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## NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee
No. prev. doc.:	5500/24
No. Cion doc.:	11960/23 + ADD 1 - COM(2023) 395 final + Annex
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 - Mandate for negotiation with the European Parliament

## I. INTRODUCTION

1. On 14 July 2023, the Commission transmitted to the European Parliament and the Council a 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.

2. The proposal aims at prohibiting (i) the use of dental amalgam 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, (ii) the manufacturing in the Union and export of dental amalgam as from 1 January 2025; (iii) the manufacturing, import and export of six classes of lamps (mercury-added products) that contain mercury as from 31 December 2025 or 31 December 2027 (depending on the class of lamp).
3. In the European Parliament, the file was referred to the Committee on the Environment, Public Health and Food Safety (ENVI), which appointed Marlene Mortler (EPP, Germany) as rapporteur. The ENVI Committee adopted its report on 11 January 2024. The European Parliament adopted its position on 17 January 2024.
4. The European Economic and Social Committee delivered its opinion on 26 October 2023. The Committee of the Regions decided not to deliver an opinion<sup>1</sup>.
5. At working group level, the proposal was presented on 9 October 2023 under the Spanish Presidency, after which delegations had several opportunities to provide written comments. Under the Belgian Presidency, a compromise text was presented in the Working Party on the Environment on 18 January 2024 and a revision of the entire compromise took place at another meeting at working party level on 25 January.

## II. MAIN ELEMENTS OF THE PRESIDENCY COMPROMISE TEXT

6. The Presidency compromise text amends the Commission's proposal on a rather limited number of aspects and builds on the comments received from delegations. The compromise aims at addressing the concerns of delegations expressed, while maintaining the right balance between the necessary flexibilities and the need to preserve the objectives and integrity of the proposal. The main elements of the compromise are set out below. Recitals have been aligned with the proposed amendments of provisions. Moreover, recitals were also corrected or complemented to make them consistent with the work under the Minamata Convention.

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<sup>1</sup> Letter from the Committee of the Regions on 31 October 2023.

7. On dental amalgam, the compromise text maintains the ambition of a total phase-out of the use of dental amalgam for dental treatment in the Union as of 1 January 2025, except when – as already the case for patient groups of the population, for which the use of dental amalgam is already prohibited under the current provisions of the Regulation - a dental practitioner considers the use of dental amalgam necessary due to specific medical needs.
8. For several Member States phasing out the use of dental amalgam as of 1 January 2025 poses considerable difficulties as regards their dental care systems because the transition to mercury-free alternatives will not be completed by that date. This includes questions regarding the training on mercury-free alternatives or the framework for reimbursement of dental treatment by the national health care systems. To minimise any negative socio-economic effects, in particular for low-income patients, in those Member States, in Article 10(2a) the Presidency is therefore proposing a derogation until 31 December 2026 for Member States in that situation. This will allow those Member States to find suitable solutions for their healthcare systems.
9. However, to be transparent and ensure that this derogation is only used for those very exceptional situations laid out above, Member States will have to justify the reasoning for making use of the derogation and set out the measures how to achieve the phase-out of the use of dental amalgam by 1 January 2027. This reasoning should then also be made publicly available and notified to the Commission.
10. As regards the ban on the export and manufacturing of dental amalgam in Article 10(7), the Presidency suggests to stick to the phase-out date as of 1 January 2025 for the ban on exports.
11. However, it is suggested to adapt the application date for the ban on manufacturing to the possible derogation for Member States in need of an adjustment of their healthcare system as laid out above. This should ensure the supply with dental amalgam for those Member States making use of this derogation and should therefore be moved to 1 January 2027.

