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PROPOSAL

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
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To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union

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

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

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2023/0272 (COD)

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

(Text with EEA relevance)

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EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

- **Reasons for and objectives of the proposal**

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 Union 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 effects¹.

Considering the risk posed by mercury to both human health and the environment, the Commission developed in 2005 a dedicated *Mercury Strategy*² as reviewed in 2010³ inviting the Union to address all facets of mercury, including its use in products. As a result, the Council of the European Union concluded 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.’⁴

The proposal also falls within a broader policy context by contributing to meeting the objectives of the *European Green Deal*⁵, the *EU Chemicals Strategy for Sustainability*⁶ and the *Zero Pollution Action Plan* (hereafter; ‘ZPAP’)⁷ adopted under it. In particular it aims to fulfil the Union’s commitment to lead by example and ensure that hazardous chemicals banned in the Union are not produced for export in accordance with *Flagship 8* of the ZPAP on the minimisation of the Union’s external pollution footprint, including by amending relevant legislation. Furthermore, this initiative contributes to the development of a new *Union framework for sustainable products*⁸, as well as to the *EU decarbonisation agenda*⁹

¹ 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).

² Communication from the Commission ‘Community Strategy Concerning Mercury’ 20 final, 28.01.2005.

³ Communication from the Commission on the review of the Community Strategy Concerning Mercury, 723 final, 7.12.2010.

⁴ Council conclusions *Review of the Community Strategy concerning Mercury*, 3075th Environment Council meeting, Brussels, 14 March 2011.

⁵ COM(2019) 640 final, 11.12.2019.

⁶ Communication from the Commission ‘Chemicals Strategy for Sustainability - Towards a Toxic-Free Environment’ 667 final, 14.10.2020.

⁷ Communication from the Commission, ‘Pathway to a Healthy Planet for All EU Action Plan: ‘Towards Zero Pollution for Air, Water and Soil’ 400 final, 12.5.2021.

⁸ COM(2022) 142 final, of 30.03.2022.

⁹ 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.

by promoting the substitution of mercury-containing lamps with more energy-efficient lighting alternatives such as light-emitting diode (LED) lamps.

Regulation (EU) 2017/852¹⁰ (hereinafter, ‘the **Mercury Regulation**’) is the main instrument of Union law dedicated to mercury and mercury compounds (hereafter, ‘mercury’ or ‘Hg’) addressing the entire life-cycle of this substance from primary mercury mining to the final disposal of mercury waste and transposing the Minamata Convention on Mercury (hereafter, ‘Minamata Convention’ or ‘Convention’)¹¹ ratified by the Union in May 2017¹² and all the Member States. One key aspect addressed by the Mercury Regulation concerns mercury use in products by establishing prohibitions on the manufacture, import and export of a range of mercury-added products (hereafter, ‘MAPs’)¹³, hence complementing provisions established in other Union instruments setting restrictions on the placing on the market and import of MAPs. With a view to establishing a mercury-free Europe, the proposal addresses the *last intentional remaining uses of mercury in products* in the Union.

According to the review clause established in **Article 19**¹⁴ of the **Mercury Regulation**, the Commission is asked to report to the European Parliament and to the Council on the outcome of its assessment regarding:

- (a) the feasibility of a total phase-out of the use of dental amalgam preferably by 2030 and the need for the EU to regulate associated mercury emissions from crematoria;
- (b) the environmental benefits and the feasibility of prohibiting the manufacturing, import and export of other remaining MAPs, which are already or will soon be banned from being placed on the market in accordance with other Union instruments.

Paragraph 3 of Article 19 provides that the Commission shall, if appropriate, present a legislative proposal based on the above-mentioned assessment.

The Commission adopted in August 2020¹⁵ its **Review Report** on the feasibility of phasing out the use of mercury in dental amalgam and other products. Both this report and the subsequent Commission’s impact assessment pointed to the appropriateness of presenting a legislative proposal to phase out the use of dental amalgam and to restrict the manufacture and export of certain mercury-containing lamps.

Dental amalgam is the largest remaining intentional use of mercury in the Union estimated at around 40 t in 2019. Article 10(2) of the Mercury Regulation already sets a partial ban on the use of dental amalgam by prohibiting it since 1 January 2018 for dental treatment of deciduous teeth and of vulnerable members of the population (i.e., children under the age of

¹⁰ 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, p. 1–21).

¹¹ The text of the Minamata Convention on Mercury is available here: <https://mercuryconvention.org/en/about>

¹² 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).

