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.	mercury-free alternatives per Member State (Table 6 on pp. 38 and 39) and Section 2.2 provides an explanation as to why transboundary effects of price differences in cremation costs between Member States are considered negligible.
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.	• Sections 2.2, 6.2.1 and 6.2.2 provide a more detailed description of the current and expected future situation of crematoria emissions in the EU and per Member State, providing a description of the current and expected number of crematoria (Table 2 on pp. 17-18 and Annex 5), size/capacity of crematoria, and mercury emissions from these crematoria. • Section 5.1.3 presents the baseline for MAPs more clearly and Section 1.2 clarifies the envisaged prohibition of additional MAPs under the Minamata Convention (p. 10 and Annex 8). Section 5.1.3 explains why such a prohibition cannot be considered as forming part of a dynamic baseline but merits from being assessed as a real Policy Option (p. 31). • Section 5.1.3 also provides a more detailed explanation of the baseline considerations concerning the shift towards using LED technology. • Section 5 provides justified reasoning for the inclusion of communication campaigns (dental amalgam) and non-legally binding guidance (abatement technologies for crematoria) as real Policy Options rather than as part of a 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. The environmental impacts should be monetised (to the extent possible) and the results should be brought into the cost benefit analysis. It should provide an overview of the costs and benefits, the net impacts and	• Section 7 includes further assessment and an overview of costs and benefits in a tabular format describing all available quantitative and qualitative information, and more specifically for PO3 and PO4 (p. 45-48). • Sections 6.2.1, 6.2.2 and 7 present and describe in more detail the link between impacts of a dental amalgam phase-out and costs of crematoria emissions abatement. • Metrics are presented in a more specific

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.	and clear manner and, where metrics differ or where multiple metrics are used, information is provided on their (non-) comparability. This is specifically addressed in Section 7 and Annex 3. • Environmental impacts have been monetised as much as possible and these and been integrated into the cost-benefit analysis (see also response to point 6). • However, for PO2, indirect emissions to soil and water bodies cannot be accurately nor robustly quantified. 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. • Furthermore, 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. • However, benefits of reductions in mercury exposure for dental practitioners and patients cannot be robustly quantified or monetised so health benefits are underestimated. • Therefore there are limitations to the monetisation of several environmental impacts and as to how far the cost-benefits of the individual options can be compared, as these have been calculated using different methodologies. These uncertainties and limitations are now better described in Annex 3 and 5.
4. 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	• Additional information included in Section 6.3.2 and Annex 7 on the substitution rate assumed as well as the mercury content in substituted products. • Additional information on competitiveness and estimated job losses have been included in Section 6.3.2

pollution in third countries. 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.	
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.	• A new Policy (sub) Option has been included in Sections 5.2 and 6.2.2, 7, 8 and Annex 3 and 7 (PO4c) whereby mandatory application of abatement technology would be set for crematoria with a capacity of ≤ 3000 cremations per year.
6. 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.	• Further assessment provided additional information on environmental impacts for all options, specifically the fate of mercury from dental amalgam (p. 40-43). • Where quantitative information was lacking, the Impact Assessment filled data gaps with qualitative information. Uncertainties and limitations are better described in Annex 5. • Tables 12 and 13 on the comparison of options (Section 7) have been re-drafted to include as much quantitative data as possible and are accompanied by a narrative on the comparison of options within problem areas (p. 55-57). • Whilst the Impact Assessment provides information on EU manufacturers including employment, export volumes and values as well as mercury content of exported MAPs, the assessment of the impacts on the competitiveness of EU manufacturers at global level remains uncertain due to unpredictable global market responses. • Within the Impact Assessment, an SME test was performed in accordance with the Better Regulation Guidelines. The economic impacts on SMEs of the preferred Policy Options were deemed limited to non-significant. This conclusion results from several factors, which are described in more detail in

	Sections 6 and 7. • The Impact Assessment clarifies the potential source of mercury to be used in dental amalgam for the application for specific medical conditions in Section 5.2 (p. 33). • Sections 6.2.1 and 6.2.2 include a cost/benefit analysis for the Policy Option concerning guidance for crematoria on the use of Best Available Techniques (BAT) including assumptions made on the uptake of such a non-legally binding measure. It also provides a cost/benefit analysis of the option of mandatory abatement/BAT for crematoria divided into different thresholds depending on the size and capacity of crematoria and taking into account a dental amalgam phase-out.
7. 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.	• Tables 12 and 13 on the comparison of options (Section 7) were re-drafted to include quantitative data and where not available, qualitative information on effectiveness and efficiency of Policy Options per Problem Area. • Section 7 also assesses the coherence of Policy Options between Problem Area 1 and 2 (qualitatively and quantitatively). • Annex 7 includes a list of Policy Options discarded at different stages during the Impact Assessment as well as reasoned justification for doing so. • Annex 3 includes a comparison for different policy sub options i.e., PO2a will lead to reductions in mercury emissions from crematoria of 54 kg (by 2030), whereas the discarded PO2b would lead to 31 kg (by 2030) and PO2c would lead to 3 kg (by 2030). Annex 3 also contains comparisons between sub-options for PO4, taking into account PO2.
8. 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	• The report has assessed in a more detailed and granular way various options related to the mandatory abatement of mercury emissions from crematoria, depending on the size and capacity of crematoria (Section 6.2.1 and

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).	6.2.2), providing additional information as to the cost-benefits of these options (Table 12) and forming the basis for a more substantiated choice of the preferred option. • In light of further analysis, Sections 6.2.1 and 6.2.2 on the Policy Options concerning mercury emissions from crematoria were amended and include a new sub-option assessing the impact of mandatory abatement technologies for crematoria (using capacity thresholds of > 4000 cremations per year). • Section 7 clarifies the impact of a dental amalgam phase-out on mercury emissions from crematoria, taking into account the average longevity of a dental amalgam filling (legacy dental amalgam) (p. 34).
9. The report should systematically refer to the views of stakeholders, including diverging views, in particular with regard to the options, impact and comparison sections.	• The Impact Assessment describes in more detail the positions of relevant stakeholders (in Section 6), in particular concerning the preferred Policy Options as well as in Annex 2.

13. EVIDENCE, SOURCES AND QUALITY

To support the analysis of the different options, the European Commission awarded a **support contract** to external experts.

The consortium of consultants comprised:

- BioIS and AQC – Policy impact assessment and links to wider policies
- RPA – Stakeholder engagement
- Ineris – Risk expertise
- BioIS, AQC and GRS – Mercury policy and technical evaluation

Evidence was compiled from previous studies, as well as via specific desk studies and data collection performed as sub-assignments, feeding into the overall Impact Assessment work. Further information is given regarding the evidence bases compiled by the external consultants in the following Annexes:

- Annex 5 – Baselines
- Annex 7 – Impact of shortlisted measures

In addition, extensive consultation of stakeholders was carried out by the external experts, as detailed in:

- Annex 2 – Stakeholder consultation synopsis

The external expert consultants worked in close cooperation with the European Commission throughout the different phases of the study, and particularly in the latter stages of assembling a coherent evidence base and in assessing, screening and adjusting policy measures and options.

Annex 2: Stakeholder Consultation

INTRODUCTION

The Impact Assessment accompanying the Mercury Regulation Review was subject to a thorough consultation process. This included a variety of different consultation activities aimed at gathering the views of all relevant stakeholders and ensuring that the views of different organisations and stakeholder types were presented and considered.

This Annex describes the consultation activities that have taken place and presents a summary of views.

PART 1: DESCRIPTION OF CONSULTATION ACTIVITIES

In order to collect primary data to support the Impact Assessment, a range of different consultation activities were organised to engage with stakeholders. Key stakeholders were consulted through a targeted questionnaire containing specialised questions in the three areas of interest (dental amalgam, mercury emissions from crematoria and mercury-added products), follow-up interviews, two consultation workshops and a focus group. All other relevant stakeholders were consulted through the public consultation questionnaire hosted on the "Have Your Say" portal.

Inception Impact Assessment

The Inception Impact Assessment

[1] was published on the Commission's "Have Your Say" interactive portal (38 responses; consultation period 5 March 2021 to 2 April 2021).

Public consultation

A public consultation[2] was published online via the Commissions' "Have Your Say" interactive portal (146 valid responses; consultation period 8 February 2022 to 3 May 2022). The survey consisted of two sections: one section aimed at the general public, and the other aimed at those with technical expertise or professional experience within the three areas of interest. The questionnaire contained 66 questions, most of which directly concerned gathering stakeholder opinions on the use of mercury in dental amalgam, the impact of crematoria emissions, and perceptions about the export of mercury-added products. Questions for technical experts aimed at gathering insights into potential policy options. Stakeholders were invited to submit attachments to their response, such as policy briefs or position papers.

Targeted stakeholder survey

A targeted stakeholder survey consisted of an online survey of a more detailed nature (36 valid responses; 15 December 2021 to 15 Aril 2022). The questionnaire was developed in discussion and agreement with the European Commission including the ISSG. The structure and design of the TSS was similar to the public consultation and included a general section, followed by sections for each of the three areas of interest. These latter three sections were more technically detailed than the questions in the public consultation. The TSS was provided by invitation only, to stakeholders with a known stake in the Mercury Regulation. The

[1] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12924-Mercury-review-of-EU-law_en

[2] Mercury – review of EU law (europa.eu)

questionnaire script included a number of multiple-choice questions. Stakeholders were invited to submit policy briefs, position papers, and other articles of interest as part of their response.

In-depth interviews

Interviews (undertaken via telephone or video-conferencing software) were undertaken (13 key stakeholders) and provided in-depth insight into data gaps in all three areas of interest. Stakeholders invited to an interview were selected from responses to the targeted survey, as well as other stakeholders with specific relevant knowledge. Data obtained from interviews was used to validate and clarify concepts and issues identified elsewhere in the consultation.

Because many interviewees had expert roles within highly specialised sectors, a semi-structured interview approach was applied. This approach enabled flexibility in discussing topics relevant to each stakeholder type, whilst also ensuring the structure of the interview was maintained and the desired data collected. Interviews took place between March and July 2022.

Workshops

Two (online) workshops were organised and conducted (December 2021, September 2022) with selected stakeholders to discuss the overall conclusions drawn from the study. The aim of these workshops was to validate the findings of the study, discuss and refine possible policy options available, and discuss the potential impacts of the policy options. Each workshop targeted about 40 participants.

Stakeholders invited to participate in the workshops were carefully selected to ensure that the different sectors within all three areas of interest were adequately represented.

Focus groups

After the completion of the public consultation and targeted stakeholder survey, a focus group was organised, on mercury-added products. This focus group consisted of nine experts. The purpose of the focus group was to provide an expert opinion on the development of the policy options and took place on 14 June 2022.

STAKEHOLDER GROUPS PARTICIPATING IN CONSULTATIONS

This section outlines the type of respondents that participated in the survey. As shown below 49% (72/146) were EU Citizens, 19% (28/146) were companies, 14% (21/146) were NGOs. All other stakeholder types provided less than 10% of all responses. In total 87% (127/146) of responses were from an EU Member State, and 13% (19/146) from non-EU countries. Significantly more responses were received from Germany than any other country (34%, 49/146), with Romania being the second highest (19%, 28/146). The six public authority responses were from: the Swedish Chemicals Agency; the City of Gothenburg Environmental Administration; the Estonian Ministry of the Environment; an undeclared French authority; an Italian Joint Research Centre member, and the Norwegian Environment Agency. Tables 1 and 2 below describe the types of stakeholder groups participating in the consultations whilst Table 3 indicated responses per country of origin.

Table 1: Respondent stakeholder types (OPC)

Stakeholder types	Stakeholder types (percentage of total (count/total))
Academic/research institution	1% (2)
Business association	3% (5)
Company/business organisation	19% (28)
Consumer organisation	1% (2)
Environmental organisation	1% (1)
EU citizen	49% (72)
Non-EU citizen	5% (8)
Non-governmental organisation (NGO)	14% (21)
Other	1% (1)
Public authority	4% (6)
Total	**100% (146)**

Totals may not equal 100% due to rounding

Table 2: Respondent stakeholder types (TSS)

Stakeholder types	Stakeholder types (percentage of total (count/total))
Business association	39% (14/36)
Company/business organisation	14% (5/36)
EU Citizen	3% (1/36)
Public authority	28% (10/36)
Consumer organisation	3% (1/36)
Non-governmental organisation (NGO)	11% (4/36)
Trade union	3% (1/36)
Total	**100% (36/36)**

Totals may not equal 100% due to rounding

Table 3: Responses by country of origin

Country	Stakeholder types (percentage of total (count/total))	Country	Stakeholder types (percentage of total (count/total))
Austria	1% (2)	Malaysia	1% (1)
Belgium	5% (8)	Malta	1% (1)
Bulgaria	1% (1)	Netherlands	1% (1)
Cameroon	1% (1)	New Zealand	1% (1)
Czechia	1% (1)	Norway	1% (2)
Denmark	1% (2)	Poland	2% (3)

Estonia	1% (1)	Portugal	2% (3)
France	3% (4)	Romania	19% (28)
Germany	34% (49)	Slovakia	1% (2)
Greece	1% (1)	Spain	1% (1)
Hungary	1% (1)	Sweden	3% (5)
Iran	1% (1)	Ukraine	1% (1)
Ireland	1% (2)	United Kingdom	7% (10)
Italy	8% (11)	United States	1% (2)
Total			**100% (146)**

Figures 1 to 4 below illustrate the overall numbers of respondents with technical expertise or experience for the OPC, as well a breakdown of the proportion of the types of stakeholders for each of the three topics i.e., dental amalgam, crematoria and mercury-added products.

Figure 1: Number of respondents with technical expertise or experience (OPC)

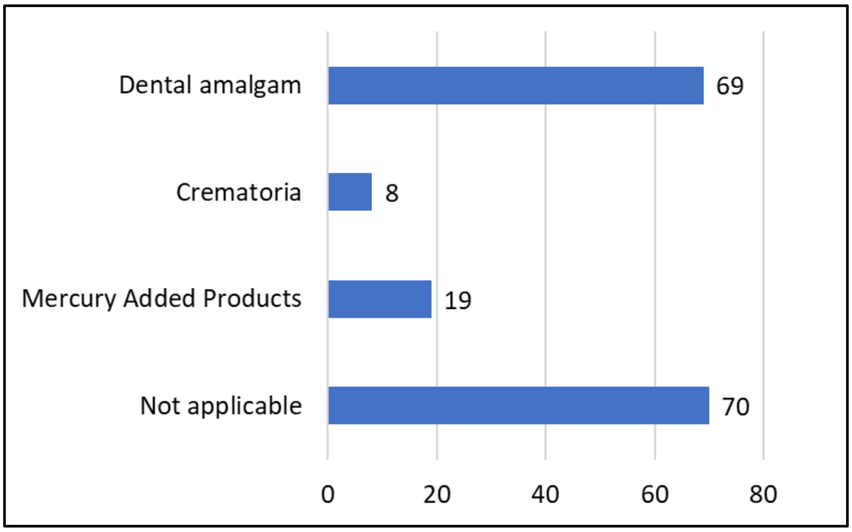


Figure 2: Sub-sectors of operation: Dental Amalgam

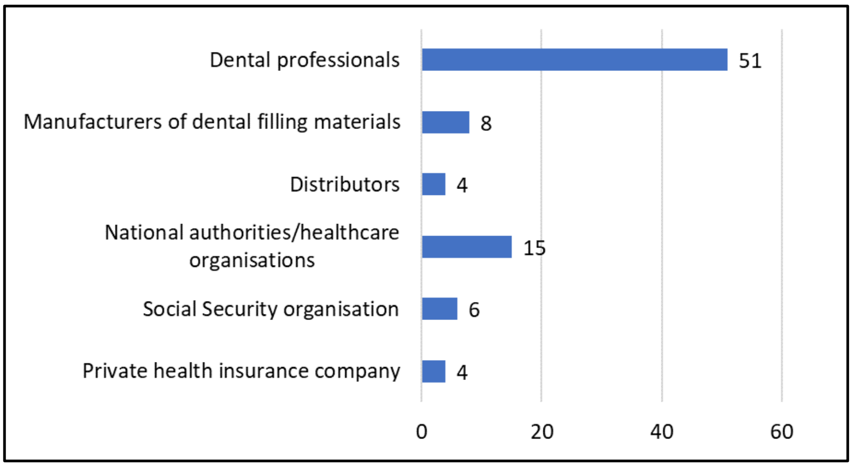


Figure 3: Sub-sectors of operation: Crematoria

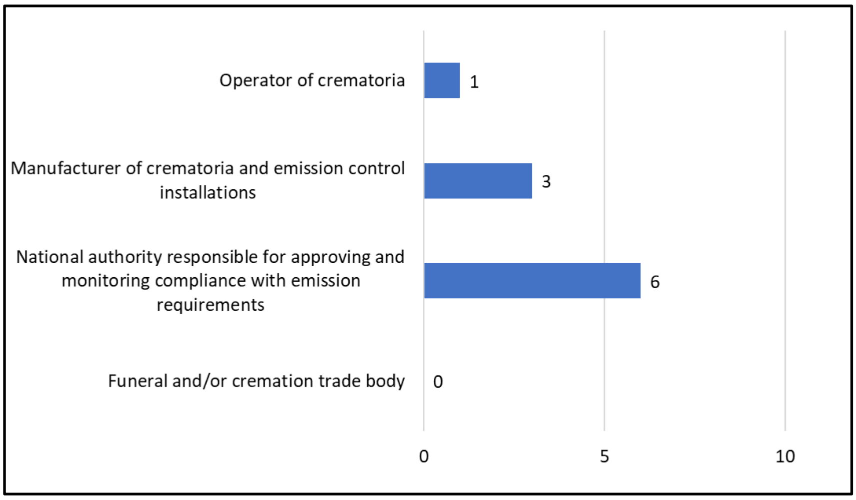
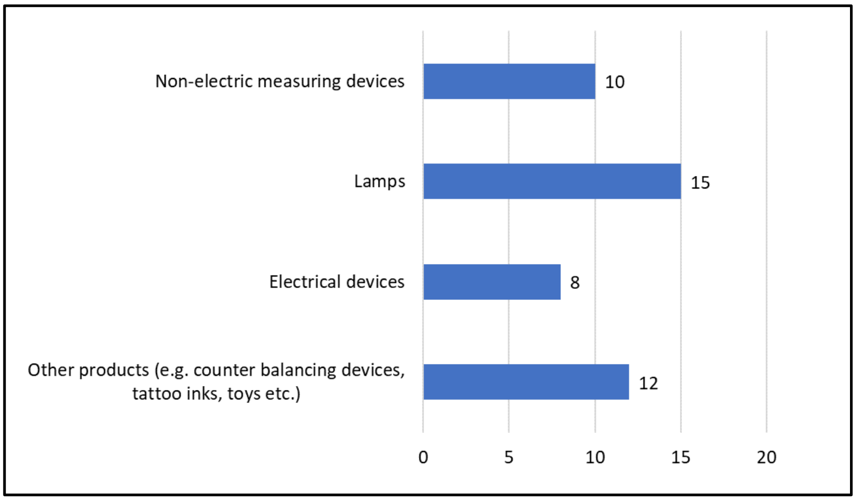


Figure 4: Sub-sectors of operation: Mercury-added Products



Figures 5 to 8 below illustrate the overall numbers of respondents with technical expertise or experience for the TSS, as well a breakdown of the proportion of the types of stakeholders for each of the three topics i.e., dental amalgam, crematoria and mercury-added products.

Figure 5: Number of respondents with technical expertise or experience (TSS)

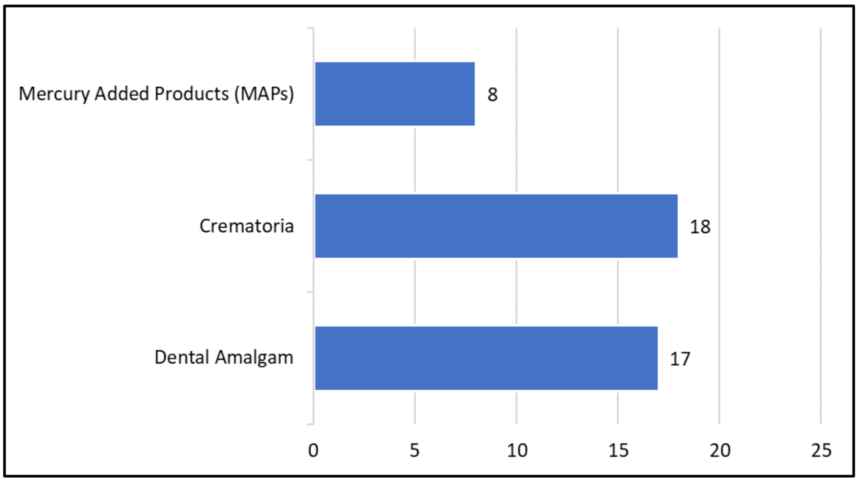


Figure 6: Sub-sectors of operation: Dental Amalgam

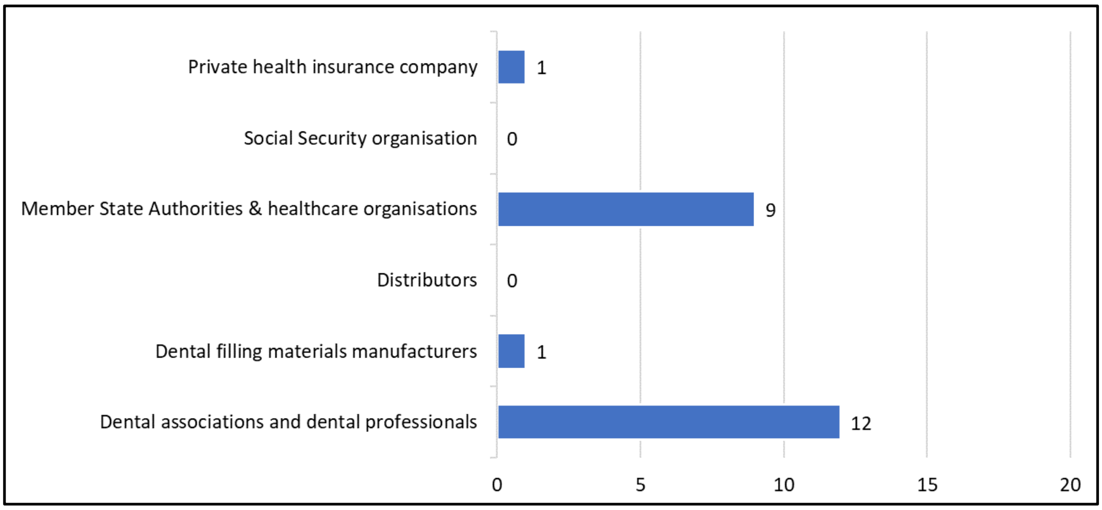


Figure 7: Sub-sectors of operation: Crematoria

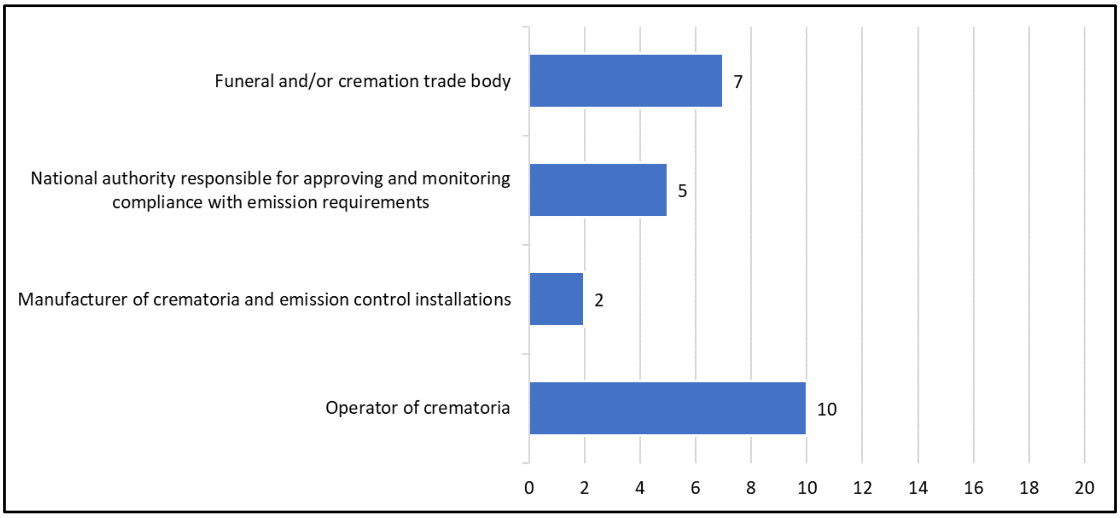
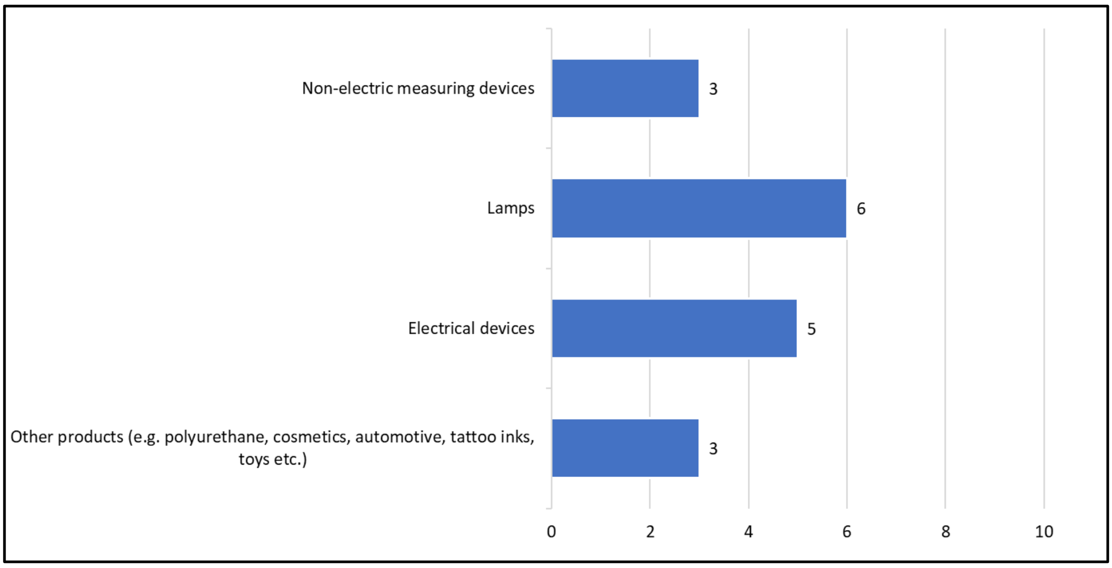


Figure 8: Sub-sectors of operation: Mercury-added Products



PART 2: SUMMARY OF STAKEHOLDER VIEWS ON THE PROBLEMS AND OPTIONS

This section summarises the view of different types of stakeholders with regard to the two problem areas as well as view on possible policy options.

2.1. SUMMARY OF OPC RESULTS

Dental amalgam: A total of 95% (129/136) of the general public would choose a mercury free material, of which 88% (114/129) stated this was because of the associated lower potential health risk, and 60% (78/129) stated this was to reduce environmental impact. Another 74% (102/137) stated they would pay more for non-mercury materials to be used, 44% (44/100) suggested they would pay more than 50% increase in price. Finally, 91% (125/137) believed amalgam be banned for use in dental fillings (except for a limited number of cases where other materials cannot be applied due to specific health conditions of the patient).

Crematoria: A total of 61% (80/131) stated they were aware that mercury is emitted through crematoria emissions, 77% (101/131) were concerned about these emissions, and 86% (115/113) believed there should be an EU wide policy limit to these emissions. Of experts, 71% (5/7) believed emission limits should apply to all crematoria facilities. In addition, 88% (7/8) of experts believed state-of-the-art emission control technologies should be made obligatory across the EU.

MAPs: A total of 56% (9/16) of experts believed there is no future for EU exports of MAPs, whereas 31% (5/16) believed there may be a future for a narrow range of specialist products. Of experts, 56% (9/16) believed demand for MAPs (that are banned in the EU but still being exported) will further decrease in importing countries; only 19% (3/16) believed it will increase. Finally, 47% (7/15) of experts believed an EU export ban would be effective in reducing the sale of MAPs in importing countries, whereas 33% (5/15) believed the exports need to be accompanied by global trade restrictions.

Position papers: In total 21 respondents uploaded a total of 33 additional documents, two were removed due to being corrupt & irrelevant, leaving a total of 31 valid documents (submitted by 19 respondents) suitable for analysis: 20 regarding dental amalgam, one regarding the environmental effects of mercury emissions, two regarding MAPs, and eight papers on general issues unspecific to the three interest areas. Of the 19 respondents, five were from Belgium, seven from Germany, one from Greece, three from Sweden, one from Cameroon, and two from the United Kingdom. Not all documents were position papers, however information from non-position papers has been used elsewhere in the study.

2.2. SUMMARY OF TSS RESULTS

Dental amalgam: A total of 75% (3/4) of experts estimated the average decayed missing and filled teeth (DMFT) score for those under 18 years of age to be 0-1.1, 75% (3/4) believed those between 18-60 years of age to have a score of greater than 6.5, and 100% (3/3) believed those over 60 years of age to have a score greater than 6.5. Experts showed no consensus as to whether filling therapy would change in cost if alternatives to dental amalgam were used, although 67% (2/3) believed there would be an increase in cost. In total 60% (3/5) of experts believed that less than 5% of all ages would require exemptions from the phase-out, 20% (1/5) believed it would be 11%-25% of the population, and 20% (1/5) believed it would be 5-10%. A total of 75% (6/8) of experts did not believe alternatives to amalgam are impractical to implement, and 88% (7/8) stated their patients ask for alternatives, and generally oppose the continued use of amalgam.

Crematoria: A total of 75% (12/16) of experts believed it is important to restrict mercury emissions from crematoria, and 53% (9/17) stated that these emissions are already regulated in their Member State (41% (7/17) stated regulations were not in place in their country). Again, 75% (12/16) believed EU legislation is the right method to control mercury emissions. A total of 75% (12/16) believed crematoria should be treated similarly to other point emission sources in Europe (31% (5/16) suggesting through application of minimum emission limit values, and 44% (7/16) stating through applied Best Available Techniques to reduce emission levels). Furthermore, 65% (11/17) believed emission limits should apply to facilities of all sizes (35% (6/17) were in favour of lower limits for crematoria with lower numbers of annual cremations. A total of 88% of all experts (15/17) believed cremations are increasing in their Member State, and 82% (14/17) believed emission abatement technologies will be more common in the future.

MAPs: Experts provided little to no data regarding TSS questions on MAPs.

Position papers

In total, 13 respondents provided 22 additional documents. Of these, only eight were classified as position papers (submitted by six respondents). The remaining 14 documents provided additional sources of information could not be classified as position papers. Therefore, a total of eight valid position papers have been included in the analysis. In total, one paper covered MAPs, and the remaining seven papers (submitted by five respondents) covered dental amalgam. In total, 67% (4/6) of those who submitted a position paper were business associations (the remainder were NGOs). A total of 33% (2/6) of respondents that submitted a paper were from Belgium, 33% (2/6) were from Germany, and 17% (1/6) were from Ireland, and the United Kingdom.

Annex 3: Who is affected and how?

INTRODUCTION

This Annex sets out the practical implications of the preferred policy package for the various types of stakeholders concerned. It describes the actions that the enterprises or public authority might need to take in order to comply with the obligations under the revised legislation and indicated the likely costs to be incurred in meeting those obligations, or where quantitative information is not available the nature and magnitude of such costs. It also presents the implications for the public.

14. 1. PRACTICAL IMPLICATIONS OF THE INITIATIVE

Dentists

For dentists, the economic impact of a phase-out can be positive or negative depending on their skills in handling various filling materials. In the beginning, it may be negative but may become positive because of increased revenues (the handling and application of alternatives usually is more expensive). A phase-out of dental amalgam is also expected to affect costs that are borne by dentists for the collection and treatment of waste from amalgam separators. This cost will vary across Member States and within countries. However, these costs won't disappear until the last amalgam filling has been removed. Maintenance cycles of separators do not depend on the amount of waste collected and would remain constant as well.

Dental amalgam manufacturers

The phase-out of amalgam use will impact on dental fillings manufacturers with a high share of dental amalgam in their overall production. On the other hand, companies with a high share of mercury-free materials in their production will gain an even more significant competitive advantage. The supporting study to the impact assessment identified only four main EU companies producing encapsuled dental amalgam, therefore overall, the economic impact on the dental industry is expected to remain limited.

Crematoria operators

For crematoria, the preferred policy package could include the development of guidance for controlling mercury emissions (PO3), or the mandatory abatement of mercury emissions abatement at all crematoria (PO4a), or at large crematoria (PO4b; defined as those operating at annual capacity of 4,000 cremations per year and higher). Where crematoria are required (under PO4a and PO4b) or choose (under PO3) to install abatement equipment for reducing mercury emissions then the operators will incur additional capital and operational costs although these would be expected to be passed on to the consumer in higher prices. Measures mandating emissions abatement systems at crematoria would present additional administrative costs to crematoria operators, arising from the need to submit information on their abatement systems and any periodic emissions monitoring and reporting to Member State competent authorities. Measure PO3 would present an additional, albeit limited, administrative burden on European institutions in the development of guidance for the cremation sector, although this is not anticipated to be significant.

Mercury abatement technology manufacturers

Where crematoria operators are required to install abatement equipment for reducing mercury emissions (PO4a and PO4b), or choose to do so (PO3), then there would be benefits for manufacturers of such equipment as demand would increase.

Businesses that are currently engaged in manufacturing and/or exporting mercury-added products that are no longer allowed to be placed on the EU market

By the date specified for each product group, businesses would have to stop manufacturing and export of MAPs. In case of an export ban in 2026 (halophosphate FLs)/ 2028 (all other relevant MAPs), an export value in the order of €97 - €190 million would be lost. This is connected to several hundred jobs at two manufacturing sites in Poland and Germany.

Depending on the time gap between an EU export ban and the entering into force of a global manufacture and trade ban, a considerable part of this loss will likely be compensated by increased manufacture and sale of LED products and by the general increase of the global lighting market. Export losses for other MAPs than lamps could not be quantified but are considered low.

Products that have been legally imported into the EU for the purpose of distribution to non-EU countries would have to be shipped to distribution centres outside the EU before the specified phase-out date to be available for future trade with non-EU countries. With a sufficient time between adoption of the instruments and entering into force such secondary shipments could be largely avoided by directly shipping products made outside the EU to distribution centres in third countries.

Competent authorities

The preferred policy package is not expected to have any significant impacts on public authorities. The phase-out of dental amalgam would apply uniformly across the EU. Member States may choose to undertake some level of surveillance to ensure that the phase-out is being implemented across their territory but this would not be mandated by the preferred policy package. Overall, a phase-out should have a positive economic impact on municipalities (and taxpayers), as it will reduce the environmental costs associated with managing mercury pollution from dental amalgam.

For crematoria, PO4a and PO4b mandating application of abatement emissions systems would result in additional administrative burden on Member State competent authorities arising from the need to process information submitted by crematoria operators on their abatement systems and any periodic emissions reporting. The development of guidance to the sector (PO3) would present no such burden.

Concerning MAPs, the policy package does not have an impact on public authorities.

The public

The phase-out of dental amalgam use would have two main impacts on the general public:

1. It has implications on the dental health treatment options available in that amalgam would no longer be available (except for certain medical exemptions). This may have cost implications in that, at least in the short term, there is an additional cost for consumers of amalgam alternatives.
2. Human health and environmental benefits from the phase-out of the use of dental amalgam. This includes a reduction in associated emissions from crematoria.

Where crematoria are required to install abatement equipment for reducing mercury emissions (PO4a and PO4b), or choose to do so (PO3), then the overall costs to consumers of cremations may rise slightly. However, there would also be human health and environmental benefits from a reduction in emissions and exposure.

Concerning MAPs, the policy package does not have an impact on the European public.

Other

There is an impact for the public in importing non-EU countries. Banning the export of EU products will lead to decreased supply of MAPs to national markets which may cause higher product prices in the short-term. Also, substituting imports from third countries are expected to have higher mercury contents per unit, so that the total net mercury content of imported products may increase in the short-term. Such a potentially negative effect is likely to be compensated due to a globally observed decreasing demand for MAPs, notably lamps and would be eliminated once a global ban under the Minamata Convention enters into force.

15. 2. SUMMARY OF COSTS AND BENEFITS

15.1. Policy Option 2a – Dental amalgam phase-out in 2025

I. Overview of Benefits (total for all provisions) – PO2a		
Description	***Amount***	***Comments***
Direct benefits		
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.
Indirect benefits		
Compliance cost reductions	Reduced costs associated with dental amalgam waste (collected by authorised waste management establishments or undertakings)	Not possible to robustly quantify. These benefits would be realised once all legacy amalgam restorations have been disposed of.

	borne by dentists.	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) *Note: Discarded PO2b would lead to 31 kg (by 2030) and PO2c would lead to 3 kg (by 2030).*	
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.

II. Overview of costs – PO2a							
		Citizens/Consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
Compliance costs	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.
Admin costs	Direct costs	0	0	0	0	0	0
	Indirect costs	0	0	0	0	0	0

15.2. Policy Option 3 – EU guidance on emissions abatement in crematoria

The following tables provide a summary of the costs and benefits of Policy Option 3.

I. Overview of Benefits (total for all provisions) – PO3		
Description	***Amount***	***Comments***
Direct benefits		
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.
Indirect benefits		
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, $PM_{2.5}$, 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 emissions of mercury, $PM_{2.5}$, 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.

II. Overview of costs – PO3							
		Citizens/Consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
Compliance costs	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
Admin costs	Direct costs	0	0	0	0	Limited cost to institutions to develop guidance	0
	Indirect costs	0	0	0	0	0	0

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

The following tables provide a summary of costs and benefits of Policy Option 4a.

I. Overview of Benefits (total for all provisions) – PO4a		
Description	***Amount***	***Comments***
Direct benefits		
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.
Indirect benefits		
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, $PM_{2.5}$, 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, $PM_{2.5}$, 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.

II. Overview of costs – PO4a							
		Citizens/Consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
Compliance costs	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
Admin costs	Direct costs	0	0	0	€400,000	0	€500,000
	Indirect costs	0	0	0	0	0	0

15.4. Policy Option 4b – Mandatory abatement of mercury emissions at large crematoria (operating at an annual capacity of ≥4,000 cremations per year)

The following tables provide a summary of costs and benefits for Policy Option 4b.

I. Overview of Benefits (total for all provisions) – PO4b		
Description	***Amount***	***Comments***
Direct benefits		
Mandatory abatement of mercury emissions at large crematoria (operating at an annual capacity of ≥4,000 cremations per year)	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.
Indirect benefits		
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, $PM_{2.5}$, 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, $PM_{2.5}$, 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.

II. Overview of costs – PO4b							
		Citizens/Consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
Compliance costs	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
Admin costs	Direct costs	0	0	0	€23,000	0	€28,000
	Indirect costs	0	0	0	0	0	0

15.5. Policy Option 4c – Mandatory abatement of mercury emissions at large crematoria (operating at an annual capacity of ≥3,000 cremations per year)

The following tables provide a summary of costs and benefits for Policy Option 4c.

I. Overview of Benefits (total for all provisions) – PO4c		
Description	***Amount***	***Comments***
Direct benefits		
Mandatory abatement of mercury emissions at large crematoria (operating at an annual capacity of ≥3,000 cremations per year)	N/A	A consequence of PO4c is a reduction in mercury emissions to air. This has indirect benefits in terms of environmental quality and human health.
Indirect benefits		
Quality of natural resources	Mercury emissions reductions of 191kg (82-302kg). Mercury emissions reductions of 156kg (39-268kg) 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 €3.6 million (€1.6 million-€5.7 million) as a result of reductions in emissions of mercury, $PM_{2.5}$, lead, cadmium, arsenic, chromium, nickel and dioxins and furans. Human health benefits valued at €3.0 million (€0.9 million-€5.1 million) as a result of reductions in emissions of mercury, $PM_{2.5}$, 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.

II. Overview of costs – PO4c							
		Citizens/Consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
Compliance costs	Direct costs	0	0	€24.9 million	€780,000 per year	0	0
	Indirect costs	Costs to operators are passed on to consumers. Not quantified.	0	0	0	0	0
Admin costs	Direct costs	0	0	0	€42,000	0	€53,000
	Indirect costs	0	0	0	0	0	0

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

The following tables provide a summary of costs and benefits for Problem 3 for the options included in the preferred policy package.

I. Overview of Benefits (total for all provisions) – PO6a and PO6b		
Description	***Amount***	***Comments***
Direct benefits		
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.
Indirect benefits		
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.

II. Overview of costs –PO6a and PO6b							
		Citizens/Consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
PO6a Export ban 2025 (Dental amalgam)	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
PO6b Export ban 2026/ 2028 (MAPs)	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

Annex 4: Analytical methods

Introduction

Due to the two distinct issues covered, the Impact Assessment is not based on a single methodology, but rather on a variety of qualitative and quantitative approaches that have been synthesised. Most Policy Options will likely induce various magnitudes of effects on operators, associated manufacturers, Member States' Authorities, National Health Care Systems and the general public, which is very difficult to quantify at high accuracy levels at an overall EU level. The assumptions and methods used for the assessment of these impacts are described in the respective sections in Annex 7.

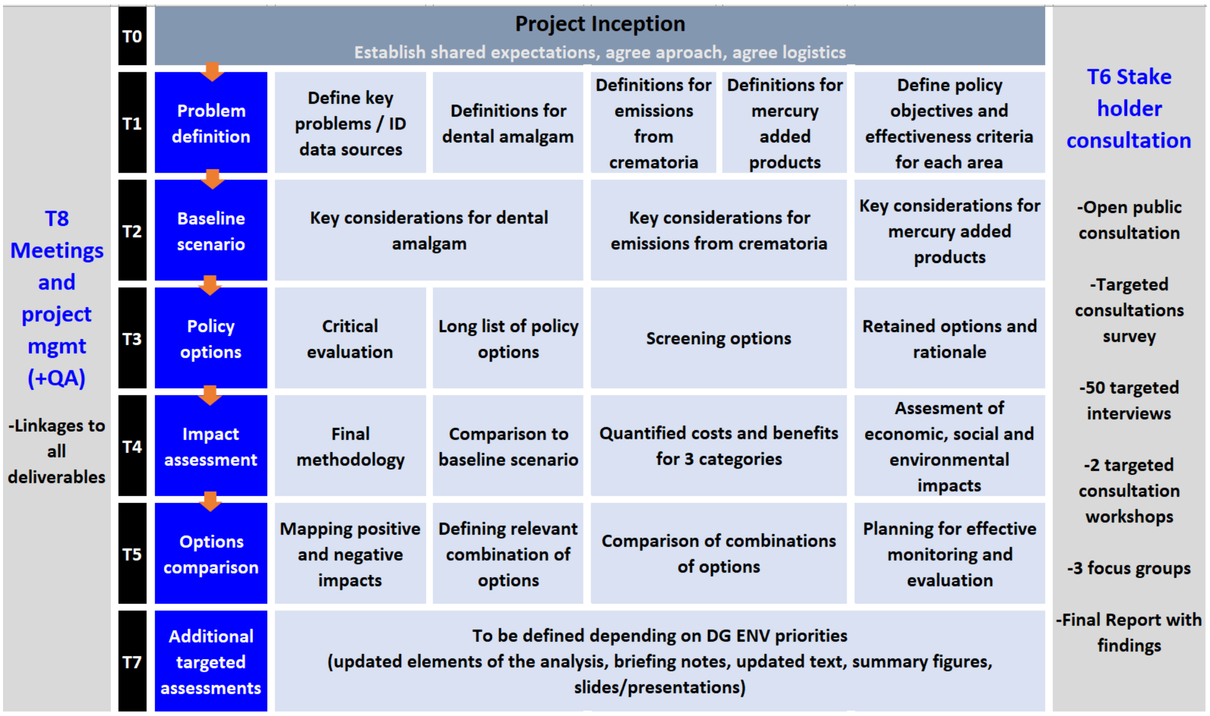
The following summary provides information on the analytical methods used.

1. Overview of tasks and methods

The methods employed were developed according to the European Commission's Better Regulation Guidelines and Toolbox, adapted based on the time available to complete the Impact Assessment support work and the report team's wealth of practical experience in delivering Impact Assessments.

The Impact Assessment support work was structured around seven tasks, represented in Figure 1.

Figure 1: Overview of the tasks of the Impact Assessment support work



Each task was based on and/or followed the EC's Better Regulation Guidelines and Toolbox.

These tasks are described below:

- **Task 1: Define and clarify the problem to be addressed**
  This tasked aimed at setting the scene by developing an overall problem definition as well as specific definitions for each of the three focus areas of this study (dental amalgam, mercury emissions from crematoria and mercury-added products).

- **Task 2: Construct the baseline scenario against which impacts of options will be assessed**
  The study considered how the status quo would likely evolve and based on that developed baseline scenarios, which form the basis for comparing the impacts of different policy options (developed, assessed and compared under tasks 3, 4 and 5).

