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From:	General Secretariat of the Council
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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 - Mandate for negotiation with the European Parliament

Delegations will find attached the mandate for negotiations with the European Parliament on the abovementioned proposal, as agreed by the Permanent Representatives Committee at its meeting on 30 January 2024.

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,

¹ OJ C , , p. .

² 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 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 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 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 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.

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

- (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 ~~C~~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 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 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~~ **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 Mercury⁷, **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) 2022/549⁸ **and Council Decision (EU) 2023/2417⁹.** 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 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 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).

⁹ **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:

Mercury-added products	Date from which the export, import and manufacturing of the mercury-added products are prohibited
‘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:

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