¹³ of Regulation (EU) 2017/852 as a product or product component that contains mercury or a mercury compound that was intentionally added.

¹⁴ References to Articles and Annexes in this document are deemed references to Articles and Annexes to the Mercury Regulation, unless otherwise specified.

¹⁵ 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.

15 and pregnant and breastfeeding women), except when deemed strictly necessary by the dental practitioner based on the specific medical needs of the patient. In addition, under Article 10(3), Member States had to develop by 1 July 2019 a national plan on the phase-down on the use of dental amalgam.

As regards **other MAPs**, Article 5 prohibits the manufacture, import and export of the MAPs listed in Annex II as from the phase-out dates specified therein (as from 31 December 2018 or 2020), except when they are deemed essential for civil protection and military uses or to those used for research, calibration of instruments or as a reference standard. The MAPs referred to in Annex II are products for which technically and economically feasible mercury-free alternatives are available. Annex II currently lists the following six types of MAPs:

- batteries and accumulators,
- certain switches and relays,
- a range of mercury-containing lamps, including certain compact fluorescent lamps (CFLs) and linear fluorescent lamps (LFLs) for general lighting purposes, mercury-added cold cathode fluorescent lamps and external electrode fluorescent lamps (CCFLs and EEFLs) for electronic displays and high-pressure mercury vapour lamps (HPMV) for general lighting purposes,
- cosmetics (except some eye products),
- pesticides, biocides and topical antiseptics,
- certain non-electronic measuring devices (e.g., thermometers, barometers).

At the time of the adoption of the Mercury Regulation (May 2017), the above-listed MAPs contained in Annex II were products that had already been prohibited from being placed on the market and imported in the Union in accordance with other Union instruments, including Directive (EC) 2006/66 on batteries¹⁶, Regulation (EC) 1907/2006 REACH¹⁷, Regulation (EC) 1223/2009 on cosmetic products¹⁸ and Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (hereafter, ‘RoHS Directive’)¹⁹.

However, considering the increasing availability of technically and economically feasible mercury-free alternatives, additional MAPs have in the meantime been subject to new restrictions on their placing on the market and import under the RoHS Directive. In this

¹⁶ 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).

¹⁷ 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).

¹⁸ 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).

¹⁹ 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).

respect, the continued manufacture and export of those MAPs is a significant cause of mercury pollution, especially in third countries who often lack resources to ensure the environmental sound management of waste and where EU-made products therefore add to the national burden of hazardous products and increase the risk for local retailers, end-users, and inhabitants. In 2018, 13-38 t of mercury were exported from the Union in the form of dental amalgam as well as 0.5 t of mercury in lamps (equivalent to 156 million mercury-containing lamps) in 2020.

Hence, the proposal aims to ensure **coherence between the Mercury Regulation and the RoHS Directive** and thereby **contributing to the Union's commitments under Flagship 8 of the Zero Pollution Action Plan** by phasing out the manufacturing and export of the following mercury-containing lamps:

- Current Annex II (Part A) (entry 3) to the Mercury Regulation prohibits the manufacturing, import and export of the following **CFLs for general lighting purposes**: (i) CFL.i ≤ 30 watts with Hg content $> 2,5$ mg per lamp burner and (ii) CFL.ni²⁰ ≤ 30 watts with Hg content $> 3,5$ mg per lamp burner.

As a follow-up to the adoption of Commission Delegated Directive (EU) 2022/276²¹ 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 if they contain zero mercury content.

- Current Annex II (Part A) (entry 4, point a) to the Mercury Regulation prohibits the manufacturing, import and export of **triband phosphor LFLs** for general lighting purposes of < 60 W with Hg content > 5 mg per lamp burner.

As a follow-up to the adoption of Commission Delegated Directive (EU) 2022/284²² 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 if they contain zero mercury content.

- Whereas current Annex II to the Mercury Regulation does not cover **non-linear triband phosphor fluorescent lamps**, Commission Delegated Directive (EU) 2022/282²³ amending Annex III (entry 2(b)(3)) to the RoHS Directive only allows, as

²⁰ 'CFL ni' means compact fluorescent lamps without integrated ballast i.e., non-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).

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).

²³ Commission Delegated Directive (EU) 2022/282 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

from 24 February 2025, the placing on the EU market and import of such lamps if they contain zero mercury content.

- Current Annex II (Part A) (entry 4, point b) to the Mercury Regulation prohibits the manufacturing, import and export of *halophosphate phosphor (LFLs)* of < 40 watts with Hg content > 10 mg per lamp burner.