- **Task 3: Develop policy options**
  Whilst the baseline was being defined, the study team engaged with the European Commission and stakeholders to develop a longlist of policy options that could address the problems identified, taking into account the problem drivers. As not all policy measures or actions were viable, the external expert team defined the screening criteria to shortlist the most relevant options.

- **Task 4: Assessment of impacts of identified options**
  A longlist of possible impacts was developed and screened. From these, impact categories were identified as likely to be significant for a more in-depth assessment. Across these impact categories, different types of costs and benefits were considered.

- **Task 5: Comparison of the options and concluding results**
  The evidence on impacts, costs and benefits was employed to compare policy measures and options and develop conclusions as to whether a given option would contribute to achieving set objectives and generate benefits that would likely outweigh costs.

- **Task 6: Stakeholder consultations (public and targeted)**
  Stakeholder engagement was a horizontal task and key to this support study, feeding into all of the aforementioned tasks. The consultation activities and data analysis carried out in this study included an open consultation, a targeted survey, workshops, focus groups and interviews.

- **Task 7: Additional targeted assessment**
  This task aimed at allowing the external expert team to provide ad-hoc additional targeted assessments addressing the feedback received from the Regulatory Scrutiny Board. This task addressed the need for additional information, complementing the information on dental amalgam and mercury emissions from crematoria, to enable a more detailed assessment of the types and magnitude of the impacts with respect to a phase-out of the use of dental amalgam (in terms of costs borne by stakeholders) and mercury emissions from crematoria (in terms of geographical distribution).

Multiple methods were employed across these tasks, which are presented in Table 1.

Table 1: Overview of the approach for the synthesis of evidence

Element	Approach
Desk research	• Clearly set out what sources were used giving an indication of the reliability of the data sources and possible bias (for example, date of the report, geographical coverage, which stakeholder group commissioned/produced it, whether it was peer reviewed or not.) • Indicate what specific data gaps were there (e.g., lack of studies at the national level, or a lack of recent studies etc.) and the approach taken to fill them.
Field research (survey, interviews and public consultation submissions)	• Indicate which stakeholders were asked about each topic and what research tools were used (interviews/surveys). • Report on the responses provided where relevant or cross-reference to the stakeholder consultation report. • Indicate which groups the responses came from and how representative the responses were (for surveys). • Reflect as to whether the input refers to facts, estimates or opinions and their relevance for the specific questions. • Indicate limitations such as low number of responses, low quality of responses, or views of some stakeholder groups not being well-represented.
Case studies	• Use a similar approach as for desk research presenting the relevant findings to the illustrate impacts in a specific context (e.g., country, product, issue) • Identify the limitations (in terms of scope, ability to extract more general conclusions).
Technical Workshops / Focus groups	• Indicate which types of stakeholders participated • Report on the responses provided by stakeholder type • Indicate which groups the responses came from and how representative the responses were. • Reflect the level of agreement among different categories of stakeholders
Overall conclusions for impact assessment	
Synthesis of evidence	• Set out clear conclusions for the specific impacts drawing together the evidence presented from the different assessment methods • Compare to what was anticipated in the baseline Reflect and comment on the balance and strength of evidence and conclusions (triangulation or cross-checking of conclusions from alternative sources)
Comment on level of certainty and robustness of conclusions	• Summarise the level of certainty of the conclusions based on the robustness of available evidence and taking into account the nature of the sources used. • Be clear on where conclusions are stemming from the stakeholder input and where they are stemming from the literature review. For example, conclusions based predominantly on the online stakeholder consultation that were not possible to triangulate (or at least cross-check) with other sources will need to be considered as less robust than those based on analysis of data collected from

Element	Approach
	validated datasets or peer reviewed studies.

The **analysis of problems** followed the major steps advised in BR Guidelines Tool #14. For the **Intervention logic**, links between problem drivers and policy options were established.

The development of the **baseline and analysis of options**, including the development of baseline, was based on the principles set out in BR Guidelines Tool # 17. In particular, an initial set of (sub)policy options were screened by using a set of criteria for determining which options to include or not as advised in BR Guidelines Tool # 17.

A description and, where possible, quantification of the economic, social and environmental **impacts** of the short-listed options was performed, following BR Guidelines Tool # 19. The main direct impacts were quantified and monetised (for both the baseline and the policy options under consideration). Furthermore, indirect impacts were quantified, where possible, and if not then they were assessed qualitatively with a clear indication of their nature and likely magnitude. **Costs and benefits** identified according to the standard typology of costs (e.g., administrative, enforcement) and benefits (BR Guidelines Tool #58 and #59). The **assessment** was undertaken in line with the Better Regulation Guidelines and, in particular, Chapter 8 of the Toolbox ("Methods, models and costs and benefits").

Stakeholder consultation followed the advice outlined in BR Guidelines Tools # 53 – # 56. In line with BR Guidelines Tool #54, **questionnaire surveys** were used to allow the stakeholders and the public to voice their opinions on the review of the Mercury Regulation. To avoid limitations of a questionnaire survey in terms of the focus on pre-defined answer options, open questions and follow-up **interviews** were designed. **Descriptive statistics** and MS Excel were used for the analysis of quantitative data. Visual aids were used for the presentation of quantitative data. For interpreting qualitative data **thematic analysis** was applied and supported by NVivo content analysis software.

16. 2. DATA RESOURCES AND ANALYTICAL SUPPORT

Evidence utilised has been collected from literature (studies, reports, articles) to support the analyses in most of the tasks, especially in Tasks 1-5.

- Review of the core sources for this report, such as the recent Commission Review Report[1], the Assessment of the feasibility to phase-out dental amalgam[2] as well as the Commission's Inception Impact Assessment and associated feedback.

- Carry out evidence mapping exercise to identify key needs and/or data gaps.

[1] Communication from the Commission on the review of the Community Strategy Concerning Mercury, COM(2010) 723 final, 7.12.2010.

[2] Deloitte and Woods study (2020)

- Undertake a literature review through systematic web searches, coverage of a wide range of stakeholders' sources and considering a diverse set of document types.

- Screening of literature to determine the types of information contained and the extent that the data is reliable and sound.

The output of this process is the evidence base that underpins the impact assessment.

17. 3. CONSULTATIONS AND FIELD RESEARCH

a. Open public consultation (OPC)

The online OPC offered the opportunity for interested individuals from any type of stakeholder groups to give their opinion on the review of the Mercury Regulation. The OPC was launched on the Commission's website[3].

b. Targeted stakeholder engagement: online survey

To gather more in-depth information from those stakeholders already possessing a good understanding of mercury and the associated problem areas addressed, a combination of targeted stakeholder consultation methods was used. A targeted online survey was utilised to gather the views of key groups of stakeholders, including Member States' authorities, industry sector (individual companies or trade associations) or other types of organisations (e.g., environmental or civil society NGOs, research bodies, etc).

c. Interviews

Targeted telephone interviews to complement the online survey took place with representatives of regional and national competent authorities, industry associations, civil society, and other key stakeholders.

d. Focus group

A focus group discussion was held on mercury-added products to complement the online survey and interviews. Representatives of industry associations and the NGO community took part in the discussion. Attendance at the focus group was by invitation only.

e. Stakeholder workshops

Two workshops were held online.

18. 4. ROBUSTNESS OF THE EVIDENCE

a. Consultations

The level of credibility varies with regard to each source of information that has been used for the assessment. In principle, sources of information that are based on measured or reported information are believed to be quite certain. However, even in these cases the

[3] Mercury – review of EU law (europa.eu)

robustness depends on the correct measuring and/or reporting of the parameter concerned. It is assumed that even if there are errors, these are not systematic.

In other cases, literature may draw itself on a lot of stakeholders opinion, or be based on a small sample or have other features that weaken its robustness.

Literature which originates from stakeholders with a particular vested interest are treated with greater caution. Such literature may selectively present information or present it in a certain manner to support an argument that the interested party may wish to pursue.

Stakeholder opinion presents similar risks to stakeholder-sourced literature. In their opinions, stakeholders may be seeking to manipulate the results to support their preferred outcome.

In the case of this assessment, one dentist association holds opposite views to researchers and NGOs, specifically on problem 1a (phase-out of the use of dental amalgam). In general, it opposes a short-term phase-out of the use of dental amalgam, pointing to the potential for problems in access to dental health care. Conversely, researchers and NGOs would like to see a complete phase-out of the use of dental amalgam in 2025.

b. Analytical methods

Dental amalgam

Uncertainties of the estimate

The quantification estimate bears some uncertainties, which are discussed below:

The use of the DMFT index to quantify the amount of caries in the European Union's population: Indeed, this index is the Decayed, Missing, and filled Teeth index, meaning that not only filled teeth and teeth to treat are considered but also the missing teeth. This index is well correlated with the amount of treated caries for the population up until 40 to 50 years, when teeth removal starts to increase and outweigh cavity treatment. So, the model is expected to overestimate the total use of mercury per year.

Inconsistencies in historical data: The historical datasets used for extrapolation of the estimates are poorly collected. Most importantly, the time of recording age and the DMFT index is inconsistent. This reduces the power of forecasting. Moreover, we have extant data on DMFT per median age for every member state. Using the same to estimate a distribution across age intervals can lead to overestimation and/or high variance.

The model does not consider the replacement of failing filling material: Materials used for teeth filling when treating cavities does is not everlasting, so it needs sometimes to be replaced. The replacement was not considered due to too much uncertainty on the failure rate of the different materials as well as on the share of dental amalgam used to replace the failed materials. So, a small underestimation of the quantity of mercury used per year is expected.

The share of the dental amalgam used in tooth filling: These estimates for all Member States come from the 2012 BioIS report, and no better values could be found. Unfortunately, it cannot be said what type of deviation can be expected from this source of uncertainty.

The assumption under which the improvement of dental health in the EU follows the same trend in all Member States: Indeed, our assumption is that the evolution of dental health in different MS can be compared to Germany (for which a lot of data was available). It cannot be said what type of deviation from reality this model can cause, however, we expect it to be small.

It is believed that the overestimation due to the use of the DMFT index will compensate the underestimation due to the unconsidered replacement of failed filling material.

Emissions from crematoria

Data gaps and uncertainties

The assessment of impacts associated with measures addressing emissions from crematoria follows the same quantitative framework as used to establish baseline emissions. The uncertainties in quantification are set out in Annex 5. These include uncertainties and assumptions made in aspects including uptake of abatement technology across the EU in the baseline scenario, cremation rates across different Member States, and the use of dental amalgam across Europe. In quantifying emissions in the future baseline and measure scenarios, projections of key parameters have been made based on historical data and there are uncertainties associated with such forecasting.

Limited information could be obtained through the literature review and stakeholder consultation on the role of SMEs in the sector across Europe. It is assumed that SMEs will form at least part of the sector, especially in countries with a high number of small-capacity crematoria, but specific information upon which to base an assessment of the impacts on SMEs was not available. Further engagement with the industry through Member State surveys could provide further details which could inform a judgement on the impacts to SMEs.

Mercury-added products

Data gaps and uncertainties

For the estimation of impacts of policy measures, models were developed that allow quantitative statements on future export volumes, export values and mercury contents, at least for fluorescent lamps for general lighting purposes. The models and the associated assumptions and model parameters are described in the Annex 5. For most of the factors used, bandwidths describing the known or assumed uncertainties were used. Many of these factors and ranges were discussed with stakeholders or derived based on information from stakeholders. Some factors are based on assumptions in the absence of concrete data. These factors are discussed in detail and the range used is explained. Nevertheless, it cannot be ruled out that individual factors will turn out differently in the actual future development. For example, unforeseen political decisions in important importing countries can cause a significant drop in demand that exceeds the forecast range. Special effects, such as strong price increases for components, could make certain lamp types considerably more expensive and less attractive.

A quantitative assessment was only possible for fluorescent lamps and, with restrictions, for dental amalgam. For other lamp types as well as for other MAPs, the data material was missing. Based on the available information, however, it is assumed that fluorescent lamps have the highest export volume and dental amalgam the highest mercury content. These two products are thus the most important from an economic and environmental point of view. When a quantitative assessment of measures appeared too uncertain, either a qualitative assessment was made, or the magnitude of an effect was estimated.

Annex 5: Detailed Baseline

The baseline option represents a 'no policy change' scenario. That is, the baseline assumes that the current EU-level and national policies and measures continue to be in force and that the sectors are affected by baseline expectations.

1. Baseline for dental amalgam

To develop a baseline for the mercury used in the EU due to the use of dental amalgam as a tooth filling material, an epidemiologic approach was used. A German study[1] used data from national dental health studies, which showed good correlation and predictive capacity for DMFT in the country using the DMFT for different age groups[2] and specific years (2000, 2005, 2015, and 2030). A similar approach has been applied in this assessment using the German data to create a model approximating the DMFT for Germans at different ages and dates of birth to a good degree.

The approach uses non-linear estimation methods to calculate a close estimate of total mercury in dental patients on an average across EU Member. There are primarily three reasons for the application of this method:

1. The DMFT index and age groups in the baseline data show a clear non-linear trend. The share of people that require dental care (sorted by mean age) spikes during adolescence and puberty. There is a relative fall and stabilisation of this share during working age while spiking again during retirement years. A 3rd-degree polynomial fit for the data is hypothesised.
2. The baseline raw data has been poorly maintained, with inconsistency in DMFT recorded for each age and the time of recording. German data was found to be the most consistent among the EU Member States.
3. For the German dataset, age has not been recorded as a discrete variable but as a categorical interval ("6-9 years old", "10-19 years old", etc.). Therefore, standard Ordinary Least Squares (OLS) methods may be inconsistent[3]. Even if the age intervals may record frequencies to be later used as weights, the inconsistency of data recording makes robust estimation a big challenge.

Since the German data was used as a baseline for estimation across the other EU Member States, consideration needs to be given to the interval nature of age groups. Using midpoints for each interval for OLS estimation does not take into account the distribution of frequencies assigned to each interval. Hence, we cannot substitute the midpoint as a proxy for mean age in each interval. Moreover, there are some statistical concerns with this form of estimation – the errors of predictions (and standard deviation) for each age interval can be non-constant. Since OLS assumes constant variance of error terms, a significant scatter in standard deviation values (or heteroscedasticity) can have the following issues:

[1] Jordan, Rainer A. et al. "Trends In Caries Experience In The Permanent Dentition In Germany 1997–2014, And Projection To 2030: Morbidity Shifts In An Aging Society". Scientific Reports, vol 9, no. 1, 2019. Springer Science And Business Media LLC, doi:10.1038/s41598-019-41207-z. Accessed 4 Mar 2022.

[2] 6-9, 10-19, 20-29, 30-39, 40-49, 50-59, 60-69, 70-79, 80-89, ≥90 year-olds

[3] Caudill, Steven B., and John D. Jackson. "Heteroscedasticity and Grouped Data Regression." *Southern Economic Journal* 60, no. 1 (1993): 128–35. https://doi.org/10.2307/1059937.

- The point estimates are unbiased, meaning they converge to the true estimate over large samples. However, they are inconsistent i.e., they do not have a minimised variance out of all other unbiased point estimates.
- Statistical tests to prove the significance of the point estimates are invalidated as they assume a constant variance of error terms across all observations.

Since the German data for the baseline includes a categorical variable, an approach to the estimation is made via choice models. As the categories, i.e., age intervals, are ordered, an ordered logistic regression was used to build the model.

Considering the following estimation:

$$Age *= \beta DMFT_{t,i} + \sigma\epsilon_{t,i}$$

Where β is the point estimate for the regression coefficient, and ε is the error residual in time,

$t \in \{2000, 2005, 2015, 2030\}$, and observation (*i*). We assume a symmetric and cumulative probability density function for the error term, *F(.)*. The error terms are normalised with their standard deviation, σ. *Age** is a latent variable as we cannot observe the exact age given some *DMFT*. Hence, we introduce cut off points to observe this variable. This is done to accommodate the categorical nature of the dependent variable.

Observing category *j* for *Age*,

$$\mathrm{Age_i} = j$$

$$iff\ A_{j-1} < \mathrm{Age_i^*} < A_j$$

For cut off points *A* at each category *j*. For estimation purposes, we find the probability of observing a certain age category as a proxy for the share of people that require dental care given a non-zero DMFT.

$$\Pr\{Age_i = j\} = \Pr\{A_{j-1} < Age^* < A_j\}$$

$$\Leftrightarrow \ \Pr\left\{\frac{A_{j-1} - \beta DMFT_{t,i}}{\sigma}\right\} < \epsilon \ < \Pr\left\{\frac{A_j - \beta DMFT_{t,i}}{\sigma}\right\}$$

$$\Leftrightarrow F\left[\frac{A_{j-1} - \beta DMF\,T_{t,i}}{\sigma}\right] - F\left[\frac{A_j - \beta DMFT_{t,i}}{\sigma}\right]$$

Where *F[.]* is the cumulative density function of the error terms.

To find the optimum point estimates, we use maximum likelihood estimation. The log-likelihood function of the exercise above is given by finding the joint density of the observed data and taking the natural log for computational simplicity.

$$\ln(L) \ = \sum_{i=1}^{10}\sum_{j=1}^{10} \imath\{i = j\} \ln\left\{F\left[\frac{A_{j-1} - \beta DMF\,T_{t,i}}{\sigma}\right] - F\left[\frac{A_j - \beta DMFT_{t,i}}{\sigma}\right]\right\}$$

Over 10 observations, *i*, and 10 age intervals, *j*. 1{i=j} is an indicator function that returns a value of 1 when observation *i* belongs to category *j*.

For identification of the point estimates, we introduce 9 cut off points *A*. Hence, we obtain estimates with reference to one age category. We also assume a parallel regression assumption, i.e., the point estimates are constant along all thresholds. Also, we take the logistic function as the cumulative density for the error terms.

The ordered logistic regression is used to calculate expected probabilities for each age interval at the mean level of DMFT. Using collected data on each Member State's average DMFT at median age, we find the expected probability of being in the corresponding age group. This extrapolation is supplemented through a linear trend of expected probabilities where the year 2000 is taken as the base (*t=00*). The probabilities extrapolated thus far are used to estimate the share of the population sorted by age that requires dental care, the total amount of dental operations, and the absolute share of amalgam in said operations. Finally, we estimated the average mercury content in patients and wasted away from the calculations above.

Ordinal logistic regressions for the German data over four years (2000, 2005, 2015, 2030) are summarised in the following table.

Table 1: Ordinal regressions for the German Data

Odds Ratio for Age Categories	Year 2000	Year 2005	Year 2015	Year 2030
Point Estimate of DMFT	1.43438 (0.1493) t = 2.417*	1.5184 (0.1655) t = 2.524*	1.6968 (0.1975) t = 2.678**	1.9457 (0.239) t = 2.785**

Note: Cut off points for age categories omitted for brevity
Brackets denote standard errors
*Significant at 95% Confidence
**Significant at 99% Confidence

The point estimate reports the odds of a dental patient moving from a younger age group to a higher one. The regression model predicts that as the DMFT score rises by one unit, the patient is 43% more likely to be older than 10-19 years old (the reference category) in 2000. The odds over the years have risen to the point that the 2030 projection predicts that the patient's chance of being older nearly doubles. A case in point to explain this trend can be a rise in dental health and demographic change wherein the median age of dental patients is moving away from younger populations.

Figure 1: Predicted Probabilities for each Age Interval, Germany 2000

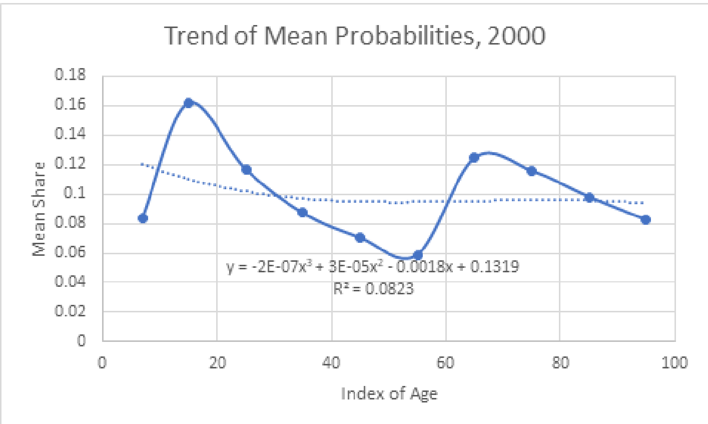


Figure 2: Predicted Probabilities for each Age Interval, Germany 2005

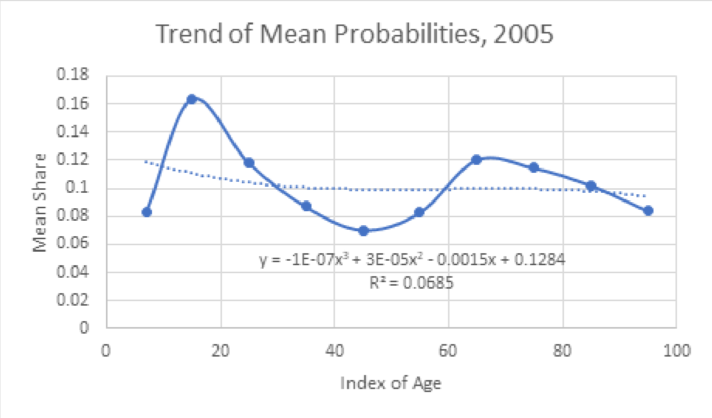


Figure 3: Predicted Probabilities for each Age Interval, Germany 2015

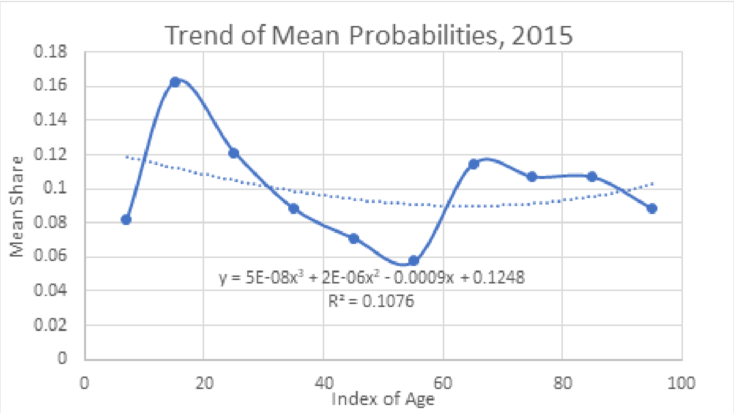
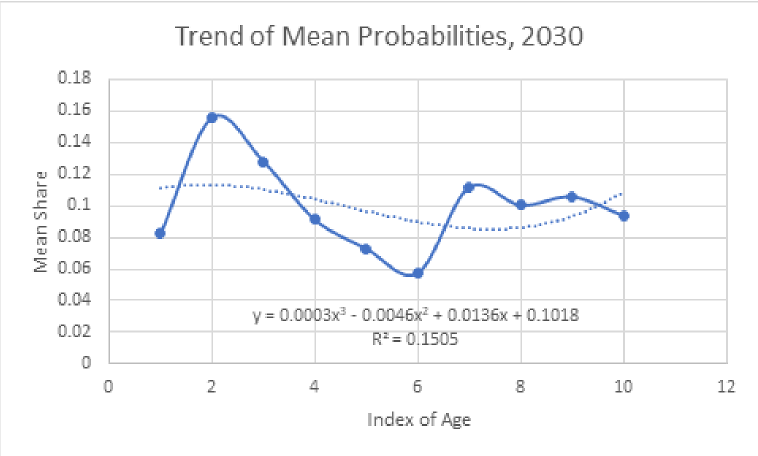


Figure 4: Predicted Probabilities for each Age Interval, Germany 2030



The predicted probabilities above are used to forecast expected population shares for all other Member States. We assume a third-degree polynomial forecast. Having well characterised the German case, other Member States can be compared to it and will either experience a "delay" when compared to it or a "head start". To perform this comparison, the DMFT index for all Member States at different ages for a given year was compared to that of Germany. The aim was to determine in which year in Germany could the same DMFT and age combination be observed. Once this was determined, the delay or head start was determined e.g., for Austria, the DMFT of 40-year-olds in 2000 was 14.7 meaning that in Germany, this set of conditions was met in 1996. Thus, Austria has a 4-year delay when comparing its population's dental health with that of Germany. This same calculation was done for all Member States, and the corresponding data is available in Table 2 below.

Table 2: DMFT at specific ages and year for all Member States and year at which the same conditions were met in Germany for 2019

	DMFT	Age	Year in Member State	Corresponding year with German model	Year equivalent to 2019 for model (corresponding year + 2019 – year)	Dental health "delay" or "head start"
Austria	14.7	40	2000	1996	2015	-4
Belgium	10.3	40	2008	2011	2022	3
Bulgaria	12.1	35	2006	1998	2011	-8
Croatia	3.5	12	1999	1981	2001	-18
Cyprus	2	15	2010	2013	2022	3
Czech Republic	17.1	40	2006	1990	2003	-16
Denmark	13.5	40	2008	2000	2011	-8
Estonia	6.75	17	1993	1984	2010	-9
Finland	0.9	12	2010	2016	2025	6
France	14.6	40	1994	1997	2022	3
Germany			2022	2022	2019	0
Greece	1.95	12	2011	1999	2007	-12
Hungary	15.4	40	2003	1995	2011	-8
Ireland	15.4	40	1990	1995	2024	5
Italy	26.3	70	1993	1987	2013	-6
Latvia	18.5	40	1993	1987	2013	-6
Lithuania	17.3	40	1997	1990	2012	-7
Luxemburg	3	12	1990	1986	2015	-4
Malta	1.4	12	2003	2007	2023	4
Netherlands	17.4	40	1986	1989	2022	3
Poland	19.2	40	1997	1985	2007	-12
Portugal	10.4	40	2013	2010	2016	-3
Romania	6.9	18	1995	1987	2011	-8
Slovakia	4.1	12	2005	1996	2010	-9
Slovenia	19	40	1993	1986	2012	-7
Spain	7.4	40	2020	2024	2023	4
Sweden	0.7	12	2017	2021	2023	4

Thanks to this model, the baseline for the state of dental health in the EU in 2019 was calculated and expected population given a DMFT for all ages for all Member States was determined. These values were then used together with the share that dental amalgam represents in the fillings used for restorations in all Member States, the mercury content of dental amalgam capsules and the share of said capsules fitted in the tooth to calculate the amount of mercury used in the EU every year.

To estimate the quantity of mercury used for the treatment of dental cavities, three datasets are crucial:

1. The mercury content of the dental amalgam capsules used by dentists,
2. The share of dental amalgam used in the treatment of caries in the different MS, and
3. The share of the dental amalgam capsule put in the tooth.

Mercury content of dental amalgam capsules

It was identified for different types of capsules namely

- Pre-dosed amalgam capsules permite, logic+ and gs-80[4]
- Megalloy® EZ[5]
- Septalloy NG 70, Securalloy[6]
- Dispersalloy®[7]

Using the mercury content of the medium size capsules, the mercury content of dental amalgam capsules was approximated to range between 480 mg and 700 mg (data was available for capsules ranging from small to large sizes, the choice was made to use the data for the medium-sized capsules to have a narrower range of mercury content since medium-sized capsules are expected to be the most used).

Share of dental amalgam use

Share of dental amalgam use was approximated using data from the different sources. Where more recent data was available it was used, else the data from previous sources were used such as BioIS (2012), Deloitte (2020) or the final Staff Working Document 2016/017 (which also relied on BioIS (2012)[8].

The share of dental amalgam use (minimum and maximum) per country is presented in Table 3 below, along with the data source and whether the data is estimated or reported. It also indicates which Member States have (known) phase-out plans, by when and the phase-out objective.

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[4] Sdi.Com.Au, 2022, https://www.sdi.com.au/pdfs/instructions/pt-br/gs-80_sdi_instructions_pt-br.pdf. Accessed 29 Mar 2022.

[5] Accessed March 29, 2022, from : Mode d`emploi - DSM dentaire | Manualzz

[6] Uploads-Ssl.Webflow.Com, 2022, https://uploads-ssl.webflow.com/571024186d8e1cce4121d731/5be974bc16344085fcc0f4d6_S%2005%2086%20050%2005%2000_6amalgam-SP.pdf. Accessed 29 Mar 2022.

[7] Dentsplyestore.Com.Au, 2022, http://www.dentsplyestore.com.au/www/770/files/dispersalloy_capsules_dfu.pdf. Accessed 29 Mar 2022.

[8] SWD/2016/017 final

Table 3: Dental amalgam data for all Member States

	Amalgam use %			Method	Ref. year	Phase-out plan	Goal	Comment
	Min.	Mean	Max.					
Austria	35%	43%	50%	estimated	2010			
Belgium	7%	7%	7%	reported	2018			
Bulgaria	6%	21%	35%	estimated	2010			
Croatia	35%	43%	50%	estimated	2010	2025		IGU[(1)]
Cyprus	6%	21%	35%	estimated	2010	2025?		under consideration
Czechia	35%	43%	50%	estimated	2016	2030	1%	
Denmark	1.7%	1.7%	1.7%	reported	2017			
Estonia	1%	2.5%	5%	estimated	2010			
Finland	1%	1%	1%	reported	2019	2030		
France	20%	25%	30%	reported	2021			Reimbursement scheme 2021 100% Alternative, assumption: 50% reduction
Germany	5%	6%	7%	reported	2018			
Greece	35%	43%	50%	estimated	2010			
Hungary	5%	7%	9%	reported	2018	2030	1%	IGU <1%
Ireland	20%	20%	20%	reported	2018	2030		

	Amalgam use %			Method	Ref. year	Phase-out plan	Goal	Comment
	Min.	Mean	Max.					
Italy	1%	2.5%	5%	estimated	2010	2025		IT NAP: end of 2014[(2)]
Latvia	6%	21%	35%	estimated	2010			
Lithuania	4.6%	4.6%	4.6%	reported	2019			
Luxembourg	6%	21%	35%	estimated	2010			
Malta	35%	43%	50%	estimated	2010			
Netherlands	0.5%	0.5%	0.5%	reported	2018			
Poland	35%	43%	50%	estimated	2010	2022		0% in public, but private?
Portugal	5%	10%	15%	reported	2025			
Romania	7.5%	7.5%	7.5%	reported	2018			
Slovakia	40%	50%	60%	reported	2010	2031		
Slovenia	70%	70%	70%	reported	2019	2030		IGU
Spain	1%	1%	1%	reported	2019	2030		
Sweden	0%	0%	0%	reported	2009	2020		

(1) IGU https://www.ig-umwelt-zahnmedizin.de/aktuelles/update-nationale-aktionsplaene-zum-ausstieg-aus-der-verwendung-von-amalgam-in-der-eu/
(2) IT NAP Trova Norme & Concorsi - Normativa Sanitaria (salute.gov.it)

Share of the dental amalgam capsule actually put in the tooth

Only one number could be found regarding the share of dental amalgam capsule content put in patients' teeth. It was estimated to range from 26% up to 66% [1], which would represent a range of 125 mg, up to 462 mg of mercury put in patients' teeth per capsule used.

Quantification of Mercury in the EU due to dental amalgam use

Using the above information in combination with the population data from Eurostat for 2019 with projections to 2030 and the DMFT estimates for all MS for 2019 and 2030, it was possible to estimate the quantities of mercury used in the EU due to dental amalgam use in 2019 and 2030 using the following formula:

$$\sum_{i=1}^{n}\left(\frac{DMFT_n}{n}\right) * Pop_n * DA_{\%} * Hg * DA_{tooth}$$

Where:

a) n is the age of the population group

b) $DMFT_n$ is the DMFT index at age n

c) Pop_n is the population number at age n

d) $DA_{\%}$ is the share of dental amalgam use

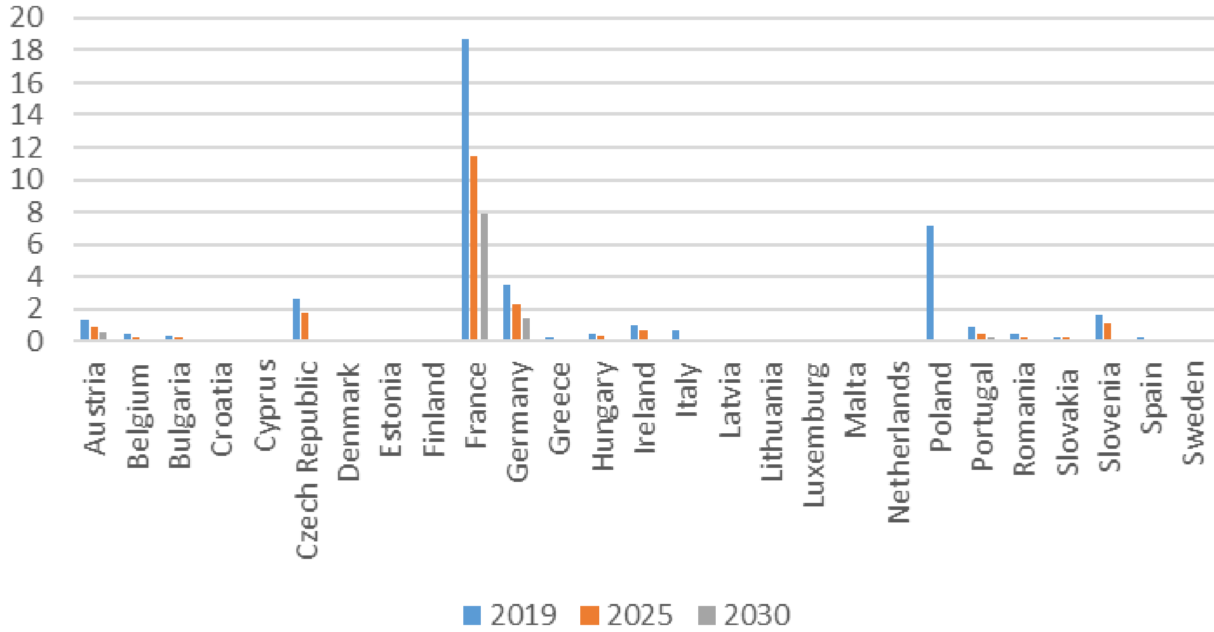
e) Hg is the mercury content of dental amalgam capsules

f) DA_{tooth} Is the share of the dental amalgam capsule actually put in the tooth.

The mean total mercury used in dental amalgam in the EU and its fate is displayed in the Figure 5 below.

[1] Drummond, James L. et al. "Mercury Generation Potential from Dental Waste Amalgam". Journal Of Dentistry, vol 31, no. 7, 2003, pp. 493-501. Elsevier BV, doi:10.1016/s0300-5712(03)00083-6. Accessed 29 Mar 2022.

Figure 5: Baseline mercury consumption in the EU Member States in the form of dental amalgam in 2019, 2025 and 2030 (tonnes)



The mean total mercury used in the EU for dental amalgam use is estimated to be **40.4 tonnes** (18.6 tonnes in teeth and 21.8 tonnes wasted) in 2019 (with the lower estimate being 31.6 tonnes and the upper estimate 50.3 tonnes). In 2030, mercury use is expected to decrease to **11.2 tonnes** (with the lower estimate being 7.2 tonnes and the upper estimate being 16.8 tonnes). The lower and upper estimates were calculated using the extreme values for the three parameters discussed earlier. The values used for the different estimates are listed in Table 4 (except the share of dental amalgam use per Member State displayed in Table 3).

The previous study estimated the total dental amalgam use in the EU in 2018 between 26.9 tonnes and 58.3 tonnes. Our estimate range is slightly different; several factors may explain this:

- This study's estimate is for the EU27, whereas the previous one considered the EU28.
- This study uses a total mercury content of amalgam capsules of ~590 ± 110 mg, whereas the previous study used a mercury content per capsule of 850 mg.
- This study based the calculation of dental amalgam use on the DMFT index and an extrapolation model based on an epidemiologic approach, whereas the previous study used population data to fill in data gaps related to the number of treatments (assuming the same number of procedures per person but using a different population total for different countries which does not consider the varying status of dental health in different Member States).

Table 4: Values of the parameters used for the lower, mean and upper values of the estimate of dental amalgam use in 2019

Parameter	Lower estimate	Mean estimate	Upper estimate

Parameter	Lower estimate	Mean estimate	Upper estimate
Mercury content in dental amalgam capsule (mg)	474	587	701
Share of dental amalgam capsule put in the tooth (%)	26	46	66

Figure 6 demonstrates the number of dentists per 100,000 inhabitants for each Member State as per the latest date of data collection. It illustrates that Greece has the highest density of dentists, with around 126 dentists per 100,000 inhabitants. Furthermore, it illustrates that Poland has the lowest density of dentists, with around 35 dentists per 100,000 inhabitants.

Figure 6: Number of dentists per 100,000 inhabitants in Member States

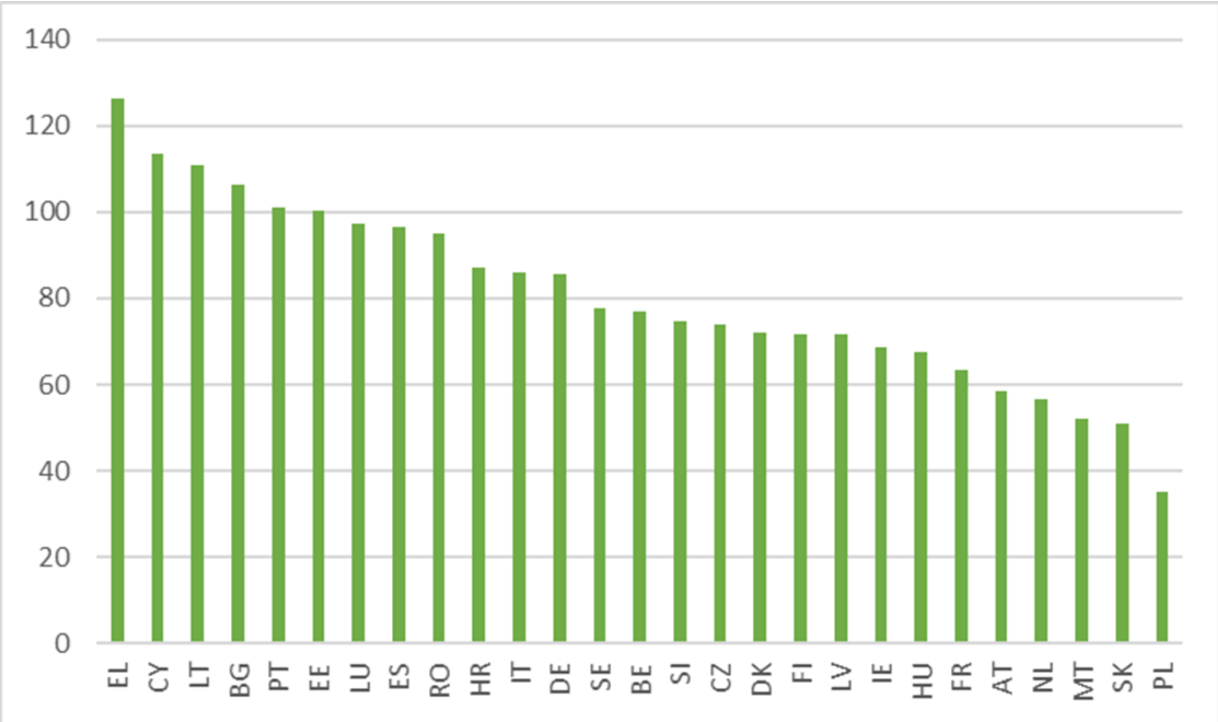


Table 5: Number of dentists and access to dentists across Member States

Member State	Number of dentists for latest year of data	Latest year of data	Number of dentists per 100,000 population									
			2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
AT	5,206	2020	56.9	57	57.25	57	56.7	57	56.86	58	58.38	ND

Member State	Number of dentists for latest year of data	Latest year of data	Number of dentists per 100,000 population									
			2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
BE	8,871	2020	70.85	71.37	72.33	73.54	74.82	74.86	75.38	75.7	76.84	ND
BG	7,373	2020	94.92	97.23	99.56	100.26	104	106.06	103.66	106.64	106.33	ND
CY	1,001	2019	94.45	96.18	98.42	103.34	103.57	109.25	112.18	113.5	ND	ND
CZ	7,914	2020	70.98	70.63	75.11	ND	75.29	74.77	73.79	73.32	73.98	ND
DE	71,108	2020	84.42	84.84	85.57	85.75	85.58	85.65	85.78	85.5	85.51	ND
DK	4,190	2019	79.67	78.27	77.01	76.06	74.18	71.83	71.84	72.06	ND	ND
EE	1,336	2020	90.42	90.29	92.98	94.19	95.53	96.02	96.6	98.2	100.49	ND
EL	13,464	2019	131.8	129.5	128.5	124.8	124.5	125.5	125.4	ND	ND	ND
ES	1,303	2019	90.4	90.2	92.9	94.2	95.5	95.9	96.5	ND	ND	ND
FI	3,954	2018	73.64	71.98	72.87	73.05	72.68	71.77	71.69	ND	ND	ND
FR	42,844	2020	61.8	62.06	61.69	61.97	62.44	62.37	63.36	63.29	63.59	ND
HR	3,526	2020	75.5	75.8	78.54	79.54	80.07	83.13	84.82	87.01	87.12	ND
HU	6,578	2020	56.54	60.27	62.87	60.31	61.98	67.32	70.28	73.12	67.47	ND
IE	1,303	2020	57.7	57.4	59.6	60.8	62.8	65.5	66.8	68.5	ND	ND
IT	50,993	2021	ND	78.09	78.32	78.39	80.09	81.85	83.63	86.98	86.93	86.05
LT	3,100	2020	89/87	90.54	91.02	91.02	97.17	100.37	103.23	105.44	110.92	ND
LV	1,362	2020	71.03	72.49	70.22	71.76	72.01	71.05	70.62	71.27	71.67	ND
LU	581	2017	83.06	84.66	85.56	88.83	94.27	97.43	ND	ND	ND	ND
MT	269	2020	45.24	46.25	46.25	46.29	47	47.65	47.87	50.19	52.2	ND
NL	9,879	2020	49.48	49.48	48.87	51.54	51.11	55.07	55.58	56.51	56.64	ND
PL	13,331	2017	32.82	32.39	34.43	33.18	35.05	35.1	ND	ND	ND	ND
PT	10,896	2018	80.4	84.7	87.6	91.3	95.6	101.2	ND	ND	ND	ND
RO	18,298	2020	68.1	71.3	74.57	77.66	82.66	79.11	83.51	86.8	95.02	ND

Member State	Number of dentists for latest year of data	Latest year of data	Number of dentists per 100,000 population									
			2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
SE	8,003	2019	82.06	81.72	81.52	81.69	81.5	81.36	80.76	77.86	ND	ND
SI	1,570	2019	63	64.9	66.2	67.46	68,81	70.41	71.94	72.5	74.68	ND
SK	2,852	2019	49.2	47.7	48.7	48.7	49.6	50	51	ND	ND	ND

ND = No data

Data expressed as total number of dentists and number of dentists per 100,000 inhabitants obtained from Eurostat available here. With the exception of Greece, Estonia, Ireland, Portugal and Slovakia where data was obtained from the World Health Organisation available here and here.

Uncertainties of the estimate

The quantification estimate bears some uncertainties, which are discussed below:

- **The use of the DMFT index to quantify the amount of caries in the European Union's population**: The DMFT does not only consider filled teeth and teeth to be treated but also missing teeth. This index is well correlated with the amount of treated caries for the population up until 40 to 50 years, at which point when teeth removal starts to increase and outweigh cavity treatment. So, the model is expected to overestimate the total use of mercury per year.
- **Inconsistencies in historical data:** The historical datasets used for extrapolation of the estimates are poorly collected. Most importantly, the time of recording age and the DMFT index is inconsistent. This reduces the power of forecasting. Moreover, we have extant data on DMFT per median age for every Member State. Using the same to estimate a distribution across age intervals can lead to overestimation and/or high variance.
- **The model does not consider the replacement of failing filling material**: Materials used for teeth filling when treating cavities is not everlasting, so it needs to be replaced sometimes. The replacement was not considered due to too much uncertainty on the failure rate of the different materials as well as on the share of dental amalgam used to replace the failed materials. So, a small underestimation of the quantity of mercury used per year is expected.
- **The share of the dental amalgam used in tooth filling**: These estimates for all Member States come from the 2012 BioIS report, and no better values could be found. Unfortunately, it cannot be said what type of deviation can be expected from this source of uncertainty.
- **The assumption under which the improvement of dental health in the EU follows the same trend in all Member States**: The assumption is that the evolution of dental health in different Member States can be compared to

Germany (for which a lot of data was available). It cannot be said what type of deviation from reality this model can cause, however, we expect it to be small.