12. Regarding the import of dental amalgam the Commission did not propose a ban, and the Parliament did neither consider such an amendment in the report adopted. However, based on the comments from delegations at working party level, the Presidency considers that for consistency reasons the import of dental amalgam should also be prohibited from the same date as for the manufacturing (1 January 2027).
13. To be even further consistent, the Presidency also considers in a new subparagraph in Article 10(7) that manufacturing in the Union and import into the Union from 1 January 2027 should still be allowed for dental amalgam used for patients with specific medical needs, as at this stage there are no guarantees that existing stocks within the Union would be sufficient to cover for the purpose of that provision.
14. To complement that derogation, the compromise text also introduces an amendment to Articles 18 and 19, which asks importers and manufacturers of dental amalgam as covered by that derogation in relation to specific medical needs for each calendar year to their competent authority for the preceding calendar year the amount of the import and manufacturing of dental amalgam. Moreover, is asked to provide an assessment by 2030 of the necessity of that derogation.
15. In the negotiations with the Parliament the Presidency intends to present the compromise text on dental amalgam covering all those elements laid out as package and will defend it as such. Delegations are invited to share their flexibilities with a view to such a package and its elements.
16. As regards the amendments to Annex II and the prohibition of manufacturing, import and export of six classes of lamps, delegations signaled their general support to the Commission proposal at technical level. Apart from linguistic corrections in the compromise text, the Presidency also included a clarification in paragraph 5a on ‘High pressure sodium (vapour) lamps (HPS)’ which precisely mirrors Parliament amendment 15, and as confirmed by the Commission, ensures that the ban on HPS lamps is compatible with the provisions of the RoHS Directive.

17. It is to be noted that the Parliament has proposed in amendments 13 and 14 to bring forward the phase out of certain categories of mercury-containing lamps from 31 December 2027 to 31 December 2025. There was certain openness by some delegations towards this proposal. However, in view of the majority of Member States preferring the phase out date of 31 December 2027, which is also supported by data in the Commission's impact assessment, the Presidency intends to stick to the Commission proposal in the negotiations.
18. Regarding the other proposed amendments by the Parliament the Presidency has duly noted the feedback so far by delegations at technical level. There is still an open call for comments at technical level that can be used for providing feedback to the Presidency for that purpose. Delegations are invited to raise their further flexibilities but also in particular their red lines towards the Parliament proposals.

### III. CONCLUSION

19. The Permanent Representatives Committee is invited to examine the Presidency compromise text set out in the Annex, with a view to agreeing on a negotiation mandate with the European Parliament and, based on this compromise text, reaching a first-reading agreement.

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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 Committee<sup>2</sup>,

Having regard to the opinion of the Committee of the Regions<sup>3</sup>,

Acting in accordance with the ordinary legislative procedure,

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<sup>2</sup> OJ C , , p. .

<sup>3</sup> OJ C , , p. .

Whereas:

- (1) In accordance with Article 19(1) **and (2)** of Regulation (EU) 2017/852 of the European Parliament and of the Council<sup>4</sup>, 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 Union** 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 report<sup>5</sup> and its subsequent Impact Assessment<sup>6</sup>, the Commission found it appropriate to present a legislative proposal, in accordance with Article 19(3) of Regulation (EU) 2017/852, on the 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.

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<sup>4</sup> 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).

<sup>5</sup> 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.

<sup>6</sup> 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

- (4) Recognising that the Union and its Member States have ratified the Minamata Convention on Mercury of 2013 and noting that measures should be taken by Parties to prioritise dental caries prevention and health promotion, thereby minimising the need for dental restoration as a key measure to support the phasing down of the use of dental amalgam, and ~~€~~considering the availability of mercury-free alternatives, it is appropriate to prohibit the use of dental amalgam for dental treatment ~~of all members of~~ in the Union 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.~~
- (4a) In order to limit the socio-economic impact, especially for low-income patients, Member States where treatment with dental amalgam is the only publicly reimbursed material at a rate of at least 90% under national law, while this is not yet possible for mercury-free alternatives as of 1 January 2025, should have more time to find appropriate solutions to adapt their healthcare system and therefore be allowed to have a later phase-out date for dental amalgam.
- (4b) As that derogation will allow Member States to use dental amalgam in very specific circumstances until the end of 2026, the manufacture and import of dental amalgam should be prohibited only from 1 January 2027. However, after 1 January 2027, manufacturing and import should still be possible only to cover specific medical needs. Article 10 of Regulation (EU) 2017/852 should therefore be amended accordingly.
- (4c) In order to assess the continuing need for use of dental amalgam in relation to specific medical needs, importers and manufacturers should inform the competent authorities annually of the quantities manufactured or imported for those purposes. Moreover, by 1 January 2030 the Commission should assess if there is still a necessity to maintain the derogation for the manufacture and import of dental amalgam used for patients with specific medical needs, taking into account the availability of mercury-free alternatives for ~~that specific~~ the relevant patient groups. ~~Articles 40~~ 18 and 19 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 Council<sup>7</sup> 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~~ **already** expired on 24 February 2023 or **will expire** 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~~ **were** 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 Mercury<sup>8</sup>, **and phase out dates were set up for them by Decision MC-5/4x adopted at the fifth meeting, held from 30 October to 3 November 2023.** These ~~at Decisions~~ **were** as supported by the Union by means of Council Decision (EU) 2022/549<sup>9</sup> **and Council Decision (EU) 2023/2417**<sup>10</sup>. 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.~~