Annex III (entry 2(b)(1)) to the RoHS Directive only allows, as from 13 April 2012, the placing on the Union market and import of linear halophosphate phosphor lamps with tube diameter > 28 mm (e.g., T10 and T12) if they contain zero mercury content.

- Whereas current Annex II to the Mercury Regulation does not cover *non-linear halophosphate phosphor fluorescent lamps*, Annex III (entry 2(b)(2)) to the RoHS Directive only allows, as from 13 April 2016, the placing on the EU market and import of non-linear halophosphate phosphor lamps if they contain zero mercury content.

- Whereas current Annex II to the Mercury Regulation does not cover *high pressure sodium (vapour) lamps (HPS)*, Commission Delegated Directive (EU) 2022/283²⁴ amending Annex III (entries 4(b)(I), 4(b)(II) and 4(b)(III)) to the RoHS Directive only allows, as from 24 February 2023, the placing on the EU market and import of HPS with improved colour rendering index $R_a > 60$: $P \leq 155 \text{ W}$, > 60 : $155 \text{ W} < P \leq 405 \text{ W}$ or > 60 : $P > 405 \text{ W}$ if they contain zero mercury content.

In addition, not only does the proposal aim at ensuring coherence within Union law on MAPs, but it also seeks to implement **Decision MC-4/3** of the **Minamata Convention** adopted by Parties at the fourth meeting of the Conferences of the Parties to that Convention in March 2022 (hereafter, ‘**COP4**’), amending, *inter alia*, Annex A (Part I) to the Convention on the list of other MAPs that are subject to a manufacture and international trade prohibition²⁵.

De facto, in aligning Annex II of the Mercury Regulation with RoHS, this proposal includes into that Regulation lamps covered by **Decision MC-4/3 (paragraph 5)** to be considered at **COP5** (November 2023), thereby putting the Union in a leadership position for future international negotiations. This concerns the following lamps:

Parliament and of the Council as regards an exemption for the use of mercury in non-linear tri-band phosphor lamps (OJ L 43, 24.2.2022, p. 51–53).

²⁴ 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).

²⁵ UNEP/MC/COP.4/Dec.3 - Decision MC-4/3: *Review and amendment of annexes A and B to the Minamata Convention on Mercury*, available at <https://www.mercuryconvention.org/en/documents/review-and-amendment-annexes-and-b-minamata-convention-mercury>

- Halophosphate phosphor LFLs > 40 watts;
- Halophosphate phosphor LFLs ≤ 40 watts with a Hg content not exceeding 10 mg per lamp;
- Triband phosphor LFLs < 60 watts with a Hg content not exceeding 5 mg/lamp

Whilst, thanks to the mandate to align Annex II of the Mercury Regulation with RoHS, this proposal therefore covers the three above-mentioned entries irrespective of Decision MC-4/3 paragraph 5, this decision remains relevant regarding the phase-out dates. Hence, this initiative proposes the most ambitious phase-out dates envisaged under paragraph 5 for these products and in doing so demonstrates the continuous ambition of the EU under Minamata, reflected by the formal proposal made by the Union ahead of COP4²⁶ and the relevant negotiating mandate²⁷ provided by the Member States to the Commission.

Furthermore, this proposal also complements **Decision MC-4/3 (paragraph 1)** which added eight new MAPs to Annex A (Part I) to the Minamata Convention, including CFLi for general lighting purposes that are ≤ 30 watts with a Hg content not exceeding 5 mg per lamp burner. These products will be prohibited from being manufactured, imported and exported as from 1 January 2026. This is transposed into Annex II (Part A) to the Mercury Regulation by means of the concomitantly proposed Commission Delegated Regulation²⁸. The use of a Delegated Act is justified as per Article 20 of the Mercury Regulation.

Considering the above, **objectives** of this proposal are:

- (i) extend the prohibition to use dental amalgam to include all members of the population in the Union as from 1 January 2025 (total phase-out), whilst safeguarding the right of the dental practitioners to still use it when deemed strictly necessary for addressing specific medical needs of the patient (e.g., allergies, moisture control issues etc.).
- (ii) set a prohibition on the manufacturing in the Union and export of dental amalgam as from 1 January 2025.
- (iii) make the following six additional MAPs subject to a manufacturing, import and export prohibition by adding them to Annex II:
 - CFLs for general lighting purposes, not yet covered by Annex II nor by the concomitant amendment to Annex II resulting from above-cited Delegated Act;

²⁶ 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).

