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## NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee
No. prev. doc.:	5981/24
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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 - Analysis of the final compromise text with a view to agreement

## 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 (“the Regulation”) as regards dental amalgam and other mercury-added products subject to manufacturing, import and export restrictions.
2. The European Economic and Social Committee delivered its opinion on 26 October 2023, while the Committee of the Regions decided not to deliver an opinion due to the very limited local and regional aspects of the proposal.

3. In the European Parliament, the file was referred to the Committee on the Environment, Public Health and Food Safety (ENVI), which adopted its report on 11 January 2024. The Parliament adopted its position on 17 January 2024 and referred it back to the ENVI Committee for trilogue negotiations.

## **II. WORK IN THE COUNCIL**

4. At Working Group level, the proposal was presented on 9 October 2023 under the Spanish Presidency.
5. 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 text took place on 25 January.
6. On 30 January 2024 the Committee of Permanent Representatives agreed on a Council position and gave a mandate to the Presidency to engage in negotiations with the European Parliament.
7. On the basis of this mandate a political trilogue took place on 8 February 2024. The Belgian Presidency reached a provisional political agreement with the European Parliament on the entirety of the proposed Regulation. The text contained in the Annex reflects the agreement reached following technical finalisation after the trilogue.

### III. ANALYSIS OF THE FINAL COMPROMISE

8. The provisional agreement with the Parliament includes the following key elements:

#### **Dental amalgam**

On dental amalgam, the agreed 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 a dental practitioner considers the use of dental amalgam necessary due to specific medical needs.

Exports of dental amalgam will also be banned from 1 January 2025.

To minimise any negative socio-economic effects, in particular for low-income patients, in those Member States, where phasing out the use of dental amalgam as of 1 January 2025 poses considerable difficulties because the transition to mercury-free alternatives will not be completed by that date, Article 10(2a) of the Regulation is allowing for a derogation until 30 June 2026. Member States in that situation will need to justify the reasoning for making use of the derogation and set out the measures how to achieve the ban of that use of dental amalgam from 1 July 2026. This justification should then also be made publicly available and notified to the Commission. In line with this derogation and to ensure the supply of dental amalgam to those Member States, the ban on manufacturing and import should also only apply from 1 July 2026. However, from 1 July 2026 import and manufacturing of dental amalgam should still be allowed to cover its use for the specific patient groups with specific medical needs, for which mercury-free alternatives cannot be used.

The agreed text also introduces amendments to Articles 18 of the Mercury Regulation, which asks importers and manufacturers of dental amalgam covered by the derogation in relation to specific medical needs for each calendar year to report the amount of the import and manufacturing of dental amalgam to their competent authority for the preceding calendar year. Member States are then also asked to share this information with the Commission.

## **Lamps**

As regards the amendments to Annex II and the prohibition of manufacturing, import and export of six classes of lamps, the phase-out dates for the placing on the market and the import under Directive 2011/65/EU have been clarified in a recital and the overall rationale that this should also be aligned with a phase-out of export of those lamps under the Mercury Regulation has been further explained.

The Parliament had asked in its amendments to bring forward the phase out of triband phosphor lamps for general lighting purposes, as well as non-linear triband phosphor lamps, from 31 December 2027 to 31 December 2025. Since there are no data in the Commission's impact assessment to support a two years shortening of this phase-out and to ensure some certainty for lamp manufacturers, a phase-out date of 31 December 2026 was agreed in the final compromise package.

## **Other issues**

On the question of reduction of emissions from crematoria an immediate duplication of reporting duties for Member States will be avoided. Member States will only be asked to report on their experiences on the Commission guidance document that will be established by 31 December 2025.

On the Parliament amendment on separate waste streams, it was agreed to clarify in a recital the importance of proper collection systems for mercury-added products in non-electronic and electronic waste in accordance with Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE).

Moreover, it was agreed that on a number of issues, inter alia the necessity of the derogations for dental amalgam in relation to the specific medical needs, the results of the implementation of the Commission guidance related to crematoria emissions or the need to phase out the remaining mercury uses, the Commission should deliver a report to Parliament and Council by 31 December 2029.