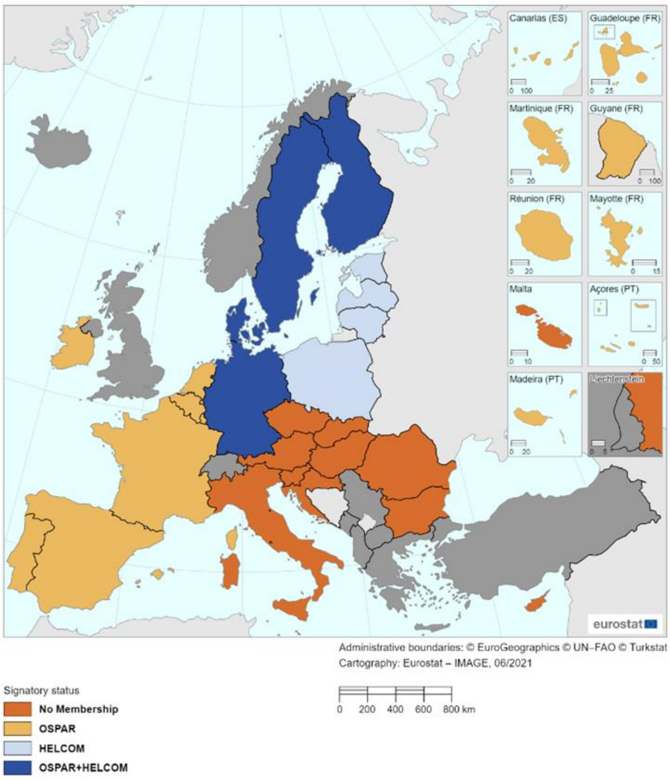
It is believed that the overestimation due to the use of the DMFT index will compensate the underestimation due to the unconsidered replacement of failed filling material.

2. Baseline for emissions from crematoria

At present, there is no EU-level legislation requiring Member States to install mercury abatement systems in crematoria. The OSPAR Commission adopted its non-binding Recommendation 2003/4, which states that *"Contracting Parties should ensure that the operators of crematoria apply BAT at their crematoria to prevent the dispersal into the environment of mercury from human remains, especially from dental amalgam".* The Recommendation also identifies a number of abatement options including co-flow filtration, solid-bed filtration, and gas scrubbing.

Similarly, the Baltic Marine Environment Protection Commission (Helsinki Commission – HELCOM) adopted Recommendation 29/1 in 2008, which recommends that governments of the Contracting Parties implement measures to ensure that crematoria operators with a capacity exceeding 500 cremations/year implement BAT to comply with an emissions limit value of 0.1 mg/Nm^3. Recommendation 29/1 also identifies the same techniques set out in OSPAR Recommendation 2003/4 as potential BAT. Parties to OSPAR and/or HELCOM within the EU are highlighted in Figure 6.

Figure 7: Members of OSPAR and/or HELCOM



National-level legislation addressing mercury emissions from crematoria is varied. Information on national regulatory approaches gained through the stakeholder survey and literature review is set out in Table 6 below.

Table 6: National-level regulation of crematoria mercury emissions (based on information fathered to date)

Member State	Regulation of crematoria mercury emissions
AT	**No regulation identified, although some sources indicate an emissions limit value (ELV) of** 0.1 mg/Nm^3 **applies**[1]**.**
BE	ELVs of **0.2 mg/Nm^3** and **0.1 mg/Nm^3** in effect in Flanders and Brussels, respectively[2].
BG	No regulation identified.
CY	No regulation identified.
CZ	No regulation identified.
DE	No legislation, but Germany has adopted guidance on BAT in human cremation installations, which indicates that when dust filters and/or sorbents are utilised, typical mercury emissions range between 0.0001 and 0.05 mg/m^3 (fixed bed or sorbent injection).
DK	Legislation BEK nr 2079 af 15/11/2021[3] sets a mercury ELV of **0.1 mg/Nm^3** (dry gas) for crematoria with an annual capacity of over 400 cremations. Flue gas must be tested once yearly for mercury.
EE	No regulation identified.
EL	No regulation identified.
ES	No regulation identified.
FI	No regulation identified.
FR	The *Arrêté du 28 janvier 2010 relatif à la hauteur de la cheminée des crématoriums et aux quantités maximales de polluants contenus dans les gaz rejetés à l'atmosphère*[4] sets an ELV of **0.2 mg/Nm^3**.
HR	Regulation NN 87/2017[5] establishes an ELV of **0.05 mg/Nm^3**.
HU	No regulation identified.
IE	No national-level regulation in place. Crematoria emissions are regulated locally through the permitting system, where ELVs are specified on an installation-by-installation basis.
IT	No national regulation in effect. Regional rules generally establish an hourly average emission limit value of **0.05 mg/Nm^3**.

[1] Eurocrematoria (2008) Cremation and respect for the environment. https://www.funeralnatural.net/sites/default/files/articulo/archivo/ecn_manifesto_definitive.pdf

[2] Deloitte, Ineris, Wood (2020), Assessment of the feasibility of phasing-out dental amalgam – Final report

[3] Retsinformation (2021). BEK nr 2079 af 15/11/2021. https://www.retsinformation.dk/eli/lta/2021/2079

[4] Légifrance (2010) Arrêté du 28 janvier 2010 relatif à la hauteur de la cheminée des crématoriums et aux quantités maximales de polluants contenus dans les gaz rejetés à l'atmosphère. https://www.legifrance.gouv.fr/loda/id/JORFTEXT000021837100/

[5] Narodne Novine (2017) Uredba o graničnim vrijednostima emisija onečišćujućih tvari u zrak iz nepokretnih izvora. https://narodne-novine.nn.hr/clanci/sluzbeni/2017_08_87_2073.html

LT	Order No. D1-357[6] sets an ELV of **0.1 mg/Nm³**.
LU	No regulation identified.
LV	No regulation identified.
MT	No regulation identified.
NL	Article 4.119 of the Environmental Management Activities Decree[7] sets an ELV of **0.05 mg/Nm³**.
PL	No regulation identified.
PT	No regulation identified.
RO	No regulation identified.
SE	All crematoria require environmental permits, either from national or local authorities depending on operating capacity. Permits specify best practices and BAT.
SI	No regulation identified.
SK	No regulation identified.

The Commission's Article 19(1) review report estimated that mercury emissions from crematoria totalled 1.6 tonnes in 2018 in the EU; the basis for this estimate is not clear. Data officially submitted by EU27 Member States as part of their reporting requirements under the CLRTAP indicate that emissions totalled 0.9 tonnes in 2019[8]. These figures have been derived following methodologies specific to crematoria emissions set out in the EMEP/EEA air pollutant emission inventory guidebook[9]. The guidebook sets out a 'Tier 1' methodology as the default approach to quantifying crematoria emissions; this involves applying emission factors to activity data (number of bodies cremated). The **recommended emission factor for mercury emissions, 1.49 grams per cremated body (95% CI 0.149 – 14.9 g/body)**, is based on sources from 1992, and is an average factor covering different abatement technologies. While the guidebook highlights that more detailed information should be used where available, it does not specifically set out any more detailed 'Tier 2' and 'Tier 3' methodologies for quantifying emissions from human cremation. It is therefore likely that the emissions inventory data reported under the CLRTAP are largely derived using a top-down approach based on the broadly averaged EMEP/EEA emission factors, and there is significant uncertainty in the estimated total emissions across the EU27.

As part of the Impact Assessment, information was gathered for each EU Member State on the number of cremations (derived using mortality statistics and reported cremation rates), as well as the number of crematoria operating in the country. Additionally, information on the split of crematoria by capacity band was collated from publicly

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6 Valstybės žinios (2008). Dėl Aplinkosaugos reikalavimų kremavimo įmonėms aprašo patvirtinimo. https://www.e-tar.lt/portal/legalAct.html?documentId=TAR.09B74C209D3A

7 Overheid.nl (2022) Activiteitenbesluit milieubeheer. https://wetten.overheid.nl/BWBR0022762/2022-07-01/

8 No emissions for Cyprus and Greece are included in these figures. As Cyprus had no operational crematoria as of 2019, and the first crematorium opened in Greece in 2019, the figures reported to CLRTAP are considered a near-complete EU27 picture.

9 EEA (2019). EMEP/EEA air pollutant emission inventory guidebook 2019 : 5.C.1.b.v Cremation 2019. https://www.eea.europa.eu/publications/emep-eea-guidebook-2019/part-b-sectoral-guidance-chapters/5-waste/5-c-1-b-v/view

available data sources and through stakeholder consultation for Denmark, Finland, and France.

Informed by the data available for a small subset of countries, as well as the average crematorium annual capacity calculated for each Member State, the total number of crematoria in each Member State was manually allocated to the annual capacity bands; these allocations are displayed in Table 3-5. As outlined, these figures have been obtained based on a number of assumptions in the absence of any specific national data and are therefore subject to high uncertainty.

The table also presents data for 2030; the number of crematoria by capacity band in each Member State in 2019 were adjusted to 2030 based on the anticipated change in cremation numbers between those two years. Where the change in cremations between 2019-2030 is forecast to be less than ±10%, it was judged that the change in cremation numbers could be absorbed by existing crematoria numbers, and no adjustment was applied.

The data indicate that Spain has the largest number of crematoria (434) in 2019 and 2030, followed by France and Germany. Looking at the EU27 as a whole, over half of crematoria in 2019 and 2030 are in the smallest capacity band (<1,000 cremations per year). Most countries are expected to see an increase in the number of crematoria from 2019 to 2030.

Table 7: Number of crematoria by capacity band by Member State (2019 and 2030)

Member State	Number of crematoria, 2019 (by capacity band)							Number of crematoria, 2030 (by capacity band)						
	<1k	1k – k	2k – 3k	3k – 4k	4k – 5k	>5k	Total	<1k	1k – 2k	2k – 3k	3k – 4k	4k – 5k	>5k	Total
AT	1	2	4	2	3	1	13	1	3	6	3	4	1	18
BE	1	3	6	4	4	1	19	1	4	7	5	5	1	24
BG	1	0	0	0	0	0	1	1	0	0	0	0	0	1
CY	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CZ	2	5	10	4	4	2	27	2	5	10	4	4	2	27
DE	8	22	50	30	38	11	159	11	29	67	40	51	15	213
DK	1	10	6	0	0	2	19	1	12	7	0	0	2	22
EE	2	0	0	0	0	0	2	4	0	0	0	0	0	4
EL	1	0	0	0	0	0	1	1	0	0	0	0	0	1
ES	434	0	0	0	0	0	434	434	0	0	0	0	0	434
FI	3	12	4	0	1	0	20	4	16	5	0	1	0	27

Member State	Number of crematoria, 2019 (by capacity band)							Number of crematoria, 2030 (by capacity band)						
	<1k	1k – k	2k – 3k	3k – 4k	4k – 5k	>5k	Total	<1k	1k – 2k	2k – 3k	3k – 4k	4k – 5k	>5k	Total
FR	88	71	21	3	1	1	185	110	89	26	4	1	1	231
HR	0	0	0	0	0	1	1	0	0	0	0	0	1	1
HU	1	1	2	5	5	3	17	1	1	2	5	5	3	17
IE	5	1	1	0	0	0	7	9	2	2	0	0	0	13
IT	29	19	26	8	2	1	85	46	30	41	13	3	2	135
LT	0	0	0	0	1	0	1	0	0	0	0	2	0	2
LU	0	0	1	0	0	0	1	0	0	1	0	0	0	1
LV	0	0	0	1	0	0	1	0	0	0	2	0	0	2
MT	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NL	66	24	6	1	1	1	99	80	29	7	1	1	1	120
PL	12	13	17	7	2	1	52	21	23	30	12	4	2	92
PT	1	4	6	3	4	2	20	1	4	6	3	4	2	20
RO	4	0	0	0	0	0	4	5	0	0	0	0	0	5
SE	25	24	5	2	0	2	58	28	27	6	2	0	2	65
SI	0	0	0	0	0	2	2	0	0	0	0	0	2	2
SK	0	0	0	0	1	2	3	0	0	0	0	2	4	6
EU-27	**685**	**211**	**165**	**70**	**67**	**33**	**1,231**	**762**	**274**	**224**	**94**	**87**	**42**	**1,482**

Table 8: Number of crematoria by capacity band by Member State (2019 and 2030)

Member State	Number of crematoria, 2019 (by capacity band)							Number of crematoria, 2030 (by capacity band)						
	<1k	1k – 2k	2k – 3k	3k – 4k	4k – 5k	>5k	Total	<1k	1k – 2k	2k – 3k	3k – 4k	4k – 5k	>5k	Total
AT	1	2	4	2	3	1	13	1	3	6	3	4	1	18
BE	1	3	6	4	4	1	19	1	4	7	5	5	1	24
BG	1	0	0	0	0	0	1	1	0	0	0	0	0	1

Member State	Number of crematoria, 2019 (by capacity band)							Number of crematoria, 2030 (by capacity band)						
	<1k	1k – 2k	2k – 3k	3k – 4k	4k – 5k	>5k	Total	<1k	1k – 2k	2k – 3k	3k – 4k	4k – 5k	>5k	Total
CY	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CZ	2	5	10	4	4	2	27	2	5	10	4	4	2	27
DE	8	22	50	30	38	11	159	11	29	67	40	51	15	213
DK	1	10	6	0	0	2	19	1	12	7	0	0	2	22
EE	2	0	0	0	0	0	2	4	0	0	0	0	0	4
EL	1	0	0	0	0	0	1	1	0	0	0	0	0	1
ES	434	0	0	0	0	0	434	434	0	0	0	0	0	434
FI	3	12	4	0	1	0	20	4	16	5	0	1	0	27
FR	88	71	21	3	1	1	185	110	89	26	4	1	1	231
HR	0	0	0	0	0	1	1	0	0	0	0	0	1	1
HU	1	1	2	5	5	3	17	1	1	2	5	5	3	17
IE	5	1	1	0	0	0	7	9	2	2	0	0	0	13
IT	29	19	26	8	2	1	85	46	30	41	13	3	2	135
LT	0	0	0	0	1	0	1	0	0	0	0	2	0	2
LU	0	0	1	0	0	0	1	0	0	1	0	0	0	1
LV	0	0	0	1	0	0	1	0	0	0	2	0	0	2
MT	0	0	0	0	0	0	0	0	0	0	0	0	0	0
NL	66	24	6	1	1	1	99	80	29	7	1	1	1	120
PL	12	13	17	7	2	1	52	21	23	30	12	4	2	92
PT	1	4	6	3	4	2	20	1	4	6	3	4	2	20
RO	4	0	0	0	0	0	4	5	0	0	0	0	0	5
SE	25	24	5	2	0	2	58	28	27	6	2	0	2	65
SI	0	0	0	0	0	2	2	0	0	0	0	0	2	2
SK	0	0	0	0	1	2	3	0	0	0	0	2	4	6

Member State	Number of crematoria, 2019 (by capacity band)							Number of crematoria, 2030 (by capacity band)						
	<1k	1k – 2k	2k – 3k	3k – 4k	4k – 5k	>5k	Total	<1k	1k – 2k	2k – 3k	3k – 4k	4k – 5k	>5k	Total
EU-27	**685**	**211**	**165**	**70**	**67**	**33**	**1,231**	**762**	**274**	**224**	**94**	**87**	**42**	**1,482**

In defining an assessment baseline, the study has adopted a bottom-up approach to quantifying emissions. This involved exploring trends and activity levels in the underlying drivers in order to build up to an estimate of crematoria emissions. This method is detailed in the following section.

Approach

Mercury emissions from crematoria are influenced by a number of underlying drivers including the following:

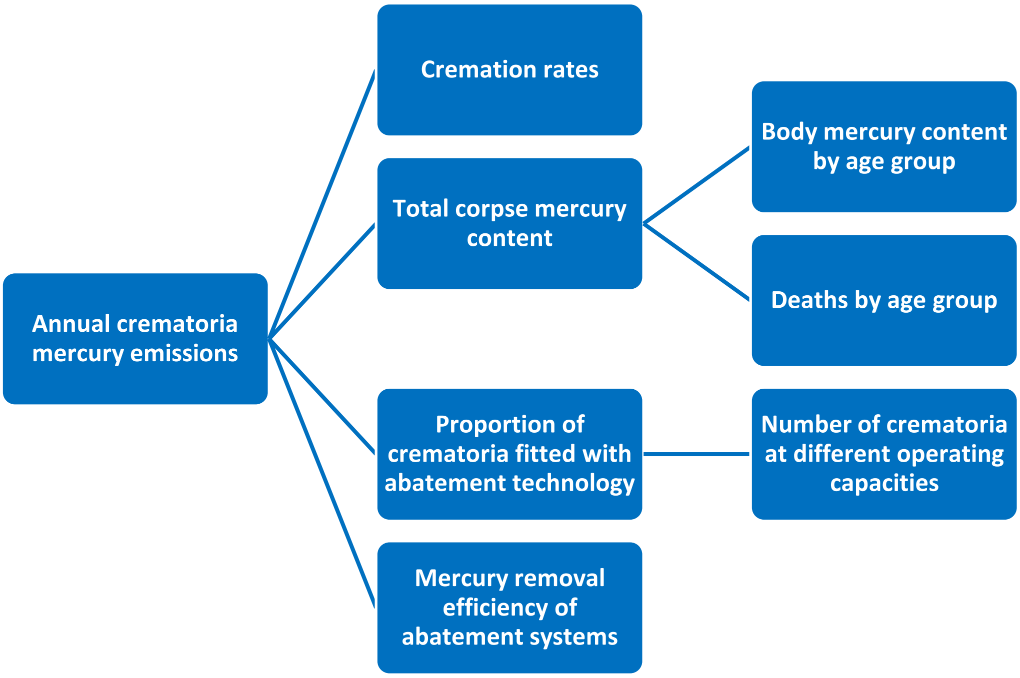
- Mercury content of corpses, which is determined predominantly by the presence of dental amalgam restorations
- The prevalence of cremation relative to other funeral options. This can be expressed as a cremation rate, and varies significantly across the EU27
- The level of uptake of emissions abatement technologies, which have varying mercury removal efficiencies

In constructing an assessment baseline, these underlying drivers have been considered separately before they were drawn together to estimate crematoria emissions. The framework for combining these separate factors into a quantified reference scenario of mercury emissions from crematoria is set out in Figure 7, and includes the following steps:

- The annual cremation rate is defined
- Total mercury content among corpses is estimated based on (i) the estimated body mercury content for different age groups, and (ii) the number of deaths per age group
- The proportion of crematoria fitted with emissions abatement systems is defined and, where data are available, a distinction can be drawn between crematoria at different annual operating capacities
- The mercury removal efficiencies of emissions abatement systems are accounted for

The framework is applied to each Member State separately to account for variation in the drivers across the EU, and emissions for the EU as a whole can be aggregated from the granular data.

Figure 8: Framework for quantifying baseline mercury emissions from crematoria

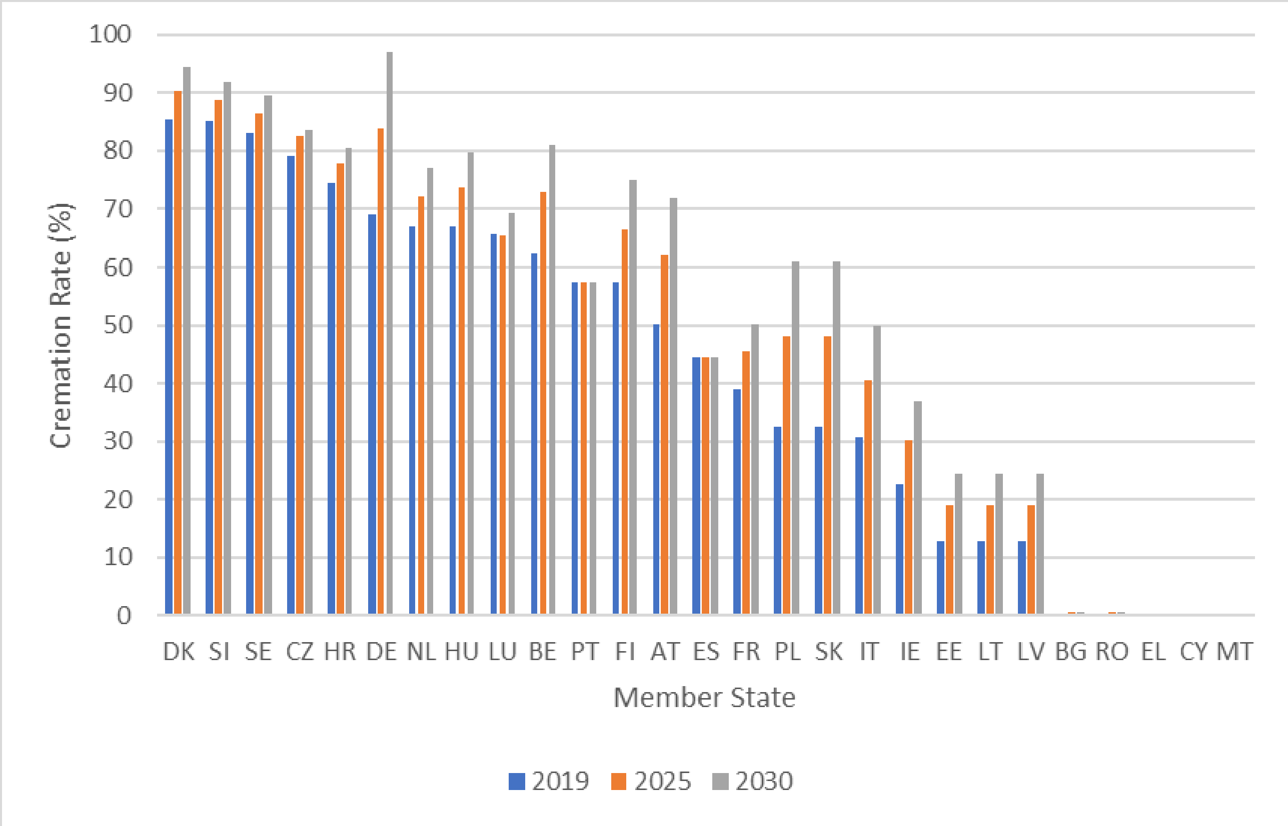


The following sections detail the methodologies applied in quantifying the underlying drivers, and how they have been forecast into the future to provide a future baseline with no further EU intervention.

Cremation rates

Data on national annual cremation rates are collated by the Cremation Society; these are displayed in Figure 8. Data for each Member State were obtained for the period 2010 to 2019 where available and used to extrapolate historical trends to future baseline years of 2025 and 2030 using a linear regression. For Spain and Portugal, there is no discernible trend in the historical data upon which to base future projections, therefore the cremation rates for 2019 were adopted for future years. There are challenges in projecting future cremation rates for countries with no, or very low, cremations in 2019. Data indicates that neither Malta nor Cyprus operated any crematoria in 2019, while Greece saw its first crematorium commence operation that year. With no reliable indication from past trends as to how future cremation rates may evolve in these countries, it has been assumed that rates will remain at their current low levels.

Figure 9: National annual cremation rates (2019, 2025 and 2030[10])



Complete data are available only up to the year 2019 and therefore do not reflect changes brought about by the COVID-19 pandemic. Limited data on 2020 cremation rates in some Member States were accessed during targeted stakeholder consultation[11]. Although most cremation rates had increased in 2020 in comparison to 2019 rates, the amount by which they increased varied greatly, and some Member States even saw modest decreases in cremation rates (the Netherlands and Sweden). The largest increases were seen in countries with very low cremation rates in 2019, for example Greece which saw a 435% increase from 2019-2020 but only observed a 0.4% cremation rate in 2019. Most other Member States for which data is available saw an increase closer to 5-7% from 2019 rates. Therefore, it is likely that the COVID-19 pandemic caused an increase in cremation rates in some Member States. However, data is too limited at this point to make an informed assessment of how the pandemic affected rates above the increase already expected by changing funerary trends in the EU. It is also expected that as the pandemic diminishes, cremation rates will return to pre-pandemic trends. Consequently, future projections are based solely on pre-pandemic trends. There is, however, uncertainty concerning nearer-term trends in cremation rates.

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[10] Data obtained from The Cremation Society (2021). In the absence of cremation rates for the following Member States, rates for other Member States were used as a proxy: Bulgaria (Romania used as proxy); Latvia and Estonia (Lithuania used as proxy); Croatia (average of Hungarian and Slovenian rates used); Slovakia (Czechia used as proxy).

[11] 2020 Cremation Rates for BG, CZ, DE, DK, EL, FI, HU, IE, LT, NL, PT, SE and SL were provided via direct correspondence with the International Cremation Federation on 25th July 2022.

In the absence of any more granular data, it was assumed that cremation rates are uniform across deaths in different age groups within a country (i.e., a 50% cremation rate in Austria in 2019 means that 50% of individuals that die at age 50 are cremated, 50% that die at age 51 are cremated, etc.).

Mercury content of corpses

The mercury content for corpses has been calculated for each Member State. This was based on (i) the mean number of decayed, missing and filled teeth (DMFT) for each Member State; (ii) the relative share of amalgam use in dental restorations and; (iii) the typical mercury content of a dental amalgam filling. Details on this methodology are set out in the Section above, which discusses the baseline for the dental amalgam problem area. For each Member State and for each year group, a lower, mean and upper value was produced for the mercury content per corpse to account for the uncertainty in the share of amalgam use. Additionally, the future share of amalgam use in different Member States has been estimated based on the available data.

Dental amalgam restorations in bodies arriving at crematoria will have been fitted in varying years, which will have had varying rates of dental amalgam use. Consequently, it is necessary to account for the lag in a dental amalgam restoration being made, and its arrival at a crematorium. A study concluded that the average age of replaced amalgam fillings is 15.3 $\pm$ 6.6 years[12]. Therefore, for any given assessment year, the rate of dental amalgam use in restorations was based on the average dental amalgam share over the lifetime of the restoration; this accounts for the fact that a restoration could be any age up to 15.3 $\pm$ 6.6 years. For example, the dental amalgam share used in estimating emissions from crematoria for the year 2019 was based on the average dental amalgam share over the years 2004 to 2019. As a sensitivity test, longer (21.9 years) and shorter (8.7 years) amalgam lifespans were used in calculating a higher and lower estimate, respectively.

Data on historical deaths by age group are available from Eurostat; figures for 2019 were obtained from the demo_magec dataset[13]. The dataset also includes figures for 2020 at 5.2 million deaths in the EU27, compared with 4.7 million deaths in 2019, 2018 and 2017. This increase in deaths is attributable to the COVID-19 pandemic and, as discussed in the context of cremation rates above, increased deaths are anticipated to return to pre-pandemic trends as the pandemic abates. As such, 2019 has been selected as the baseline year that would be most consistent with long-term projections for future year scenarios. Eurostat also includes future population projections by year group (dataset proj_19np) and forecasts for probability of dying by age in future years (proj_19naasmr). These datasets were combined to provide projections for the number of deaths by age group in 2030.

The mass of mercury in all corpses was then quantified by combining the figures on mercury content per body with the number of deaths per corresponding age group. By applying the cremation rates determined above, the mass of mercury in corpses reaching crematoria was calculated. Masses for each Member State are displayed in Figures 9, 10 and 11. The figures indicate that the mass of mercury reaching crematoria is decreasing

[12] Kirsch et al. (2016) Decision criteria for replacement of fillings: a retrospective study. https://doi.org/10.1002/cre2.30

[13] European Commission (2022). Eurostat. https://ec.europa.eu/eurostat/data/database

from 2019 to 2030 in most Member States with a few exceptions, most notably Poland. The increase in these countries appears to be driven by increasing rates of cremation as well as increased mortality resulting from aging populations.

Figure 10: Masses of mercury in corpses reaching crematoria (low estimates) for 2019, 2025 and 2030

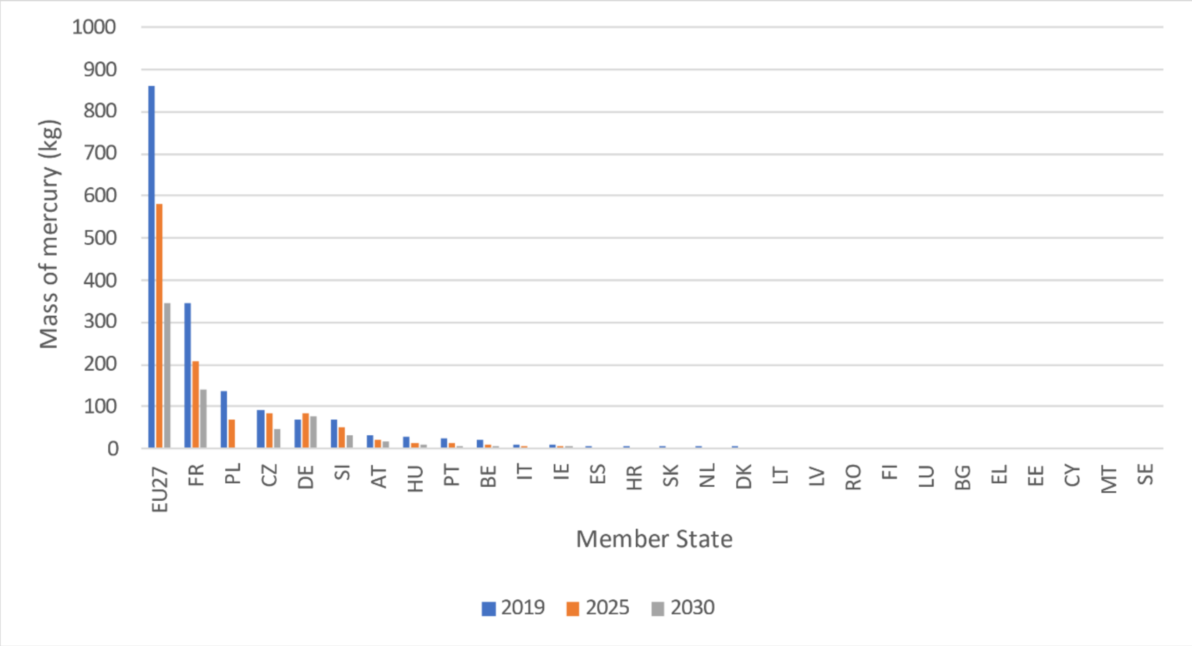


Figure 11: Masses of mercury in corpses reaching crematoria (central estimates) for 2019, 2025 and 2030

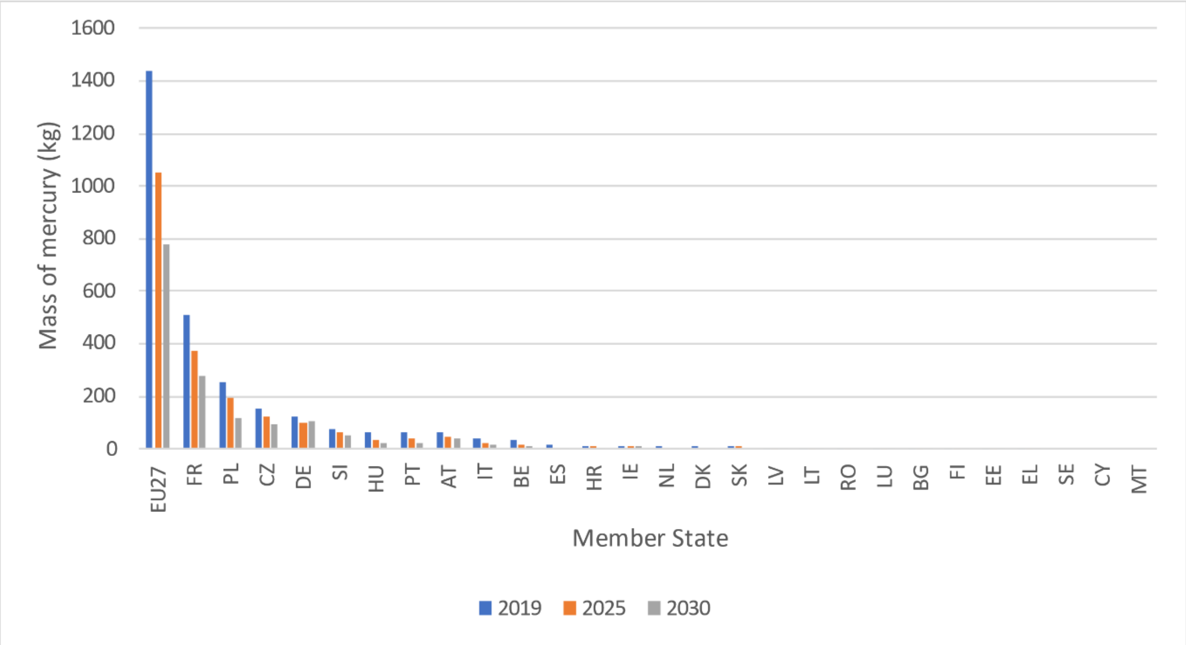
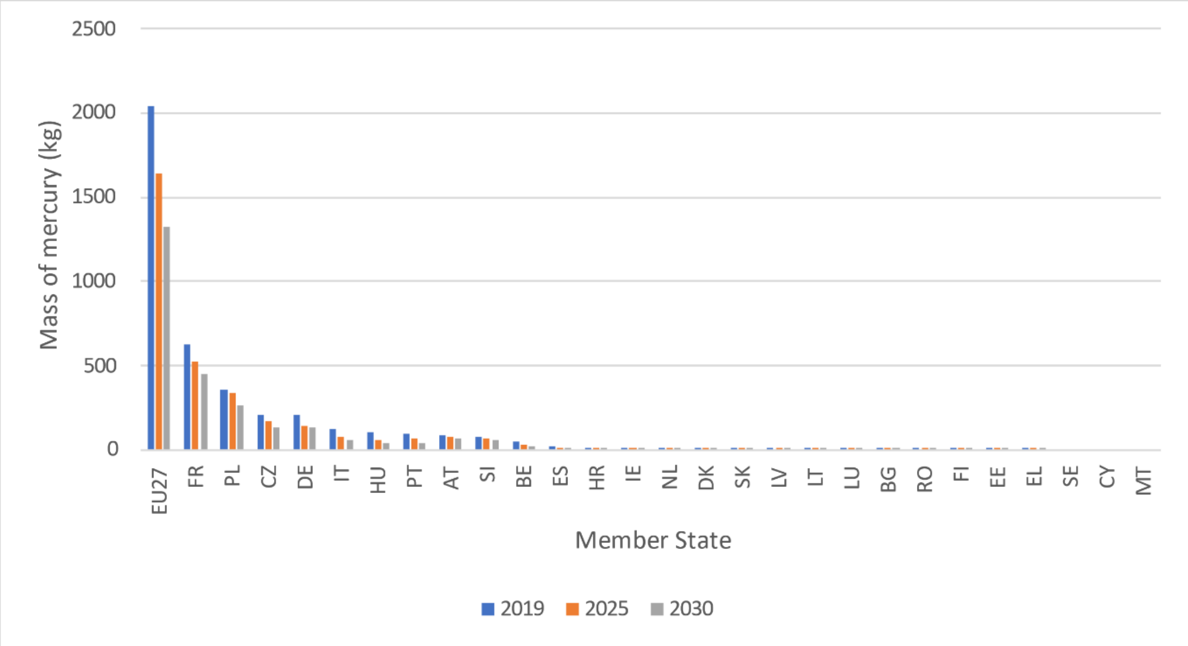


Figure 12: Masses of mercury in corpses reaching crematoria (high estimates) for 2019, 2025 and 2030



Uptake of emissions abatement technologies

Data on uptake of emissions abatement technologies at crematoria for some OSPAR members have been collated via the following phased approach:

- Where up-to-date information was provided through the stakeholder survey and consultations, this was adopted as the default assumption
- Where no stakeholder response was provided, but data were available from other sources, assumptions were made based on these sources
- For Member States where there was neither a stakeholder response, nor any data in the literature, it was conservatively assumed that emissions abatement uptake was 0% where there was no evidence of regulation addressing crematoria emissions

Assumed abatement uptake rates are displayed in Table 9 below.

Table 9: Percentage of crematoria with/without abatement technologies

Member State	Crematoria with abatement (%)	Source / notes
AT	30	30% uptake in 2005. No requirements for crematoria emissions identified; uptake rate conservatively assumed to remain at 2005 levels.
BE	100	Targeted stakeholder survey response.
BG	0	No survey response; assumed to be 0%.
CY	0	No crematoria in Cyprus.
CZ	0	0% uptake in 2018; assumed to be at same level[2].
DE	100	Targeted stakeholder survey response.
DK	95	Targeted stakeholder survey response.

Member State	Crematoria with abatement (%)	Source / notes
EE	0	No survey response; assumed to be 0%.
EL	0	No survey response; assumed to be 0%.
ES	4	Assumed consistent with 2014 data in OSPAR 2016 report[14].
FI	0	OSPAR member, but no survey response provided and no information found indicating any regulation in place. Previous assessment work does not identify any regulation addressing mercury emissions from crematoria. Assumed to be 0%.
FR	100	100% uptake in 2018; assumed to be at same level[2].
HR	0	0% uptake in 2018[1]; assumed to be at same level[2].
HU	70	Targeted stakeholder survey response.
IE	71	Targeted stakeholder survey response.
IT	90	Targeted stakeholder survey response.
LT	100	Targeted stakeholder survey response.
LU	100	Assumed consistent with 2014 data in OSPAR 2016 report[14].
LV	0	No survey response; assumed to be 0%.
MT	0	No crematoria in Malta.
NL	100	Assumed consistent with 2014 data in OSPAR 2016 report[14].
PL	0	No survey response; assumed to be 0%.
PT	0	Targeted stakeholder survey response.
RO	0	No survey response; assumed to be 0%.
SE	83	Targeted stakeholder survey response.
SI	0	No survey response; assumed to be 0%.
SK	0	No survey response; assumed to be 0%.

Historical data on the uptake of emissions abatement systems at crematoria are lacking, nor was any information obtained through the stakeholder survey. It was therefore not possible to project uptake trends into the future and it was therefore assumed that, under a business-as-usual baseline scenario, future uptake of abatement systems would remain at the same level as the historical data.

Data on the percentage of cremations carried out by crematoria falling into different annual operating classes was also requested through the survey (e.g., fewer than 1,000 cremations a year, over 5,000 cremations a year, etc.). Information was received for a number of Member States (Germany, Ireland and Sweden), and publicly available data were used for several other Member States (Finland, France and Denmark). For other Member States, the distribution of cremations into different capacities was estimated based on the average cremation capacity in the country. The total number of crematoria in each Member State, obtained from the Cremation Society, was then manually apportioned into each operating capacity. Total emissions can therefore be disaggregated by crematoria size to identify whether larger or smaller installations are currently the greatest sources of emissions.

[14] OSPAR Commission (2016) Implementation of OSPAR Recommendation 2003/4 on Controlling the Dispersal of Mercury from Crematoria: Second Overview assessment. https://www.ospar.org/documents?v=35427

In the absence of capacity-specific abatement uptake rates, it was assumed that abatement rates are constant across all capacity bands.

Mercury removal efficiency of abatement systems

For the assessment, it has been assumed that 100% of mercury reaching crematoria in corpses is emitted to air during cremation; while in reality a small proportion of mercury released from a cremation will adhere to the surfaces of the crematorium or remain in the ash. This assumption is considered a generally accurate approximation of operating conditions[15]. Data collated from the literature on mercury removal efficiencies for the most widely used abatement technologies are displayed in Table 4.

Table 10: Mercury removal efficiency of different abatement technologies

Technology	Lower value (%)	Upper value (%)	Source / notes
Unabated emissions	0.0	0.0	Assumed 100% of mercury mass reaching crematoria are emitted to air
Injection of adsorbent (AC)	90.0	98.0	Lower value: Umwelt Bundesamt (2021)[16] Upper value: OSPAR Commission (2003)[17]
Solid bed filtration using adsorbent (AC)	90.0	99.9	OSPAR Commission (2003)

Data on the relative uptake of specific abatement technologies in Member States was not available, and therefore it was not possible to apply technology-specific removal efficiencies in calculating emissions. Information on typical removal efficiencies was sought from Member States through the consultation activities; data received are displayed in Table 5.

Table 11: Typical mercury removal efficiency reported by Member States

Member State	Typical mercury removal efficiency (%)	Notes
DE	90 – 98	Response states that carbon injection is the BAT, with a removal efficiency of 90-98% (see Table)
DK	98	-
IT	90 – 95	-
SE	97	-

[15] Piagno and Afshari (2020). Mercury from crematoriums: human health risk assessment and estimate of total emissions in British Columbia. https://doi.org/10.17269%2Fs41997-020-00327-0

[16] Umwelt Bundesamt (2021). Text 68/2021: Quecksilberemissionen aus industriellen Quellen – Status Quo und Perspektiven Abschlussbericht - Teil 2. https://www.umweltbundesamt.de/sites/default/files/medien/5750/publikationen/2021-04-26_texte_68-2021_quecksilberemissionen_teil_2_0.pdf

[17] OSPAR Commission (2003). Mercury emissions from crematoria and their control in the OSPAR Convention Area. https://www.ospar.org/documents?v=6971

Where no further country-specific removal efficiency could be obtained, an upper value of 99.9% was assumed along with a lower value of 90% and a central estimate of 95%. This was based on reported removal efficiencies for carbon injection and solid bed filtration (see Table 5), the most widely used abatement technologies.

There is limited information in the literature to indicate that mercury removal efficiencies have changed historically as a result of improvements to existing systems, or introduction of new technologies. Emissions estimates are therefore based on the assumption that removal efficiencies will remain constant into the future.

Summary

Crematoria mercury emissions have been calculated by combining the data on the underlying drivers, discussed above. Estimated emissions for individual Member States in 2019, 2025 and 2030 are presented in Figure 12, and for the EU27 as a whole in Figure 13 (below).

Total mercury emissions for the EU27 are estimated at 689 kg in 2019. This is slightly lower than the figure reported to the CLRTAP (0.9 tonnes). Figures reported to the CLRTAP are largely based on Tier 1 emission factors dating from 1992, which represent an average of crematoria both with and without abatement systems. As uptake of emissions abatement technologies has likely increased since these emissions factors were produced, it is likely that they overestimate emissions in 2019.

Emissions are forecast to gradually decline to 519 kg in 2025, and 355 kg in 2030. All Member States are predicted to see a decline in emissions over this period.