²⁷ 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).

²⁸ C(2023) 4683 - Commission Delegated Regulation amending Regulation (EU) 2017/852 of the European Parliament and of the Council as regards mercury-added products subject to manufacturing, import and export prohibitions.

- Triband phosphor LFLs for general lighting purposes not yet covered by Annex II;
- Halophosphate phosphor LFLs for general lighting purposes not yet covered by Annex II;
- Non-linear triband phosphor lamps for general lighting purposes;
- Non-linear halophosphate phosphor lamps;
- HPS lamps for general lighting purposes.

This proposal does not introduce an EU-wide obligation for Member States and operators to equip crematoria with mercury emissions abatement technology. While the Commission assessed the need for the Union to regulate the associated mercury emissions from crematoria in compliance with requirements set in Article 19 of the Regulation, the assessment concluded that the costs and administrative burdens would not be proportionate *vis-à-vis* the environmental objectives pursued and also unevenly spread across Member States (see also Section 3).

- **Consistency with existing policy provisions in the policy area**

The Mercury Regulation does not apply in isolation, but in combination with mercury provisions established in other Union instruments setting specific controls on *inter alia* mercury emissions to air and water²⁹, including from industrial installations³⁰, the temporary storage of mercury waste³¹ and the mercury content in seafood³². As specified above, the set of Union instruments and provisions on mercury aim at achieving a mercury-free Europe.

This proposal contributes to this policy objective by adding further restrictions on mercury use in certain MAPs, i.e. dental amalgam and mercury-containing lamps. In doing so, it increases the internal consistency of Union law on MAPs by complementing the prohibition to place on the Union market and to import the concerned mercury-containing lamps established under the RoHS Directive with a ban on the manufacture in the EU and export of such lamps.

There is also a parallelism established between the Mercury Regulation and Regulation (EU) No 649/2012 concerning the export and import of hazardous chemicals (PIC Regulation)³³ since the content of Annex II to the Mercury Regulation is systematically included in Annex V (Part 2) to the PIC Regulation for consistency purposes. It implies that amendments to

²⁹ 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).

³⁰ 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).

³¹ Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste (OJ L 182, 16.7.1999, p. 1–19).

³² 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).

³³ Regulation (EU) No 649/2012 of the European 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).

Annex II to the Mercury Regulation stemming from this proposal will then be integrated into Annex V ((Part 2) to PIC Regulation, once adopted by the co-legislators.

- **Consistency with other Union policies**

This initiative contributes to implementing the 2020 EU *Chemicals Strategy for Sustainability* and 2021 EU *Zero Pollution Action Plan (ZPAP)* adopted under the *European Green Deal (EGD)*.

Under those policy documents, the Commission calls notably for banning the most harmful chemicals in consumer products and has pledged 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 (flagship 8 of the ZPAP).

Additionally, this initiative contributes to the implementation within the Union of two Sustainable Development Goals (SDGs) i.e., good health and well-being ensuring healthy lives and promoting well-being for all ages (Goal 3) and ensuring sustainable consumption and production patterns (Goal 12)³⁴, as well as to the EU decarbonisation agenda by promoting the substitution of mercury-containing lamps with more energy-efficient lighting alternatives, i.e., light-emitting diode (LED) lamps.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

- **Legal basis**

The main objective and content of the envisaged act relate to the protection of the environment and human health. Thus, the substantive legal basis of the proposed Regulation is Article 192(1) TFEU.

- **Subsidiarity (for non-exclusive competence)**

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.

As stated above, the Review Report concluded on the necessity of Union action to, *inter alia*, establish a complete EU phase-out of the use of dental amalgam and to align Union legislation on MAPs. Whilst this can be achieved by Member States but considering the nature of the measures to be taken (i.e., uniform prohibition on the use of dental amalgam, alignment of EU law on MAPs), would be more effective and efficient if undertaken at Union level.

Mercury pollution is transboundary, travelling across national borders, both between Member States and across the frontiers of the Union. Hence appropriate and effective pollution control

³⁴ Agenda 2030 for Sustainable Development: <https://www.un.org/sustainabledevelopment/development-agenda/>

can be achieved more quickly and efficiently at Union level compared to Member States acting alone in an uncoordinated manner.

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 Union has always been an instrumental player at global level, advocating the rapid phase-out of all mercury uses and trade. Union law that is coherent with this policy will therefore strengthen the credibility of the Union and generate a positive impact on health and environment at international level.