#### IV. CONCLUSION

9. Against this background, the Permanent Representatives Committee is invited to:
- (a) approve the final compromise text as set out in the Annex to this note with a view to reaching an agreement at first reading with the European Parliament;
  - (b) authorise the Chair of the Permanent Representatives Committee to send a letter to the Chair of the European Parliament's Committee on the Environment, Public Health and Food Safety (ENVI) confirming that, should the European Parliament adopt its position at first reading in the exact form as set out in the Annex to this note, subject to revision by the lawyer-linguists of both institutions, the Council will approve the European Parliament's position and the act will be adopted in the wording which corresponds to the European Parliament's position at first reading.
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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>1</sup>,

Having regard to the opinion of the Committee of the Regions<sup>2</sup>,

Acting in accordance with the ordinary legislative procedure,

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<sup>1</sup> OJ C , , p. .

<sup>2</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>3</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 **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.
- (1a) Mercury is a chemical of global concern for the environment, owing to its long-range atmospheric transport, its persistence following its anthropogenic introduction into the environment and its ability to bioaccumulate in ecosystems. Mercury also has significant negative effects on human health and is passed from mothers to children via the placenta or through breastfeeding. Mercury pollution of the environment can result from anthropogenic activities, including insufficient management of mercury waste, cremation or improper implementation of mandatory separators in dental practices.***
- (2) Following the conclusion reached by the Commission in its report<sup>4</sup> and its subsequent Impact Assessment<sup>5</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.

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<sup>3</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>4</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>5</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.

- (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) *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 encourage dental caries prevention and health promotion, thereby minimising the need for dental restoration as an additional measure to support the phase out of the use of dental amalgam, and considering the availability, affordability and current transition to mercury-free alternatives in many Member States, it is appropriate to prohibit the use of dental amalgam for dental treatment in the Union, whilst maintaining the possibility of using dental amalgam for patients with specific medical needs, when deemed strictly necessary by the dental practitioner.* ■
- (4a) *Crematoria are a significant source of releases of mercury into the atmosphere and even with a phase-out of dental amalgam, crematoria will continue to contribute to mercury pollution of air, water, and soil. It is necessary to develop guidance on abatement technologies for mercury emissions from crematoria and to collect information on measures implemented based on that guidance in Member States, in order to achieve appropriate pollution prevention and to mitigate the impact on the environment and human health.*
- (4b) *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 whilst fully respecting Member States' competence for the organisation and delivery of health services and medical care. The phase-out of dental amalgam should be accompanied by professional training for dentists, where appropriate, in order to adjust to new techniques.*



- (4c) As that derogation will allow Member States to use dental amalgam in very specific circumstances until 30 June 2026, the manufacture and import of dental amalgam should be prohibited only from 1 July 2026. However, after 1 July 2026, 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.*
- (4d) 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 31 December 2029 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 the relevant patient groups. Articles 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>6</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, **■** on 24 February 2023 **■** for certain compact fluorescent lamps, *and on 24 August 2023 for linear fluorescent lamps for general lighting purposes. For non-linear triband phosphor fluorescent lamps, the exemption expires on 24 February 2025. The exemption for most high pressure sodium (vapour) lamps for general lighting purposes with an improved colouring index expired on 24 February 2023, whereas for the remaining ones as well as for other high pressure sodium (vapour) lamps for general lighting purposes, the exemption expires on 24 February 2025.* In addition, certain linear fluorescent lamps for general lighting purposes *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>7</sup> *and phase out dates were set up for them by Decision MC-5/4 adopted at the fifth meeting, held from 30 October to 3 November 2023. These Decisions were supported by the Union by means of Council Decisions (EU) 2022/549<sup>8</sup> and (EU) 2023/2417<sup>9</sup>. As it is appropriate to prohibit the export from the Union of the remaining mercury-added lamps as soon as possible, and some of those lamps are currently not covered*

<sup>6</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, p. 88).