Figure 13: Estimated mercury emissions from crematoria (2019, 2025 and 2030)

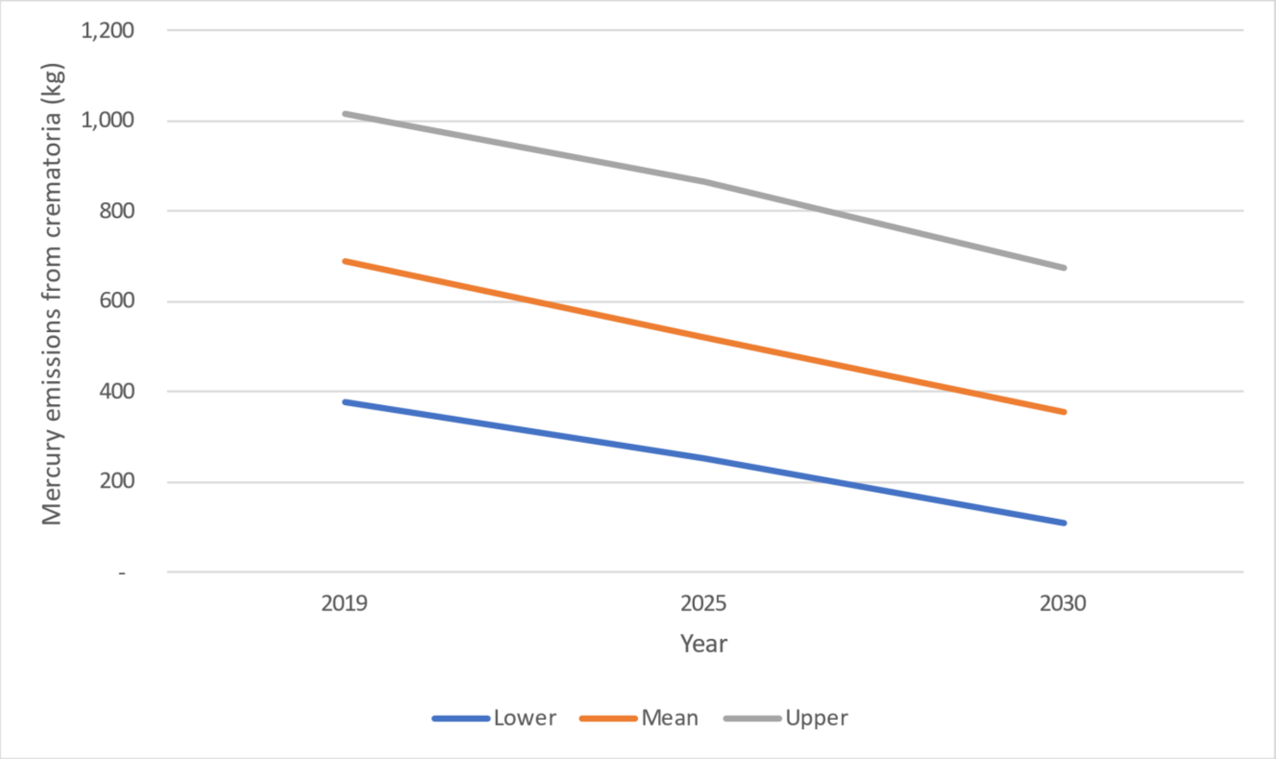
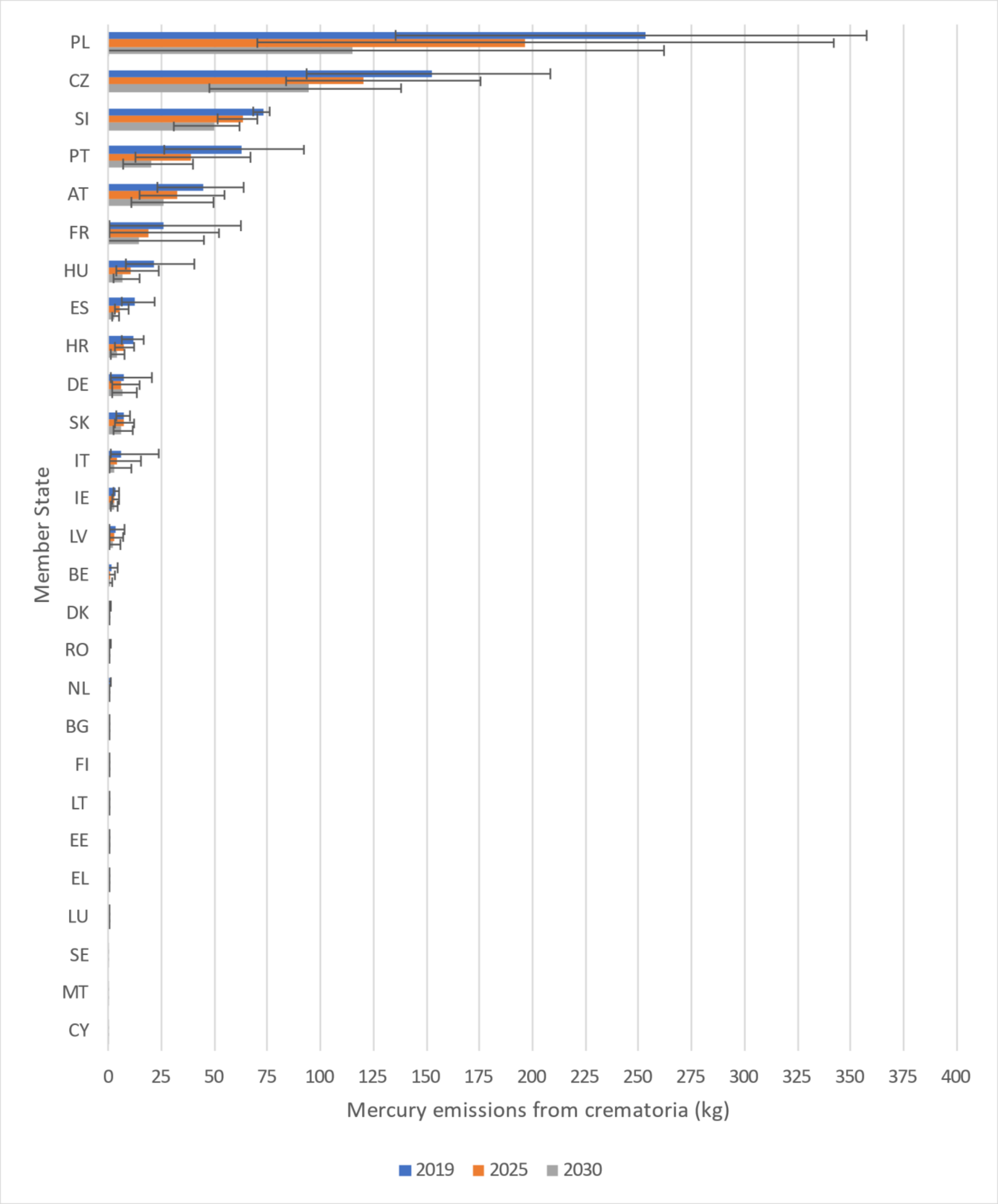


Figure 14: Estimated mercury emissions per Member State from crematoria (2019, 2025 and 2030[18])



[18] Error bars denote lower and higher emissions estimates.

3. Baseline for MAPs

Approach

The purpose of the baseline scenario is to predict manufacture and export of MAPs, the associated mercury use and the probable impacts in the near future. While the relevant legal framework in the EU is considered as constant (taking into account restriction that will enter into force the coming years), the legal situation in importing countries and on the global level is currently changing or may change soon. The legal situation as well as national programmes/ initiatives that will lead to a change of demand products exported from the EU was analysed and considered. Moreover, rising environmental awareness, as well as technical progress and increasing price competitiveness, may also lead to a decline in end-user demand. Such developments are indicated by past and current trends in export volume or sale patterns in importing countries. Such data are available for lamps, but time series may not be readily at hand for other relevant products. In that case, opinions from industry experts were invited to allow at least rough estimates about future trends.

On the background of these considerations, a baseline scenario was calculated covering central boundary conditions of future developments:

- No further legal actions in the EU beyond those already agreed or planned to take place in the near future, but consideration of existing legal measures in importing countries that become effective in the near future
- The impact of potential national measures in importing countries that follow or lead to similar results as the EU restrictions laid down in the RoHS directive and the subsequent Commission regulations.

The baseline scenario considers that several countries have implemented legislation or are considering adopting legislation that mirrors, at least in part, European product-related law, especially the REACH regulation, the RoHS Directive, and the Ecodesign Directive and any associated delegated acts. Furthermore, the legal situation in some selected countries or regions were looked at in more detail.

For these scenarios, future exports of relevant MAPs in terms of number, value, and mercury content were estimated based on identified current and past trends. Trend data were available only for compact fluorescent lamps (CFL) and double-capped fluorescent lamps (linear and non-linear FL). Almost all lamps of these types are addressed by the recent Delegated Acts under the RoHS directive so that data on past trends will allow the prediction of impacts of future measures.

The situation is different for high-intensity discharge lamps (HID, HPS, HPMV, MH). Although export data are available for this group, only a part of export is related to lamp types banned within the EU.

Limited information from other sources could be gathered to allow an overview of the situation and trends for other relevant products within the scope of the present study. For them, no quantitative recent export data were available and there is currently no basis to predict future trade volumes.

The export value and the amount of mercury in CFLs and double-capped FLs was estimated for the years 2025 to 2030. For importing countries, it was calculated how much mercury will likely end up in the environment due to inappropriate waste management practices. Minamata Initial Assessments (MIAs) as well as reports on mercury waste management provided an indication which percentage of mercury in products is likely to be released during disposal.

Based on the problem description, three groups of MAPs were selected for which quantitative or at least semi quantitative data on export volumes were available:

- CFL lamps for general lighting purposes
- LFL lamps for general lighting purposes except those addressed by RoHS Annex III 2(b)4
- Dental amalgam

These three product groups most likely constitute the vast majority of MAPs both in number as well as in value currently exported from the EU.

Expected global market development: fluorescent lamps

According to a study by the IEA (2021)[19], fluorescent lamps for general lighting purposes continue to lose significant market share. Their share (CFL+LFL) of the global market fell from 43% to 33% between 2013 and 2020. In turn, the share of LED lamps rose from 3% to 51%. While market penetration in industrialised countries is already well advanced, the situation in less developed countries is still somewhat different. A higher share of non-LED lamps is also observed in existing light sources. The authors of the IEA study expected that the LED share of the total market will increase to close to 100% by 2025. In the authors' view, there are several reasons for this:

- The price of LED lamps and light sources continues to fall relative to other lamp types, making them even more competitive.
- The energy efficiency of LEDs has continued to increase and has doubled in five years. It is now on average well above that of CFLs and slightly above that of LFLs. A further increase (doubling again) is technically possible but is expected to be slower. In contrast, no further increase in efficiency can be expected for fluorescent lamps.
- The use of energy-saving LEDs are a low-hanging fruit to decrease energy consumption and to contribute achieving climate goals. Many, especially less developed countries (e.g., India) have started programmes to make LEDs accessible to broad sections of the population.

In an earlier publication, the IEA predicted a less optimistic expectation of future developments. It is no longer available online but cited in a recent JRC report[20]. According to this prediction, LED would dominate the market in 2025 with a 75.8% market share and would further rise to 87% in 2030. In this scenario, the share of fluorescent lamps would decrease to a market share of 23.5% in 2025 and to 12.5% in 2030. This prediction may be more realistic as for example in the EU many exemptions

[19] IEA (2021) Lighting. Tracking Report – November 2021. Available online at: https://www.iea.org/reports/lighting (last checked 12 March 2022)

[20] Zissis, G.; Bertoldi, P.; Serrenjo, T. (2021) Update on the Status of LED-Lighting world market since 2018. JRC Tech. Rep. JRC122760

for lamps extend to 2025 or beyond. A global ban for all remaining fluorescent lamps for general lighting purposes cannot be agreed before COP5 of the Minamata Convention (2023) and would enter into force not earlier than two years after (rather considerably later, considering the extended time needed for national ratification and preparation).

In the area of street lighting, the share of LED lamps in new installations is expected to rise to 80% already in 2020, reaching 89% globally in 2017. Replacing existing sodium lamps with LEDs usually requires higher investments and pays off only over a longer period (4-12 years), so it will progress more slowly. The focus of investment will be in Europe, North America, and South Asia, while countries in the Arab region and Southeast Asia will continue to prefer traditional solutions.

A summary study of CLASP concluded that 48% of European exports go to countries that have RoHS-like regulations, which will also phase out CFL and LFL by 2024/2025[21]. In addition, it must be taken into account that 61% of current production is shipped to other EU countries, a market that will disappear in 2023. Thus, about 80% of the current CFL and LFL production would no longer find a market by the end of 2025 and may pose a serious challenge for the few remaining EU manufacturers to maintain their manufacturing lines.

Another major incentive to accelerate the shift to LEDs are the strongly increasing energy-prices observed since 2021 due to the combined effect of higher demand in the course of economic recovery after the COVID-19 pandemic and the aftermath of the Russian invasion of Ukraine. Higher energy prices will likely strengthen the demand for more cost-effective LEDs. However, it is too early to quantify the effect.

***Business*-as-usual scenario**

In the baseline scenario, it was assumed that the EU does not take any further measures to restrict MAP exports. Global restrictions agreed at COP4.2 of the Minamata Convention were taken into account. The decrease in exports was extrapolated into the future according to the observed continuous development from 2008 to 2020. This represents an average global trend that already includes more or less ambitious measures taken by non-EU countries in the past.

In addition to that, based on historical experience and observed legal practice, it is considered that the EU is a forerunner in product-related policy and that countries outside the EU may decide to translate restrictions imposed in the EU into their national legislation (especially the most recently adopted restrictions on CFL and LFL). Depending on national circumstances and ambition, this will probably take place with some delay and possibly only in part (see RoHS, Ecodesign). Moreover, third country manufacturers that export products to the EU need to comply with EU rules. Establishing a RoHS-compliant product line while maintaining a non-compliant line causes extra costs in research and production so that even without domestic legislation EU law could have an effect.

An overview was prepared to gain an impression of how many years later the main recipient countries may follow the EU example or implement policies with a comparable

[21] CLASP (2022) Refurbishing Europe's Fluorescent Lamp Manufacturing Facilities

effect (Table 9). According to the analysis, the ten countries with the highest share in EU exports could be categorized in five groups:

- Identical rules with no delay: Switzerland, Norway
- Similar rules in 2028: United Kingdom
- Similar rules in 2030: Russian Federation, United Arab Emirates
- Partially similar rules in some states: United States
- No additional national measures before 2031: China, Egypt, Republic of Korea, Saudi Arabia, Turkey

Table 12: RoHS-like legislation/programmes/standards in main recipient countries

Country	RoHS 1 (2003)	RoHS 2(2011)	Years between EU RoHS and national RoHS-like legislation
China		2018	7
Egypt			Not applicable
Norway		2013	2 (but exemptions and entry into effect identical)
Republic of Korea	2008 (lamps are not included)		Not applicable
Russia/ Eurasian Union		2016 (adopted by Member States in 2018)	7
Saudi Arabia		2021	10
Switzerland	2005		2 (but exemptions and entry into effect identical)
Turkey	2012		9
United Arab Emirates		2017[31]	6
United Kingdom			So far consistent (including ban on CFL.i and c, but UK may decide differently/ later on new product bans
USA		Different approach (incentives)	Not applicable
Turkey	2012		9
United Arab Emirates		2017[22]	6
United Kingdom			So far consistent (including ban on CFL.i and c, but UK may decide differently/ later on new product bans
USA		Different approach (incentives)	Not applicable

For each country, the percentage of lamps that are likely not affected by national measures was derived for the years 2025, 2028 and 2030 (100% or 0%, for USA: 85%

[22] Businesstat (2021) Between 2016 and 2020, sales of electric lamps in Russia fell by 21%: from 960 million to 756 million units (translates). Available at: http://marketing.rbc.ru/articles/12262/ (last checked on 12 March 2022).

and 70%, Table 10). These values were multiplied with predicted EU exports to the individual countries. This resulted in a reduced number of total exports.

Table 13: Impact of national policy measures on export of FLs from the EU (100% = no specific national impact)

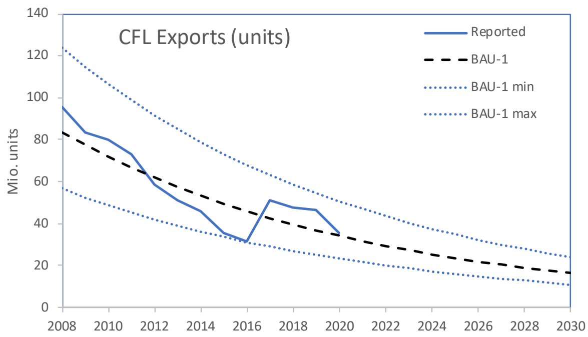
Country	2025-2027	2028-2029	2030
China	100%	100%	100%
Egypt	100%	100%	100%
Norway	0%	0%	0%
Rep. of Korea	100%	100%	100%
Russian Federation	100%	100%	0%
Saudi Arabia	100%	100%	100%
Switzerland	0%	0%	0%
Turkey	100%	100%	100%
United Arab Emirates	100%	100%	0%
United Kingdom	100%	0%	0%
United States	85%	85%	70%

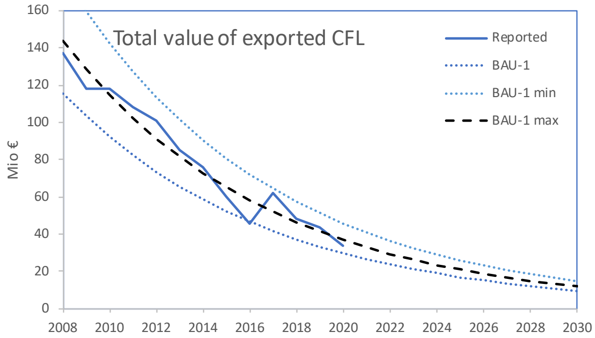
Predicted export volumes in 2025 to 2030 (lamps)

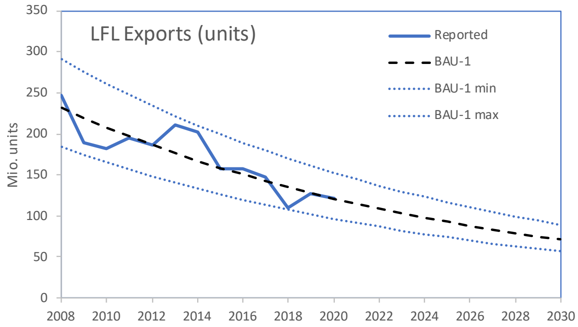
Export data for discharge lamps was obtained from the EU-PRODCOMM and UN-COMTRADE databases.

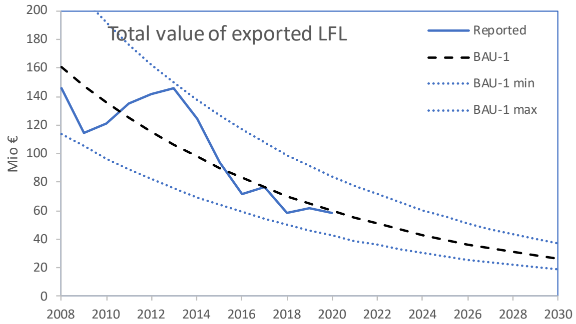
Based on the data from 2008 to 2020, trends were developed from which the future development was predicted. The year 2008 was chosen as starting point because a historic peak in the export volume of discharge lamps was achieved in this year. In the following years, exports declined continuously. The development of exports in this period can be represented by different function types. From a statistical point of view, the decrease in exports would be best described linearly. However, this would inevitably lead to a complete disappearance of exports in a few years. As long as there are still existing installations that can be fitted with fluorescent lamps at low or no cost, demand will continue to exist, even if the use of LEDs would be more economical in the long-term. It therefore seems more obvious to describe the decrease in exports by an exponential function. It also leads to a continuous decrease, but it slows down more and more. To derive a bandwidth, standard deviations were calculated from the deviations between the smoothing curve and the reported export volumes. The upper and lower limits of the range were derived from the predicted curve by adding or subtracting twice the standard deviation. This was done on the basis of the logarithmic export figures due to high relative differences in size between the older and more recent export figures. The range, therefore, becomes narrower in absolute terms, but it is constant on a relative scale. The following figures show that all export data lie within or at least just outside this range (Figure 20).

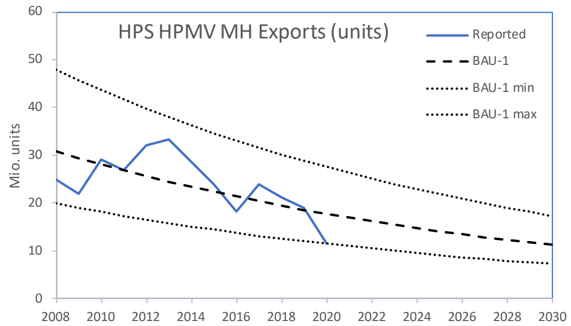
Figure 15: Reported and predicted amount and value of exported CFLs and double-capped FLs (incl. LFLs) between 2008 and 2030

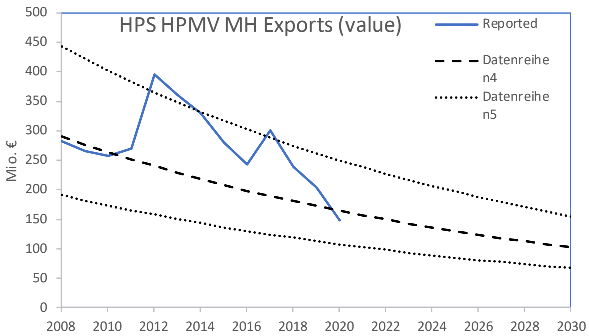

CFL Exports (units)
Mio. units
Reported
BAU-1
BAU-1 min
BAU-1 max


Total value of exported CFL
Mio €
Reported
BAU-1
BAU-1 min
BAU-1 max


LFL Exports (units)
Mio. units
Reported
BAU-1
BAU-1 min
BAU-1 max


Total value of exported LFL
Mio €
Reported
BAU-1
BAU-1 min
BAU-1 max


HPS HPMV MH Exports (units)
Mio. units
Reported
BAU-1
BAU-1 min
BAU-1 max


HPS HPMV MH Exports (value)
Mio. €
Reported
Datenreihe n4
Datenreihe n5

Future development of exports can also take a different course. Decisions by individual manufacturers to rearrange production capacity among production sites worldwide or changed international flows of goods (which affect lamps that are only distributed via the EU to countries outside the EU) can influence exports beyond the calculated ranges. It was observed, for example, that the value of exports decreases faster than the number of exported lamps – the average price achieved thus decreases so that in individual cases the limit of profitability could be reached. This may lead to an abrupt end of individual production lines. In addition, production exceeding annual demand has been observed in recent years. Thus, stocks may have been built up in view of expected restrictions on placing on the market. Reducing these stocks by relocating them abroad would lead to exports that exceed expectations.

Also, the legal framework in the current export markets is not predictable. Increased efforts to meet climate targets are already leading to increased scrutiny of the lighting sector. A forced phase-out of less efficient fluorescent lamps could be one of the rather easy ways for more countries to save energy. The forecast presented here therefore only sketches one of several possible development paths.

The projected exports for the BAU scenario are summarised in Table 11. According to these and under BAU, by 2025, export volumes for all CFLs and LFLs would fall to around 83-141 million units. By 2030, the numbers would fall to between 49 and 83 million units. The calculated decrease is stronger for CFL lamps. In comparison to 2020, exports are predicted to decrease by 47-68%.

The value of exported lamps decreases from €92.2 million to approx. €59 million i.e., €42-76 million by 2025 and to €21-38 million by 2030.

The amount of mercury exported (via CFLs and LFLs) was estimated at **450-501 kg in 2020**[23]. This quantity would decrease to about **245-414 kg by 2025** and to about **146-246 kg by 2030**. The wide range follows from the uncertainty of the average mercury content of the exported lamps.

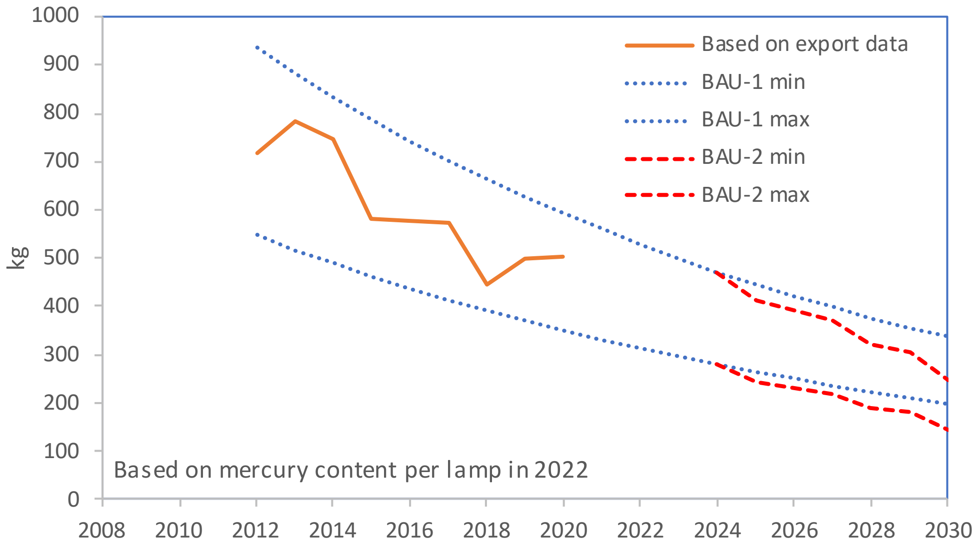
Table 14: Baseline scenarios BAU-1 and BAU-2. Predicted range of export volume, value and mercury content (all FLs for general lighting purposes) in 2025, 2028 and 2030

Parameter	Export from EU (2020)	BAU 2025	BAU 2028	BAU 2030
CFL (million units)	35,5	15 – 32	11 – 24	8 – 17
Double-capped FL (million units)	121,6	69 – 108	54 – 85	41 – 65
Total export (million units)	**157,1**	**83 – 141**	**65 – 109**	**49 – 83**
CFL (million EUR)	33,6	16 – 24	10 – 16	7 – 11
Double-capped FL (million EUR)	58,6	26 – 52	19 – 37	14 – 27
Total export value (million EUR)	**92,2**	**42 – 76**	**29 – 53**	**21 – 38**

[23] This value was calculated on basis on of available information on the mercury content per lamp in 2022. The actual value in 2020 was probably higher.

Parameter	Export from EU (2020)	BAU 2025	BAU 2028	BAU 2030
Mercury content CFL (kg)	62-64	26 – 58	19 – 43	14 – 31
Mercury content in, double-capped FL (kg)	388-438	219 – 356	172 – 280	132 – 214
Total mercury content (kg)	**450-501**	**245 – 414**	**192 – 323**	**146 – 246**

Figure 16: Calculated and predicted total mercury content of exported discharge lamps (all FLs for general lighting purposes) between 2012 and 2030



Dental amalgam

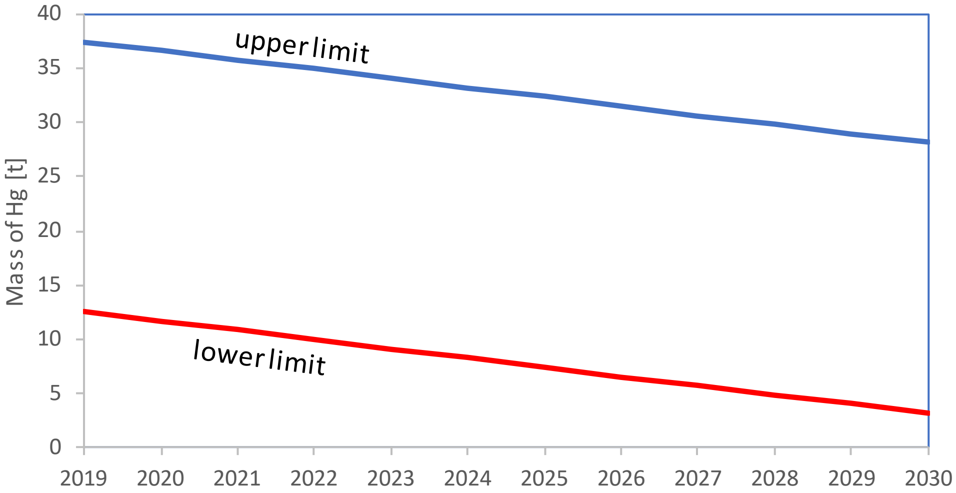
Considering the expectations expressed in the WHO study (75% of participants expected a phase-out by 2030) and data on declining use in the USA and Canada, it is expected that the demand for EU-made encapsulated amalgam will decrease strongly until 2025 and even further until 2030. That coincides with the assumption of an EU manufacturer who expressed that by 2025 exports would likely decrease by 25% and by 2030 by 26-50%. On the other hand, demand may increase in those (low-income) countries that need to implement the recent MC COP decision to prohibit the preparation of dental amalgam from bulk mercury. Based on these assumptions it is expected that exports decrease linearly by 25% to 75% of the current levels by 2030. The already large uncertainty concerning current dental amalgam exports only allowed a rough calculation of the order of future export volumes.

Based on these assumptions the following ranges are expected:

2025: 13 - 55 million capsules with a total mercury content 7 – 32 t

2030: 5 - 48 million capsules with a total mercury content 3 – 28 t

Figure 17: Predicted mercury content in dental amalgam exports



Annex 6: Problems and Drivers

1. The Mercury Problem

Mercury in air

Mercury is naturally emitted into air from various natural sources such as volcanoes, erosion and natural fires. Its accumulation in the air in Europe is largely influenced by external sources, as it is estimated that mercury emissions from outside Europe contribute about 50% of the anthropogenic mercury deposited annually within the continent, of which 30% originates in Asia

[1,2]. Globally, the most prominent sources of mercury emissions to air are artisanal and small-scale gold mining (ASGM) (37%), coal combustion (24%) and non-ferrous metal production (13%)[3]. Most estimates indicate that global mercury emissions to the atmosphere stand at 2000 to 2500 t per year, with a persistence of up to two years, before deposition into water or soil[4]. Mercury emissions to air in the EU were around 200 tonnes in 1990 and decreased to around 60 t in 2016[5].

Mercury in water

Mercury deposited in water poses a greater danger to human health than that emitted to air and deposited on soil, as water can store mercury for longer periods and, under certain conditions, can be converted into methylmercury[6,7]. Data on historical and future mercury releases to water are less comprehensive than for air, but an approximate assessment of global mercury emissions deposited into the oceans in 2018[8] concluded that global emissions from anthropogenic sources in 2015 amounted to around 54.6 t. The main activities contributing to this level of deposition were waste management and discharges; non-ferrous metals production; and coal-fired power plants. It is estimated that the European contribution of mercury emissions to freshwater is around 8 t[9].

Mercury in European waters

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[1] UEP (2018), Global Mercury Assessment, https://wedocs.unep.org/bitstream/handle/20.500.11822/27579/GMA2018.pdf?sequence=1&isAllowed=y

[2] UNEP (2018), Global Mercury Assessment, https://wedocs.unep.org/bitstream/handle/20.500.11822/27579/GMA2018.pdf?sequence=1&isAllowed=y

[3] These emissions do not arise from mercury employed in the processes themselves, but rather because this is present in fuels and raw materials used. These are classified as "unintentional releases"

[4] https://www.des.nh.gov/organization/commissioner/pip/factsheets/ard/documents/ard-28.pdf

[5] European Environment Agency (2018) "Mercury in Europe's environment. A priority for European and global action", https://www.eea.europa.eu/highlights/mercury-pollution-remains-a-problem

[6] Methylmercury is formed from inorganic mercury by the action of microbes that live in aquatic systems. People are exposed to methylmercury when eating fish and shellfish that contain this compound or when inhaling mercury vapour. In pregnant women, methylmercury can adversely affect a baby's brain and nervous system. Similar effects can be observed in adult population (World Health Organization).

[7] UNEP (2018), Global Mercury Assessment, https://wedocs.unep.org/bitstream/handle/20.500.11822/27579/GMA2018.pdf?sequence=1&isAllowed=y

[8] UNEP (2018), Global Mercury Assessment, https://wedocs.unep.org/bitstream/handle/20.500.11822/27579/GMA2018.pdf?sequence=1&isAllowed=y

[9] AMAP/UNEP, 2008. Technical background report to the global atmospheric mercury assessment

The EEA State of Water Report[10] highlights that in the 2nd River Basin Management Plans (2015-2021), only 38% of surface water bodies (e.g., rivers, lakes and coastal waters) were reported to be in good chemical status; 46% of water bodies failed to achieve good chemical status; and for 16% of surface water bodies their status is unknown. Mercury is one of the few substances responsible for a widespread failure to achieve good chemical status with 24 Member States reporting water body failures caused by mercury.

Across Europe, mercury (alongside brominated diphenylethers) is also responsible for failure to achieve good chemical status in the highest number of water bodies: out of a total of 111,062 surface water bodies, 45,973 are not achieving good chemical status for mercury equating to about 41% of all surface water bodies in Europe[11]. If the widespread pollution by ubiquitous priority substances[12], including mercury (priority hazardous substance), were omitted, the proportion of water bodies failing to achieve good chemical status would fall to 3% (as opposed to 46% for all such ubiquitous priority substances).

According to the EEA State of Water Report, **atmospheric deposition** of mercury leads to contamination of over 45,000 water bodies that fail to achieve good chemical status, while **releases from urban wastewater treatment plants** (UWWTP) lead to contamination with mercury and other heavy metals[13] of over 13,000 water bodies. Whilst dental amalgam appears to be the main contributor to releases of mercury from UWWTP to water bodies, it must be noted that inputs from UWWTPs constitute a less significant factor in achieving good environmental status of water than atmospheric depositions[14]. Currently, atmospheric deposition affects 38% of surface water bodies, with mercury being the main pollutant responsible for failure to achieve good chemical status[15]. The EEA State of the Environment Report states that diffuse pollution remains a problem in Europe due to both historical and current emissions of mercury to the atmosphere and subsequently surface waters[16].

Mercury in soil and groundwater

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[10] EEA (2018) European waters. Assessment of status and pressures 2018. Report No 7/2018

[11] European Commission (2019). COMMISSION STAFF WORKING DOCUMENT European Overview – River Basin Management Plans. SWD(2019) 30 final, February 2019

[12] Other ubiquitous, persistent, bioaccumulative and toxic substances causing failure to meet good chemical status next to mercury are pBDEs, tributyltin and certain polycyclic aromatic hydrocarbons (benzo(a)pyrene, benzo(g,h,i)perylene, indeno(1.2.3-cd)pyrene, benzo(b)fluoranthene and benzo(k)fluoranthene). Mercury is the most common. Out of some 111 000 European water bodies identified in an EEA report No 18/2018, more than 45 000, across 24 Member States, are failing to reach good chemical status due to mercury pollution

[13] EEA (2018) European waters. Assessment of status and pressures 2018. Report No 7/2018

[14] European Commission (2016), Commission Staff Working Document Impact Assessment Ratification and Implementation by the EU of the Minamata Convention on Mercury

[15] COMMISSION STAFF WORKING DOCUMENT EVALUATION of the Council Directive 91/271/EEC of 21 May 1991, concerning urban waste-water treatment, available at: https://ec.europa.eu/environment/water/water-urbanwaste/pdf/UWWTD%20Evaluation%20SWD%20448-701%20web.pdf

[16] EEA (2020), State of the Environment reporting 2020, available at: https://forum.eionet.europa.eu/nrcstate-environment/library/soer-2020-working-place-eionet/external-review-of-the-soer2020/4.4.-keytrends-europe-and-european-countries-including-outlooks

Climate change has a negative effect on mercury content in soil, through intensification of various phenomena, e.g., increased floods can lead to mercury releases through erosion and sediment fluxes, while increased rainfall will cause higher deposition of mercury from the atmosphere. Mercury accumulated in trees and forest litter is released during forest fires caused by increasingly occurring draughts causing higher emissions to air. In addition, mercury contained in permafrost is predicted to be released to the oceans, as this is expected to thaw over the coming centuries. Once mercury is deposited on land, it can enter the food chain, especially through food grown in water environments (e.g., rice). Deposited mercury has a long lifetime, especially when transformed into methylmercury, which can persist in soils for decades[17]. The anthropogenic mercury contamination in soil and groundwater may result in much higher concentrations compared to other environmental media, particularly in contaminated sites[18]. Unlike in water bodies, where mercury tends to accumulate over time, in soils, mercury tends to accumulate until an event (e.g., erosion, floods and forest fires) causes its release. Globally, it is estimated that there are approximately 10,000 tonnes of mercury in vegetation, 863,000 t in the active layer of the soil, 793,000 t in permafrost and 454,000 tonnes in other types of soil[19]. In EU, the estimated mercury stocks in topsoil (0-20cm) is about 45,000 tonnes[20] according to the topsoils Land Use/Land Cover Area Frame Survey (LUCAS) survey[21]. High values of Hg are measured especially close to past mining activities, chlor-alkali industries and coal combustion sites. The level of local mercury contamination in the EU also depends on past or present local diffuse pollution activities such as small-scale industries employing mercury (scientific instruments, electrical equipment, dental amalgam, felt making, disinfectants, and production of caustic soda).

Movement of mercury

Mercury is a global pollutant, as airborne mercury can be transported over long distances (i.e., across continents) depending on the speciation of mercury emissions and reaction pathways, before being deposited on the Earth's surface. Across different areas of the EU, the origin of atmospheric mercury deposition can differ substantially[22]. Currently it is estimated that European emissions contribute up to 60% in certain areas, while in others (e.g., the Mediterranean), the atmospheric deposition originating from sources in Europe corresponds to only 20% or less of the total deposition. This significant transboundary component of mercury indicates that addressing the problem requires action at the global level together with measures implemented at EU level. Despite this transboundary nature of mercury, in the last two decades only the EU and a few other countries (e.g., Norway, Switzerland, the USA, Canada and Japan) have implemented

[17] EEA (2018) European waters. Assessment of status and pressures 2018. Report No 7/2018

[18] UNEP (2019), Technical information report on mercury monitoring in soil, available at: https://wedocs.unep.org/bitstream/handle/20.500.11822/30818/Soil_report.pdf?sequence=1&isAllowed=y

[19] UNEP (2019), Technical information report on mercury monitoring in soil, available at: https://wedocs.unep.org/bitstream/handle/20.500.11822/30818/Soil_report.pdf?sequence=1&isAllowed=y

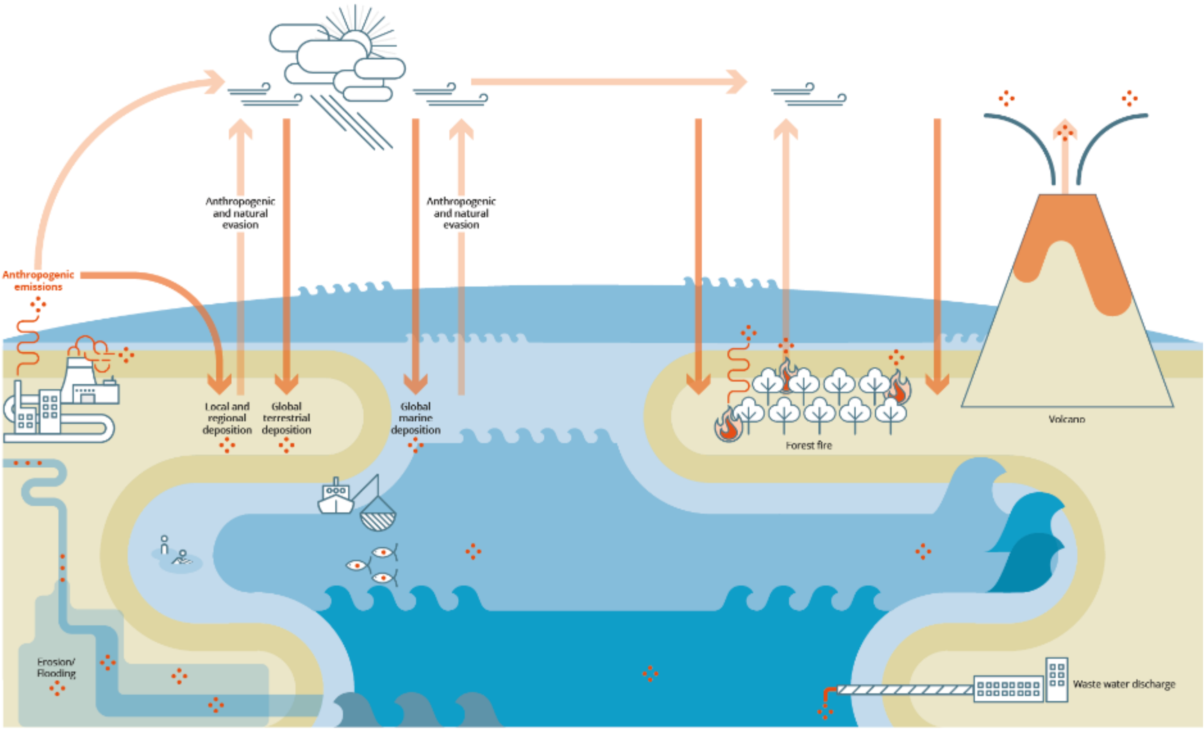
[20] Ballabio et al. (2021), A spatial assessment of mercury content in the European Union topsoil https://www.sciencedirect.com/science/article/pii/S0048969720382887

[21] Orgiazzi et al. (2018), LUCAS Soil, the largest expandable soil dataset for Europe: a review https://bsssjournals.onlinelibrary.wiley.com/doi/10.1111/ejss.12499

[22] European Commission (2016), Commission Staff Working Document Impact Assessment Ratification and Implementation by the EU of the Minamata Convention on Mercury

restrictions and other measures that aim to decrease or cease the use of mercury and eventually the contribution to the global pool of mercury. In fact, in several countries in Asia the exact opposite trend has been observed with increases of mercury pollution in several Asian countries due to their industrialisation[23]. Mercury can be displaced from topsoils with water erosion and runoff and transferred with sediments to river basins and eventually released to coastal Oceans. On average, around 6 tonnes of Hg may end in the EU rivers and released to costal oceans due to water erosion[24].

Figure 1: The global mercury cycle



Prod-ID: INF-90-enPublished 27 Sep 2018 (https://www.eea.europa.eu/media/infographics/the-global-mercury-cycle/view)

Properties

Mercury, an elemental heavy metal, is a persistent pollutant and a toxic compound for humans and the environment, which exists in different forms on earth (elemental, inorganic and organic). Under anaerobic conditions, in soil or water, bacteria can metabolise inorganic mercury to a highly potent neurotoxin, methylmercury. In contaminated ecosystems, methylmercury can enter organisms, especially plants and predatory fish that are tolerant to a high amount of mercury.

Source

[23] European Commission (2016), Commission Staff Working Document Impact Assessment Ratification and Implementation by the EU of the Minamata Convention on Mercury

[24] Panagos et al (2021) Mercury in European topsoils: Anthropogenic sources, stocks and fluxes. https://www.sciencedirect.com/science/article/pii/S0013935121008501

Mercury is a global pollutant, as airborne mercury can be transported over long distances (i.e. across continents) before being deposited on the Earth's surface. Mercury emissions are distributed in all environmental media including air, water and soil and affect human health, fauna and flora.

Human health

The release of mercury from anthropogenic sources, including dental amalgam, induces a progressive increase in the amount of mercury in the environment. Mercury, as a persistent substance which can enter the water cycle. Under anaerobic conditions, in soil or water, bacteria can metabolise inorganic mercury to a highly potent neurotoxin, methylmercury.

In contaminated ecosystems, methylmercury can then bioaccumulate in organisms, especially plants and fish that are tolerant to a high amount of mercury. Levels of mercury in fish vary by species and their environment. Methylmercury introduced into the food chain via plants or fish can be ingested by humans.

The mercury concentrations in organisms, including humans are affected by two major amplification processes: bioaccumulation that refers to the increase of mercury concentrations along the lifetime of an individual and biomagnification that is defined as the increment of mercury concentration between the successive consumer levels of the food chain[25]. In humans, these processes can lead to toxic effects (nervous system damage in adults and neurological development damages in infants)[26].

Minamata Accident

Between 1932 and 1968, a devastating incident occurred in the city of Minamata, Kumamoto Prefecture, Japan, whereby a large amount of mercury was released by a petrochemical factory directly into the Minamata Bay via industrial wastewater. The released mercury subsequently converted into methylmercury, contaminating shellfish and fish. The contaminated seafood was consumed by the local population of Minamata, leading to mercury poisoning and significant and lasting impacts on their health. Specifically, the poisoning affected the central nervous system. This effect was named the Minamata disease. It's signs and symptoms include ataxia, numbness in the hands and feet, general muscle weakness, loss of peripheral vision, and damage to hearing and speech. In extreme cases, coma and death follow within weeks of the onset of symptoms. This unprecedented incident led to an increased awareness of the risks of exposure to mercury and particularly the effect of methylmercury on human health.

Environmental health

Mercury emitted to the atmosphere, travels through the air and is eventually deposited to soil and water bodies. Current global levels of mercury in the atmosphere are about 500%

[25] Pouilly M. et al (2013), Trophic Structure and Mercury Biomagnification in Tropical Fish Assemblages, Iténez River, Bolivia, https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0065054

[26] According to the US Agency for Toxic Substances and Disease Registry (ATSDR) when mercury is swallowed, only a small amount (less than 0.01%) will be absorbed by the body unless the stomach or intestines, are diseased. However, when mercury is breathed most (about 80%) of the mercury enter the bloodstream directly from your lungs, and moves to other parts of the body, including the brain and kidneys where it can be accumulated for weeks or months.

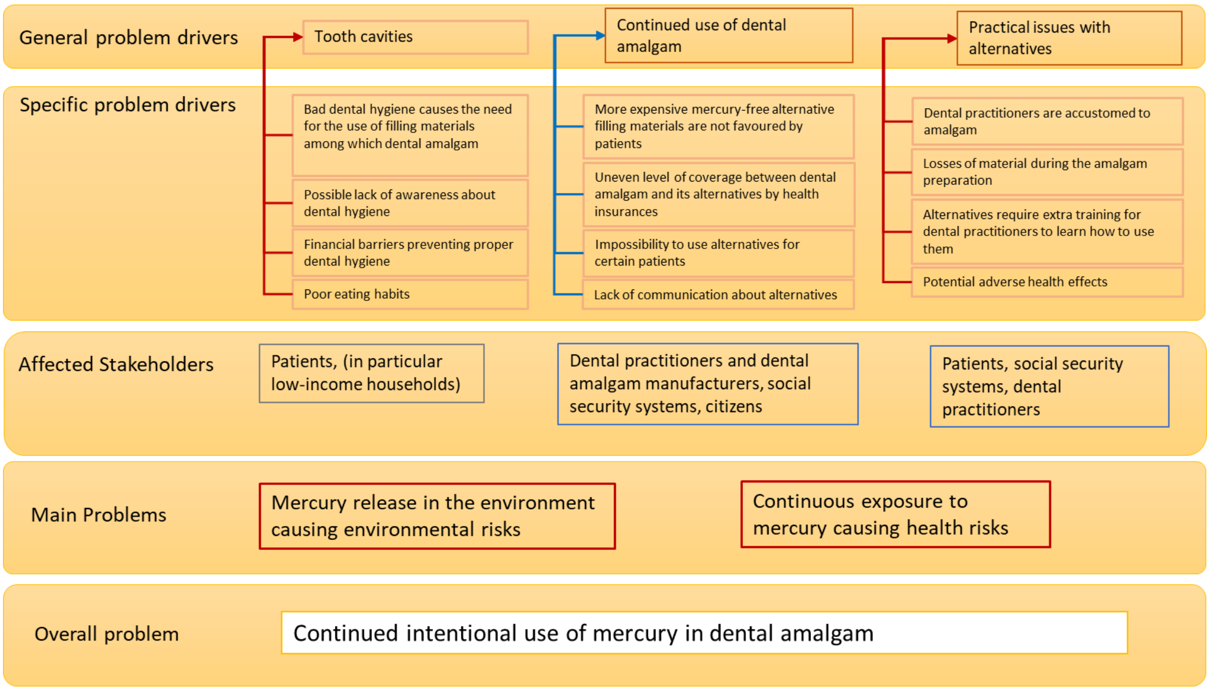
above natural levels resulting from anthropogenic activities and around 40% of the EU's surface water bodies are currently assessed as contaminated with dangerous levels of mercury[27].