- **Proportionality**

The Impact Assessment document accompanying this proposal contains an environmental, economic and social assessment of each policy option. The content of this proposal takes full account of the outcome of this analysis. The proposed phase-out of the use, manufacture and export of dental amalgam and the proposed prohibition on the manufacture, import and export of relevant mercury-containing lamps are deemed to be proportionate. By providing for the above-mentioned phase-out and prohibition, this proposal does not go beyond what is necessary to achieve the environmental objective being pursued, i.e., a mercury-free Europe, which will no longer export MAPs for which toxic-free and more energy-efficient alternatives are available.

The assessment of the policy option consisting in regulating mercury emissions from crematoria based on an obligation to make use of abatement technology concluded that the associated costs and administrative burdens would not be proportionate to the pursued objectives and, therefore, the option is not retrieved in this proposal.

- **Choice of the instrument**

Considering that the Union instrument that is being amended is a Regulation, the proposal takes the form of a Regulation.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

- **Stakeholder consultations**

In the framework of the development of the Impact Assessment, a range of different consultation activities were organised between December 2021 and September 2022 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 MAPs), 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. The main input received on the three problem areas is outlined below:

As regards dental amalgam, over 70% of the consulted stakeholders 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. Based on the results of the Online Public Consultation (OPC), citizens, civil society organisations, environmental non-governmental organisations (NGOs) and associations of environmental dental practitioners broadly support a dental amalgam phase-out by 2025. Business associations and dental practitioners highlighted the need to ensure that the lower-income populations have access to alternative solutions including a full range of dental hygiene prevention measures and that due account is taken 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.

Concerning associated emissions of mercury 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 supported EU-wide policy to control mercury emissions from crematoria.

Mercury-added products: Business associations, Member State authorities and NGOs agree that, within the context of the Minamata Convention, the Union 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 Union 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 expressed a preference for an international prohibition in light of demand in and supply by third countries.

- **Collection and use of expertise**

Under framework contract (FWC) ENV.F.1/FRA/2019/0001, the European Commission contracted an external consultant to carry out a specific contract assisting with the Impact Assessment for the Review of the Mercury Regulation.

- **Impact assessment**

An impact assessment was carried out³⁵, which resulted in a positive opinion from the Regulatory Scrutiny Board of 24 March 2023³⁶.

³⁵ Commission Staff Working Document – 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*’. SWD (2023) 395

³⁶ Ref. Ares(2023)2149020

On the use of dental amalgam, the Impact Assessment concluded that the preferred policy option is to introduce an EU-wide obligation to phase-out the use of dental amalgam as from 2025, given that (i) it would lead to the greatest environmental and health benefits, including in terms of reductions in mercury emissions from crematoria, (ii) this timeframe is implementable as demonstrated by those Member States that have already phased out or plan to phase out dental amalgam use and the overall declining trend in dental amalgam use, (iii) the cost difference between dental amalgam and mercury-free alternatives is expected to narrow with greater demand and innovation, (iv) it would ensure a uniform phase-out across all Member States and hence place the Union in a first-mover leadership role in relation to future international negotiations within the Minamata Convention and the Union's future market competitiveness, (v) this prohibition would contribute to meeting the objectives set out under the EGD, the Zero Pollution Action Plan and the *Chemicals Strategy for Sustainability*.

The economic impacts of a phase-out of the use of dental amalgam by 2025 are expected to be small as only four of the former 23 EU-based dental amalgam manufacturers have not yet announced that they have ceased their production (however, their certifications will expire in 2023), highlighting that there has already been a steady transition towards a phase-out in recent years with the availability of mercury-free alternatives. Limited additional costs associated with a transition to affordable alternatives are expected to be covered by social security systems and/or private healthcare.

As regards mercury emissions from crematoria, the Impact Assessment concluded that a policy option consisting in a legal obligation to equip crematoria (regardless of their capacity) with mercury emissions abatement technology (i) would not or only marginally be cost-beneficial and not lead to significant environmental benefits, (ii) if applied to all crematoria, would place considerable economic pressure on small and medium size enterprises (SMEs) operating crematoria with low capacity, (iii) would result in significant administrative burden on operators and competent authorities and (iv) would decrease in efficiency and effectiveness especially when considering it in combination with a dental amalgam phase-out.

The policy option consisting in the development by the Commission of a non-legally binding guidance document was therefore retained as the preferred policy option. The Commission will prepare this guidance document after adoption of the proposal to amend the Mercury Regulation. It is therefore not part of this initiative.

