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#### NOTE

From:	General Secretariat of the Council
To:	Delegations
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 - Presidency compromise text

With a view to the meeting of the Working Party on the Environment of 18 January 2024, delegations will find in the Annex a Presidency compromise text on the above Commission proposal.

Changes to the Commission proposal (11960/23 + ADD 1) are set out in **bold underlined**, while ~~striketrough~~ indicates deletions.

The Belgian Presidency team looks forward to the discussion of this text at the Working Party. A deadline for the submission of written comments will be announced at the end of the Working Party.

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 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 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.
- (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>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

- (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~~ in the Union population, whilst maintaining the possibility of using dental amalgam for patients with specific medical needs. In order to prevent the use of 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~~ and import of dental amalgam. **However, with a view to ensuring supply security within the Union, the manufacture and import of dental amalgam used for patients with specific medical needs should remain permitted. In order to assess the continuing need for dental amalgam for those specific uses, 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.** Articles 10, 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, 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>7</sup>, **and phase out dates were set up for them by Decision MC-5/x 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>8</sup> **and Council Decision (EU) 2023/2417<sup>9</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>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).

<sup>7</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>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 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.’;

(b) the following paragraph 7 is added:

‘7. From 1 January [2025], ~~the manufacture and export,~~ **import and manufacturing** of dental amalgam shall be prohibited.

**By way of derogation from the first 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 January 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), second 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), second 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*

*The President*

*For the Council*

*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 (CLFs) 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:

<b>Mercury-added products</b>	<b>Date from which the export, import and manufacturing of the mercury-added products are prohibited</b>
‘5a High pressure mercury sodium (vapour) lamps (HPS) for general lighting purposes.	31.12.2025’.