2. Problem drivers

2.1 Dental amalgam and associated emissions from crematoria

Dental amalgam is the biggest source of intentionally used mercury in the EU, and despite its use steadily decreasing, it is expected to still be in use in the EU in 2030 if no action is taken. Mercury from dental amalgam is released into the environment (soil, atmosphere, water) via dental practices (surplus of amalgam or tooth extraction); deterioration in the mouth; burial or cremation; and waste management. The overall problem tree for dental amalgam is presented below.

Figure 2: Overall problem tree for dental amalgam

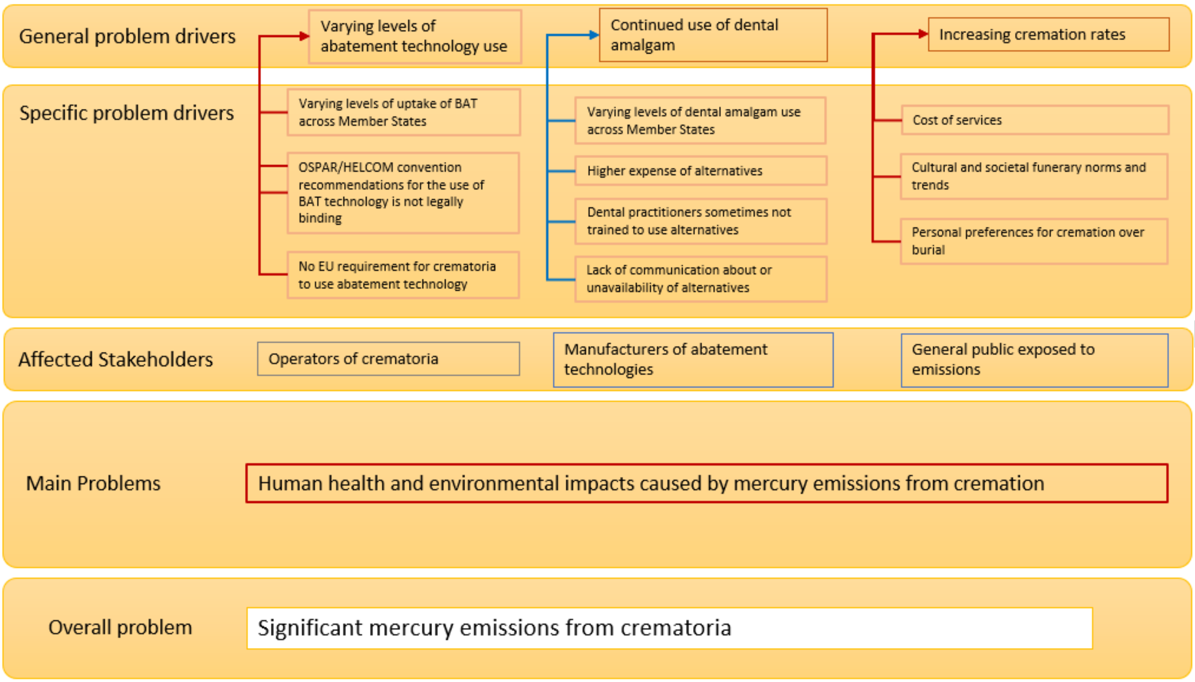


2.2 Mercury emissions from crematoria

Recognising the transboundary nature of mercury pollution, crematoria are an important source of mercury emissions in the EU which are expected to follow the general trends of dental amalgam use. The OSPAR and Helsinki (HELCOM) Commissions recommend the use of Best Available Techniques (BAT) to address mercury emissions from crematoria but, with only 11 and 8 EU Member States signatories to the Conventions respectively, the level of action on crematoria emissions varies across Europe. The overall problem tree for crematoria is presented below.

[27] EEA (2018) European waters. Assessment of status and pressures 2018. Report No 7/2018

Figure 3: Overall problem tree for mercury emissions from crematoria



2.3 Mercury-added products

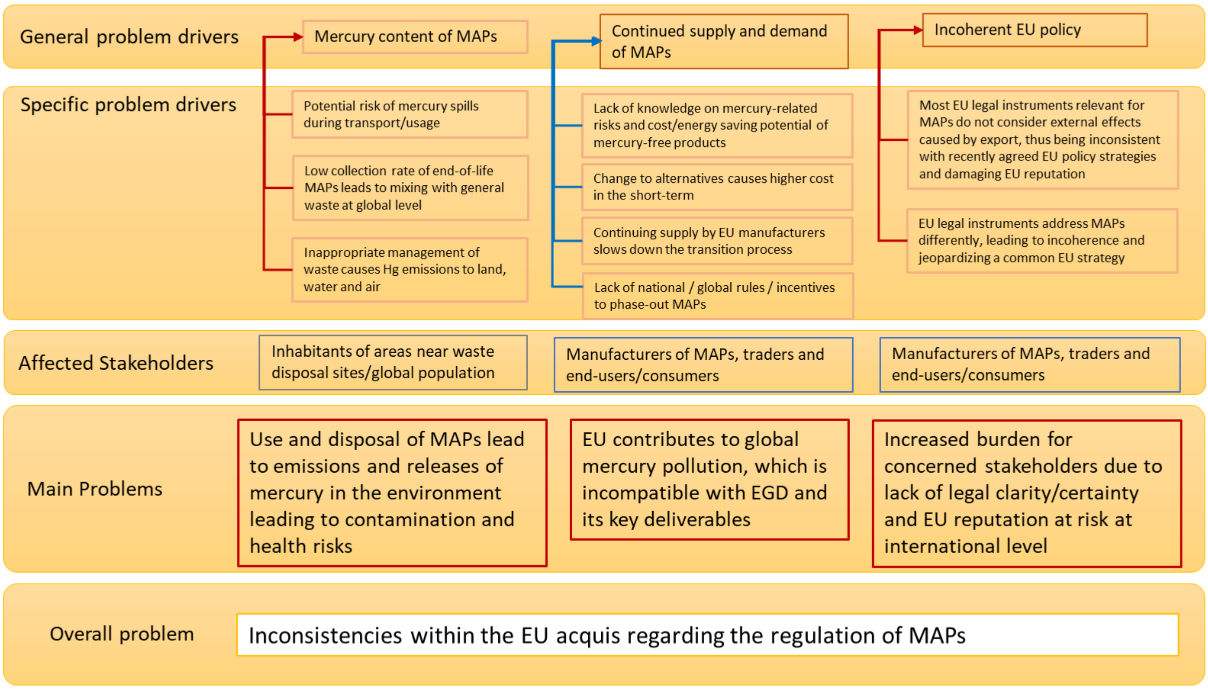
Some mercury-added products (MAPs) although already banned for sale within the EU are still allowed for manufacture and export to third countries. This situation causes continuing demand for mercury within the EU, sustains supply for MAPs and contributes to mercury releases in importing countries.

Due to its unique physical and chemical properties, mercury has historically been used in a wide range of products. Concerns about its environmental and health risks pushed manufacturers and legislators to develop and promote effective mercury-free alternatives and to restrict or ban the manufacture, sell and trade of mercury-added products. Most known MAPs are no longer allowed to be placed on the European market. The European Mercury Regulation also bans the export of a range of products, but it mainly limits the scope of trade restrictions to those products that are addressed by the Minamata Convention. Consequently, export is still allowed for numerous products that are prohibited for sale within the EU.

Products that contain a hazardous substance such as mercury pose a risk to human health and the environment during use and disposal. Stopping the manufacture and export of such products for which effective, affordable, and safer alternatives already exist, would further decrease EU internal demand for mercury, reduce the supply of MAPs to non-EU countries and may contribute to lower mercury emissions and releases. For some products such as lamps reduction of supply may also be an incentive to switch to more energy-efficient lamp types such as LEDs, leading to lower CO_2 emissions and contribute to achieving climate change goals.

The overall problem tree for mercury-added products is presented below.

Figure 4: Overall problem tree for mercury-added products



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Problem Area 1: Dental Amalgam

There are three measures shortlisted to address the use of dental amalgam in the EU:

- **DA#1**: Establish legally binding end date for the use of dental amalgam in the EU (sub-options with different end dates)
- **DA#2**: Communication campaigns to raise awareness and change of dental patients (and practitioners) towards mercury-free dental filling alternatives
- **DA#3**: Raise prices of dental amalgam reflecting risks due to mercury exposure

The measures considered are a combination of hard measures (DA#1 mandatory phase-out with different deadlines with respective sub-options) and soft measures (DA#2 awareness raising and DA#3 reducing the financial burden on citizens for getting treatment using amalgam alternatives). The phase-out measures consider 2025 (DA#1a), 2027 (DA#1b) and 2030 (DA#1c) as the deadlines. We assume that the legislative proposal on a decision on the phase-out date will be adopted most probably in 2024.

The three sub-options DA#1a, DA#1b and DA#1c will lead to an almost complete cessation of mercury releases associated with the placement of new fillings, which will occur by 2025, 2027 or 2030, with DA#1a and b leading to a particularly steep decline in use of dental amalgam. Once the decision is taken, a significant decrease in dental amalgam use is expected to occur, as the main actors (amalgam manufacturers and dentists) will tend to anticipate the change in policy. Also, the communication on phase-out plans will increase awareness on the environmental problems caused by dental amalgam among patients, making dental amalgam a less favoured material.

The overall assessment of impacts builds on the baseline model developed to estimate amalgam use currently and up to 2030.

The policy measures were shortlisted to address the identified problems and shortcomings and to achieve a set of objectives. The objectives are:

1. Establish the phase-out of dental amalgam in the EU whilst ensuring access to oral health care including affordable mercury-free alternatives
2. Reduce emissions from crematoria to reduce pollution to levels not considered significant to human health and the environment

Each measure has been assessed individually, covering a more in-depth description of the measure, an outline of the requirements for implementation and an assessment of their economic, environmental, and social impacts supported by evidence.

Measure DA#1: Establish a legally binding end date for the use of dental amalgam in the EU by: DA#1a (2025) DA#1b (2027) or DA#1c (2030)

Environmental impacts

When the phase-out starts to apply through DA#1a assuming that it will be announced in 2024, there will be a sudden drop to zero in 2025. In the two other two sub-options (DA#1b and DA#1c), a significant immediate decrease can be expected in mercury use compared to the baseline and then at a slower rate as shown in Figure 1 below. However, small amounts of mercury may still be used to treat specific medical conditions. For the phase-out scenario in 2027 (DA#1b) and 2030 (DA#1c), a polynomial trend is used for estimating the trends. Assuming a proportionate decline in amalgam shares in total treatments distributed over the period until the phase-out, the decline of mercury content is much steeper than the baseline. The following figure shows both the data point and the polynomial fit curves (dotted curves).

Figure 1: Phase-out of mercury based on policy measures

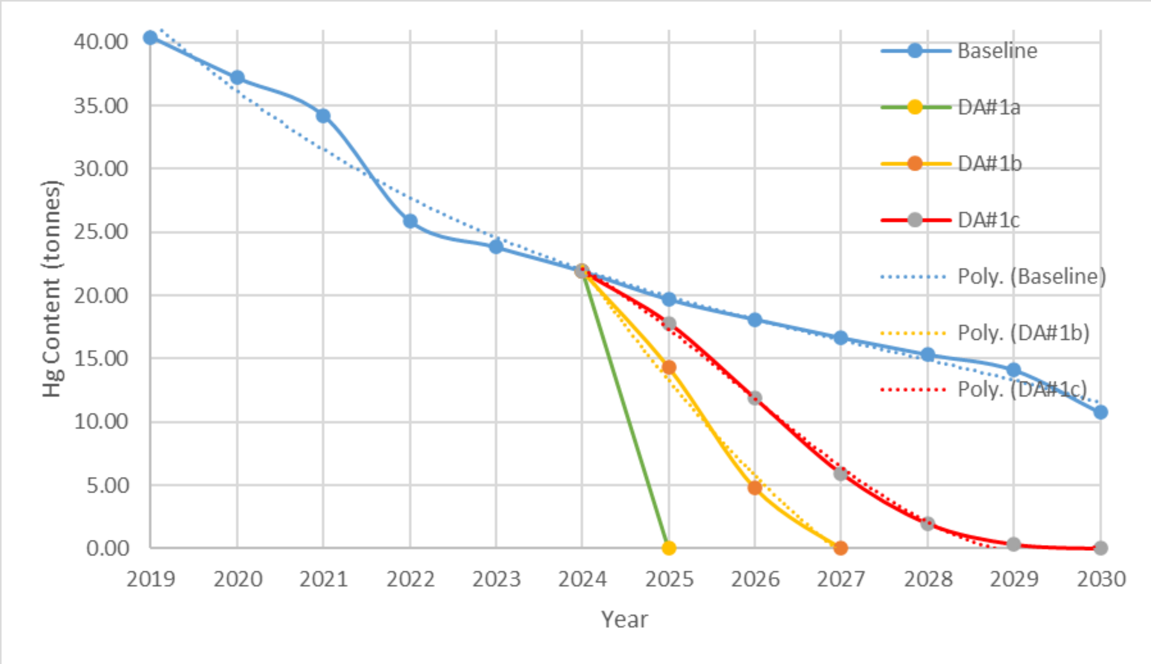


Table 1 provides estimates on the mean mercury use and Table 2 on the number of dental amalgam treatments for specific years. Dental amalgam usage is assumed to be zero from the specified phase out date although, in practice, it is expected that there may still be some low levels of usages for specific cases, exemptions etc. (if allowed for).

Table 1: Mean mercury use for specific years (includes both in teeth and wasted) (EU average, tonnes)

Policy option	2024	2025	2026	2027	2028	2029	2030
DA#1a	21.9	0	0	0	0	0	0
DA#1b	21.9	14.3	4.8	0	0	0	0
DA#1c	21.9	17.8	11.9	5.9	2.0	0.3	0

Table 2: Number of dental amalgam treatments (million) for specific years

EU Average Projected	2024	2025	2026	2027	2028	2029	2030

DA#1a	37.3	0	0	0	0	0	0
DA#1b	37.3	16.8	8.1	0	0	0	0
DA#1c	37.3	20.9	20.2	7	3.4	0.6	0

A phase-out of dental amalgam would lead to a sudden drop to zero of its use in the deadline year. Small amounts of mercury may however still be used to treat patients with specific medical conditions.

Mercury used in dental amalgam restorations is released to the air, soil and water via a number of pathways. Previous assessment indicated that approximately 1% of mercury in used and waste dental amalgam in dental practices is released to air as restorations are created[1]. Use of amalgam separators (which are required to remove 95% of amalgam particles in accordance with Article 10 of the Mercury Regulation) in dental practices results in the formation of solid waste and sludge, of which 85% is treated as hazardous waste, 10% is treated as non-hazardous waste, and 5% is treated as biomedical waste[1]. An estimated 1% of mercury in hazardous waste, 29% in non-hazardous waste, and 25% in biomedical waste is estimated to be released to air[1].

Dental amalgam use (including wasted amalgam) in 2019 and 2030 (as part of the baseline) as well as their estimated emissions are presented in Table 3 below.

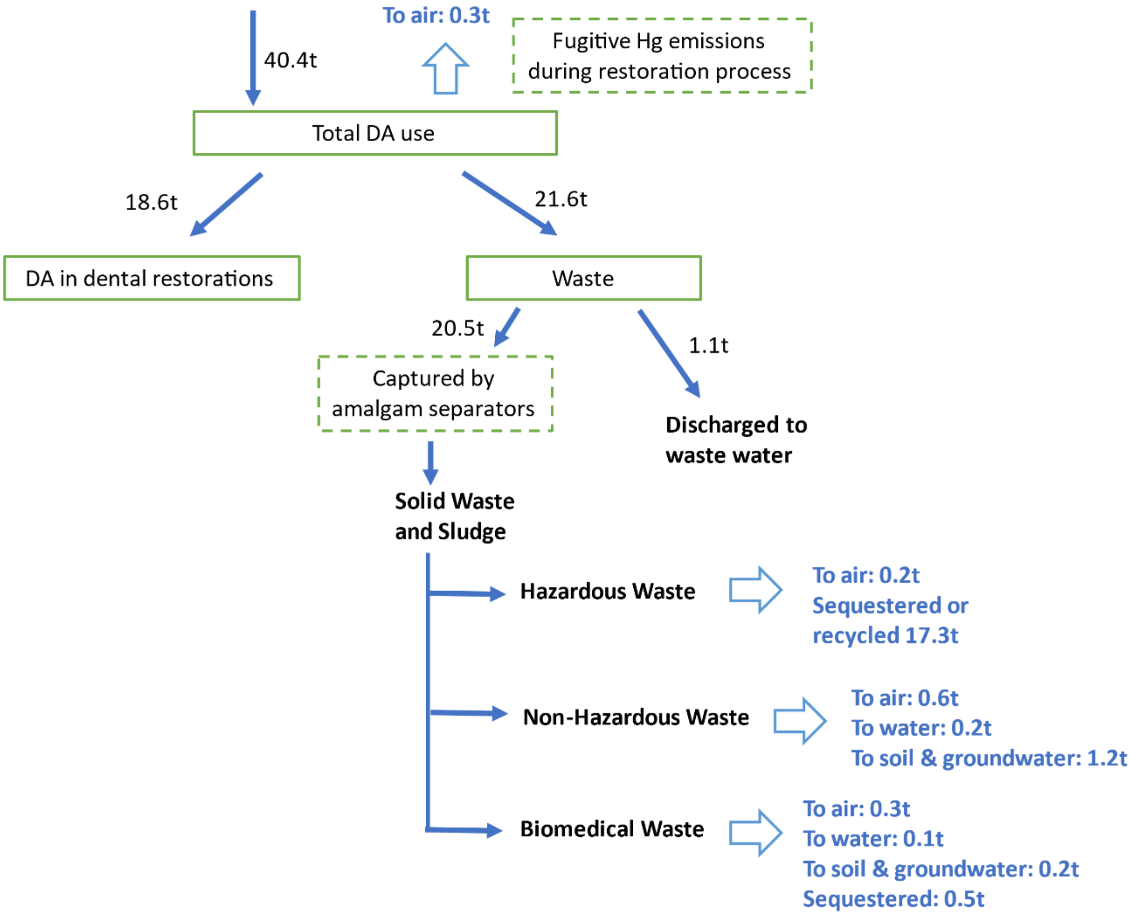
Table 3: Total dental amalgam inputs and outputs (2019 and 2030)

Fate of Dental Amalgam (DA)	**T of Hg per year (2019)**	**T of Hg per year (2030)**
Total DA Inputs		
Total DA	40.4	11.2
DA used in restorations	18.6	5.2
DA to waste	21.6	6.0
TOTAL DA OUTPUTS		
Emissions to air	1.3	0.4
Emissions to water[2]	0.3	0.1
Discharged to wastewater[3]	1.1	0.3
Emissions to soil	1.4	0.4
Sequestered or recycled	17.8	4.9

Any mercury used in dental amalgam will, in the short, medium or long-term, enter the environment via various pathways (see Figure 2).

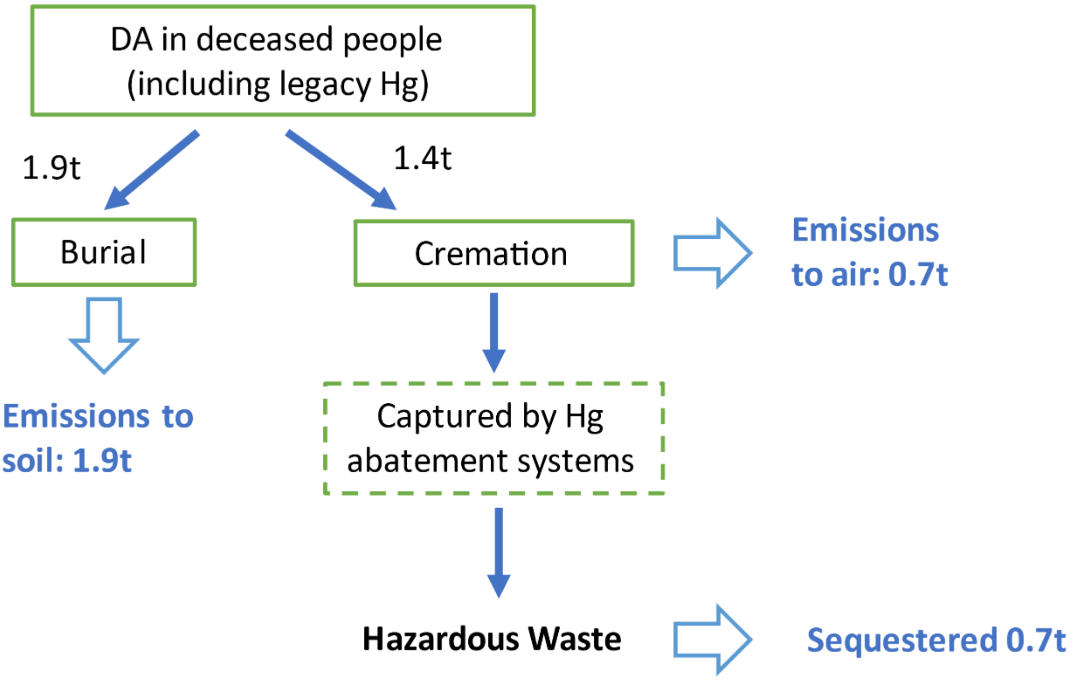
[1] Deloitte, INERIS & Wood (2020) Assessment of the feasibility of phasing-out dental amalgam. https://circabc.europa.eu/sd/a/4fd46a0f-54aa-48c6-8483-288ad3c1c281/Dental%20Amalgam%20feasbility%20study%20-%20Final%20Report.pdf
[2] Refers to discharges direct to the aquatic environment.
[3] Refers to discharges to wastewater streams, ultimately reaching wastewater treatment plants.

Figure 2: Fate of mercury and flows into the environment resulting from dental amalgam use (2019)



Additionally, the releases of mercury to the environment in 2019 as a result of dental amalgam in deceased people' mouths are displayed in Figure 3. *These emissions are displayed separately from the releases from dental use, as the former account for legacy mercury (i.e., mercury in dental amalgam restorations fitted in patients' teeth in 2019 as well as previous years), while the latter only account for releases in 2019 (i.e., mercury used in restorations fitted in patients' teeth in 2019 only).*

Figure 3: Fate of mercury and flows into the environment resulting from dental amalgam in deceased people (2019)



The three phase-out scenarios assessed within this Policy Option would reduce these environmental releases to zero as the underlying source, continued dental amalgam use, is eliminated, except in the few cases where such a use will remain justified to address specific medical conditions. However, there would be a time lag for releases to the environment via cremations and burial to drop to zero due to the legacy issue associated with dental amalgam i.e. the dental amalgam already in teeth in the general population will gradually be replaced over time.

The cumulative reductions in mercury used in dental restorations up until the year 2035 are given below for each of the three phase-out scenarios:

- **DA#1a (2025 phase-out)**: a reduction in mercury use of 114.4 t by 2035
- **DA#1b (2027 phase-out)**: a reduction in mercury use of 75.9 t by 2035
- **DA#1c (2030 phase-out)**: a reduction in mercury use of 29.8 t by 2035

Previous assessment estimated the total mass of mercury in people's mouths in the EU-27 (excluding Croatia but including the UK) at over 1,000 tonnes[4]. The total population mercury load will be declining as a result of existing actions taken by the Member States to eliminate or reduce the use of dental amalgam. The phase-out scenarios would facilitate a quicker reduction in the population mercury load, although it is not possible to reliably quantify this change in reduction.

[4] European Commission (2012). Study on the potential for reducing mercury pollution from dental amalgam and batteries: Final report. https://ec.europa.eu/environment/chemicals/mercury/pdf/mercury_dental_report.pdf

The cumulative reductions in environmental releases of mercury up until the year 2030 resulting from the phase-out scenarios, considering the mass flows set out in Figure 2, are displayed in Table 4.

Table 4: Cumulative reductions in environmental mercury releases resulting from phase-out scenarios

Fate of Dental Amalgam (DA)	T of Hg (DA#1a 2025 phase-out)	T of Hg (DA#1b 2027 phase-out)	T of Hg (DA#1c 2030 phase-out)
Emissions to air	3.1	1.3	0.4
Emissions to water[5]	0.6	0.3	0.1
Discharged to wastewater[6]	2.6	1.1	0.3
Emissions to soil	3.4	1.4	0.4
Sequestered or recycled	42.1	17.9	4.9

In addition, a phase-out of dental amalgam would result in indirect environmental benefits through reduced mercury emissions from crematoria, although the continued arrival of mercury to crematoria in 'legacy' restorations means that emissions reductions would be delayed and would not follow dental amalgam use in immediately dropping to zero. Relative to a baseline assuming no EU-level phase-out of dental amalgam, the phase-out scenarios are anticipated to have the following impacts in terms of mercury emissions to air from crematoria in 2030 (relative to baseline emissions of 355 kg). The below figures represent a snapshot of changes in emissions in 2030, and not cumulative emissions savings over a set period of time. They take account of emissions from 'legacy' amalgam in old dental restorations, hence continued crematoria emissions even after the phase-out of dental amalgam. The figures highlight that an earlier dental amalgam phase-out would deliver much greater crematoria emissions reductions sooner (both in 2030 and cumulatively from the date of a ban).

- **2025 phase-out**: a reduction in mercury emissions of 54 kg in 2030
- **2027 phase-out**: a reduction in mercury emissions of 31 kg in 2030
- **2030 phase-out**: a reduction in mercury emissions of 3 kg in 2030

Even if the use of mercury is reduced or phased out entirely under these scenarios, its release into the environment will continue as a result of old amalgam fillings through crematoria as well as through corrosion of fillings, not properly working amalgam separators, disposal of amalgam in general waste and subsequent disposal/ incineration. Aside from emissions from crematoria, emissions will arise from the removal of old dental amalgam restorations at the end of their service life, and their disposal. Sources indicate that the typical lifespan of a dental amalgam restoration is approximately 15 years[7], indicating that environmental impacts will persist for some time after a phase-out.

[5] Refers to discharges direct to the aquatic environment.

[6] Refers to discharges to wastewater streams, ultimately reaching wastewater treatment plants.

[7] Kirsch et al., (2016). Decision criteria for replacement of fillings: a retrospective study. https://onlinelibrary.wiley.com/doi/10.1002/cre2.30

This will result in releases to air, soil and water via the same pathways as discussed above, but it is not possible to reliably quantify these emissions. Even after a complete phase-out, some mercury could still continue reaching crematoria, e.g.:

- Some fillings exceed the average lifetime. A filling obtained in adolescence may remain in the mouth until the person dies of natural causes.)
- Expatriated EU citizens and immigrants to the EU who could have amalgam fillings done in a country outside the EU., and because of
- Specific cremation practices, e.g., in Italy where the cremation can take place several years after the burial.

Social impacts

It is expected that new jobs will be created to train the dentists who did not receive training for using alternatives or haven't practiced it much, some of which will need to improve their skills or acquire new skills in mercury-free restoration techniques within a short timeframe. New jobs would also be expected to support R&D activities in the dental fillings industry due to the need for companies to maintain a high level of innovation in mercury-free materials.

A phase-out of dental amalgam is expected to have both direct and indirect health benefits for EU society. Benefits will be observed for the general population as mercury exposure reduction will lead to lower mercury levels in the blood, and reduction of associated health risks, which could range from neurological and cardiovascular to the immune system. In particular, the greatest direct benefits will be for dental practitioners as they are directly exposed to mercury vapours and the mercury body burden of dental personnel is usually higher than in the general population[8]. These benefits are expected to be higher under DA#1b as the exposure will cease sooner. The reduction of releases to water (e.g., via deposition from the atmosphere and emissions from crematoria) is likely to reduce mercury content in the marine food chain and, ultimately in fish, which is directly linked to human exposure to mercury.

Regarding potentially avoided indirect health damages, the phase-out would result in reduced emissions from crematoria. The crematoria workers may still be exposed to mercury vapours from the effluents and solid mercury-containing waste if no adequate protection measures are in place, but this exposure should strongly decrease 10-15 years after the phase-out the fully effective. However, some emissions could still occur through corrosion of fillings, not properly working amalgam separators, disposal of amalgam in general waste and subsequent disposal/ incineration.

It would also reduce the exposure of the personnel working in hazardous waste management (from amalgam separators). However, this benefit would be rather in the long term as the removal of existing teeth with amalgam still need to be collected and treated as well as in the case of patients with special health needs where dental amalgam would still be used. These benefits are expected to be higher under DA#1a as the exposure will cease sooner. The reduction of releases to water (e.g., via deposition from

8 SCENIHR (2015) Opinion on the safety of dental amalgam and alternative dental restoration materials for patients and users

the atmosphere and emissions from crematoria) is likely to reduce mercury content in the marine food chain and, ultimately in fish, which is directly linked to human exposure to mercury.

The reductions in mercury emissions from crematoria in 2030 outlined in the previous section are estimated to result in the following human health benefits, valued using EEA damage cost functions:

- **DA#1a**: human health benefits valued at €900,000
- **DA#1b**: human health benefits valued at €500,000
- **DA#1c**: human health benefits valued at €50,000

Another benefit of substituting amalgam with mercury-free filling materials such as resin-based composites or glass ionomers is the ability to preserve a healthier tooth structure in patients, as these alternative materials have good adhesive properties and do not require to enlarge the cavity because amalgam needs to be mechanically linked to the remaining tooth structure. It must be noted that amalgam alternatives potentially can also have health impacts, for example, allergic reactions and possible health impacts due to the release of small quantities of endocrine-disrupting substances. This is the case for the risk of release of bisphenol A, a recognized endocrine disruptor and classified as a category 2 carcinogen, mutagen, reprotoxic (CMR) for reproduction, i.e., "likely to harm fertility or the foetus", potentially observed after the application of composites, some of which are made from monomers derived from this compound, or the use of biomaterials containing nanomaterials. The latter requires further scientific evidence regarding their safety.[9] Furthermore, it should be noted that medical device manufacturers are still not required to inform users about dental biomaterials and their full chemical composition. It is, therefore, impossible to be sure of their biocompatibility. However, alternatives to Bis-GMA, Bis-EMA and Bis-DMA-based resins exist, such as Urethane DiMethAcrylate (UDMA) based resins[10] and, more recently, alternative resins based on siloranes[11] in place of methacrylates[12].

Economic impacts

The main economic impacts of the phase-out of dental amalgam will be the direct and indirect impacts on economic actors, citizens and public authorities. The magnitude between DA#1, DA#1b and DA#1c will differ, but the rationale is similar. The main actors impacted by it are citizens, amalgam producers, manufacturers of alternatives, dental clinics, and crematoria.

Impacts on citizens

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[9] CENIHR. The safety of the use of bisphenol A in medical devices. 2015 and Van Landuyt KL et al. Nanoparticle release from dental composites. Acta Biomater 2014

[10] https://substitution.ineris.fr/sites/substitution-portail/files/newsletter/newslettersna_10_1216_v2b_gb_0.pdf

[11] Siloranes are a combination of siloxane and oxiranes. The silorane composites generate lower volume shrinkage and stress upon polymerization.

[12] SCENIHR, 2015. Scientific opinion on the Safety of Dental Amalgam and Alternative Dental Restoration Materials for Patients and Users.(https://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_046.pdf)

Currently, the use of dental amalgam affects EU citizens mainly through their tax contributions to the costs of managing mercury-contaminated urban wastewater and municipal waste (usually included in local taxes). If the installation of separators has not already led to sufficiently low levels of mercury in sewage sludge, an amalgam phase-out would ultimately (in the long-term) result in an even lower input of mercury into the wastewater system. Overall, this will have a positive economic impact on municipalities and taxpayers, as it will reduce the environmental costs associated with managing mercury pollution from dental amalgam.

The main economic aspect for dental patients is the cost of dental restorations using alternatives. In scenario DA#1a, the change will be abrupt and the cost impact will be high in the short run. In scenarios DA#1b and DA#1c, the expected gradual change in dental filling materials will affect the costs incurred by dentists for performing the restorations, and it can be assumed that any changes in such costs will be fully passed on to dental patients. Dental restoration costs borne by the patients depend on four main factors: cost of the filling material, labour cost for the treatment, reimbursement by the social security and/or private medical insurance, and the longevity of restorations.

Under DA#1a and b, the substitution of dental amalgam with mercury-free restorations will be faster than under DA#1c. Given the currently higher labour cost of composite or glass ionomer restorations (the material costs are negligible), the phase-out will lead to additional costs for dental patients (and/or private health insurance, social security systems) compared to the baseline. However, this effect is expected to be partly offset by a decrease in the cost of restorations using alternatives in the mid-term and longer average lifetime of fillings as we have seen in Sweden. Increased competition within the dental fillings industry and technological improvements will likely lead to decreases in material costs (though negligible). Improved dentists' skills will lead to further, reduced average durations for carrying out mercury-free restorations due to and subsequently to a decrease in the labour costs of dental treatment.

The use of mercury-free alternatives is expected to increase overall costs for treatment in most countries because of the cost of filling material (negligible), the labour cost for the treatment using amalgam alternatives, and the longevity of restorations. The overall cost estimates are very sensitive to the cost differential between the treatment cost using dental amalgam and alternatives. The amount of this cost differential varies considerably, and this information is not available for all Member States. Dental restoration costs borne by the patients depend on four main factors, i.e. (i) the cost of the filling material (negligible difference between dental amalgam and alternatives), (ii) reimbursement by the social security and/or private medical insurance, (iii) the longevity of restorations and (iv) labour cost for the treatment. The difference in cost of restorations can vary across the EU (see Table 5 although the data is from 2018 and cost differentials are expected to have further narrowed as more Member States phase out dental amalgam use and experience with use of alternatives increases).

Table 5: Price difference between dental amalgam and its alternatives per Member State

Country	Price per restoration (dental amalgam) (EUR)	Price per restoration (alternatives) (EUR)	Price difference (EUR)
AT	97.5	97.5	0
BE	52.5	52.5	0
BG	13.0	13.1	0.1

Country	Price per restoration (dental amalgam) (EUR)	Price per restoration (alternatives) (EUR)	Price difference (EUR)
CY	60.0	60.0	0
CZ	19.2	19.3	0.1
DE	48.2	75.0	26.8
DK	54.2	60.6	6.4
EE	28.3	28.5	0.2
ES	46.1	46.1	0
FI	50.0	50.0	0
FR	40.0	40.0	0
EL	50	60	10
HR	23.0	23.2	0.2
HU	20.4	20.6	0.2
IE	50.0	51.5	1.5
IT	125.0	175.0	50
LT	19.9	20.0	0.1
LU	58.0	71.0	13
LV	15.0	25.0	10
MT	70.0	70.0	0
NL	45.0	67.3	22.3
PL	19.0	19.1	0.1
PT	33.7	33.7	0
RO	13.9	14.0	0.1
SE	N/A	105.0	N/A
SI	26.0	48.5	22.5
SK	22.7	22.9	0.2
UK	42.7	45.8	3.1
EU 28	40.8	50.5	9.7

In Denmark, amalgam use in dental fillings decreased 92% in 10 years; from 22% in 2007 to 1.7% in 2017, showing a long-term experience with the phase-out and a cost difference of about 6 euros per filling. This figure is therefore considered most representative of the cost differential if a full EU phase-out were to be applied. Based on this differential, the additional annual costs of using alternatives in the first year of the phase out of dental amalgam (i.e., 2025, 2027 or 2030) are estimated as follows.

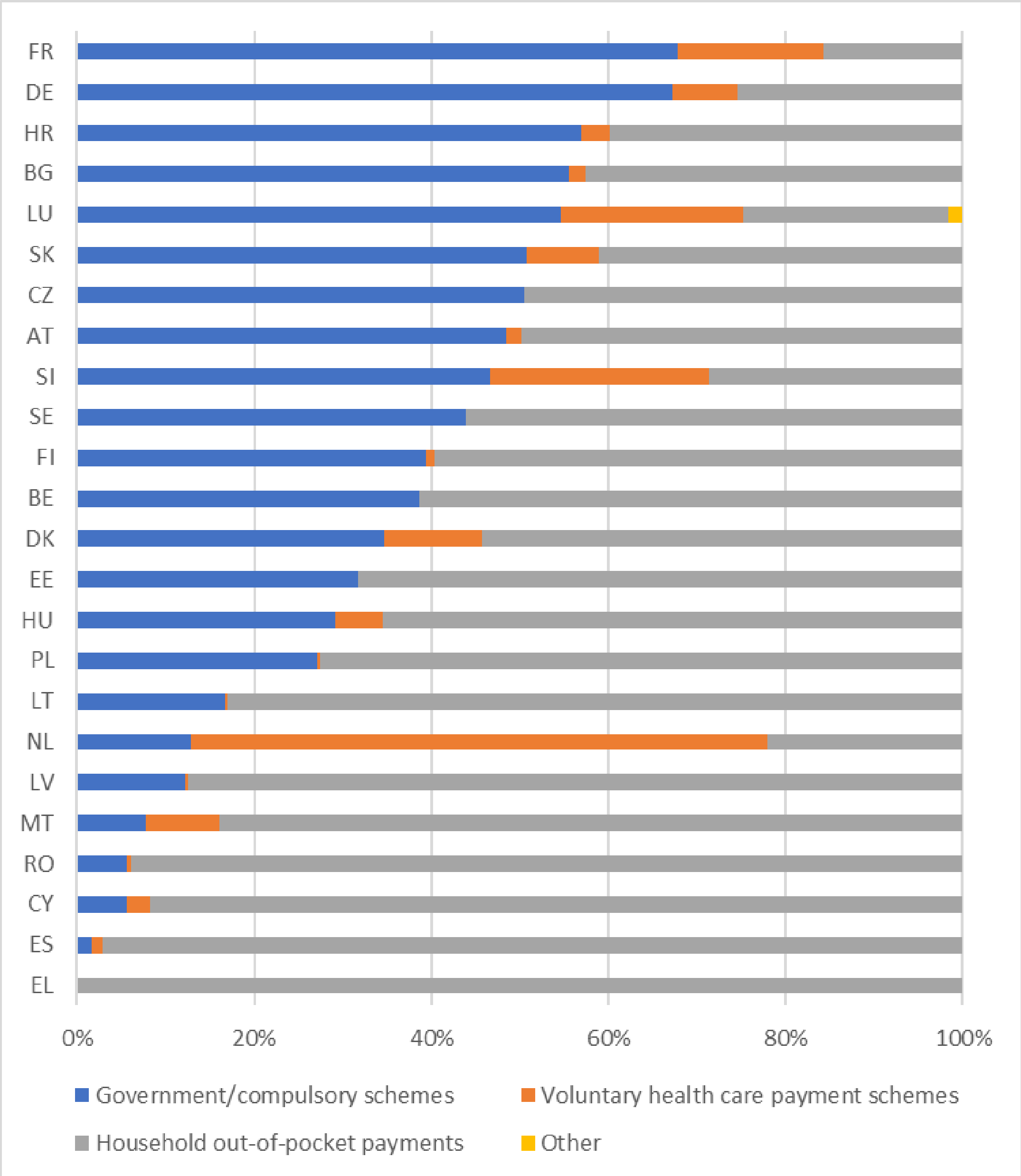
Table 6: Range of additional cost estimates for 2025, 2027 and 2030 (in million euros)

	2025 additional costs	2027 additional costs	2030 additional costs
Austria	€9.1m	€6.8m	€5.9m
Belgium	€2.9m	€2.2m	€1.5m
Bulgaria	€2.3m	€2m	€1.5m
Croatia	€0	€0	€0
Cyprus	€0	€0	€0
Czechia	€18m	€13.9m	€1m
Denmark	€0.4m	€0.3m	€0.3m
Estonia	€0m	€0	€0
Finland	€0m	€0	€0
France	€116.9m	€98.3m	€80.3m

	2025 additional costs	2027 additional costs	2030 additional costs
Germany	€23.6m	€18m	€14.9m
Greece	€1.1m	€1m	€0.7m
Hungary	€3.1m	€2.5m	€0.8m
Ireland	€6.7m	€5.2m	€0
Italy	€0m	€0m	€0
Latvia	€1.1m	€0.9m	€0.8m
Lithuania	€0.6m	€0.6m	€0.5m
Luxembourg	€0.1m	€0	€0
Malta	€0m	€0	€0
Netherlands	€0.3m	€0.2m	€0.2m
Poland	€0	€0	€0
Portugal	€4.5m	€4.5m	€2.7m
Romania	€2.9m	€2.4m	€1.5m
Slovakia	€1.9m	€1.5m	€1.5m
Slovenia	€11.2m	€8.7m	€0m
Spain	€1m	€1m	€0m
Sweden	€0	€0	€0m
EU total	**€208m**	**€170m**	**€114m**

Considering the difference in the use of dental amalgam across the EU, the distribution of these costs will affect Member States differently. The share of the dental filling cost covered by social security and the premium charged by the private medical insurance will also impact the magnitude of direct economic impacts on citizens. However, the share of these additional costs that will be borne by the patients depends on reimbursement by the social security and/or private medical insurance. Figure 4 provides an overview of the existing financing structures in the dental sectors of a number of Member States. FR and DE have the greatest share of public expenditure in their total dental expenditure (>60%), followed by HR, BG, LU and SK. Dental care expenditure in EL, ES and CY is dominated by private financing, while voluntary health insurance schemes make up the majority (>60%) of expenditure in the NL.

Figure 4: Government, voluntary and out-of-pocket spending for dental care as % of total dental outpatient curative care expenditure



Data from the OECD Health Statistics 2022 database. Data for 2020, except for Denmark and the Netherlands (2021 data), and Malta (2019 data). No data for Portugal, Italy or Ireland.

In the case of DA#1a and b, the prices of mercury-free restorations can be expected to decrease at a faster pace because of the time constraint (especially where dentists have been using mostly amalgam) and the economy of scale due to improved skills in mercury-free restorations and innovation. However, it can be assumed that private medical insurance companies will adapt better in the case of DA#1c (and possibly DA#1b) as the insurers will have more time to analyse the medical history of patients and their dental treatments and thus define the insurance premiums adapted to real-life situations. The direct impact on citizens will vary significantly across Member States because of different social security schemes and private health insurance.

The short-term economic impact of the phase-out on patients will depend on the proportion of the costs reimbursed by national health insurance schemes. Dental patients would therefore bear additional treatment costs, except in a few Member States where a higher amount is reimbursed for mercury-free restorations (compared with amalgam restorations). Also, private medical insurance may increase the premium to cover the increased cost.

The projected increase in dental restoration costs for patients is expected to affect the private health insurance industry positively, as it will increase the demand for insurance services covering dental treatment.

The possible deterioration of dental health in disadvantaged communities due to higher treatment costs if more expensive restoration techniques are used has been raised as an important issue by the Council of European Dentists (CED). The CED reports that, while dental decay rates are falling in developed countries, approximately 80% of oral diseases can be found in 20% of the population, usually disadvantaged communities[13]. However, the Swedish experience with the phase-out of dental amalgam shows that no adverse clinical effects have been observed in the Swedish population following the adoption of the ban. In fact, the possible adverse public health effects due to reduced affordability of dental treatment depend very much on the public health policy of the Member State, i.e., whether there are effective dental decay prevention programmes in place and whether dental care is subsidised for the most vulnerable and disadvantaged categories of the population.

It is also important that possible adverse health effects due to reduced affordability of dental treatment for disadvantaged citizens, and public spending to ensure affordability of dental care, are put in perspective with the currently high environmental and indirect health impacts and costs of mercury pollution caused by dental amalgam use, and the benefits associated with a reduction of these impacts for the society at large.

Impacts on dental filling industry

The phase-out measures will put significant pressure on dental fillings manufacturers with a high share of dental amalgam in their overall production. On the other hand, companies with a high share of mercury-free materials in their production will gain an even more significant competitive advantage.

Overall, since the present study identified only four main EU companies producing encapsuled dental amalgam, the economic impact on the dental industry is expected to remain limited. According to the observed global trends, demand for dental amalgam and exports from the EU are likely to decrease. An EU export ban from the EU would accelerate this process. All four identified manufacturers that have not yet announced an exit from the market belong to SMEs. According to publicly available information, the total turnover of all companies is around €40 million, and the number of employees is around 200. Only part of these sums is attributable to the manufacture and sale of dental amalgam. Two of these companies specialize to a large extent in dental amalgam. They also offer other dental products but no other filling materials (Global Dental Trade, World Work Srl). Depending on the relevance of the amalgam business, a phase-out would result in a significant reduction in sales and employment.

[13] Source: targeted consultation (interview with the dentists)

However, if a company already produces alternatives or can easily switch its production, it can compensate for the negative impact.