Concerning the manufacture and export of dental amalgam, the Impact Assessment concluded that the preferred policy option is the establishment of an obligation to ban this manufacture and export. This ban would take place as from 2025 to align it with the proposed phase-out of its use. An export ban of dental amalgam to third countries will likely result in increased demand for mercury-free alternative filling materials for which the Union has a growing market.

Regarding the manufacture, import and export of the other concerned MAPs, i.e., mercury-containing lamps, the Impact Assessment concluded that the preferred policy option is the introduction in the Mercury Regulation of an EU-wide prohibition of the manufacture and export of mercury-containing lamps which are prohibited from being placed on the internal market, thanks to the RoHS Directive. The phase-out dates would be 2026 and 2028 based on the earliest phase-out dates retained for negotiations at COP5 to the Minamata Convention on Mercury (see above). An EU-wide ban would allow the Union to take immediate action and to further decrease export of MAPs independently from the unpredictable outcome of future negotiations under the Minamata Convention. Such an action is a strong signal to third

countries and ensures upholding the Union's market competitiveness and credibility *vis-à-vis* the objectives set out in the EGD, the Zero Pollution Action Plan and EU Chemicals Strategy for Sustainability.

The impacts of such a manufacturing and export ban are expected to be small as it concerns only four manufacturers across the Union who have to a large extent converted their production lines focussing on LEDs. Furthermore, it would allow the Union to reduce its contribution to the mercury stock in line with its commitments to reduce its external pollution footprint under in particular the EGD, the Zero Pollution Action Plan and the EU Chemicals Strategy for Sustainability and strengthen internal coherence of Union law on MAPs.

- **Regulatory fitness and simplification**

In line with the Commission's commitment to better regulation, this proposal has been prepared inclusively, based on full transparency and continuous engagement with stakeholders with due regard to avoiding unnecessary burdens. It is based on the best available evidence, referenced in the Impact Assessment accompanying this proposal, and expert knowledge taking into account the external feedback. 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 low (30 000 – 100 000 EUR/p.a. for the whole Union) and is based on data that should already be available to authorities.

- **Fundamental rights**

The proposal respects fundamental rights, in particular those in the Charter of Fundamental Rights of the European Union. It also contributes to the right to a high level of environmental protection in line with the principle of sustainable development, as laid down in Article 37 of the Charter.

4. BUDGETARY IMPLICATIONS

There are no budgetary implications linked to this initiative.

5. OTHER ELEMENTS

- **Implementation plans and monitoring, evaluation and reporting arrangements**

To secure an effective phase-out of the use of dental amalgam, Member States will have to undertake market surveillance and compliance checking in accordance with Regulation (EU) 2019/1020³⁷. For the prohibition to manufacture and export dental amalgam and to manufacture, import and export concerned mercury-containing lamps, the amendment to

³⁷ 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) No 765/2008 and (EU) No 305/2011 (OJ L 169, 25.6.2019, p. 1–44).

Article 10 of the Mercury Regulation (dental amalgam) and the extension of Annex II (Part A) to that Regulation will not lead to an ad-hoc Union obligation to monitor implementation. Any relevant information will be provided to the Commission via Member State reports on the implementation of the Mercury Regulation, in accordance with Article 18 and the Reporting Decision adopted under it³⁸. Jointly with the ongoing decarbonisation efforts, this proposal 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.

- **Detailed explanation of the specific provisions of the proposal**

Article 1 proposes firstly to complement Article 10 of Regulation (EU) 2017/852 with a **new paragraph 2a** introducing an EU-wide prohibition to use dental amalgam for dental treatment as from 1 January 2025. This new paragraph 2a complements the current paragraph 2, which already prohibits such use for the treatment of milk teeth and for dental treatment of children below the age of 15, pregnant and breastfeeding women. In line with the existing paragraph 2, the new paragraph 2a also foresees the possibility for dental practitioners to continue using dental amalgam for patients having specific medical conditions (e.g., allergies).

Article 1 proposes secondly to complement Article 10 of Regulation (EU) 2017/852 with a **new paragraph 7** introducing an EU-wide prohibition to manufacture and export dental amalgam as from 1 January 2025. This proposed prohibition complements the proposed ban on the use of dental amalgam for all members of the population and, in doing so, contributes to meeting the objective of the Union to reduce its external pollution footprint, in accordance with the ZPAP and the EU Chemicals Strategy for Sustainability. The import of dental amalgam remains allowed in order to enable dental practitioners to keep on using it for the very few cases where patients' specific medical conditions so require.