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<sup>7</sup> 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).

<sup>8</sup> ~~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).~~

<sup>9</sup> 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).

<sup>10</sup> **Council Decision (EU) 2023/2417 of 23 October 2023 on the position to be taken on behalf of the European Union at the fifth 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 XXX, 6.11.2023, p. XX).**

(6) Regulation (EU) 2017/852 should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

*Article 1*

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

(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~~ **in the Union**, except when deemed strictly necessary by the dental practitioner based on the specific medical needs of the patient.’;

**By way of derogation from the first subparagraph, where in a Member State dental amalgam is the only publicly reimbursed material at a rate of at least 90 % under national law for patients who are not eligible for other reimbursed materials of dental filling and persons with low income are socio-economically disproportionately affected by a phase-out date of 1 January 2025, dental amalgam may be used for dental treatment until 31 December 2026. Member States shall make publicly available reasoned explanations for making use of this derogation, including the appropriate measures to be implemented by 31 December 2026, and notify them to the Commission by [Please insert the date of 1 month after the entry into force of this Regulation].**

(b) the following paragraph 7 is added:

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

**From 1 January 2027, the import and manufacturing of dental amalgam shall be prohibited.**

**By way of derogation from the second subparagraph, the import and manufacturing of dental amalgam shall be permitted for the specific medical needs referred to in paragraph 2a.’;**

**(1a) Article 18 is amended as follows:**

**The following paragraph 1a is inserted:**

**‘1a. By 31 May of a given calendar year, importers and manufacturers of dental amalgam shall report to their competent authority for the preceding calendar year the amount of the import and manufacturing of dental amalgam referred to in Article 10(7), third subparagraph.’;**

**(1b) Article 19 is amended as follows:**

**The following paragraph 4 is added:**

**‘4. By 1 January 2030, the Commission shall assess the necessity to maintain the derogation as referred to in Article 10(7), third subparagraph, which shall be accompanied, if the Commission deems it appropriate, by a legislative proposal.’;**

(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*

*For the Council*

*The President*

*The President*

## ANNEX

Part A of Annex II is amended as follows:

(1) the following entry 3b is inserted:

<b>Mercury-added products</b>	<b>Date from which the export, import and manufacturing of the mercury-added products are prohibited</b>
‘3b. All other compact fluorescent lamps (CFLs) for general lighting purposes not already covered by entries 3 and 3a	31.12.2025’;

(2) the following entries 4a to 4d are inserted:

<b>Mercury-added products</b>	<b>Date from which the export, import and manufacturing of the mercury-added products are prohibited</b>
‘4a. Triband phosphor lamps for general lighting purposes that are not included in entry 4, point (a).	31.12.2027
4b. Halophosphate phosphor lamps for general lighting purposes that are not included in entry 4, point (b).	31.12.2025
4c. Non-linear triband phosphor lamps.	31.12.2027
4d. Non-linear halophosphate phosphor lamps.	31.12.2025’;

(3) the following entry 5a is inserted:

Mercury-added products	Date from which the export, import and manufacturing of the mercury-added products are prohibited
<p>‘5a High pressure <del>mercury</del> sodium (vapour) lamps (HPS) for general lighting purposes <b><u>with:</u></b></p> <p><b><u>(a) <math>P \leq 105\text{ W}</math> exceeding 16 mg Hg;</u></b></p> <p><b><u>(b) <math>105\text{ W} &lt; P \leq 155\text{ W}</math> exceeding 20 mg Hg;</u></b></p> <p><b><u>(c) <math>P &gt; 155\text{ W}</math> exceeding 25 mg Hg.</u></b></p>	31.12.2025’.