The use of mercury-free alternatives has been growing in recent years; this trend is expected to continue. In the baseline, it is estimated that both policy options will increase revenues from the manufacturing of dental filling materials. The cumulative revenues of the dental filling manufacturing industry per scenario by 2025, 2027 and 2030 are presented in the table below.

Table 7: Cumulative revenues of the dental filling manufacturing industry by 2025, 2027 and 2030 (million euros)[14]

Option	Cumulative revenues since 2018		
	2025	**2027**	**2030**
Baseline	10,811 - 11,189	15,564 - 16,039	18,755 - 19,284
DA#1a	10,927 -11,243	15,863 - 16,179	19,154 - 19,470
DA#1b	10,877 - 11,220	15,788 - 16,144	19,079 - 19,435
DA#1c	10,856 - 11,210	15,726 - 16,115	19,011 - 19,403

This increase results from the gradual substitution of dental amalgam with mercury-free materials and is based on the changes in the share of dental amalgam and mercury-free restorations. This estimate assumes that the total number of restorations will remain the same regardless of the selection of the restoration material. Therefore, it is assumed that the longevity between the different types of materials is not different. However, the evidence of differences in the performance of dental amalgam and mercury-free restorations is inconclusive. Even if the performance of mercury-free materials is gradually improving due to the enhanced skills of dentists, this assumption has a considerable level of uncertainty. In addition, the use of dental amalgam will also drop significantly under the BAU, and this trend will accelerate due to the implementation of the Member State NAPs. Under these assumptions, the revenue will not change substantially between the BAU and the assessed policy options.

Impacts on dentists

In the EU27, in 2020 there were approximately 75 dentists for every 100,000 inhabitants on average, however the range varies from about 35 in Poland to 125 in Greece. Costs incurred by dentists because of dental amalgam use mainly include costs for the maintenance of amalgam separators and the collection and treatment of amalgam waste as hazardous waste, assuming all dentists have the separators installed by now. In all three sub-options, the costs related to the maintenance of amalgam separators and the collection and treatment of amalgam waste as hazardous waste will not disappear until the last amalgam filling has been removed; it may take 80 years or so. Also, this cost is included in the fees and therefore they are passed to the patients or to the health insurance.

[14] Source: Deloitte (2020) study

On the one hand, in DA#1a, the shorter time to achieve a complete phase-out of dental amalgam may put more pressure on dentists with limited experience in carrying out mercury-free restorations. On the other hand, in the short term, this may generate a competitive advantage for dentists already fully skilled in mercury-free restoration techniques.

For dentists, the economic impact can be positive or negative depending on their skills in handling various filling materials. In the beginning, it will be negative but may become positive because of increased revenues (the handling and application of alternatives usually is more expensive).

The cumulative revenues of dentists based on the number of restorations are presented in the table below.

Table 8: Revenues of the dentists by 2025, 2027 and 2030 (million euros)[15]

Option	Cumulative revenues since 2019		
	2025	**2027**	**2030**
Baseline	180,808 - 181,148	226,159 - 226,549	271,538 - 271,971
DA#1a	181,025 -181,287	226,508 - 226,771	271,992 - 272,254
DA#1b	180,926 - 181,219	226,401 - 226,696	271,884 - 272,179
DA#1c	180,874 - 181,182	226,310 - 226,632	271,786 - 272,110

This increase results from the gradual substitution of dental amalgam with mercury-free materials and is based on the changes in the share of dental amalgam and mercury-free restorations. This estimate assumes that the total number of restorations will remain the same regardless of the selection of the restoration material. Therefore, it is assumed that the longevity of the different types of materials is not different.

As highlighted by the Deloitte (2020) study, a phase-out of dental amalgam is also expected to affect costs that are borne by dentists for the collection and treatment of waste from amalgam separators. This cost will vary across Member States and within countries. For example, in Czechia, the cost per kg of sludge from amalgam separators is estimated at €15 and in DE at €60. According to an expert opinion, in Germany, the collection from some contractors is free of charge as the costs are covered by the revenues of the waste treatment facilities from the recovery of valuable metals from the alloys. This may change because without dental amalgam production there remain few legal uses of mercury within the EU. The amounts of waste from historical use will remain high within the assessed timeframe (i.e., up to 2027 or 2030, depending on the phase-out scenario). In addition, as per Article 10(2) of the Mercury Regulation, the effectiveness and monitoring of the performance of the dental amalgam separators and the collection and treatment of the collected waste will improve. However, these costs will not disappear until the last amalgam filling has been removed. Maintenance cycles of separators do not depend on the amount of waste collected and would remain constant as well.

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[15] Source: Deloitte (2020) study

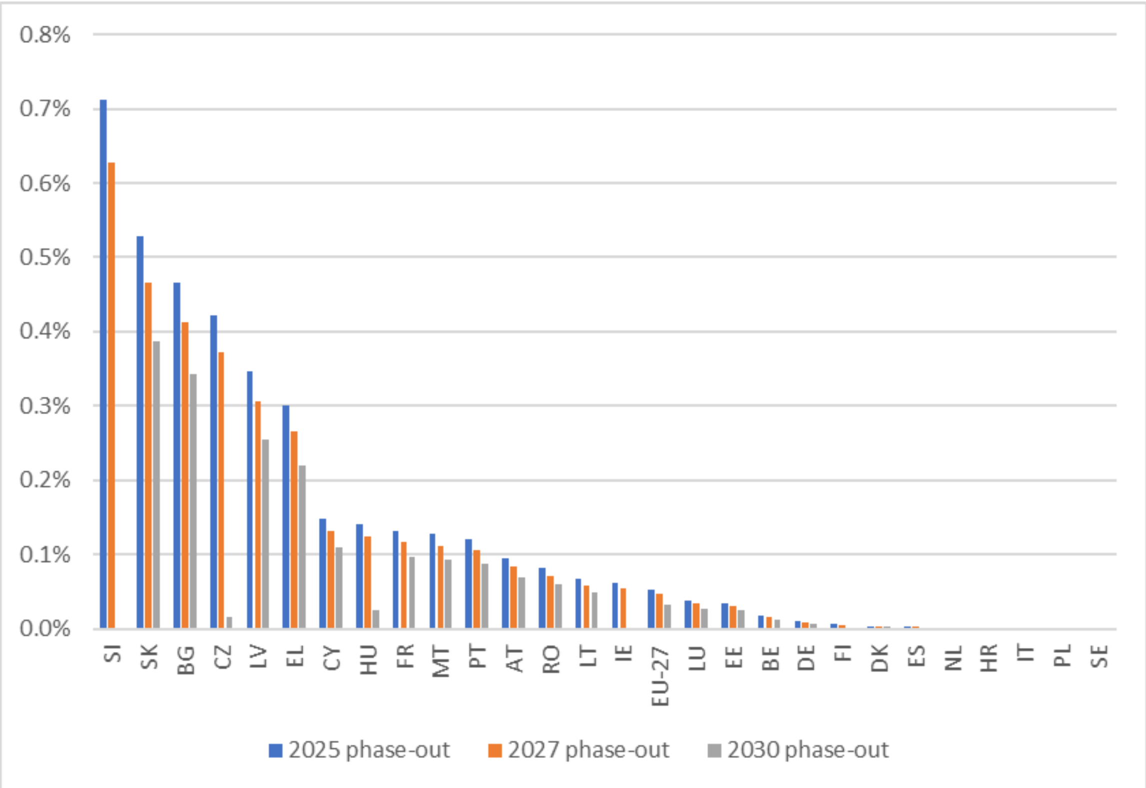
Impacts on public authorities

According to Article 14 of the Mercury Regulation, Member State Authorities report on the implementation of the Regulation, including the progress of implementation of their National Action Plans concerning the phase down of dental amalgam. The monitoring and reporting of the phase-out and the implementation and monitoring of the requirements on the efficiency and maintenance of amalgam separators will continue longer in the case of DA#1c; thus, DA#1a and b represents a lower administrative burden on the Member States.

If Member States impose financial penalties as a tool to enforce compliance, some revenues might be generated through the collection of fines, which may offset labour costs for any enforcement they may choose to take.

As discussed earlier, the impacts on citizens, social security systems (public budgets) and private healthcare providers will depend on the level of reimbursement by social security and/or private medical insurance (Figure 4). However, overall the economic impact of a phase-out of the use of dental amalgam is expected to be minimal compared to Member States national healthcare budgets. Figure 5 illustrates that the greatest burden of a dental amalgam phase-out on the national healthcare budget may be incurred by SI, SK, BU, and the CZ (between 0.4% and 0.7% of their national healthcare budgets). This is based on the assumption that all costs associated with a shift towards mercury-free alternatives are covered by national insurance schemes. However, it is likely that this will not be the case for all Member States where costs may be shared over national or private insurance schemes or transferred to patients.

Figure 5: Cost to Member States associated with dental amalgam phase-out (2025, 2027 and 2030), expressed as a % of national healthcare budgets



Impacts on crematoria

All the measures will lead to a gradual reduction in mercury emissions from crematoria with DA#1a starting this decline sooner than the others. However, given the lifetime of dental amalgam restorations and the existence of specific cremation practices in certain Member States, this positive effect will only be observed in the long term. In the mid-term, the phase-out is not expected to significantly reduce mercury abatement costs incurred by crematoria. In the long-term, the dental amalgam phase-out will ultimately have a positive economic effect by avoiding the need for installing mercury abatement devices in new EU crematoria or operating the systems already in place (only small quantities of dental amalgam would still be used within the EU). However, these benefits will materialise following a delay due to the lag in dental restorations reaching crematoria. Where measures are adopted to increase uptake of emissions abatement at crematoria, these benefits would be reduced due to the costs of implementing abatement.

Impacts on waste management companies

In the case of a phase-out dental amalgam use will drastically decrease, but this will not change the volume of sludge captured in amalgam separators, and there is no efficient way to separate dental amalgam particles from mercury-free filling particles captured by the separator. In the long term, it can be expected that there will be reduced revenues for companies that manufacture, install and maintain amalgam separators as well as for companies that collect and treat dental mercury-containing waste. Some companies offer several or all these services to dentists. However, in the short term (a few decades after the phase-out), there will still be a need for amalgam separators and treatment of the collected hazardous waste.

The cost arising from recycling services related to amalgam separators include the collection of amalgam waste from dental offices and the provision of related supplies, such as packaging, labels, etc. At the EU level, according to the stakeholders consulted during the 2012 study, there is a significant variation in the costs incurred by dentists for the management of amalgam sludge: reported costs range from €100 to €600 per year, with an average cost of approximately €310 per year per dentist. With the reduction of dental amalgam, these costs will be reduced.

For wastewater treatment plant (WWTP) operators, the consequence of mercury levels in sewage sludge above allowed thresholds is the impossibility of discarding the sludge as fertilizer for agricultural use. Instead, mercury-contaminated sludge needs to be incinerated at a high cost. Thus, reducing mercury release is a positive economic impact for these operators from a sludge utilisation point of view. However, the installation of separators should already have reduced mercury input into the sewage system if the separators are correctly operated. A certain amount of mercury is expected to evade control measures and still enter the sewage system. Moreover, historic mercury-containing sediments in sewage pipes may still contaminate ‘fresh’ sewage so mercury levels remain too high.

Impacts on competitiveness and innovation

The positive effect of the phase-out on innovation within the EU dental industry is expected to be greater for DA#1a and b than under DA#1c, given the limited time scale to fully substitute dental amalgam, although impacts for innovation are expected to be minimal. The use of mercury-free alternatives has been growing in recent years, and this trend is expected to continue. In turn, projected demand for mercury-free materials is expected to boost further investments in research and development (R&D) and innovation.

The phase-out would accelerate the shift from the use of dental amalgam in dentistry towards mercury-free alternatives, stimulating research and innovation for improving technical characteristics and increasing the competitiveness of the dental filling industry. The acceleration will be highest for DA#1arelative to DA#1b and DA#1c as it would be conducted in a shorter time span. Such innovations are likely to improve the performance of alternatives (e.g., longevity, negative impacts such as allergies) and decrease production, handling and application costs, thereby making them more affordable.

Most dentists in the dental care sector are micro-enterprises, while all remaining dental amalgam manufacturers in the EU are SMEs. Other companies linked to amalgam use are manufacturers of supplies, tools and amalgam separators as well as companies specialised in amalgam waste disposal.

The impacts on those producing amalgam will indeed be negative (reduced demand) and those manufacturing alternatives positive (increased demand), while for other actors, it will vary, e.g., initially positive for those dealing with mercury-containing waste and then it will decrease gradually as the waste quantities will decrease.

Other impacts

Because mercury pollution is a global issue, it is important to note that the phase-out's environmental, public health, and safety benefits are likely to extend outside the EU territory.

Furthermore, it may trigger the adoption of a similar phase-out in some non-EU countries, especially given the context of recent discussions as part of the Minamata Convention and the fact that dental amalgam is among the main mercury uses worldwide.

Measure DA#2: Communication campaign to raise awareness and change behaviour of dental patients (and practitioners) towards mercury-free dental filling alternatives

This option may contain several campaigns to improve the knowledge and understanding of patients and health practitioners such as:

- a patient awareness campaign on the current knowledge of the risks associated with amalgam and the indications for the removal of old amalgam
- a campaign to evaluate current professional practices in relation to monitoring of urinary mercury in health professionals
- the publication of a standard protocol for removal issued by a learned society, specifying, among other things, whether a chelating agent should be prescribed to the patient prior to removal, its nature and the dosage indicated, and the information that only the HgP3 mask is likely to protect against mercury vapours
- the continuation of initial training for future practitioners on the risks associated with removal and waste management beyond 2030

Some European countries have adopted a policy focused on access to oral health, with a strong emphasis on prevention. These policies were adopted several years ago, particularly in Germany, and are now bearing fruit[16]. However, new campaigns cannot improve the dental health status of people who already have treated cavities. In Germany, for example, the number of cavities per children (12 years) decreased by 90% between 1989/1992 and 2014. At the same time (1991 2016), the number of dental restorations decreased only by half[17] . Therefore, while measures to improve prevention are effective to avoid new cavities, a strong impact on the total number of restorations per year can only be expected after several decades.

Assessment of social and economic impacts

The impact of health improvement campaigns cannot be measured in absolute magnitude but on the degree of their effectiveness. For such campaigns, studies have highlighted various aspects of socio-economic inequality which will impact their effectiveness, such as:

- Coverage of state social security versus private medical insurance across Member States
- Dependence on public versus private insurance for dental care
- Income disparities among patients
- Density of dental personnel available for citizens more likely to improve than the median household

The impact of the measures taken by Member States under this measure is expected to be positive with regard to employment. Jobs may first be created for organising awareness-raising activities, although these jobs may use the existing personnel or temporary ones created only for a short period. Jobs may also be created to train dentists in mercury-free restoration techniques. Finally, as this option is expected to foster innovation in mercury-free filling materials, it may also generate new employment opportunities in R&D activities of the dental industry.

Assessment of environmental and health impacts

The actual impacts of this measure are difficult to quantify because of the non-mandatory nature of this option. Member States would be free to choose which measure or combination of measures they would implement to promote a reduction in dental amalgam use, with no binding target to achieve.

However, for the present assessment, it can be assumed that this policy option would achieve a slightly better result than the baseline but nowhere near as good as DA#1 (phase-out).

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[16] Association de la santé publique bucco-dentaire (ASPBD). La santé bucco-dentaire, un enjeu de santé publique. Mis en ligne 14/06/2019. //aspbd.fr/la-sante-bucco-dentaire-un-enjeu-de-sante-publique/
Association dentaire Française. Démarche écoresponsable au cabinet dentaire. Grille d'aide à la mise en œuvre : enjeux, outils et pistes de réflexion. Dossier ADF 2021.

[17] Hagemann, S. (2021): Entwicklung von Kriterien zur Beurteilung der Wirksamkeit der Minamata-Konvention zu Quecksilber (UBA-Texte, 110/2021)

Measure DA#3: Raise prices of dental amalgam reflecting risks due to mercury exposure

Improvements in social security coverage are broadly expected to accelerate the reduction of mercury content, as shown in the previous consultations[18]; patients tend to prefer mercury-free alternatives and are likely to benefit from improved reimbursement shares or higher amalgam prices (which should discourage demand). Making quantitative estimates of the impacts of this measure is difficult because of the lack of data on the price difference between amalgam and alternatives across the Member States and different systems of reimbursement by the state social security and private medical insurance.

The elasticity measures for mercury-free options and better reimbursement shares in this measure shall improve consumer welfare and access to sustainable and safe dental care. The other side of the argument stands in understanding the increase in public costs for reimbursement, whose financing shall need further scrutiny. There is also a need to analyse the dependence of complementary private medical insurance versus state-sponsored insurance schemes. A further incentive to improve the impacts of this measure would be to promote better dental coverage within the market of private insurers.

As the social security schemes vary significantly across Member States and the EU cannot directly influence the fiscal and social taxation systems, the EU's role in decreasing the price difference between dental amalgam and mercury-free alternatives would be rather limited. However, the EU could encourage knowledge sharing and inform Member States of good practices and approaches. Recently, France has adopted a new programme, "100% Santé", which helps patients to get treatments with 100% cost reimbursed (through social security and complementary private insurance) even when getting the dental treatment using alternatives; see the infographic below.

[18] https://ec.europa.eu/eusurvey/publication/MinamataConvention


100% SANTÉ
UN ACCES À DES SOINS DE QUALITÉ POUR TOUS
Un large choix de prothèses dentaires esthétiques et de qualité
Une gamme étendue de prothèses adaptées à la localisation de la dent
Inlays core et couronnes transitoires
Bridges métalliques et céramo-métalliques
Plusieurs options de couronnes céramiques, céramo-métalliques...
Au 1er janvier 2021, prothèses amovibles (dentiers)
À partir du 1er janvier 2021 remboursement intégral de l'offre 100% Santé(1)
(1) Valable uniquement sur les prestations de soins et d'équipements 100% Santé, 100% pris en charge après remboursement par l'Assurance maladie et les complémentaires santé.
En pratique
Patrick, 33 ans, a besoin de se faire poser une couronne en céramique.
Avant la réforme
Patrick paie sa couronne en céramique.................... 550 €
La Sécurité sociale et sa complémentaire lui remboursent.. 355 €(2)
Il reste à sa charge... 195 €
Après la réforme, à partir du 1er janvier 2021
Si Patrick choisit une couronne dans le panier 100% Santé
Il paiera sa couronne en céramique .... 500 €
La Sécurité sociale et sa complémentaire lui remboursent.. 500 €
Il restera à sa charge...0 €
(2) Montants basés sur les remboursements moyens constatés de 355 € sur une couronne en céramique monolithique (Assurance Maladie : 75 € et complémentaire santé : 280 €).

Similarly, there are specific measures in France for those with limited income (called Complémentaire Santé Solidaire) to get medical treatment without spending money and seeking reimbursement.

Problem Area 2: Mercury emissions from crematoria

The following impacts from measures addressing emissions from crematoria have been assessed quantitatively by adapting the quantitative framework developed for the baseline:

- Capital and operational costs to crematoria operators of installing and using mercury emissions abatement techniques
- Where relevant, administrative burdens to operators and Member State Competent Authorities (MSCAs) from any monitoring, reporting and enforcement requirements under the measure
- Health and environmental benefits resulting from mercury emissions reductions; and
- Benefits resulting from emissions reductions for other pollutants, primarily particulate matter (PM).

Impacts for each measure were assessed for a scenario year of 2030 taking account of a number of potential crematoria activity thresholds, expressed in numbers of cremations undertaken at an installation annually. In addition to considering no activity threshold, the following annual cremation thresholds were assessed: 1,000; 2,000; 3,000; 4,000; and 5,000. Crematoria operating below these thresholds are considered exempt from the requirements of the measure, in much the same way that activity thresholds are implemented in other policy, including the Medium Combustion Plant Directive (MCPD) and Industrial Emissions Directive (IED).

The impact of each measure was assessed by considering its impact on the uptake of emissions abatement techniques. As such, the first step in the impact assessment was defining assumptions on the increased uptake of abatement technologies for each measure, over and above the baseline.

Measure CRE#1a: Issue EU guidance on emissions abatement in crematoria

Assessment of economic impacts

The introduction of EU guidance on emissions abatement in crematoria is assumed to result in a 5% increase in mercury emissions abatement across the EU27. This is low as such voluntary guidance typically does not have a significant impact in practice without supporting legislation.

The potential EU-wide capital and operational costs to crematoria operating in different activity bands are displayed in Table 9, along with an equivalent annual cost (EAC) calculated over a 17.5-year appraisal period[19], and assuming a 3% discount rate in line with the Better Regulation Guidelines[20]. The greatest costs are incurred among crematoria operating at fewer than 1,000 cremations annually, largely driven by the

[19] Information gained through stakeholder consultation indicated that crematoria have a typical operational life of 15 to 20 years; the average of these estimates was used as the appraisal period. As a sensitivity test, EACs have also been calculated assuming a 15- and 20-year appraisal period.

[20] EC (2021). Better Regulation Toolbox. https://ec.europa.eu/info/sites/default/files/br_toolbox-nov_2021_en_0.pdf

proportionally greater number of crematoria operating at this capacity compared to other capacity bands. It is important to note that the costs presented assume that EU guidance would lead to some uptake of abatement over and above the baseline situation. In practice, this would be down to the individual operators of crematoria and/or the Member States e.g., in case they use the guidance to implement requirements at a national (or local or regional) level.

Table 9 : Capital and operational costs to crematoria operators under CRE#1a, 2030

Cost	Crematoria in annual capacity band						
	<1,000	1,000 - 2,000	2,000 – 3,000	3,000 – 4,000	4,000 – 5,000	>5,000	Total
Capital[21]	€6.5 million	€1.0 million	€1.3 million	€600,000	€500,000	€400,000	€10.3 million
Operational[22]	€200,000	€30,000	€40,000	€20,000	€20,000	€10,000	€320,000
EAC[23]	€680,000	€110,000	€130,000	€60,000	€50,000	€40,000	€1.1 million[21]
EAC sensitivity test	€640,000 – €740,000	€100,000 – €120,000	€130,000 – €150,000	€60,000 – €70,000	€50,000 – €60,000	€40,000 – €50,000	€1.0 million – €1.2 million

The cremation sector is not anticipated to incur any administrative burdens from the introduction of sector-specific guidance. European Union institutions producing the guidance are likely to face some level of cost in doing so. This would vary depending on the scope of the guidance; a light-touch approach which sets out BAT, like the OSPAR Recommendation, is unlikely to require significant resources; guidance more prescriptive in its requirements, such as the UK's Process Guidance Note 5/2 (12)[24], which also sets out ELVs and monitoring requirements, would require more time and input to draft. However, it is not anticipated that any guidance produced would require time and resources exceeding existing institutional resources and budgets.

Crematoria operators that implement abatement technologies are likely to pass some or all of the capital and operational costs on to consumers, who would pay more for the same services. The extent to which crematoria operators would pass on these costs is not known, although information provided by stakeholders indicated that operators had introduced an 'environmental fee' to offset their abatement costs, and that this was largely accepted by customers.

Assessment of social impacts

Mercury exposure is associated with cardiovascular mortality, IQ loss in younger age groups, and anaemia. The human health benefits associated with this measure have been estimated by combining the resulting mercury emissions reductions (estimated at 17 kg

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[21] Rounded to the nearest €100,000.
[22] Rounded to the nearest €10,000.
[23] Rounded to the nearest €10,000 unless otherwise stated.
[24] Defra (2012). Process Guidance Note 5/2 (12): Statutory Guidance for Crematory. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/611478/process-guidance-note-crematoria.pdf

(6-29 kg)) with EEA human health damage costs; estimated benefits are presented in Table 10. The figures show that this measure is expected to deliver human health benefits of approximately €300,000 (€100,000-€520,000) when applied across all crematoria, with the greatest benefit gained through emissions reductions among crematoria operating at capacities of between 2,000-3,000 cremations annually.

Table 10 : Human health benefits of mercury emissions reductions under CRE#1a, 2030[25]

Benefit estimate	Crematoria in annual capacity band						
	<1,000	1,000 - 2,000	2,000 – 3,000	3,000 – 4,000	4,000 – 5,000	>5,000	Total
Low	€0	€0	€20,000	€10,000	€20,000	€50,000	€100,000
Central	**€20,000**	**€30,000**	**€70,000**	**€50,000**	**€50,000**	**€90,000**	**€300,000**
High	€30,000	€60,000	€130,000	€90,000	€80,000	€130,000	€520,000

Human health benefits would also be experienced through reductions in emissions of $PM_{2.5}$ and other pollutants (including lead, cadmium, arsenic, chromium, nickel and dioxins and furans); estimated benefits are presented in Table 11. Total human health benefits assuming no activity threshold are estimated at €36,000 (€23,000-€49,000).

Table 11: Human health benefits of $PM_{2.5}$ and other emissions reductions under CRE#1a, 2030[26]

Benefit estimate	Crematoria in annual capacity band						
	<1,000	1,000 - 2,000	2,000 – 3,000	3,000 – 4,000	4,000 – 5,000	>5,000	Total
Low	€6,000	€3,000	€4,000	€3,000	€3,000	€5,000	€23,000
Central	**€9,000**	**€4,000**	**€7,000**	**€4,000**	**€4,000**	**€7,000**	**€36,000**
High	€13,000	€6,000	€9,000	€6,000	€6,000	€10,000	€49,000

Assessment of environmental impacts

This measure is estimated to result in an estimated mercury emissions reduction of **17 kg** (6-29 kg) in 2030, compared to 2030 baseline emissions of **355 kg** (107-674 kg). Any reduction in mercury emissions would result in an improvement in the quality of natural resources. Most directly, it would result in improved air quality which would indirectly result in reduced mercury deposition to soil and waterbodies. In turn, the improved environmental quality could result in further indirect human health benefits; seafood is the primary source of human exposure to mercury, and reduced presence of mercury in environmental media would lead to reduced mercury in human food sources. However, it is not possible to quantify (or value) the environmental impacts with any certainty.

Summary

The total quantified costs and benefits of implementing this measure are displayed in Table 12, assuming no activity threshold. The net impact of the measure is estimated at a cost of €750,000 in 2030.

[25] Figures rounded to the nearest €10,000.
[26] Rounded to the nearest €1,000.

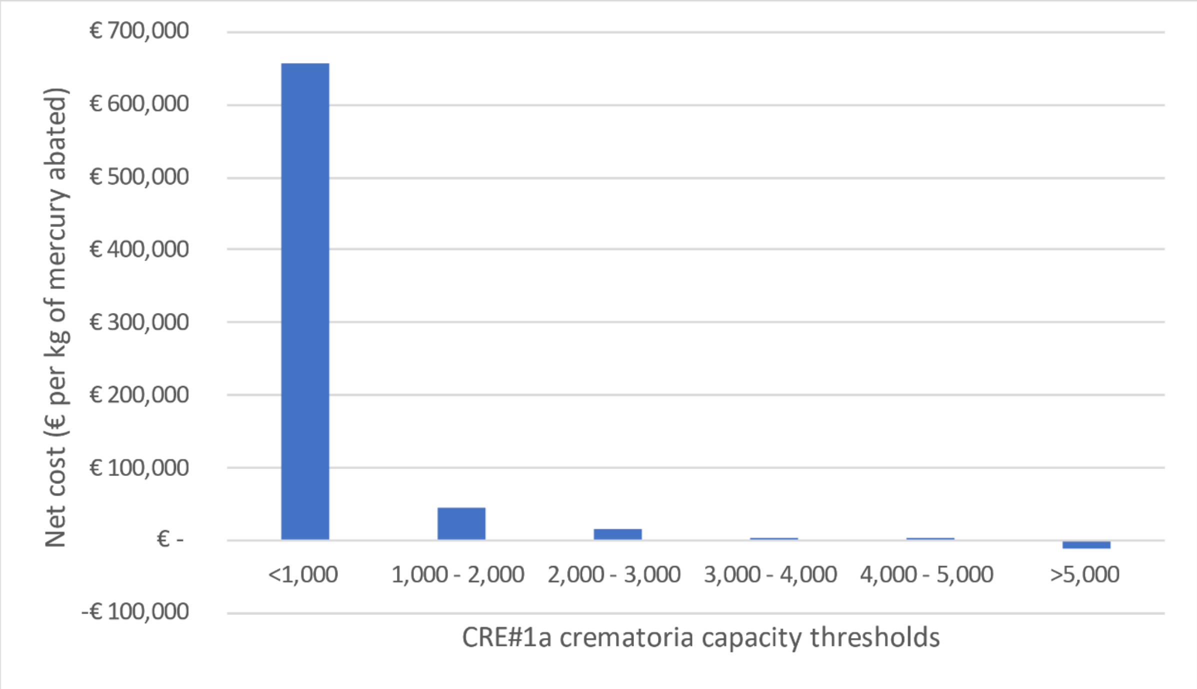
Table 12 : Net impact of CRE#1a, assuming no threshold, 2030[27]

Cost/benefit estimate	Crematoria in annual capacity band <1,000	1,000 - 2,000	2,000 – 3,000	3,000 – 4,000	4,000 – 5,000	>5,000	Total
Mercury emissions reduction[28]	-€20,000	-€30,000	-€70,000	-€50,000	-€50,000	-€90,000	-€300,000
$PM_{2.5}$ and other pollutant emissions reduction[28]	-€9,000	-€4,000	-€7,000	-€4,000	-€4,000	-€7,000	-€36,000
Capital and operational costs (EAC) [29]	€680,000	€110,000	€130,000	€60,000	€50,000	€40,000	€1.1 million[30]
Net impact[29]	€650,000	€70,000	€60,000	€10,000	€2,000[31]	-€50,000	€750,000
Benefit-cost ratio	0.04	0.31	0.57	0.82	0.96	2.22	0.31

At a net cost of €750,000 and delivering a mercury emissions reduction of 17 kg, this measure delivers reductions at a cost of **€44,000 per kg of mercury abated**. The net impacts of abatement by crematorium capacity are displayed in Figure 6, and indicate that emissions reductions among crematoria operating at <1,000 cremations per year cost approximately €660,000 per kilogram. The cost of emissions reductions among crematoria at 1,000-2,000 cremations per year are much less (€50,000). The benefits of emissions reductions in crematoria exceeding 5,000 cremations per year outweigh the costs, as the number of installations in these bands required to implement abatement techniques is smaller than in the lower operating capacities but they emit more.

[27] Figures that are negative and presented in green font represent a benefit.
[28] Rounded to the nearest €10,000.
[29] Rounded to the nearest €10,000 unless otherwise stated.
[30] Rounded to the nearest €100,000.
[31] Rounded to the nearest €1,000.

Figure 6: Net cost effectiveness per kilogram of mercury abated under CRE#1a in different capacity bands[32]



The total quantified costs and benefits of implementing this measure in combination with different dental amalgam phase-out scenarios are displayed in Table 12 Capital and operational costs to crematoria operators, as well as the benefits in terms of $PM_{2.5}$ reductions are the same as those reported in Table 12. When combined with any dental amalgam scenario, the measure is less cost beneficial than implementation without a phase-out. This is because the costs of implementing emissions abatement remain at the same level, but the total emissions which can be abated are reduced, resulting in smaller human health benefits. The total costs range from €750,000 where a 2030 phase-out is adopted to €800,000 where a 2025 phase-out is implemented.

Table 13 : Net impact of CRE#1a along with dental amalgam phase-outs, assuming no threshold, 2030[33]

Cost/benefit estimate	Crematoria in annual capacity band <1,000	1,000 - 2,000	2,000 – 3,000	3,000 – 4,000	4,000 – 5,000	>5,000	Total
In combination with 2025 dental amalgam phase-out							
Mercury emissions reduction[34]	-€20,000	-€30,000	-€60,000	-€40,000	-€40,000	-€70,000	-€260,000
Net impact[34]	€660,000	€80,000	€70,000	€20,000	€10,000	-€30,000	€800,000
In combination with 2027 dental amalgam phase-out							

[32] Negative costs denote a net benefit.
[33] Figures that are negative and presented in green font represent a benefit.
[34] Rounded to the nearest €10,000.

Cost/benefit estimate	Crematoria in annual capacity band						
	<1,000	1,000 - 2,000	2,000 – 3,000	3,000 – 4,000	4,000 – 5,000	>5,000	Total
Mercury emissions reduction[34]	-€20,000	-€30,000	-€70,000	-€40,000	-€40,000	-€80,000	-€270,000
Net impact[34]	€660,000	€80,000	€60,000	€20,000	€10,000	-€40,000	€770,000
In combination with 2030 dental amalgam phase-out							
Mercury emissions reduction[34]	-€20,000	-€30,000	-€70,000	-€50,000	-€50,000	-€90,000	-€300,000
Net impact[34]	€650,000	€70,000	€60,000	€10,000	€3,000[35]	-€50,000	€750,000

Measure CRE#1b: Issue EU guidance accompanied by voluntary agreements for the sector

Assessment of economic impacts

Implementation of EU guidance alongside a voluntary agreement for the cremation sector is assumed to result in a 15% increase in mercury emissions abatement i.e., an increase in uptake of 10% over and above the measure just considering guidance. Such uptake rates are highly uncertain and depend on the exact content of the guidance and, for this measure, the extent of any voluntary agreement. Higher uptake rates may be possible.

The EU-wide capital and operational costs, and EAC, to crematoria operating in different activity bands are displayed in Table 14. The greatest costs are incurred among crematoria operating at fewer than 1,000 cremations annually.

Table 14: Capital and operational costs to crematoria operators under CRE#1b, 2030

Cost	Crematoria in annual capacity band						
	<1,000	1,000 - 2,000	2,000 – 3,000	3,000 – 4,000	4,000 – 5,000	>5,000	Total
Capital[36]	€19.4 million	€3.1 million	€3.8 million	€1.8 million	€1.6 million	€1.2 million	€30.9 million
Operational[37]	€600,000	€100,000	€120,000	€60,000	€50,000	€40,000	€960,000
EAC[38]	€2.0 million	€300,000	€400,000	€200,000	€200,000	€100,000	€3.3 million
EAC sensitivity test	€1.9 million – €2.2 million	€300,000 – €400,000	€400,000	€200,000	€200,000	€100,000	€3.0 million – €3.5 million

35 Rounded to the nearest €1,000.

36 Rounded to the nearest €100,000.

37 Rounded to the nearest €10,000.

38 Rounded to the nearest €100,000. Based on an appraisal period of 10 years, and assuming a discount rate of 3% in line with EC Better Regulation guidance.

Given that the measure concerns the introduction of guidance to the cremation sector alongside a voluntary industry agreement, it is not anticipated to have significant impacts on SMEs.

Sector guidance is unlikely to have any administrative implications to crematoria operators, and any administrative actions required as part of voluntary agreement membership are likely to be minor and will not require significant resources from industry. EU institutions may be required to dedicate resources in the development of sector guidance and the administration of any sector voluntary agreement, but this is not expected to require resources beyond the capacity of current institutional resources and budgets.

Assessment of social impacts

The human health benefits associated with mercury emissions reductions resulting from this measure (51 kg (18-88 kg)) have been valued using EEA damage costs; these values are presented in Table 15. This measure is expected to deliver human health benefits in the order of €900,000 (€310,000-€1.6 million) when implemented without an activity threshold.

Table 15: Human health benefits of mercury emissions reductions under CRE#1b, 2030[39]

Benefit estimate	Crematoria in annual capacity band						
	<1,000	1,000 - 2,000	2,000 – 3,000	3,000 – 4,000	4,000 – 5,000	>5,000	Total
Low	€10,000	€10,000	€50,000	€40,000	€260,000	€140,000	€310,000
Central	€50,000	€90,000	€210,000	€140,000	€140,000	€270,000	€900,000
High	€100,000	€170,000	€400,000	€260,000	€240,000	€390,000	€1.6 million[40]

Human health benefits have also been valued for the reductions in emissions of $PM_{2.5}$ and other pollutants (including lead, cadmium, arsenic, chromium, nickel and dioxins and furans) resulting from this measure (see Table 16). Assuming no activity threshold, the total human health benefits are estimated at €110,000 (€70,000-€150,000).

Table 16: Human health benefits of $PM_{2.5}$ and other emissions reductions under CRE#1b, 2030[41]

Benefit estimate	Crematoria in annual capacity band						
	<1,000	1,000 - 2,000	2,000 – 3,000	3,000 – 4,000	4,000 – 5,000	>5,000	Total
Low	€ 20,000	€ 10,000	€ 10,000	€ 10,000	€ 10,000	€ 10,000	€ 70,000
Central	**€ 30,000**	**€ 10,000**	**€ 20,000**	**€ 10,000**	**€ 10,000**	**€ 20,000**	**€ 110,000**
High	€ 40,000	€ 20,000	€ 30,000	€ 20,000	€ 20,000	€ 30,000	€ 150,000

[39] Rounded to the nearest €10,000 unless otherwise stated.
[40] Rounded to the nearest €100,000.
[41] Rounded to the nearest €10,000 unless otherwise stated.

Assessment of environmental impacts

This measure is estimated to result in an estimated mercury emissions reduction of **51 kg** (18-88 kg) in 2030, compared to 2030 baseline emissions of **355 kg** (107-674 kg). The reduction in mercury emissions would lead to improvement in environmental quality, including air, soil and water. In turn, this would result in indirect human health benefits, as less mercury enters human food sources. Due to the uncertainties in the pathways of mercury in the environment once emitted to air, and a lack of data on valuing these environmental impacts, it is not possible to quantitatively assess (or value) them. Due to the greater mercury emissions reductions from CRE#1b compared to CRE#1a, the environmental benefits will be greater.

Summary

The total quantified costs and benefits of implementing this measure are displayed in Table 17, assuming no activity threshold. The net impact of the measure is estimated at a cost of €2.3 million in 2030.

Table 17: Net impact of CRE#1b, assuming no threshold, 2030[42]

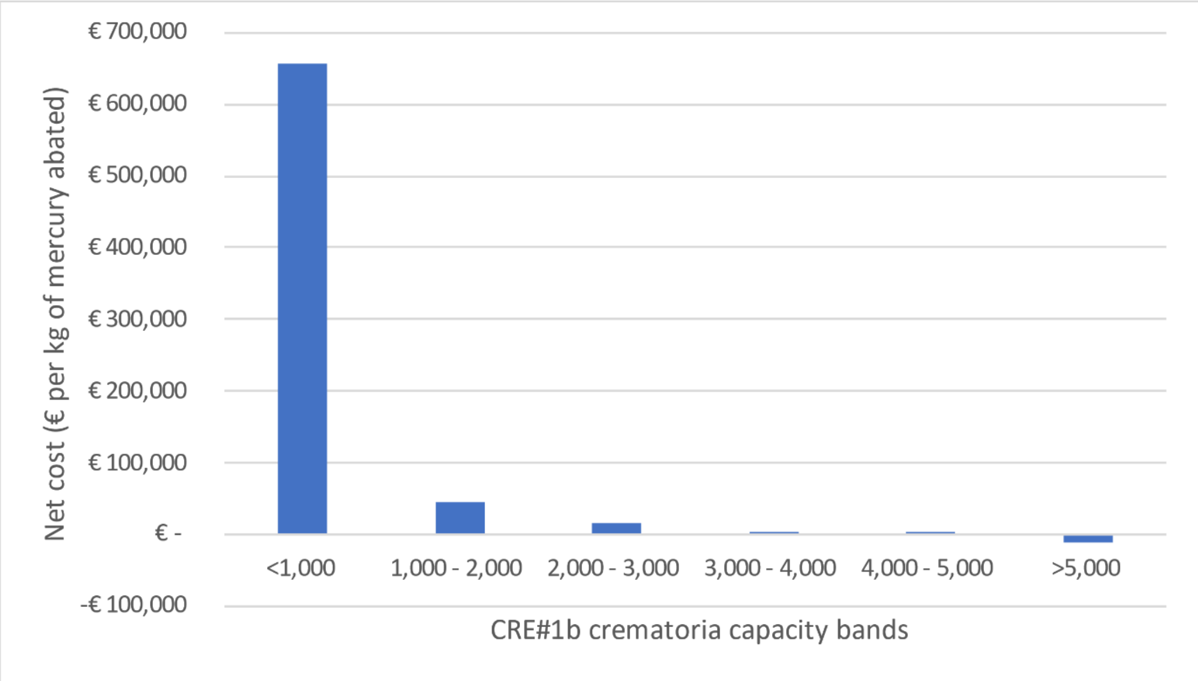
Cost/benefit estimate	Crematoria in annual capacity band						
	<1,000	1,000 - 2,000	2,000 – 3,000	3,000 – 4,000	4,000 – 5,000	>5,000	Total
Mercury emissions reduction[43]	-€50,000	-€90,000	-€210,000	-€140,000	-€140,000	-€270,000	-€900,000
$PM_{2.5}$ and other pollutant emissions reduction[44]	-€30,000	-€10,000	-€20,000	-€10,000	-€10,000	-€20,000	-€110,000
Capital and operational costs (EAC)[45]	€2.0 million	€300,000	€400,000	€200,000	€200,000	€100,000	€3.3 million
Net impact[46]	€2.0 million	€200,000	€200,000	€30,000[47]	€10,000[47]	-€200,000	€2.2 million
Benefit-cost ratio	0.04	0.31	0.57	0.82	0.96	2.22	0.31

At a net cost of €2.2 million and delivering a mercury emissions reduction of 51 kg, this measure delivers reductions at a cost of **€44,000 per kg of mercury abated**. The net impacts of abatement by crematorium capacity are displayed in Figure 7, and indicate

[42] Figures that are negative and presented in green font represent a benefit.
[43] Rounded to the nearest €100,000.
[44] Rounded to the nearest €10,000.
[45] Rounded to the nearest €100,000.
[46] Rounded to the nearest €100,000, unless otherwise stated.
[47] Rounded to the nearest €10,000.

that emissions reductions among crematoria operating at <1,000 cremations per year cost approximately €660,000 per kilogram. The cost of emissions reductions among crematoria at 1,000-2,000 cremations per year are much less (€50,000). The benefits of emissions reductions in crematoria exceeding 5,000 cremations per year outweigh the costs, as the number of installations in these bands required to implement abatement techniques is smaller than in the lower operating capacities but they emit more.

Figure 7: Net cost per kilogram of mercury abated under CRE#1b in different capacity bands[48]



The total quantified costs and benefits of implementing this measure in combination with different dental amalgam phase-out scenarios are displayed in Table 18. Capital and operational costs to crematoria operators, as well as the benefits in terms of $PM_{2.5}$ reductions are the same as those reported in Table 17. When combined with any dental amalgam scenario, the measure is less cost beneficial than implementation without a phase-out. This is because the costs of implementing emissions abatement remain at the same level, but the total emissions which can be abated are reduced, resulting in smaller human health benefits. The total costs range from €2.3 million where a 2030 phase-out is adopted to €2.4 million where a 2025 phase-out is implemented.

Table 18 : Net impact of CRE#1b along with dental amalgam phase-outs, assuming no threshold, 2030[49]

Cost/benefit estimate	Crematoria in annual capacity band <1,000	1,000 - 2,000	2,000 – 3,000	3,000 – 4,000	4,000 – 5,000	>5,000	Total
In combination with 2025 dental amalgam phase-out							
Mercury emissions	-€50,000	-€80,000	-€190,000	-€120,000	-€110,000	-€210,000	-€770,000

[48] Negative costs denote a net benefit.
[49] Figures that are negative and presented in green font represent a benefit.

Cost/benefit estimate	Crematoria in annual capacity band						
	<1,000	1,000 - 2,000	2,000 – 3,000	3,000 – 4,000	4,000 – 5,000	>5,000	Total
reduction[50]							
Net impact[51]	€2.0 million	€200,000	€200,000	€50,000[52]	€40,000[52]	-€100,000	€2.4 million
In combination with 2027 dental amalgam phase-out							
Mercury emissions reduction[50]	-€50,000	-€80,000	-€200,000	-€130,000	-€130,000	-€240,000	-€820,000
Net impact[51]	€2.0 million	€200,000	€200,000	€50,000[52]	€20,000[52]	-€100,000	€2.3 million
In combination with 2030 dental amalgam phase-out							
Mercury emissions reduction[50]	-€50,000	-€90,000	-€210,000	-€140,000	-€140,000	-€270,000	-€890,000
Net impact[51]	€2.0 million	€200,000	€200,000	€40,000[52]	€10,000[52]	-€200,000	€2.3 million

Measure CRE#2: Define Best Available Techniques (BAT) / Associated Emissions Levels (AELs)

The analysis for this measure has been undertaken for each capacity band independently and impacts aggregated assuming no activity threshold (i.e. all crematoria, CRE#2a) as well as just for large crematoria (i.e. those with a capacity of more than 4,000 cremations per year, CRE#2b, and those with a capacity of more than 3,000 cremations per year, CRE#2c).