Article 2 proposes to **amend Annex II (Part A)** to Regulation (EU) 2017/852 by adding therein five types of mercury-containing lamps.

The derogations provided for under Article 5, paragraph 2, of Regulation (EU) 2017/852 will apply to those newly prohibited MAPs, by virtue of which the manufacturing, import and export of MAPs listed in its Annex II (Part A) can legally continue for MAPs deemed essential for civil protection and military uses or for those used for research, calibration of instrumentation, or for use as a reference standard.

CFLs for general lighting purposes not already covered by entries 3 and 3a

The proposed new entry 3b in Annex II (Part A) complements existing entry 3 and seeks to align with the restrictions on the placing on the market of CFLs as newly established under the RoHS Directive, thanks to Commission Delegated Directive (EU) 2022/276. Furthermore, proposed new entry 3b refers to entry 3a, which was inserted into that Annex by means of Commission Delegated Regulation [...] transposing into Union law paragraph 1 of Decision MC-4/3 adopted at COP4 to the Minamata Convention. 31 December 2025 is indicated as the

³⁸ Commission Implementing Decision (EU) 2019/1752 of 25 February 2019 establishing questionnaires, as well as the format and frequency of reports to be prepared by the Member States in accordance with Regulation (EU) 2017/852 of the European Parliament and of the Council (OJ L 269, 23.10.2019, p. 5–11).

date from which the export, import and manufacturing of those lamps will cease in line with the phase-out date agreed at COP4 (see paragraph 1 to Decision MC-4/3). The combined reading and implementation of entries 3, 3a and 3b of Annex II (Part A) will imply that the manufacture and the export of all CFLs for general lighting purposes will be prohibited EU-wide regardless of their wattage, size or other parameters and thus complementing the ban on their placing on the market and import established under the RoHS Directive.

Triband phosphor LFLs for general lighting purposes not already covered by entry 4, point (a)

The proposed new entry 4a in Annex II (Part A) complements existing entry 4, point (a) and seeks to ensure its alignment with the restrictions established under the RoHS Directive under Commission Delegated Directive (EU) 2022/284. 31 December 2027 is the indicated date from which the export, import and manufacturing of those lamps will cease and, in doing so, takes into account the most ambitious phase-out date proposed by Parties for negotiations at COP5 under paragraph 5 of Decision MC-4/3. The combined reading and implementation of entry 4a and entry 4, point (a) of Annex II (Part A) will imply that the manufacture and the export of triband phosphor LFLs for general lighting purposes will be prohibited EU-wide regardless of their wattage, size or other parameters and will apply and thus complementing the ban on their placing on the market and import established under the RoHS Directive.

Halophosphate phosphor LFLs for general lighting purposes not already covered by entry 4, point (b)

The proposed new entry 4b in Annex II (Part A) complements existing entry 4, point (b) and seeks to ensure the alignment of Annex II (Part A) with existing restrictions on placing on the market of halophosphate phosphor LFLs established under the RoHS Directive since 13 April 2012. 31 December 2025 is the indicated date from which the export, import and manufacturing of those lamps will cease and, in doing so, takes into account the most ambitious phase-out date proposed by Parties for negotiations at COP5 under paragraph 5 of Decision MC-4/3. The combined reading and implementation of entry 4b and entry 4, point (b) of Annex II (Part A) will imply that the manufacture and the export of halophosphate phosphor LFLs for general lighting purposes will be prohibited EU-wide regardless of their wattage, size or other parameters and will apply thus complementing the ban on their placing on the market and import established under the RoHS Directive.

Non-linear triband phosphor lamps

The proposed new entry 4c in Annex II (Part A) seeks to ensure the alignment of that Annex with existing restrictions on placing on the market of non-linear triband phosphor lamps established under the RoHS Directive as from 24 February 2025. 31 December 2027 is the indicated date from which the export, import and manufacturing of those lamps will cease in line with new entry 4a (above) which addresses triband phosphor LFLs. This date takes full account of the most ambitious phase-out date to be negotiated for triband phosphor LFLs (see paragraph 5 of Decision MC-4/3) and thus seeks to align the phase-out date for linear and non-linear triband phosphor lamps.