<sup>7</sup> **Council Decision (EU) 2017/938 of 23 September 2013 on the signing, on behalf of the European Union, of the Minamata Convention on Mercury (OJ L 142, 2.6.2017, p. 2).**

<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) 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, 2023/2417, 06.11.2023, ELI: <http://data.europa.eu/eli/dec/2023/2417/oj>).**

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 *specified* in Annex III of Directive 2011/65/EU and *no later than* the most ambitious dates included in Decision MC-4/3. *Moreover, significant co-benefits can be achieved by phasing out the export of mercury-added lamps as soon as possible, given that mercury-free alternatives are more energy-efficient and would therefore prevent tonnes of CO<sub>2</sub> emissions from being released.*

- (5a) *The illegal use of mercury and mercury compounds in cosmetic products persists at global level. The fifth Conference of the Parties therefore decided in Decision MC-5/5 to collect information from Parties on challenges they face in preventing the manufacture, import and export of cosmetics listed in Part I of Annex A to the Convention. In light of the detrimental effects of mercury and mercury compounds on human health and the environment, exposure and emissions should be further minimised as much as possible. Recent reports show that European companies are manufacturing and exporting mercury compounds which are used for non-allowed uses, particularly in cosmetics. Therefore, the Commission should report on the developments under the Minamata Convention as regards the phase-out of illegal mercury use in cosmetic products, taking into account information provided by Parties to the Convention in line with Decision MC-5/5. The Commission should further assess the remaining uses of mercury, for example in porosimetry, lighthouses and vaccines, as well as the need to amend the list of large waste sources, and, where appropriate, suggest measures to phase out such uses and regulate manufacture, import and export for such purposes.*
- (5b) *Recalling the need for Member States to ensure proper collection systems for mercury-added products in non-electronic and electronic waste and to collect such products separately and in an environmentally sound manner, in accordance with Directive 2012/19/EU of the European Parliament and of the Council<sup>10</sup>.*

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<sup>10</sup> *Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) (OJ L 197, 24.7.2012, p. 38).*

(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 ■ is inserted:

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

*Fully respecting Member States’ competence for the organisation and delivery of health services and medical care and 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 30 June 2026. Member States shall make publicly available reasoned explanations for making use of this derogation, including the appropriate measures to be implemented by 30 June 2026, and notify them to the Commission by ... [1 month from the date of the entry into force of this Regulation]’;*

(b) the following paragraph ■ is added:

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

*From 1 July 2026, 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:*

*(a) in paragraph 1, first subparagraph, the following points are added:*

*‘(f) a summary of the information gathered in accordance with paragraph 1a of this Article as well as the information on the amounts of mercury used for specific medical needs;*

*(g) information on the implementation of the Commission guidance on reducing emissions from crematoria referred to in Article 19(2a), point (a).’;*

*(b) the following paragraph 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:*

*(a) in paragraph 2, the date ‘31 December 2024’ is replaced by the date ‘31 December 2029’;*

*(b) the following paragraph is inserted:*

*‘2a. By 31 December 2029, the Commission shall report to the European Parliament and to the Council on:*

*(a) based on guidance developed by the Commission by 31 December 2025, at the latest, the implementation and impact of that Commission guidance on abatement technologies for mercury emissions from crematoria applied in Member States;*

- (b) *the necessity to maintain the exemptions for the use of dental amalgam referred to in Article 10(2a), first subparagraph, taking into account the impact on the health of patients generally and patients dependent on amalgam fillings and the necessity to maintain the derogation for the manufacture and imports of dental amalgam as referred to in Article 10(7), third subparagraph;*
- (c) *the developments under the Minamata Convention as regards the phase-out of illegal mercury use in cosmetics, taking into account information provided by Parties to the Convention in line with Decision MC-5/5 on the preparation of a report on cosmetics;*
- (d) *the need to phase out remaining mercury uses;*
- (e) *the necessity to expand the list of mercury waste sources referred to in Article 11;*
- (f) *the necessity to expand the list of mercury compounds, such as for example mercuric azanide chloride (HgNH<sub>2</sub>Cl) under Annex I.’;*

(c) *paragraph 3 is replaced by the following:*

*‘3. The Commission shall, if appropriate, present a legislative proposal together with its reports referred to in this Article.’;*

(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 ( <i>CFLs</i> ) 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).	<b><i>31.12.2026</i></b>
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.	<b><i>31.12.2026</i></b>
4d. Non-linear halophosphate phosphor lamps.	31.12.2025’;



(3) the following entry 5a is inserted:

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