Assessment of economic impacts

The introduction of a system for regulating mercury emissions from crematoria based on BAT and ELVs is assumed to raise emissions abatement uptake to 100% in Member States (above any relevant activity threshold) where such a system is not already in place. The EU-wide capital and operational costs to crematoria operating in different activity bands to install and operate the required abatement are displayed in Table 19, along with an EAC value. The greatest costs are incurred among crematoria operating at fewer than 1,000 cremations annually, driven by the greater number of crematoria operating at this capacity compared to other capacity bands. Costs are aggregated for measure CRE#2a, which assumes mandatory emissions abatement at all crematoria, measure CRE#2b, which assumes emissions abatement only at crematoria at annual operating capacities of 4,000 or more, and measure CRE#2c, which assumes emissions abatement only at crematoria at operating capacities of 3,000 or more.

50 Rounded to the nearest €100,000.
51 Rounded to the nearest €100,000, unless otherwise stated.
52 Rounded to the nearest €10,000.

Table 19: Capital and operational costs to crematoria operators under CRE#2, 2030

Cost	Crematoria in annual capacity band							
	<1,000	**1,000 - 2,000**	**2,000 – 3,000**	**3,000 – 4,000**	**4,000 – 5,000**	**>5,000**	**Total (CRE#2a)**	**Total (CRE#2b)**	**Total (CRE#2c)**
Capital[53]	€119 million	€15 million	€24 million	€10 million	€8 million	€6 million	€182 million	€15 million	€25 million
Operational[54]	€3.7 million	€500,000	€700,000	€300,000	€300,000	€200,000	€5.7 million	€500,000	€800,000
EAC[53]	€13 million	€2 million	€3 million	€1 million	€1 million	€1 million	€19 million	€2 million	€3 million
EAC sensitivity test	€12 million – €14 million	€1 million – €2 million	€2 million – €3 million	€1 million	€1 million	€1 million	€18 million – €21 million	€1 million – €2 million	€2 million – €3 million

How this measure would impact the position of SMEs is dependent on the level at which activity thresholds are set (if at all) and is also highly uncertain. As shown above, implementing the measure with no, or a low, activity threshold would incur substantial costs to smaller installations. There is potential movement away from significant public sector involvement in operation of crematoria to greater involvement from private enterprises. Limited data are available on the structure of the sector across different countries across the EU, but there are likely to be SMEs involved, especially in Member States dominated by smaller crematoria (including Spain and France). The implementation of no (or a low) activity threshold is likely to have greater implications for SMEs within the sector, who would bear greater costs.

In addition to the costs of implementing and operating mercury emissions abatement systems at their installations, crematoria operators would face added administrative burdens. This would arise from the need to submit information on their abatement systems and any periodic emissions monitoring to Member State Competent Authorities, who would also encounter a new administrative burden in process information submitted by operators. It is assumed that costs to both operators and authorities would be comparable to administrative burdens under the MCPD for installations operating at 1-5 MW (see previous sections). Estimated administrative costs, assuming no activity threshold, are presented in Table 20. Administrative costs are estimated to amount to €400,000 to operators and €500,000 to authorities in 2030.

Table 20: Administrative burdens under CRE#2, 2030[55]

Actors	Crematoria in annual capacity band								
	<1,000	**1,000 - 2,000**	**2,000 – 3,000**	**3,000 – 4,000**	**4,000 – 5,000**	**>5,000**	**Total (CRE#2a)**	**Total (CRE#2b)**	**Total (CRE#2c)**
To operators	€250,000	€50,000	€50,000	€20,000	€10,000	€10,000	€400,000	€20,000	€40,000
To authorities	€310,000	€70,000	€60,000	€20,000	€20,000	€10,000	€500,000	€30,000	€50,000

[53] Rounded to the nearest €1 million.
[54] Rounded to the nearest €100,000.
[55] Rounded to the nearest €10,000.

Where the requirement to implement mercury emissions abatement is not economically feasible and crematoria cease operation, losses in employment would result. These losses are expected to be mitigated at least in part by greater employment among manufacturers of abatement systems, who would see increased demand for their products. Similarly, wider uptake of emissions abatement systems at crematoria may result in operators passing on some or all of the costs to customers.

Assessment of social impacts

The human health benefits associated with mercury emissions reductions resulting from this measure (314 kg (105-542 kg)) have been valued using EEA damage costs; these values are presented in Table 21. CRE#2 is expected to deliver human health benefits of €5.6 million (€1.9 million-€9.5 million) when implemented without an activity threshold. Where the measure is applied only to crematoria above an annual operating capacity of 4,000 or 3,000 cremations, the emissions reductions and associated human health benefits are reduced.

Table 21: Human health benefits of mercury emissions reductions under CRE#2, 2030[56]

Benefit estimate	Crematoria in annual capacity band								
	<1,000	**1,000 - 2,000**	**2,000 – 3,000**	**3,000 – 4,000**	**4,000 – 5,000**	**>5,000**	**Total (CRE#2 a)**	**Total (CRE#2 b)**	**Total (CRE#2 c)**
Low	€0.1 million	€0.1 million	€0.3 million	€0.2 million	€0.4 million	€0.9 million	€1.9 million	€1.2 million	€1.5 million
Central	€0.3 million	€0.6 million	€1.3 million	€0.9 million	€0.8 million	€1.7 million	€5.5 million	€2.5 million	€3.4 million
High	€0.6 million	€1.1 million	€2.5 million	€1.6 million	€1.4 million	€2.3 million	€9.5 million	€3.7 million	€5.3 million

Human health benefits from the reductions in emissions of $PM_{2.5}$ and a suite of other pollutants (including lead, cadmium, arsenic, chromium, nickel and dioxins and furans) resulting from this measure are displayed in Table 20. Assuming no activity threshold (CRE#2a), the total human health benefits are estimated at €620,000 (€390,000-€850,000). With an activity threshold of 4,000 cremations per year, benefits are estimated at €180,000 (€120,000-€250,000); an activity threshold of 3,000 cremations per year yields benefits of €260,000 (€160,000-€350,000).

Table 22: Human health benefits of $PM_{2.5}$ and other pollutant emissions reductions under CRE#2, 2030[57]

Benefit estimate	Crematoria in annual capacity band								
	<1,000	**1,000 - 2,000**	**2,000 – 3,000**	**3,000 – 4,000**	**4,000 – 5,000**	**>5,000**	**Total (CRE#2a)**	**Total (CRE#2 b)**	**Total (CRE#2 c)**
Low	€ 110,000	€ 40,000	€ 80,000	€ 50,000	€ 40,000	€ 70,000	€ 390,000	€ 120,000	€160,000
Central	**€ 170,000**	**€ 70,000**	**€ 120,000**	**€ 80,000**	**€ 70,000**	**€ 110,000**	**€ 620,000**	**€ 180,000**	**€260,000**
High	€ 230,000	€ 90,000	€ 170,000	€ 110,000	€ 90,000	€ 160,000	€ 850,000	€ 250,000	€350,000

[56] Rounded to the nearest €100,000.
[57] Rounded to the nearest €10,000.

Assessment of environmental impacts

Measure CRE#2a is estimated to result in an estimated mercury emissions reduction of **314 kg** (105-542 kg) in 2030, compared to 2030 baseline emissions of **355 kg** (107-674 kg). Where the measure is implemented with an activity threshold of 4,000 cremations per year (CRE#2b), emissions reductions are estimated at **141 kg** (70-210 kg); an activity threshold of 3,000 cremations per year (CRE#2c) would result in emissions reductions of **191 kg** (82-302 kg). As with CRE#1a and CRE#1b, any reduction in mercury emissions would lead to improvement in environmental quality, including air, soil and water. In turn, this would result in indirect human health benefits, as less mercury enters human food sources. Due to the uncertainties in the pathways of mercury in the environment once emitted to air, and a lack of data on valuing these environmental impacts, it is not possible to quantitatively assess (or value) them. The greater mercury emissions reductions from CRE#2 compared to CRE#1a and CRE#1b, would deliver greater environmental benefits.

Summary

The total quantified costs and benefits of implementing this measure are displayed in Table 23, assuming no activity threshold. The net impact of the measure without an activity threshold (CRE#2a) is estimated at a cost of €14 million in 2030 across all crematorium capacity bands. Where an activity threshold of 4,000 cremations per year is adopted (CRE#2b), the net impact is estimated at a benefit of approximately €1 million in 2030, while an activity threshold of 3,000 cremations per year (CRE#2c) is anticipated to result in a net benefit of €900,000.

Table 23: Net impact of CRE#2, assuming no threshold, 2030[58]

Cost/benefit estimate	Crematoria in annual capacity band								
	<1,000	1,000 - 2,000	2,000 – 3,000	3,000 – 4,000	4,000 – 5,000	>5,000	Total **(CRE#2a)**	Total (CRE#2b)	Total (CRE#2c)
Mercury emissions reduction[59]	-€0.3 million	-€0.6 million	-€1.3 million	-€0.9 million	-€0.8 million	-€1.7 million	-€5.5 million	-€2.5 million	-€3.4 million
$PM_{2.5}$ and other pollutant emissions reduction[60]	-€170,000	-€70,000	-€120,000	-€80,000	-€70,000	-€110,000	-€620,000	-€180,000	-€260,000
Capital and operational costs (EAC)[59]	€13 million	€2 million	€3 million	€1 million	€1 million	€1 million	€19 million	€2 million	€3 million
Administrative burden	€250,000	€50,000	€50,000	€20,000	€10,000	€10,000	€400,000	€20,000	€40,000

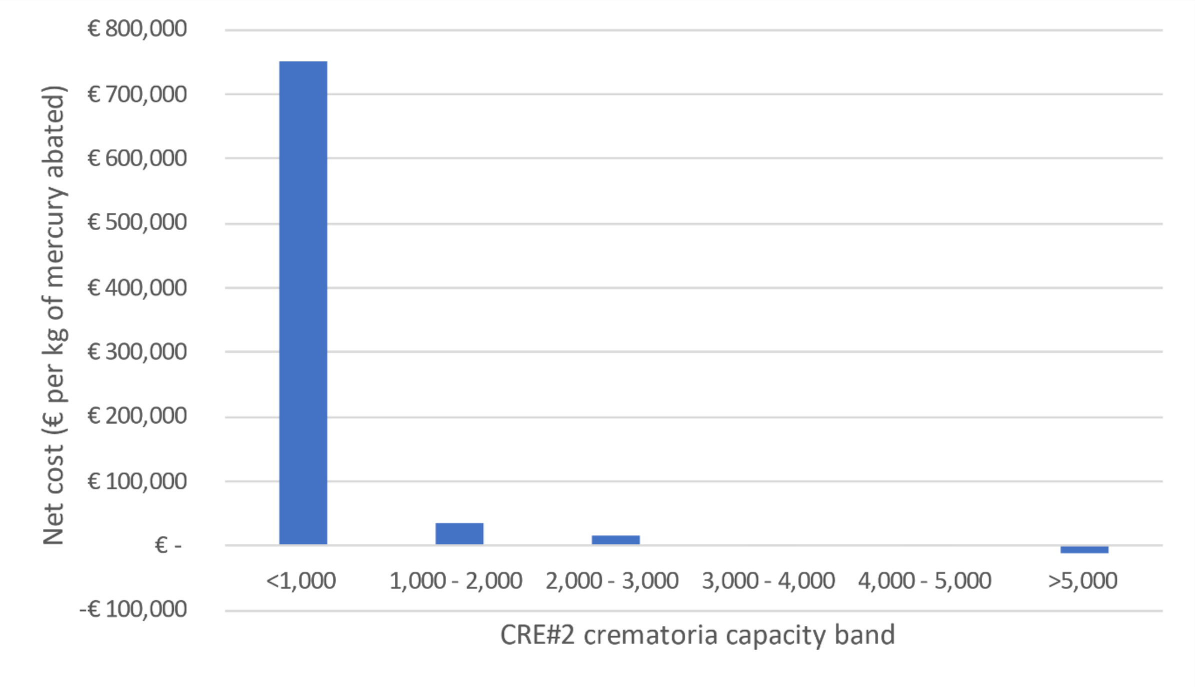
[58] Figures that are negative and presented in green font represent a benefit.
[59] Rounded to the nearest €1 million.
[60] Rounded to the nearest €10,000.

Cost/benefit estimate	Crematoria in annual capacity band								
	<1,000	1,000 - 2,000	2,000 – 3,000	3,000 – 4,000	4,000 – 5,000	>5,000	Total **(CRE#2a)**	Total (CRE#2b)	Total (CRE#2c)
to operators[61]									
Administrative burden to authorities[61]	€310,000	€70,000	€60,000	€20,000	€20,000	€10,000	€500,000	€30,000	€50,000
Net impact[62]	€13 million[59]	€1 million[59]	€1 million[59]	€200,000	€10,000[61]	-€1 million[59]	€14 million[59]	-€1 million	-€900,000
Benefit-cost ratio	0.04	0.36	0.55	0.86	0.99	2.50	0.31	1.65	1.33

At a net cost of €14 million and delivering a mercury emissions reduction of 314 kg, measure CRE#2a delivers reductions at a cost of **€45,000 per kg of mercury abated**. The net impacts of abatement by crematorium capacity are displayed in Figure 8, and indicate that emissions reductions among crematoria operating at <1,000 cremations per year cost approximately €750,000 per kilogram. The cost of emissions reductions among crematoria at 1,000-2,000 cremations per year are much less (€40,000). The benefits of emissions reductions in crematoria exceeding 5,000 cremations per year outweigh the costs, as the number of installations in these bands required to implement abatement techniques is smaller than in the lower operating capacities but they emit more. Where an activity threshold of 4,000 cremations per year is adopted with the measure (CRE#2b), an estimated 141 kg of mercury emissions are abated at a net benefit of €1 million, resulting in a benefit of **€7,000 per kg of mercury abated**. An activity threshold of 3,000 cremations per year (CRE#2c) delivers mercury emissions reductions at a benefit of **€5,000 per kg of mercury abated**.

[61] Rounded to the nearest €10,000.
[62] Rounded to the nearest €100,000, unless otherwise stated.

Figure 8: Net cost per kilogram of mercury abated under CRE#2a in different capacity bands[63]



The total quantified costs and benefits of implementing this measure in combination with different dental amalgam phase-out scenarios are displayed in Table 24. Capital and operational costs to crematoria operators, as well as the benefits in terms of $PM_{2.5}$ reductions are the same as those reported in Table 23. When combined with any dental amalgam scenario, the measure is less cost beneficial than implementation without a phase-out. This is because the costs of implementing emissions abatement remain at the same level, but the total emissions which can be abated are reduced, resulting in smaller human health benefits. The total net costs range from €14 million where a 2030 phase-out is adopted to €15 million where a 2025 phase-out is implemented. Where the measure is implemented with an activity threshold of 4,000 cremations per year, it delivers net benefits in all dental amalgam phase-out scenarios, ranging from €0.5 million in the case of a 2025 dental amalgam phase-out, to €1 million in the case of a 2030 dental amalgam phase-out.

Table 24 : Net impact of CRE#2 along with dental amalgam phase-outs, assuming no threshold, 2030[64]

Cost/benefit estimate	Crematoria in annual capacity band <1,000	1,000 - 2,000	2,000 – 3,000	3,000 – 4,000	4,000 – 5,000	>5,000	Total (CRE#2a)	Total (CRE#2b)	Total (CRE#2c)
In combination with 2025 dental									

[63] Negative costs denote a net benefit.
[64] Figures that are negative and presented in green font represent a benefit.

Cost/benefit estimate	Crematoria in annual capacity band <1,000	1,000 - 2,000	2,000 – 3,000	3,000 – 4,000	4,000 – 5,000	>5,000	Total (CRE#2a)	Total (CRE#2b)	Total (CRE#2c)
amalgam phase-out									
Mercury emissions reduction[65]	-€0.3 million	-€0.5 million	-€1.2 million	-€0.8 million	-€0.7 million	-€1.3 million	-€4.7 million	-€2.0 million	-€2.7 million
Net impact[66]	€13 million[65]	€1 million[65]	€1 million[65]	€300,000	€200,000	-€0.7 million	€15 million[65]	-€500,000	-€300,000
In combination with 2027 dental amalgam phase-out									
Mercury emissions reduction[67]	-€0.3 million	-€0.5 million	-€1.3 million	-€0.8 million	-€0.7 million	-€1.5 million	-€5.1 million	-€2.2 million	-€3.0 million
Net impact[68]	€13 million[65]	€1 million[65]	€1 million[65]	€200,000	€100,000	-€0.9 million	€14 million[65]	-€0.8 million	-€0.5 million
In combination with 2030 dental amalgam phase-out									
Mercury emissions reduction[69]	-€0.3 million	-€0.5 million	-€1.3 million	-€0.9 million	-€0.8 million	-€1.6 million	-€5.5 million	-€2.5 million	-€3.3 million
Net impact[70]	€13 million[65]	€1 million[65]	€1 million[65]	€200,000	€20,000[71]	-€1 million[65]	€14 million[65]	-€1 million	-€900,000

Measure CRE#3: Mercury benchmarks/reduction targets

Assessment of economic impacts

This measure, which entails the introduction of mercury benchmarks or emission reduction targets for the cremation sector, is assumed to increase emissions abatement uptake to 100% in Member States where there is no regulation currently in place. As such, the number of installations across the EU impacted by the measure are the same as in CRE#2a, and the economic impacts are expected to be of the same magnitude. There may be some efficiency savings for Member States in that they can choose the exact approach for regulating the sector based around the benchmark / target values, but they are expected to be limited as CRE#2a would also entail some flexibility.

[65] Rounded to the nearest €1 million.
[66] Rounded to the nearest €100,000, unless otherwise stated.
[67] Rounded to the nearest €1 million.
[68] Rounded to the nearest €100,000, unless otherwise stated.
[69] Rounded to the nearest €1 million.
[70] Rounded to the nearest €100,000, unless otherwise stated.
[71] Rounded to the nearest €10,000

There is also the option to implement measure CRE#3 such that it applies only to crematoria operating above certain activity thresholds. Where an activity threshold of 4,000 cremations per year is adopted, the impacts of measure CRE#3 are anticipated to be the same as those described for measure CRE#2b.

Assessment of social impacts

The implementation of mercury benchmarks or emission reduction targets are expected to have the same impact as CRE#2a or CRE#2b (BAT and ELVs) in terms of abatement uptake. The impact in terms of emission reductions will therefore also be the same, and the benefits in terms of human health impacts will be the same as those described for CRE#2a or CRE#2b.

Assessment of environmental impacts

Environmental benefits resulting from mercury emissions reductions induced by this measure will be the same as those described for CRE#2a or CRE#2b.

Measure CRE#4: Burden sharing agreements

Assessment of economic impacts

This measure involves the establishment of a burden-sharing agreement. The impact of a burden-sharing agreement on emissions abatement uptake at crematoria in the EU will depend on the scope of the measure, but for the purpose of assessment it is assumed to result in an uptake of 100% in Member States where there is no regulation currently in place. As such, the number of installations across the EU impacted by the measure are the same as in CRE#2, and the economic impacts are expected to be of the same magnitude.

In addition to considering 100% abatement uptake, a burden-sharing measure has also been considered with target emissions reductions of 50% and 75% for the cremation sector (building on the UK case study whereby a 50% reduction target is applied). Assuming that abatement would be adopted starting with installations in the largest capacity bands (where emissions can be reduced most cost effectively) and through progressively smaller installations, the compliance costs, and administrative burdens of this measure with these emissions reductions are displayed in Table 25.

Table 25: Economic impacts of CRE#4 with 50% and 75% emissions reductions

Cost	50% emissions reduction	75% emissions reduction
Capital and operational costs (EAC)	€2.3 million (€2.2 million – €2.6 million)	€5.1 million (€4.8 million – €5.6 million)
Administrative burdens to operators	€40,000	€90,000
Administrative burdens to authorities	€50,000	€120,000

Assessment of social impacts

The implementation of mercury benchmarks or emission reduction targets are expected to have the same impact as CRE#2 (BAT and ELVs) in terms of abatement uptake. The impact in terms of emission reductions will therefore also be the same, and the benefits in terms of human health impacts will be the same as those described for CRE#2.

Benefits in terms of human health impacts have also been quantified for this measure scenarios assuming a 50% and 75% emissions reduction for the cremation sector. The quantified impacts are displayed in Table 26.

Table 26: Human health impacts of CRE#4 with 50% and 75% emissions reductions

Cost	50% emissions reduction	75% emissions reduction
Benefits from mercury emissions reductions	€3.1 million (€1.4 million – €4.9 million)	€4.7 million (€1.7 million – €7.9 million)
Benefits from $PM_{2.5}$ and other pollutant emissions reductions	€200,000 (€200,000 – €300,000)	€400,000 (€200,000 – €500,000)

Assessment of environmental impacts

Environmental benefits resulting from mercury emissions reductions induced by measure CRE#4 will be the same as those described for CRE#2.

Summary

Assuming 100% emissions abatement uptake as a result of this measure, impacts will be the same as those set out for CRE#2.

The impacts for this measure, assuming 50% and 75% emissions reductions targets for the cremation sector are set out in Table 27 and Table 28.

Table 27: Net impact of CRE#4, assuming a 50% emissions reduction target for the cremation sector[72]

Cost/benefit estimate	Crematoria in annual capacity band						
	<1,000	1,000 - 2,000	2,000 – 3,000	3,000 – 4,000	4,000 – 5,000	>5,000	Total
Mercury emissions reduction[73]	€0	€0	€0	-€600,000	-€800,000	-€1.7 million	-€3.1 million
$PM_{2.5}$ and other pollutant emissions reduction[74]	€0	€0	€0	-€60,000	-€70,000	-€110,000	-€240,000
Capital and operational costs (EAC) [73]	€0	€0	€0	€1 million	€1 million	€1 million	€2 million
Administrat	€0	€0	€0	€10,000	€10,000	€10,000	€40,000

[72] Figures that are negative and presented in green font represent a benefit.
[73] Rounded to the nearest €100,000.
[74] Rounded to the nearest €10,000.

Cost/benefit estimate	Crematoria in annual capacity band						
	<1,000	1,000 - 2,000	2,000 – 3,000	3,000 – 4,000	4,000 – 5,000	>5,000	Total
ive burden to operators[75]							
Administrative burden to authorities[61]	€0	€0	€0	€20,000	€20,000	€10,000	€50,000
Net impact[76]	€0	€0	€0	€100,000	€10,000[75]	-€1 million[73]	-€900,000[73]

Table 28: Net impact of CRE#4, assuming a 75% emissions reduction target for the sector[77]

Cost/benefit estimate	Crematoria in annual capacity band						
	<1,000	1,000 - 2,000	2,000 – 3,000	3,000 – 4,000	4,000 – 5,000	>5,000	Total
Mercury emissions reduction[78]	€0	€0	-€1 million	-€1 million	-€1 million	-€2 million	-€5 million
$PM_{2.5}$ and other pollutant emissions reduction[79]	€0	€0	-€120,000	-€80,000	-€70,000	-€110,000	-€380,000
Capital and operational costs (EAC)[78]	€0	€0	€3 million	€1 million	€1 million	€1 million	€5 million
Administrative burden to operators[80]	€0	€0	€50,000	€20,000	€10,000	€10,000	€90,000
Administrative burden to authorities[61]	€0	€0	€60,000	€20,000	€20,000	€10,000	€120,000
Net impact[81]	€0	€0	€1 million[78]	€200,000	€10,000[80]	-€1 million[78]	€300,000

The total quantified costs and benefits of implementing this measure in combination with different dental amalgam phase-out scenarios are displayed in Table 28 and Table 30. Capital and operational costs to crematoria operators, as well as the benefits in terms of $PM_{2.5}$ reductions are the same as those reported in Table 27 and Table 28. When combined with any dental amalgam scenario, the measure is less cost beneficial than

[75] Rounded to the nearest €10,000.
[76] Rounded to the nearest €100,000, unless otherwise stated.
[77] Figures that are negative and presented in green font represent a benefit.
[78] Rounded to the nearest €1 million.
[79] Rounded to the nearest €10,000.
[80] Rounded to the nearest €10,000.
[81] Rounded to the nearest €100,000, unless otherwise stated.

implementation without a phase-out. This is because the costs of implementing emissions abatement remain at the same level, but the total emissions which can be abated are reduced, resulting in smaller human health benefits. The net impacts range from a benefit of €200,000 to €800,000 where a 50% emissions reduction target is adopted, to a cost of €400,000 to €1 million where a 75% reduction target is in effect.

Table 29 : Net impact of CRE#4 (50% emissions reduction target) along with dental amalgam phase-outs, assuming no threshold, 2030[82]

Cost/benefit estimate	Crematoria in annual capacity band <1,000	1,000 - 2,000	2,000 – 3,000	3,000 – 4,000	4,000 – 5,000	>5,000	Total
In combination with 2025 dental amalgam phase-out							
Mercury emissions reduction[83]	€0	€0	€0	-€700,000	-€700,000	-€1.3 million	-€2.7 million
Net impact[84]	€0	€0	€0	€200,000	€200,000	-€700,000	-€300,000
In combination with 2027 dental amalgam phase-out							
Mercury emissions reduction[83]	€0	€0	€0	-€700,000	-€700,000	-€1.5 million	-€2.9 million
Net impact[84]	€0	€0	€0	€200,000	€100,000	-€800,000	-€600,000
In combination with 2030 dental amalgam phase-out							
Mercury emissions reduction[83]	€0	€0	€0	-€600,000	-€800,000	-€1.6 million	-€3.1 million
Net impact[84]	€0	€0	€0	€100,000	€20,000[85]	-€1 million[86]	-€900,000

Table 30 : Net impact of CRE#4 (75% emissions reduction target) along with dental amalgam phase-outs, assuming no threshold, 2030[87]

Cost/benefit estimate	Crematoria in annual capacity band <1,000	1,000 - 2,000	2,000 – 3,000	3,000 – 4,000	4,000 – 5,000	>5,000	Total
In combination with 2025 dental amalgam phase-out							
Mercury emissions reduction[88]	€0	€40,000[89]	-€1 million	-€1 million	-€1 million	-€1 million	-€4 million

[82] Figures that are negative and presented in green font represent a benefit.
[83] Rounded to the nearest €100,000.
[84] Rounded to the nearest €100,000, unless otherwise stated.
[85] Rounded to the nearest €10,000
[86] Rounded to the nearest €1 million
[87] Figures that are negative and presented in green font represent a benefit.
[88] Rounded to the nearest €1 million.
[89] Rounded to the nearest €10,000.

Cost/benefit estimate	Crematoria in annual capacity band					
	<1,000	1,000 - 2,000	2,000 – 3,000	3,000 – 4,000	4,000 – 5,000	>5,000	Total
Net impact[90]	€0	€100,000	€1 million[78]	€300,000	€200,000	-€700,000	€1 million[88]
In combination with 2027 dental amalgam phase-out							
Mercury emissions reduction[88]	€0	€19,000[91]	-€1 million	-€1 million	-€1 million	-€1 million	-€4 million
Net impact[90]	€0	€40,000[92]	€1 million[78]	€200,000	€100,000	-€900,000	€700,000
In combination with 2030 dental amalgam phase-out							
Mercury emissions reduction[88]	€0	€0	-€1 million	-€1 million	-€1 million	-€2 million	-€5 million
Net impact[90]	€0	€0	€1 million[78]	€200,000	€20,000[80]	-€1 million[78]	€300,000

Measure CRE#5: National mercury reduction targets

Assessment of economic impacts

This measure concerns the implementation of national mercury reduction commitments, similar to those currently applied under the National Emissions reduction Commitments Directive (NECD). Reduction targets could have implications for mercury emissions from sectors beyond just crematoria, and the exact impacts of such a commitment would depend on individual Member State implementation of the targets. For the purpose of assessing impacts, it has been assumed that this measure would increase mercury emissions abatement uptake to 100% in Member States where no regulation is currently in place. Consequently, the number of impacted installations is the same as set out in CRE#2a, and the economic impacts are expected to be of the same scale.

However, in practice there may be other sectors and emission sources where mercury emissions could be reduced more cost-effectively than in crematoria thus uptake of abatement may be much lower. To estimate where emissions could be reduced more effectively, an in-depth technical assessment of emissions and abatement options and scenarios (including cost analysis) would need to be undertaken using an integrated assessment model, similar to that applied previously to underpin the NEC Directive revision.

Assessment of social impacts

The implementation of emission reduction targets is expected to have the same impact as CRE#2a (BAT and ELVs) in terms of abatement uptake. The impact in terms of emission reductions will therefore also be the same, and the benefits in terms of human health impacts will be the same as those described for CRE#2.

Assessment of environmental impacts

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[90] Rounded to the nearest €100,000, unless otherwise stated.
[91] Rounded to the nearest €1,000.
[92] Rounded to the nearest €10,000.

Environmental benefits resulting from mercury emissions reductions induced by this measure will be the same as those described for CRE#2a.

Problem Area 3: Manufacture of MAPs for export to third countries

A quantitative assessment of the impact of policy options was only possible for fluorescent lamps. For this product, export data are available from the trade statistics of the EU (PRODCOM split by CFL and double capped fluorescent lamps) and the UN (CONTRADE for all FL types). For all other products, quantitative data representing the whole market were unavailable. For these, only a qualitative analysis was performed.

The following analysis focuses on the impacts of a global ban on the production and export of fluorescent lamps from the EU. These are, at least to a large extent, the subject of negotiations at the level of the Minamata Convention. Sufficient data are available for these lamp types that allow a quantitative assessment of production and export bans. According to information from manufacturers as well as available trade data, other lamp types (fluorescent lamps for special purposes, HID lamps) are of much lower relevance in terms of trade volume and mercury content. The data situation is much worse here. Existing EU instruments address only a minor part of the total spectrum of lamps, and aggregated trade data do not allow a detailed analysis of internally prohibited subtypes. However, the qualitative effects described in the following text on fluorescent lamps also apply in principle to the other lamp types and are therefore not explicitly repeated.

If the EU further proceeds to support a global ban, an actual agreement at the MC COP remains uncertain and the impact of this policy measure may be zero. The following analysis describes the impact a global ban would have if agreed to come into effect at the beginning of 2026/2028.

Measure MAP#1: Aim at global agreement to restrict manufacture and export and subsequent implementation in EU law

Assessment of economic impacts

To quantify the monetary impact of a global ban, lost exports are accumulated for the years after a ban becomes effective within the EU (considered to be in the same year as determined under the Minamata Convention) until the end of 2030. The accumulated value of exported FLs is dominated by sales in the coming few years. The earliest possible year for a global ban would be 2026 and would affect only halophosphate LFLs

Under a global ban scenario, EU exports of FLs would stepwise decrease to zero between 2026 and 2030 (Figure 9). The accumulated number of exported FLs would be 167 to 308 Mio units in comparison to €412 to €693 million in the BAU2 baseline. The calculated accumulated loss of export value would be €97 to €190 million between 2025 and 2030 (Table 31). If it is not possible to gradually switch production to other products by the phase-out date, the allocated sales would cease completely. On the other hand, demand for lighting products in general will not be affected by a global ban but instead is expected to increase (by about 4% annually). Thus, manufacturers have opportunities to compensate for losses in the conventional lighting sector, e.g., by selling LED lamps/luminaries and smart lighting systems. A look at the export figures of the past years shows that this is only partially successful (UN COMTRADE). For example, between 2017 and 2020, the value of discharge lamps exported from the EU fell by €145 million (from €362 to €216 million), while the value of LED lamps exported increased by only €101 million, from €101 to €202 million. The overview may be incomplete as luminaires and lighting systems are not included here.

The two production sites of fluorescent lamps (Erlangen, Piła) that will remain after the end of 2022 are in different stages of increasing the level of LED production. The remaining share of FLs in factory output is not known. At least for Erlangen, it has been reported that the focus is now on LED luminaires[93]. This corresponds to a decline of 85% in value of FLs exported from Germany between 2018 and 2021. On the other hand, FL exports from Poland increased by about 10% between 2018 and 2021[94]. It has been reported that FL production from another, now closed site in the USA has recently been relocated to Poland[95] which probably contributed to stabilize the production of conventional lamps at the Piła site.

From the remaining two manufacturing sites, the smaller Erlangen factory would probably face relatively low impacts as the conversion to LED production is in an advanced state. Production at the Piła site is much more significant and would require considerable investments to maintain the level of production once FLs are no longer allowed to be manufactured. A recent study provided an estimate of about €15 to €10 million conversion costs per plant (Erlangen and Piła), although the rationale of this figure is not entirely clear[96].

Table 31: Impact of policy measures on exported lamps, their value and mercury content

Scenario/ measure	Exported units 2025-2030 (million)	Loss of export value 2025-2028 (million €)	Mercury content in exported lamps 2025-2030 (t)	Net change of mercury in imported lamps in comparison to BAU2 (related to EU exports) (t)

[93] Highlight Web (2022) Umsetzung der RoHS-Richtlinie bei Sylvania. https://www.highlight-web.de/7105/rohs-aus-fuer-leuchtstofflampen-frueher-als-gedacht/

[94] UN COMTRADE: from 156 to 169 Mio units

[95] EdisonReport (2020) Signify to Relocate Production and Close its Facility in Salina, Kansas. https://edisonreport.com/2020/08/13/signify-to-relocate-production-and-close-its-racility-in-salina-kansas/

[96] CLASP (2022) Refurbishing Europe’s Fluorescent Lamp Manufacturing Facilities. https://www.clasp.ngo/wp-content/uploads/2022/02/EU-Upgrading-Fluorescent-Manufacturing-to-LED-Report.pdf

BAU2	412 – 693	0	1.21 – 2.17	0
MAP#1 Global ban 2026/2028	167 – 308	97 – 190	0.41 – 0.72	-1.50 - -0.92
MAP#2a EU ban 2025	0	191 – 347	0	-0.53 – 1.59
MAP#2b EU ban 2026/2028	167 – 308	97 – 190	0.41 – 0.72	-0.32 – 1.12
EU ban 2026/2028 followed by a global ban 2026/2028	167 – 308	97 – 190	0.41 – 0.72	-1.50 - -0.92
EU ban 2026/2028 followed by a global ban 2028/2030	167 – 308	97 – 190	0.41 – 0.72	-0.53 - -0.23

Figure 9: Predicted FL exports 2025- 2030 under different scenarios

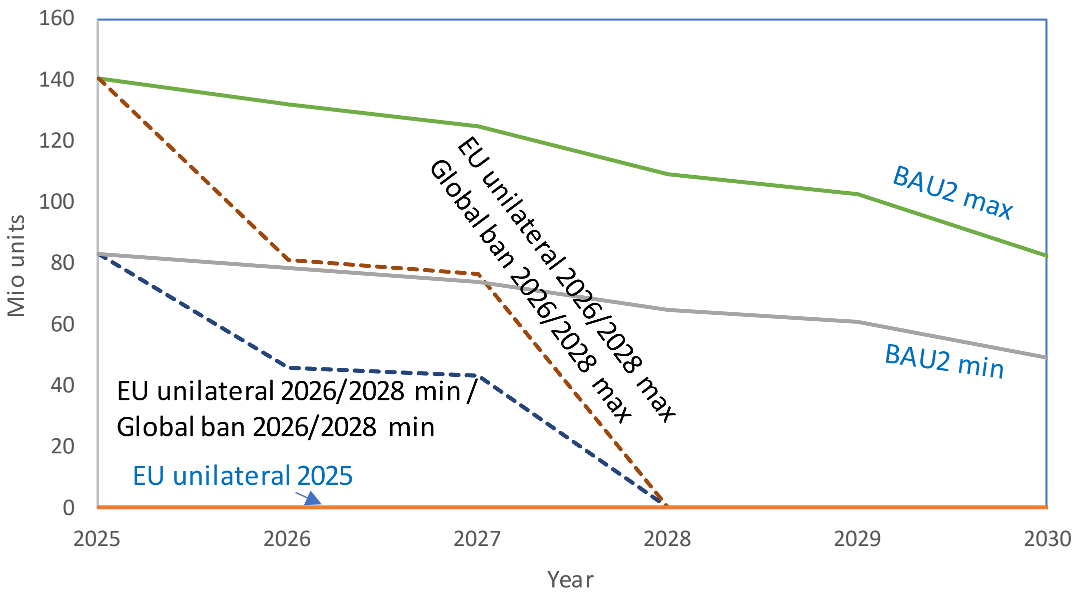
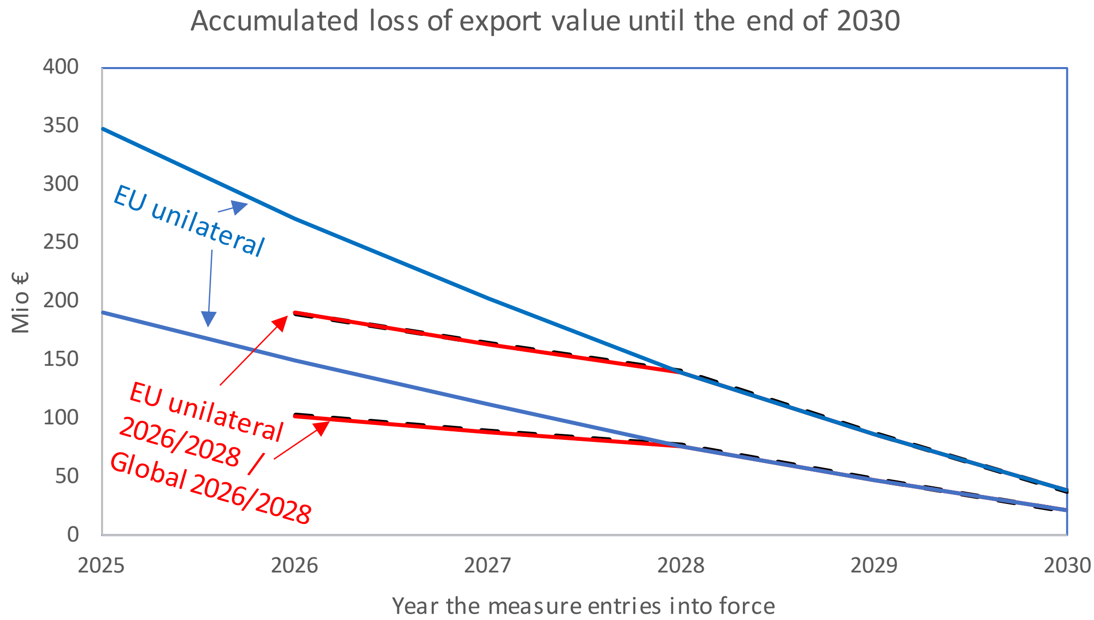


Figure 10: Accumulated loss of export value for fluorescent lamps until the end of 2030 in case of a global or an EU export ban (MAP#1, MAP#2a, MAP#2b) in comparison with the BAU2 baseline (55% halophosphate in double-capped FL)



SMEs would not be affected by an export ban for FLs since both remaining manufacturers belong to large company groups. Little administrative burden would be put on business because the ban would lead to a complete closure of production lines.

A global ban would have little impact on competitiveness since all main manufacturing countries worldwide are affected in the same way. However, some countries are not Party to the Convention and others may opt to postpone application of newly listed product by five years (opt-out) or not apply the ban at all until a national decision is taken (opt-in). These markets would become unavailable for European manufacturers while non-Parties may increase sales. Among the main importing countries are Egypt, Russia, and Turkey that receive 25% of European exports (due to the Russian invasion of Ukraine, lamp exports to Russia have partly stopped in spring 2022. It is not clear if and when they may resume[97]). Opt-out countries such as India may export higher amounts of lamps to such states at least for a couple of years until the general decrease of demand will diminish exports again.

The number of affected employees can be estimated only roughly. At the Erlangen site that already converted its production largely to LEDs, about 200 employees are working[98]. Only a small share is considered to be directly involved in the FL production. The current number of employees at the Piła site is unknown. Data from publicly available databases indicate that the total number of employees of Signify in Poland was around 3,000 in 2016. Which part of this staff can be attributed to FL production in Piła

97 Eindhoven Dagblad (2022) Eindhovens lichtbedrijf Signify staakt export naar Rusland. https://www.ed.nl/eindhoven/eindhovens-lichtbedrijf-signify-staakt-export-naar-rusland~a3b21be2/?r

98 Elektro.at (2020) Feilo Sylvania Germany flüchtet in Schutzschirm-Verfahren. https://elektro.at/2020/02/04/feilo-sylvania-germany-in-schutzschirm-insolvenz/

cannot be estimated. But if it is assumed that in 2020 50% of the staff in Erlangen (100 from 200 total) was still involved in FL production and about 50% of the production was exported[99] (15 million units, 50 employees) then the output of 170 million Units in Piła would require roughly a tenfold number (around 500). The number of current employees is expected to decrease even without a ban. A global ban becoming fully effective in 2028 would affect approximately 40-56% of the export volume of 2020 and probably the same share of the remaining workforce.

The end of FL production would also have an indirect impact on the European logistics centres as well as on suppliers of components (e.g., ballasts, glass tubes). The numbers of employees in wholesale/ logistics that would be affected is considered small in relation to the employees directly involved in the production (around 10%[100]). As the demand for lighting products in general is expected to increase[101], also because there is a need to replace old lamp types and luminaires, the global overall net effect on employment is expected to be positive. In the EU, however, this trend is likely to compensate only part of the loss of employment as about 60-70% of LED related jobs (especially for the production of LED components) is located outside the EU. Therefore, even if EU manufacturers could mostly replace current FL exports by exports of LED lamps and luminaires, the need for employees at EU factories could be lower due to the lower real net output ratio.

For Europe, average costs for replacement of T5 and T8 luminaires were estimated to be in the order of €231 and €186, respectively[102]. Outside the EU, costs will vary according to national requirements and labour costs but will remain significant. No attempt was made to calculate replacement costs in individual markets.

A global ban on other mercury-containing lamps (HID, other low pressure discharge lamps) would have a limited impact. If HID lamps in the order of 8% became subject of a ban in 2028, about 3 million lamps with a value of about €25 million could not be exported between 2028 to 2030. That is less than the typical annual fluctuation in exports. The market for these lamp types is much more heterogenous with a larger number of manufacturers, including SMEs. Due to the limited impact on the market as a whole, no further analysis of specific impact on SME was conducted.

Impact on public authorities, consumers and households

As a global export ban would mainly affect manufacturers and distributors, little to no impact is expected for public authorities, consumers and households.

Assessment of environmental impacts

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[99] The ratio of exported and produced FL lamps was about 53% between 2016 and 2020 (EU PRODCOM)

[100] European Commission (2019) Commission staff working document. Impact assessment. Commission Regulation (EU) .../... laying down ecodesign requirements for light sources and separate control gears pursuant to Directive 2009/125/EC of the European Parliament and of the Council

[101] Zissis et al. (2021) Update on the Status of LED-Lighting world market since 2018. JRC Technical Report. EUR 30500 EN

[102] Öko-Institut e.V., Institute for Applied Ecology, and Fraunhofer-Institut for Reliability and Microintegration (IZM) (2019) Study to assess socio-economic impact of substitution of certain mercury-based lamps currently benefitting of RoHS 2 exemptions in Annex III

A global ban on fluorescent lamps for general lighting purposes would primarily result in less mercury being needed within the European Union for the production of discharge lamps. To the same extent, the mercury content of exported lamps would decrease. With a ban taking effect in 2026/2028, this would affect a quantity of 0.8 to 1.5 t of mercury in the period 2026-2030. Given the low recycling rates, about 85% of this amount (0.7 to 1.3 t) would not enter the general waste stream and, at least in some importing countries would not contribute to a contamination of soil and the emission of mercury into air. After the ban of other products, fluorescent lamps are now the most relevant MAP for consumers (beside dental amalgam). Eliminating FLs and other mercury-containing lamps from circulation in the society would remove one of the most important sources of product-related mercury contamination in many importing countries.

Replacing FLs with LED retrofit lamps or LED luminaires results in significant energy saving. The degree depends on the individual solution found at each installation point, operating conditions and the use pattern (e.g., residential, non-residential). It cannot be easily calculated on a global scale. The lowest values are typically experienced with retrofit lamps the highest with smart LED lighting systems. For example, replacing CLFs with LED typically led to energy savings in the order of 25-40% in residential settings and up to 52% in commercial buildings. Considerably higher energy savings of up to 70% and more were reported for smart lighting systems[103].

No attempt was made to precisely predict global energy savings due to the high uncertainties but to get an idea of the order of magnitude the following calculation was performed:

- For simplicity it assumed that all sold lamps are 32W T8 LFLs with an annual operation time of 2200 h[104] and a lifetime of 20000 h (about 9 years)
- in 2028 (the earliest considered year, where all FLs could be banned globally) the number of sold lamps is predicted to be 65 to 109 Mio units (BAU2).
- The total annual energy consumption of these lamps in 2028 would be 4.6 to 7.7 TWh. For comparison, total energy consumption for lighting is estimated to be at 2900 TWh per year.
- If replaced by LEDs and assuming an energy saving of 25 to 40% per lamp, the energy saving would be in the order of 1.1 to 3.1 TWh in that year
- Energy savings would accumulate during the following years as more FLs are replaced. Within a typical lifetime of a new LFL T5 the total energy savings would be in the order of 10 to 28 TWh. Considering a carbon intensity of 475 g CO_2/ kWh[105] this would result in a lifetime saving of about 5 to 13 Mt CO_2.