Non-linear halophosphate phosphor lamps

The proposed new entry 4d in Annex II (Part A) seeks to ensure the alignment of that Annex with existing restrictions on placing on the market of non-linear halophosphate phosphor

lamps established under the RoHS Directive as from 13 April 2016. 31 December 2025 is the indicated date from which the export, import and manufacturing of those lamps will cease in line with new entry 4b (above) which addresses halophosphate phosphor LFLs. This date takes full account of the most ambitious phase-out date to be negotiated for halophosphate phosphor LFLs (see paragraph 5 of Decision MC-4/3) and thus seeks to align the phase-out date for linear and non-linear halophosphate phosphor lamps.

HPS lamps for general lighting purposes

The proposed new entry 5a in Annex II (Part A) seeks to ensure the alignment of that Annex with existing restrictions on placing on the market of HPS lamps established under the RoHS Directive as from 24 February 2027. 31 December 2027 is the indicated date from which the export, import and manufacture of those lamps will cease. This date takes full account of the conclusions of the Impact Assessment and ensures an adequate period of transition for EU manufacturers.

Article 3 proposes that the Regulation enters into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

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

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 192(1) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee¹,

Having regard to the opinion of the Committee of the Regions²,

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) In accordance with Article 19(1) of Regulation (EU) 2017/852 of the European Parliament and of the Council³, the Commission was to assess and report on the need to regulate, at Union level, emissions of mercury and of its compounds ('mercury') from crematoria, the feasibility of phasing-out the use of dental amalgam for all members of the population in the long term, and preferably by 2030, and on the environmental benefits and the feasibility of banning the manufacture and export of other mercury-added products, which are prohibited from being placed on the Union market and imported into the Union.
- (2) Following the conclusion reached by the Commission in its report⁴ and its subsequent Impact Assessment⁵, the Commission found it appropriate to present a legislative proposal, in accordance with Article 19(3) of Regulation (EU) 2017/852, on the

¹ OJ C , , p .

² OJ C , , p .

³ 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, p. 1).

⁴ 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.

⁵ Commission Staff Working Document – 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'. SWD (2023) 395

phasing out of the use of dental amalgam and the prohibition of the manufacturing and export of dental amalgam and certain mercury-containing lamps.

- (3) The use of mercury-added products, including the use of dental amalgam and of mercury-containing lamps, represents the largest remaining intentional use of mercury in the Union. However, the mercury-free alternatives have become economically and technically feasible and are readily available.
- (4) Considering the availability of mercury-free alternatives, it is appropriate to prohibit the use of dental amalgam for dental treatment of all members of the population, whilst maintaining the possibility of using dental amalgam for patients with specific medical needs. In order to prevent dental amalgam, which is prohibited on the Union market, being manufactured for export from the Union, it is necessary to prohibit the manufacture and export of dental amalgam. Article 10 of Regulation (EU) 2017/852 should therefore be amended accordingly.
- (5) Article 4(1) of Directive 2011/65/EU of the European Parliament and of the Council⁶ prohibits the placing on the Union market and import into the Union of certain electrical and electronic equipment containing mercury. Annex III to that Directive lists, among other items, certain mercury-added lamps exempted from the said prohibition until the dates specified therein. That exemption already expired on 13 April 2016 for non-linear halophosphate lamps, and it will expire on 24 February 2023 or on 24 February 2027 for certain compact fluorescent lamps, linear fluorescent lamps and high pressure sodium (vapour) lamps for general lighting purposes, as well as for non-linear tri-band phosphor fluorescent lamps. In addition, certain linear fluorescent lamps for general lighting purposes are listed for a future prohibition in Decision MC-4/3 adopted at the fourth meeting, held from 21 to 25 March 2022, of the Conference of the Parties to the Minamata Convention on Mercury⁷. That Decision was supported by the Union by means of Council Decision (EU) 2022/549⁸. As some of those lamps are currently not covered by Part A of Annex II to Regulation (EU) 2017/852, they should, for the sake of coherence, be included therein to prohibit their manufacturing and export from the dates in line with Annex III of Directive 2011/65/EU and the most ambitious dates included in Decision MC-4/3.
- (6) Regulation (EU) 2017/852 should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

Article 1

Regulation (EU) 2017/852 is amended as follows:

⁶ 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).

⁷ 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).

⁸ 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

(1) Article 10 is amended as follows:

(a) the following paragraph 2a is inserted:

‘2a. From 1 January 2025, dental amalgam shall not be used for dental treatment of any member of the population, except when deemed strictly necessary by the dental practitioner based on the specific medical needs of the patient.’;

(b) the following paragraph 7 is added:

‘7. From 1 January 2025, the manufacture and export of dental amalgam shall be prohibited.’;

(2) Annex II is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President