This is only a rough calculation for the impact of global ban would have in 2028. A similar but slightly smaller effect would have to be added for each following year as the predicted but decreasing FL sales are substituted by LED. Consequently, the cumulative

[103] Soheilian, M.; Fischl, G.; Aries, M. (2021) Smart Lighting Application for Energy Saving and User Well-Being in the Residential Environment. Sustainability 13, 6198

[104] VITO (2015) Preparatory Study on Light Sources for Ecodesign and/or Energy Labelling Requirements ('Lot 8/9/19'). Final report, Task 3. Use of Light Sources

[105] IEA (2019) Global Energy & CO2 Status Report 2019. https://www.iea.org/reports/global-energy-co2-status-report-2019

effect of a ban becoming effect in 2026/2028 would be multiple times this value. It must be stressed that this calculation only addresses EU exports.

Assessment of social impacts

A global ban would lead to the phase-out of more than 90% of the remaining production of mercury-containing lamps, thus removing mercury as a hazard from several production lines and many workplaces. It is understood, however, that working conditions at European manufacturing sites already reduce the risks of mercury exposure to a minimum (e.g., by automated dosing) so that the improvement of actual working conditions would be limited. Besides that, no further social impacts for citizens within the EU were identified.

For citizens in importing countries the phase-out of mercury-containing lamps would eliminate the most important source of product-related mercury exposure. New input of mercury in general waste would be avoided, so that population that is working with waste (e.g., waste pickers) or is living near waste dump sites has a lower risk of getting in contact with mercury.

Measure MAP#2(a and b): EU legal ban on MAP manufacture and export

Assessment of economic impacts

Mercury-containing lamps

A European export ban would prevent exports of MAPs to third countries unilaterally. Two variants of such a ban are considered here:

- MAP#2a: Export ban from 2025 for all MAPs for which the placing on the market within the EU is already prohibited by that time.
- MAP#2b: Gradual export ban based on the earliest deadlines under discussion in the negotiations at the Minamata Convention (COP5) level:
    - 2026: Halophosphate LFL ≤40 W
    - 2028: Triband LFL <60 W as well as all other MAPs (yet to be proposed by the EU or other Parties).

In the context of this analysis, as before, only exports of fluorescent lamps for general lighting purposes are discussed in a quantitative manner.

According to the first variant, all exports would end from 2025, so that 412 to 693 million FLs would not be exported. Their accumulated export value in the period 2025 to 2030 is 191 to €347 million (Table 31, Figure 9). With a ban only in 2026/2028, 167 to 308 million units could still be exported and the loss would decrease to €97 to €190 million, the majority of which (78%) can be attributed to double-capped fluorescent lamps. The impact on employment would be slightly higher in case of an export ban in 2025 as the measure takes effect some years earlier than a global export ban but otherwise it is expected to be in the same order of magnitude. For an export ban in 2026/2028 the effect would be the same as estimated for a global ban.

The announcement of an EU ban would likely lead to increased production and export in the time directly before the phase-out date. On the one hand, users may like to increase their stocks before EU supply is no longer available. On the other hand, distributors outside the EU are confronted with continuing demand for EU made lamps may also increase their stocks to provide such lamps after the export ban has entered into force. This extra demand is mainly limited by available shelf space, the costs for bound capital and the expectations regarding future sales. Such effects have been observed on the lamp market before[106] and are likely to repeat again, however the effect cannot be reliably quantified.

In this context, industry stakeholders suggested that lamps that have previously been legally imported by distributors for the purpose of re-export should be exempted from an export ban. Alternatively, an import ban could precede the export ban with a time lag in order to accelerate the reduction of stocks.

If it is assumed that around 8% of the current HID lamp exports would be affected by an export ban, about 6 million units of HID lamps could not be exported within 2025 to 2030. Their value is at approximately €55 million. An export ban in 2028 would reduce HID lamps exports by about 2.8 Mio units until 2030 (foregone revenues would be about 26 Mio. €).

An EU export measure would impair the competitiveness of EU manufacturers as they are cut off from markets manufacturers from third countries still have access to. EU manufacturers for fluorescent lamps belong to larger company groups that may at least partially shift production capacities to factories outside the EU. This does not necessarily apply to SMEs that are producing other lamp types. However, as said before only a small fraction of HID exports is affected and the relocation of production capacities may not be necessary.

The effect on employment for FL production would be like that described for MAP#1 (global ban). In the case of a later export ban, the value would likely be lower as exports and thus employment linked to these exports are expected to decrease even without a ban. The major difference would be that EU manufacturers could not count on a corresponding higher demand for LED products, as the demand for lamps would at least in part be met by FL exports from other countries. Accordingly, compensating employment for LED production would be lower than in the MAP#1 scenario.

Dental amalgam

According to observed global trends, demand for dental amalgam and exports from the EU are likely to decrease. An EU export ban from the EU would accelerate this process. All four identified manufacturers that have not yet announced an exit from the market belong to SMEs. According to publicly available information, the total turnover of all companies is around €40 million and the number of employees around 200. Only part of these sums is attributable to the manufacture and sale of dental amalgam. Two of these companies specialize to a large extent in dental amalgam. They also offer other dental products, but no other filling materials (Global Dental Trade, World Work Srl). Depending on the relevance of the amalgam business, a manufacturing and export ban could result in a significant reduction in sales and employment.

Based on the estimates in this study, in 2025 about 13 to 55 million amalgam capsules will be exported. At a retail price of about €1 per capsule, the retail value of exported

[106] For example low pressure sodium lamps (SOX) that went out of production in 2019. See: Lamptech (2020) Philips Hamilton Factory http://www.lamptech.co.uk/Documents/Factory%20-%20UK%20-%20Hamilton.htm

capsules would be about €13 to €55 million. An export ban in 2025 would affect predicted sales with a total retail value of about €50 – €300 million in the period 2025-2030. If export is phased-out only in 2027 the loss of sales would amount to €30 – €200 million in 2027 to 2030. Because of the costs in the intermediate trade, the manufacturers' sales value is considerably lower.

Assessment of environmental impacts

Mercury-containing lamps

An EU export ban from 2025 would avoid the use of about 1.21 to 2.17 t of mercury in European lamp products between 2025 and 2030. About 85% of this amount or 1.0 to 1.9 t would not enter the general waste stream in importing countries. With an export ban from 2026/2028, the mercury content in exports would decrease by 0.8 to 1.5 t (Table 31) and the mercury input into general waste by 0.7 to 1.3 t. However, this is countered by the amount of mercury contained in fluorescent lamps that are imported instead of European lamps. This assessment considers a level of substituting imports in the range of 50 to 90%. Higher values were expected by industry representatives and cannot be ruled out, but some probable market effects speak against this (including stockpiling before an export ban becomes effective, price increases due to lower competition, political imitation effects, non-availability of technically equivalent competing products). Low values significantly below 50% were expected by other stakeholders and cannot be completely dismissed either. However, the availability of technically equivalent products, at least for mainstream lamps from non-European manufacturers, suggests that a halt to European exports is not associated with a sudden collapse in demand. This is all the more true as the challenges of switching to LED lamps or luminaires remain unchanged (including high initial costs when rewiring or luminaire replacement becomes necessary, lack of availability of trained personnel, lack of retrofit products). The shorter the changeover period, the more likely it is that FL imports from other countries will be used as a substitute, as users have less time to adapt to alternative solutions in organisational and financial terms.

In addition, non-European FLs have a significantly higher average mercury content (Table 32). While the difference for CFL.ni lamps is often only small and amounts to only a few tenths of a milligram, the difference for FL lamps and there especially for halophosphate lamps is higher (3 to 5 mg per lamp). Since halophosphate LFLs account for about half of LFL exports and LFLs in turn account for 77% of all FL exports, this difference is reflected in the overall balance.

Table 32: Medium mercury content of fluorescent lamps made in the EU and in third countries

Lamp type	Made in the EU [mg Hg / lamp]	Made in third countries [mg Hg / lamp]
CFL	1.8	2.1 – 2.8

LFL triband	1.7 – 1.9	2.6 – 3.2
LFL halophosphate	5	8 – 10

Source: Published data from manufacturers in the EU and third countries on the mercury content of CFL and LFL subtypes weighed with their EU market share (only CFL and triband LFL) [107]

Against this background, the volume of substituting imports was first calculated and then the amount of mercury contained in these imports. For the scenario of an export ban from 2025, the substitute FLs would have a mercury content that is 0.53 t lower but can also be 1.59 t higher (Figure 11). The low values of this range are only realised when low substitution rates and low mercury contents in substituting imports coincide. The range is smaller if an export ban is considered from 2026/2028 (-0.32 to 1.12 t).

Looking at global market, total sales (and trade) are expected to further decrease. Therefore, any potential short-term increase of the total mercury content in lamps imported by third countries is compensated within a couple years by the overall trend of decreasing usage of fluorescent lamps.

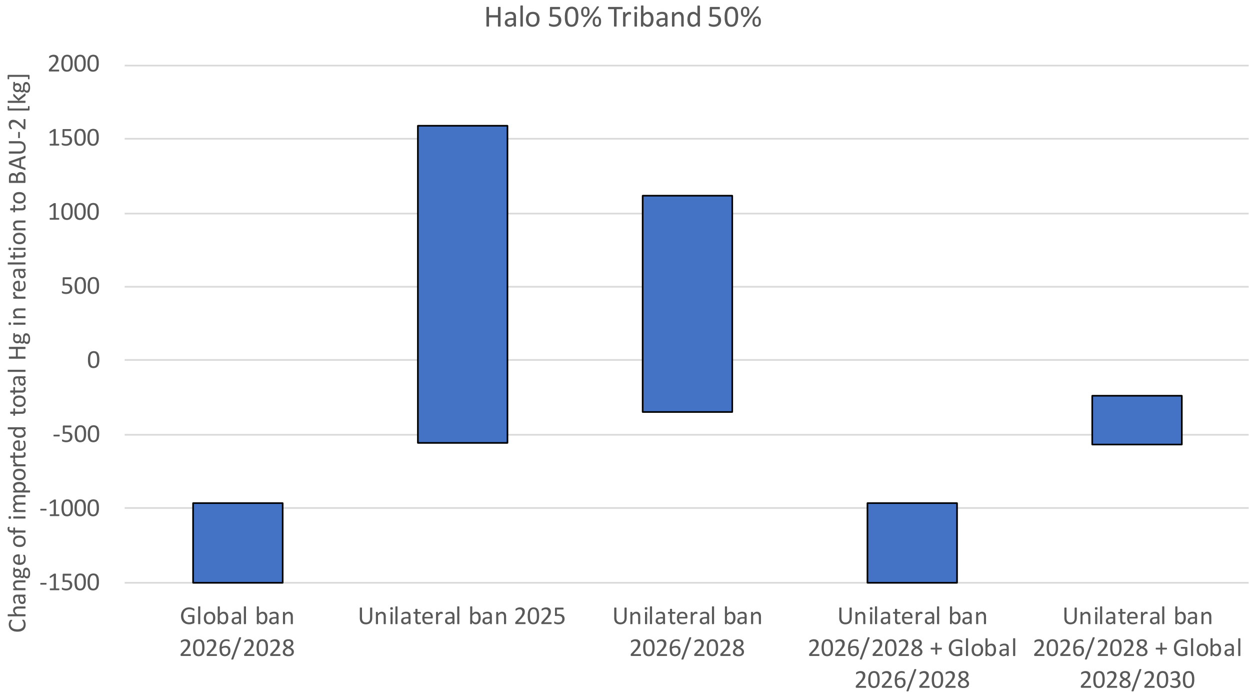
A decision by the EU is not detached from further negotiations at the international level. If the European export ban and a global ban coincide in 2026/2028, the effect is equally positive as if there had only been a global ban (-1.50 to -0.97 t). Should the global ban occur two years later (2028/2030), the net effect is still positive (-0.57 to -0.24 t), as substitute imports could only occur for a maximum period of two years.

For HID lamps the environmental impact is expected to be limited. Due to the low number of exports and the small fraction of lamps that are prohibited within the EU, the total mercury content in relevant exported lamps may be in the order of 20 kg only.

Due to the issue of substituting imports, supply of mercury-containing lamps would not be completely cut and input into the general waste stream would pertain, probably with a lower number of lamps. Based on the considerations above, the input may decrease or increase, at least if only imports from the EU and substituting imports are considered.

[107] Lighting Europe (2020); Request to renew Exemptions 1(a, b, c, e) / Request to renew Exemptions 1(g) and 2(a)5 / Request to Request to renew Exemptions 2(a)(2), 2(a)3, and 2(b)3 / Request to renew Exemptions 2(a)(2), 2(a)3, and 2(b)3

Figure 11: Accumulated net change of mercury content in imported FLs (related to EU exports)



Dental amalgam

In the case of an export ban in 2025, the mercury content of exported dental amalgam would decrease by approximately 30 to 180 t in the years 2025 to 2030. A later phase-out (2027) would result in a decrease of 20 – 120 t. The reduced exports, if not substituted by dental amalgam supply from other countries would result in reduced mercury releases to air and soil in the same order of magnitude. In the absence of national legislation or standards, demand from patients and practitioners is likely to remain at a similar level. The demand would then be met by manufacturers outside the EU that are able to provide dental amalgam capsules with similar characteristics. Among them are one or two manufacturers that have recently relocated their production from the EU to third countries. However, the lower number of competitors may lead to higher prices and making mercury-free alternatives more attractive for those who are able to pay for the price difference. Others may opt for cheaper but less durable treatments (e.g., glass ionomers) or extraction. The summary effects cannot be reliably predicted, but overall, it may be expected that total supply, use of dental amalgam, mercury consumption and mercury releases stay at the same or a slightly lower level. The net environmental impact of an EU ban is expected to be close to zero or slightly positive.

Assessment of social impacts

Mercury-containing lamps

In principle the same impacts as discussed under ‘global ban’ would apply. But in contrast to a coordinated global approach, mercury-containing lamps would still flow into the markets and circulate, so that the threat of mercury contamination of land and mercury emissions to air is not eliminated. There are scenarios that lead to a decrease of mercury input into the society, thus reducing the risk of exposure and contamination.

Other scenarios could lead to increased mercury amounts because of imports with a higher mercury content. Such negative impacts are limited to a couple of years until the predicted decrease of sales compensates a possible short-term effects or measures on the national or global scale to ban of imports from all countries.

According to feedback from an industry association, lamps no longer produced in the EU may be replaced in the markets by mercury-containing lamps manufactured outside the EU under likely lower health and safety standards.

Dental amalgam

In case of an EU ban on dental amalgam export, access of practitioners to dental amalgam could become more difficult. This affects mainly those markets that currently receive most exports. According to information from one manufacturer, these are low-income countries in North Africa, the Middle East and Asia. No information is available on the supply situation in these countries so that it is not clear whether alternative suppliers from other global regions could step in to meet the demand. The situation may get more complicated in the future because there is a decline of the number of worldwide amalgam manufacturers (for example, two major US companies have recently announced to stop amalgam production). Moreover, market entry of new providers may be slowed by registration / authorization procedures.

However, according to available information, there are several manufacturers outside the EU left, that in principle could sustain supply with dental amalgam capsules.

As a consequence, there may occur situations in third countries where amalgam supply becomes insufficient or available only at higher prices. In that case, practitioners may have no achievable, equally effective filling options to treat their patients – composites cannot be applied by all practitioners because they lack the necessary equipment and/or training while other materials such as glass ionomers have a lower lifetime and are not suitable for all cavities. An EU export ban for dental amalgam may therefore have a negative impact on dental care in certain countries and impair their autonomy to organize the health systems according to their self-defined priorities.

Measure MAP#2c: EU legal ban on MAP manufacture and export and administrative /scientific support for importing third countries

Assessment of economic impacts

Cooperation with importing countries can help to create a level playing field for all market participants, so that substitute MAP imports from third countries are reduced or eliminated. In principle, all countries that import MAPs from the EU are eligible for cooperation and support programmes. Of particular importance are discharge lamps and dental amalgam. The greatest effect is achieved when cooperation focuses on countries or groups of countries with relevant import volumes. The success of a cooperation depends on various factors. First, the willingness of the respective country to cooperate with the EU on MAP issues has to be won. Secondly, sufficient time and commitment on both sides are necessary to find solutions that are in line with the priorities and approaches of the respective country. Furthermore, depending on the type of approach, time is needed to codify the solution, whether through legal instruments, standards, or incentive programmes. Years can pass between the start of outreach and a measure taking effect.

The strong support from Parties for the phase-out periods recently discussed at MC COP4 shows that many countries are willing to phase out the use of discharge lamps. It can therefore be expected that the interest in cooperation, which ultimately also serves the implementation of the Minamata Convention, is relatively high. This should also apply to countries that have expressed reluctance or are not parties to the Convention (e.g., Egypt, Turkey, Iran), because no fundamental opposition, e.g. to the use of energy-saving lamps, has been voiced so far.

The established programmes and cooperation formats (see above) offer a good basis for initiating and deepening cooperation. To what extent and when such bilateral activities lead to effective national policies is difficult to assess – empirical values are not available here. Such activities could make an important contribution to avoiding or at least reducing the unintended negative effects of EU export bans. Regarding further product-related regulations – the RoHS directive lists nine other substances banned in electrical products in addition to mercury – cooperation is also of interest in the long term. The achievement of European environmental goals, as outlined in the European Green Deal, cannot be achieved in isolation, but only in partnership with other countries. For this reason, cooperation on the topic of MAPs can play a pioneering role here and open doors that can be used for other focal points of European environmental policy.

The cooperation programmes would have no direct impact on companies and employees, as they are only meant to complement an EU export ban. However, if successful they would open opportunities for European lighting companies to increase sales of LED systems in partnering countries as these need to replace FL based lamps and luminaires.

There is a limited, unquantified burden on those European and national authorities that actively participate in collaborations. It is assumed that the contribution is made in-kind and incurs only limited additional costs. Limited funding is required to support programmes such as U4E or projects such as the Specific International Programme. The amount depends on the level of participation desired and cannot be estimated.

Assessment of environmental impacts

The quantitative impact of cooperation and support programmes cannot be estimated. It should be borne in mind, however, that the time required between a measure being initiated and becoming effective can quickly span several years, as can be seen, for example, from legislative procedures. In the case of a relatively short-term export ban, e.g., a ban adopted at the end of 2023 and taking effect at the beginning of 2025, it is doubtful that results from other countries will already be available at the beginning of the ban. To be able to use the instrument meaningfully, it must be coordinated with the envisaged export ban. A few years' lead time seems appropriate here.

However, based on the projections of the net change in mercury content, it can be determined by back-calculation that addressing e.g., 20% of the export volume is sufficient to halve the maximum possible negative effect caused by substituting imports. Measures in one or two of the most important trading partners would be sufficient to achieve this.

A side-effect of such activities would be energy-savings, medium-term cost savings and less CO_2 emissions in the partnering countries. They would be proportional to the number of lamps not imported from third countries.

Assessment of social impacts

The measures do not have a social impact in the EU.

Measure MAP#3: Prior Informed Consent (PIC) procedure for dental amalgam

Economic impacts

A PIC procedure would give importing third countries the possibility to prevent direct imports from the EU. However, it is not possible to estimate which third countries may choose to disagree with future imports and what share of current exports may be affected by such decisions.

Administrative burden on businesses and public authorities: Impacts may be expected for public authorities and companies that are concerned with a PIC procedure to allow exports. Furthermore, such an option would require amending the existing PIC Regulation[108] which currently does not provide for PIC procedure for MAPs but simply requires exporters of MAPs to submit an export notification to their competent authorities. Such an amendment to the PIC Regulation would imply the implementation of a prior informed consent procedure whereby a significant burden on the exporter and its competent authority but also on importing third countries (information exchange, formal consent for export and import etc.).

Environmental impacts

The direct environmental effect of the PIC procedure is all but certain as it will depend on third countries' willingness to prohibit the import of EU-made dental amalgam. Should third countries not be pro-active in their objectives to eliminate dental amalgam use, exported volumes may remain high and yield low environmental benefits.

Social impacts

The measure would have no social impact in the EU but could avoid unwanted exports of mercury to third countries and a decrease of mercury input into waste streams, should those countries show political willingness as well as administrative capacities to handle burdensome prior informed consent procedures.

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[108] Regulation (EU) 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals (OJ L201, 27.7.2012, p. 60).

Discarded policy measures and rationale

The initial screening of the long list of policy measures has been carried out using the screening criteria defined in the BR Tool#16:

- **Legal feasibility**: Options should respect the principle of conferral. They should also respect any obligation arising from the EU Treaties (and relevant international agreements) and ensure respect of fundamental rights. Legal obligations incorporated in existing primary or secondary EU legislation may also rule out certain options.
- **Technical feasibility**: Technological and technical constraints may not allow for the implementation, monitoring and/or enforcement of theoretical options.
- **Previous policy choices**: Certain options may be ruled out by previous Commission policy choices or mandates by EU institutions.
- **Coherence with other EU policy objectives**: Certain options may be ruled out early due to poor coherence with other general EU policy objectives.
- **Effectiveness and efficiency**: It may already be possible to show that some options would incontrovertibly achieve a worse cost-benefit balance than some alternatives.
- **Proportionality**: Some options may clearly restrict the scope for national decision-making over and above what is needed to achieve the objectives satisfactorily.
- **Political feasibility**: Options that would clearly fail to garner the necessary political support for legislative adoption and/or implementation could also be discarded.
- **Relevance**: There is no point in retaining options that do not address the needs of the policy intervention as identified in the problem definition.
- **Identifiability**: When it can be shown that two options are not likely to differ materially in terms of their significant impacts or their distribution, only one should be retained.

The initial screening of the longlist of policy measures and those that were discarded at an early stage is set out in Table 33 along with the rationale for their exclusion.

Table 33: Discarded policy measures rationale (initial screening of long list)

Policy measure	Rationale for exclusion
1. Removal of dental amalgam pre-cremation	The removal of dental amalgam pre-cremation was deemed inappropriate for action at EU level due to sensitivity issues and the likely burden on crematoria operators to implement this, requiring expertise and time for the removal.
2. Voluntary agreement by lamp manufacturers to phase down the production of mercury containing lamps by specific dates	Choosing a voluntary approach would be in strong contract to previous EU Conclusions that only mandatory approaches are effective enough to address the production and trade of MAPs. Moreover, the approach would open legal loopholes and advantages for market participants that do not participate in the agreements.

Policy measure	Rationale for exclusion
3. Extended producer responsibility by requiring Industry-led measures to improve the management of hazardous mercury containing lamps in importing countries (outside the EU)	The EU has no means to ensure implementation or to monitor the results of these measures, considering they take place outside of the EU and its market. Experience shows that improvements in waste management systems are slow and require considerable resources. Hence, this option is unlikely to be effective.
4. Establishment of Prior-Informed Consent (PIC) procedure for mercury containing lamps	PIC sets a prior informed consent procedure for the export of hazardous substances and articles containing such substances, which does not amount to an outright prohibition. PIC sets export bans in its Annex V only once such bans are already set out in other EU instruments, such as the Mercury Regulation. Such amendments to Annex V to PIC are developed for consistency purpose across applicable Union legislation.
5. Export duty on relevant mercury-added products (MAPs)	This measure would only have a limited effect on demand in importing third countries and export would still be allowed. Moreover, this measure would incur significant additional administrative costs.
6. Raising awareness about mercury content and potential hazard of MAPs	This measure was not considered feasible on a global scale, incurring high costs and resulting in low effectiveness.
7. Reducing the allowed mercury content in manufactured and exported MAPs	This measure would not reduce EU exports. On the global scale, it would be a political backward step as the EU has been a proponent with other Parties to the Minamata Convention to a full ban of such products.

Following inter service consultation within the Commission as well as discussion with the RSB, a number of policy measures / options considered within the initial impact analysis (and documented in this annex) were discarded and not considered further within the SWD. These are described in Table 34.

Table 34: Discarded policy measures rationale (discarded at a later stage and not considered further in the SWD)

Policy measure	Rationale for exclusion

Policy measure	Rationale for exclusion
1. Decrease the price difference between dental amalgam and mercury-free alternatives	The EU has a limited competence in the field of public health and is not entitled to act as a price regulator, i.e., Union action needs to respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care, including the allocation of the resources assigned to them. Hence, whereas the option consisting of reducing the difference between the social security reimbursement rates for dental amalgam and mercury-free filling materials could prove efficient in incentivising consumers towards opting for the latter, it would require fundamental changes in terms of competence-sharing between the EU and the Member States in the field of public health, which are highly unlikely.
2. Issue EU guidance on mercury emission abatement technology for controlling mercury emissions from crematoria, alongside voluntary agreement from the sector.	The crematoria sector is not very organised at EU level as it is not a competitive sector. Experience from voluntary agreements shows that such measures result in low effectiveness and require heavy instruments to manage. Moreover, the approach would open legal loopholes and advantages for market participants that do not participate in the agreements.
3. Mercury benchmarks / reduction targets	This measure was considered to overlap with CRE#2 and the requirement for application of BAT so was discarded on this basis.
4. Burden sharing agreements	A burden sharing agreement was considered to be most applicable at a national level e.g. as it has been applied in the UK. This was not considered to be a feasible option for development or implementation at an EU level.
5. National mercury reduction targets	This measure would go beyond the focus of the problems identified for the revision of the Mercury Regulation i.e. it could capture emissions from all sectors and not just crematoria. This was not considered feasible to develop or the most effective instrument for tackling emissions specifically from crematoria.
3. Introduce a PIC procedure to enable third countries to decline the import of dental amalgam capsules from the EU	PIC sets a prior informed consent procedure for the export of hazardous substances and articles containing such substances, which does not amount to an outright prohibition. PIC sets export bans in its Annex V only once such bans are already set out in other EU instruments, such as the Mercury Regulation. Such amendments to Annex V to PIC are developed for consistency purpose across applicable Union legislation.

ANNEX 8: EU and International law on Mercury in respect of dental amalgam and mercury-added products

Current EU law addresses the use of metallic mercury (hereinafter "mercury") and mercury compounds (hereinafter "mercury compounds") in a comprehensive manner. The key Union legal instrument is Regulation (EU) No 2017/852 on Mercury (hereinafter 'Mercury Regulation'[1] which covers the whole life cycle of mercury from primary mercury mining to the final disposal of mercury as waste and transposes the Minamata Convention on Mercury (hereinafter 'Minamata Convention') into EU law.

Mercury is classified under EU chemical legislation **as a hazardous substance with the following characteristics: Reproductive toxicity (Cat. 1B), Acute toxicity (Acute Tox. 2), Specific target organ toxicity – repeated exposure (STOT RE1), Hazardous to the aquatic environment (Aquatic Acute 1 and Aquatic Chronic 1). Mercury compounds are also classified as hazardous substances[2]. Additionally, mercury is listed as a priority hazardous substance** under EU water law[3].

Considering the level of hazardousness of mercury to both human health and the environment, this substance is not only addressed in the Mercury Regulation, but also in provisions established in other EU instruments setting specific controls on *inter alia* mercury air and water emissions[4], including from industrial installations[5], the temporary storage of mercury waste[6] and the mercury content in seafood[7,8].

For the purpose of this document and in view of the scope of application of this initiative, this Annex focuses on existing EU provisions on dental amalgam and mercury-containing lamps as set in the Mercury Regulation, Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic

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1 Regulation (EU) 2017/852 of the European Parliament and of the Council of 17 may 2017 on mercury, and repealing Regulation (EC) No 1102/2008 (OJ L 137, 24.5.2017).

2 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).*

3 Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000).

4 Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council (OJ L 348, 24.12.2008, p. 84–97).

5 Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (OJ L 334, 17.12.2010, p. 17–119).

6 Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste (OJ L 182, 16.7.1999, p. 1–19).

7 Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (OJ L 364 20.12.2006, p. 5).

8 Further information on the EU acquis on mercury can be found in Annex 6 to Commission Staff Working Document Impact Assessment *Ratification and Implementation by the EU of the Minamata Convention on Mercury - Accompanying the document Proposal for a Regulation of the European Parliament and of the Council on mercury, and repealing Regulation (EC) No 1102/2008*, SWD(2016) 17 final, 2.2.2016.

equipment (hereinafter 'RoHS Directive')[9] and the Minamata Convention. This Annex addresses also the Report of the Commission established under Art. 19(1) of the Mercury Regulation (hereinafter 'Commission Review Report'), as its conclusions are part of the basis upon which this document is developed[10]. At last, this Annex touches also upon Decision MC-4/3 adopted at the fourth Conference of the Parties to the Convention (March 2022)[11] since this will also trigger amendments to Annex II (Part A) to the Mercury Regulation.

I. EU ACQUIS AND INTERNATIONAL LAW ON DENTAL AMALGAM USE

The use of dental amalgam in the EU is primarily regulated under Art. 10 of the **Mercury Regulation**. Firstly, this provision defines a set of measures aiming at promoting and hastening the ***phase down*** of amalgam use and at reducing amalgam-related mercury emissions. They include the prohibition to use mercury in bulk form by dental practitioners, the obligation for Member States to develop a national phase down plan and for dental practices to be equipped with amalgam separtors to collect dental amalgam waste. Secondly, Art. 10 sets a ***partial phase-out*** on the use of dental amalgam since it prohibits it since 1 January 2018 for treatment of deciduous teeth and for vulnerable population groups (children below the age of 15, pregnant or breastfeeding women).

The use of dental amalgam is also subject to specific provisions under the **Minamata Convention**. Like the Mercury Regulation, the Minamata Convention sets rules on both the phase-down and phase-out of the use of dental amalgam. Regarding ***phasing-down***, Art. 4(3) and Annex II to that Convention requires Parties to take at least two measures, including, for instance, the establishment of national objectives to minimise the use of dental amalgam, the promotion of research and development on mercury-free alternatives and of environmental best practices within dental facilities. Concerning ***phasing-out***, Parties agreed at the fourth Conference of the Parties to the Convention (March 2022) to prohibit dental amalagm use for the same vulnerable population groups as under the Mercury Regulation. This prohibition shall enter into force on 28 September 2023.

As requested under Article 19(1)(b) of the Mercury Regulation, the Commission reported on the feasibility of a total phase-out preferably by 2030, taking into account above-mentioned national phase down plans and whilst fully respecting Member States' competence for the organisation and delivery of health services and medical care. Whilst it concludes that such a phase-out is economically and technically feasible, the **Commission Review Report** highlights that additional information and assessment (e.g., further data on associated mercury emissions) are still necessary to enable the Union to make a well-founded legislative proposal to address the remaining use of dental

[9] Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (OJ L 174, 1.7.2011).

[10] Report from the Commission to the European Parliament and the Council on the reviews required under Article 19 (1) of Regulation 2017/852 on the use of mercury in dental amalgam and products, COM/2020/378 final.

[11] Decision MC-4/3: Review and amendment of annexes A and B to the Minamata Convention on Mercury, UNEP/MC/COP.4/Dec.3.

amalgam. Such complementary information and assessment are contained in the relevant sections of this Staff Working Document.

II. EU ACQUIS AND INTERNATIONAL LAW ON MERCURY-ADDED PRODUCTS (MAPS)

1. THE PLACING ON THE EU MARKET AND IMPORT INTO THE EU OF MAPS

The placing on the market and import of MAPs is regulated at Union level by means of several legal instruments, including e.g. Regulation (EC) 1907/2006 REACH[12], Regulation (EC) 1223/2009 on cosmetic products[13] and Directive (EC) 2006/66 on Batteries Directive[14]. The concerned products are prohibited from being placed on the market and imported when their mercury content exceeds a certain limit ranging from zero (e.g. thermometers, barometers) to a specific maximum limit (e.g. 0,007 % in eye products)[15]. In this regard and as stated earlier, this Annex addresses in particular the **RoHS Directive** that regulates the mercury content in lamps.

Whereas neither the Mercury Regulation nor the Minamata Convention addresses the placing on the (EU or international) market of MAPs, both instruments address their manufacturing, import and export.

2. THE MANUFACTURING, IMPORT AND EXPORT OF MAPS

2.1 The Mercury Regulation

Art. 5 of the Mercury Regulation provides that the manufacturing and international trade of the MAPs listed in its Annex II (Part A) are prohibited as from the dates specified therein (1 January 2019 or 1 January 2021). Currently, Annex II contains nine entries covering certain MAP, including (i) batteries or accumulators, (ii) switches and relays, (iii) cosmetic products, (iv) pesticides, biocides and topical antiseptics, (v) a set of non-electronic measuring devices, (vi) specific compact fluorescent lamps (CFLs), (vii) specific linear fluorescent lamps (LFLs) and (viii) high pressure mercury vapour lamps and (ix) certain cold cathode fluorescent lamps (CCFLs) and external electrode fluorescent lamps (EEFLs).

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[12] 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).

[13] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342 22.12.2009, p. 59).

[14] Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC (OJ L 266 26.9.2006, p. 1).

[15] For more information on identified existing mercury-added products and associated EU legislation, see the inventory developed by the Commission in accordance with Art. 8(7) of the Mercury Regulation, available at: https://circabc.europa.eu/ui/group/19e66753-84ca-4e4e-a4a1-73befb368fc2/library/d198684c-0834-4f20-9682-dc66553ed066/details

Hence, the Mercury Regulation complements above-mentioned EU legal instruments that prohibits the placing on the market and import of those MAPs.

2.2 The Minamata Convention and Decision MC-4/3

Similarly, Art. 4(1) and Annex A (Part I) to the Minamata Convention prohibits since 1 January 2021 the manufacture, import and exports of the MAPs, which are listed in Annex II (Part A) to the Mercury Regulation. This similarity in scope stems from the instrumental role played by the EU in the course of the negotiations on the establishment of the Minamata Convention.

The scope of application of the Minamata Convention regarding MAPs has recently been extended by means of **paragraph 1 of Decision MC-4/3** adopted by Parties at the fourth meeting of the Conference of the Parties to the Convention (COP4, March 2022). In particular, Parties agreed to prohibit the manufacturing, import and export of eight additional MAPs as from 1 January 2026, including:

(i) CFL.i[16] for general lighting purposes that are ≤ 30 watts with mercury content not exceeding 2,5 mg per lamp burner,
(ii) CCFLs and EEFL of all lengths for electronic displays, that are not yet included in Annex II (Part A),
(iii) Melt pressure transducers, transmitters and pressure sensors,
(iv) Mercury vacuum pumps,
(v) Tire balancers and wheel weights,
(vi) Photographic film and paper,
(vii) Propellant for satellites and spacecraft,
(viii) Strain gauges to be used in plethysmographs[17]

The adding of those MAPs to Annex A (Part I) to the Minamata Convention was fully supported by the EU[18, 19]. In such case, Article 20 of the Mercury Regulation provides that the Commission is empowered to adopt delegated acts in order to amend e.g., Annex II (Part A) to that Regulation to align it with decisions adopted by the Parties to the Minamata Convention. Hence, a Commission Delegated Regulation transposing paragraph 1 of Decision MC-4/3 is developed alongside this initiative.

16 'CFL.i' means compact fluorescent lamps with integrated ballast.

17 Those MAPs are already prohibited from being manufactured, imported and exported from the EU in accordance with Annex II (Part A)(entry 9(f) to the Mercury Regulation.

18 Council Decision (EU) 2021/727 of 29 April 2021 on the submission, on behalf of the European Union, of proposals to amend Annexes A and B to the Minamata Convention on Mercury, regarding mercury-added products and manufacturing processes in which mercury or mercury compounds are used (OJ L 55 of 5.5.2021, p. 23).

19 Council Decision (EU) 2022/549 of 17 March 2022 on the position to be taken on behalf of the European Union at the second segment of the fourth meeting of the Conference of the Parties to the Minamata Convention on Mercury as regards the adoption of a Decision to amend Annexes A and B to that Convention (OJ L 107, 6.4.2022, p. 78).

Furthemore, in accordance with **paragraph 5 of Decision MC-4/3**, Parties agreed also to consider at COP5 (November 2023) a possible supplementary extension of the list of MAPs contained in Annex A (Part I) to the Convention and possible associated phase-out dates. Concerned MAPs and phase-out dates include as follows:

(i) Button zinc silver oxide batteries with a mercury content < 2% and button zinc air batteries with a mercury content < 2%, to be prohibited from being manufactured and traded as from 2026 or 2030.

(ii) Very high accuracy capacitance and loss measurement bridges and high frequency radio frequency switches and relays in monitoring and control instruments with a maximum mercury content of 20 mg per bridge switch or relay [except those used for research and development purposes], to be prohibited from being manufactured and traded as from 2026.,

(iii) Linear fluorescent lamps (LFLs) for general lighting purposes, to be prohibited from being manufactured and traded as from 2026, 2028 or 2031:

(a) Halophosphate phosphor ≤ 40 watts with a mercury content not exceeding 10 mg per lamp
(b) Halophosphate phosphor > 40 watts

(iv) Linear fluorescent lamps (LFLs) for general lighting purposes:

(a) Triband phosphor < 60 watts with a mercury content not exceeding 5 mg/lamp, to be prohibited from being manufactured and traded as from 2028 or 2031.

Whereas those lamps are not listed amongst MAPs contained in Annex II (Part A) to the Mercury Regulation, they are subject to a prohibition from being placed on the market and imported in accordance with RoHS, and therefore fall within the scope of this initiative amongst others (HPS). In this context, the **Commission Review Report** identifies two possible approaches.

- The first approach would make the concerned MAPs subject to an EU ban on manufacturing and international trade by adding them to Annex II (Part A) to the Mercury Regulation. The environmental impacts of such an 'EU ban' could be either positive or negative depending on the extent to which EU production would be substituted by production in third countries.

- The second approach would focus on the Union's effort to negotiate and agree at global level on an extension of the list of MAPs referred to in Annex A (Part I) to the Minamata Convention at COP5 or subsequent COPs. The successful applicability of this second option depends primarily on the uncertain level of ambition of the other Parties to the Minamata Convention. This is one of the key the reasons why the preferred option identified in this document in respect of problem area 2 consists, as a first step, of amending Annex II (Part A) to the Mercury Regulation to align it with provisions set out under RoHS prohibiting the placing on the market of several mercury-containing lamps, and, as a second step, of pushing for an agreement at Minamata level to extend again the scope of application of Art. 4(1) and Annex A (Part I) to the Convention to align it with the then amended Annex II (Part A) to the Mercury Regulation.

3. TO ALIGN ANNEX II (PART A) TO THE MERCURY REGULATION WITH RELEVANT ROHS RESTRICTIONS ON MERCURY-CONTAINING LAMPS.

Without prejudice to the legal obligation to complement Annex II (Part A) to the Mercury Regulation with the seven MAPs covered by above-mentioned Decision MC-4/3 (paragraph 1), this initiative aims also, for the purpose of implementing Art. 19(1)(c) and (3) of the Mercury Regulation, at aligning Annex II (Part A) to the Mercury Regulation with the relevant restrictions set out under RoHS. The objective is to ensure below listed MAPs, which are already prohibited from being placed on the market and imported in the EU in accordance with RoHS, are also made subject to a ban on manufacturing and export by adding them to Annex II (Part A) to the Mercury Regulation. As explained in this Staff Working Document, this initiative focuses on the three types of mercury-containing lamps for general lighting purposes accounting for the most important intentional mercury uses in products alongside dental amalgam.

3.1 The case of mercury-containing compact fluorescent lamps (CFLs) for general lighting purposes

On the one hand, current Annex II (Part A) (entry 3) to the Mercury Regulation prohibits the manufacturing, import and export of the following CFLs:

(a) CFL.i ≤ 30 watts with mercury content > 2,5 mg per lamp burner for general lighting purposes

(b) CFL.ni[20] ≤ 30 watts with mercury content > 3,5 mg per lamp burner for general lighting purposes

On the other hand, as a follow-up to the adoption of Commission Delegated Directive (EU) 2022/276[21] amending Annex III (entries 1, 1(a), 1(b), 1(c), 1(d) and 1(e) to the RoHS Directive), as from 24 February 2023, all CFLs for general lighting purposes can only be placed on the Union market and imported into the EU if they contain zero mercury content.

Hence, should the co-legislators agree on an alignment between the Mercury Regulation and RoHS regarding those lamps, it would imply that above-mentioned existing entry 3 of Annex II (Part A) to this Regulation would need to be amended in such a way as to provide that all CFLs (including all CFL.i and CFL.ni.) for general lighting purposes

[20] ' CFL ni' means compact fluorescent lamps without integrated ballast.

[21] Commission Delegated Directive (EU) 2022/276 of 13 December 2021 amending, for the purpose of adapting to technical and scientific progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for the use of mercury in single capped (compact) fluorescent lamps for general lighting purposes *(OJ L 43, 24.2.2022, p. 32–34).*

containing mercury would be prohibited from being manufactured in the EU, imported into the EU and exported from the EU.

3.2 The case of mercury-containing linear fluorescent lamps (LFLs) for general lighting purposes - Triband phosphor LFLs

On the one hand, current Annex II (Part A) (entry 4)(a) to the Mercury Regulation prohibits the manufacturing, import and export of the following triband phosphor LFLs:

(a) Triband phosphor < 60 W with Hg content > 5 mg per lamp burner for general lighting purposes

On the other hand, as a follow-up to the adoption of Commission Delegated Directive (EU) 2022/284[22] amending Annex III (entries 2(a), 2(a)(1), 2(a)(2), 2(a)(3), 2(a)(4) and 2(a)(5)) to the RoHS Directive, as from 24 February 2023 or 24 August 2023, all triband phosphor LFLs for general lighting purposes can only be placed on the Union market and imported into the EU if they contain zero mercury content.

Hence, should the co-legislators agree on an alignment between the Mercury Regulation and RoHS regarding those lamps, it would imply that above-mentioned existing entry 4(a) of Annex II (Part A) to this Regulation would need to be amended in such a way as to provide that all triband phosphor LFLs for general lighting purposes containing mercury will be prohibited from being manufactured in the EU, imported into the EU and exported from the EU. In doing so, this takes full account of the phase-out dates for those lamps for consideration at COP5 or at subsequent COPs (uncertain outcome), contained in above-mentioned paragraph 5 of Decision MC-4/3.

3.3 The case of mercury-containing halophosphate fluorescent lamps for general lighting purposes

On the one hand, current Annex II (Part A) (entry 4)(b) to the Mercury Regulation prohibits the manufacturing, import and export of the following halophosphate fluorescent LFLs:

(b) Halophosphate phosphor (LFLs) < 40 watts with mercury content > 10 mg per lamp burner for general lighting purposes

On the other hand, Annex III (entries 2(b)(1) and 2(b)(2)) to the RoHS Directive prohibits, since 13 April 2012 and 13 April 2016, the placing on the market and import of (i) linear halophosphate phosphor lamps with tube diameter > 28 mm (e.g. T10 and T12) and (ii) all non-linear halophosphate phosphor lamps.

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[22] Commission Delegated Directive (EU) 2022/284 of 16 December 2021 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for the use of mercury in double-capped linear fluorescent lamps for general lighting purposes *(OJ L 43, 24.2.2022, p. 57–59).*

Hence, should the co-legislators agree on an alignment between the Mercury Regulation and RoHS regarding those lamps with a view to aligning Annex II (Part A) to the Mercury Regulation with the RoHS Directive as far as halophosphate phosphor lamps are concerned, above-mentioned existing entry 4(b) of that Annex will need to be amended in such a way as to provide that all halophosphate phosphor lamps will be prohibited from being manufactured in the EU, imported into the EU and exported from the EU. In doing so, this takes full account of the phase-out dates for those lamps for consideration at COP5 or at subsequent COPs (uncertain outcome), contained in above-mentioned paragraph 5 of Decision MC-4/3.

3.4 The case of high-pressure sodium lamps for general lighting purposes

As a follow-up to the adoption of Commission Delegated Directive (EU) 2022/283[23] amending Annex III (entries 4(b)(I), 4(b)(II) and 4(b)(III)) to the RoHS Directive, as from 24 February 2023, high pressure sodium (vapour) lamps (HPS) for general lighting purposes with improved colour rendering index Ra > 60: P ≤ 155 W, > 60: 155 W < P ≤ 405 W or > 60: P > 405 W can only be placed on the Union market and imported into the EU if they contain zero mercury content.

Hence, should the co-legislators agree on an alignment between the Mercury Regulation and RoHS regarding those lamps with a view to aligning Annex II (Part A) to the Mercury Regulation with the RoHS Directive as far as above-cited HPS lamps are concerned, that Annex will need to be amended in such a way as to provide that concerned HPS lamps will be prohibited from being manufactured in the EU, imported into the EU and exported from the EU.

4. THE SPECIFIC CASE OF THE MANUFACTURING, IMPORT AND EXPORT OF DENTAL AMALGAM

Under current EU and international law, there are no restrictions on the manufacturing, import and export of dental amalgam. Should the co-legislator agree on prohibiting the manufacture and export of dental amalgam whilst allowing the import for EU use only to cover specific medical needs of patients, the Mercury Regulation would need to be amended accordingly (either by means of an amendment to its Art. 10).

[23] Commission Delegated Directive (EU) 2022/283 of 13 December 2021 amending, for the purposes of adapting to scientific and technical progress, Annex III to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for the use of mercury in High Pressure Sodium (vapour) lamps with improved colour rendering index for general lighting purposes *(OJ L 43, 24.2.2022, p. 54–56).*