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THE EUROPEAN PARLIAMENT

THE COUNCIL

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LEGISLATIVE ACTS AND OTHER INSTRUMENTS

Subject: REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EU) 2017/852 on mercury as regards dental amalgam and other mercury-added products subject to export, import and manufacturing restrictions

REGULATION (EU) 2024/...
OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of ...

amending Regulation (EU) 2017/852 on mercury
as regards dental amalgam and other mercury-added products
subject to export, import and manufacturing 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,

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure²,

¹ OJ C, C/2024/894, 6.2.2024, ELI: <http://data.europa.eu/eli/C/2024/894/oj>.

² Position of the European Parliament of 10 April 2024 (not yet published in the Official Journal) and decision of the Council of

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 for the Union to regulate emissions of mercury and mercury compounds from crematoria, the feasibility of phasing out the use of dental amalgam in the Union in the long term, and preferably by 2030, and the environmental benefits and the feasibility of banning the manufacturing and export of other mercury-added products which are prohibited from being placed on the Union market and imported into the Union.
- (2) 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.

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).

- (3) The Commission, following the conclusion reached in its report of 17 August 2020 on the reviews required under Article 19(1) of Regulation (EU) 2017/852 on the use of mercury in dental amalgam and products, presented a legislative proposal, in accordance with Article 19(3) of that Regulation, 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.
- (4) 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, mercury-free alternatives have become economically and technically feasible and are readily available.
- (5) Considering that the Union and its Member States have ratified the Minamata Convention on Mercury⁴ of 2013 ('the Convention') and given that measures should be taken by Parties to the Convention 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 and affordability of, and the 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, while maintaining the possibility of using dental amalgam for patients with specific medical needs when deemed strictly necessary by the dental practitioner.

⁴ 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).

- (6) While fully respecting Member States' competence for the organisation and delivery of health services and medical care, in order to limit the socio-economic impact of the phase-out of dental amalgam, in particular on low-income patients, Member States in which dental amalgam is the only publicly reimbursed material at a rate of at least 90 % under national law, and in which such reimbursement is not yet possible for mercury-free alternatives as of 1 January 2025, should, by way of derogation from the requirement provided for in this Regulation to phase out dental amalgam by that date, have more time to find appropriate solutions to adapt their healthcare system and should therefore be allowed to have a later phase-out date for dental amalgam. The phase-out of dental amalgam should be accompanied by professional training for dentists, where appropriate, in order to adjust to new techniques.
- (7) Member States that benefit from the derogation from the phase-out provided for in this Regulation should be able to allow the use of dental amalgam in very specific circumstances until 30 June 2026. Accordingly, the import and manufacturing of dental amalgam should be prohibited only from 1 July 2026. However, from 1 July 2026, import and manufacturing of dental amalgam should continue to be possible only if the use of such amalgam is necessary to cover specific medical needs.

- (8) 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 every year of the quantities imported or manufactured for such medical needs. Moreover, by 31 December 2029, the Commission should assess if it is still necessary to maintain the derogation for the import and manufacturing of dental amalgam used for patients with specific medical needs, taking into account the availability of mercury-free alternatives for the relevant patient groups.
- (9) Crematoria are a significant source of mercury emissions into the atmosphere and, notwithstanding the phase-out of dental amalgam provided for in this Regulation, crematoria will continue to contribute to mercury pollution of air, water, and soil. It is necessary to develop guidance on abatement technologies for emissions of mercury and mercury compounds from crematoria and to collect information on the measures implemented on the basis of that guidance in Member States, in order to achieve appropriate pollution prevention and to mitigate the impact on human health and the environment.

- (10) The illegal use of mercury and mercury compounds in cosmetic products persists at global level. The fifth meeting of the Conference of the Parties to the Convention (‘Conference of the Parties’) therefore decided in Decision MC-5/5 to collect information from Parties to the Convention on the challenges they face in preventing the export, import and manufacturing 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 companies operating in the Union are manufacturing and exporting mercury compounds, resulting in illegal mercury use, in particular, in cosmetics. Therefore, the Commission should report on the developments under the 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, furthermore, assess the remaining uses of mercury and mercury compounds, such as its use in porosimetry, lighthouses and vaccines, as well as the need to expand the list of large waste sources, and, where appropriate, suggest measures to phase out such uses and to regulate export, import and manufacturing for such purposes.
- (11) Member States are 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 Council⁵.

⁵ 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).

- (12) 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, inter alia, certain mercury-added lamps which are exempt from that prohibition until the dates set out therein. That exemption 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 tri-band phosphor fluorescent lamps, the exemption expires on 24 February 2025. The exemption for most high pressure sodium (vapour) lamps for general lighting purposes that have an improved colouring index expired on 24 February 2023, whereas for the remaining high pressure sodium (vapour) lamps for general lighting purposes listed in entry 4 of Annex III to Directive 2011/65/EU, the exemption expires on 24 February 2027.

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, p. 88).

- (13) In addition, certain linear fluorescent lamps for general lighting purposes were listed, with a view to them being prohibited, in Decision MC-4/3, adopted at the fourth meeting of the Conference of the Parties, held from 21 to 25 March 2022, and phase-out dates were set for them in Decision MC-5/4 adopted at the fifth meeting of the Conference of the Parties, held from 30 October to 3 November 2023. Those Decisions were supported by the Union by means of Council Decisions (EU) 2022/549⁷ and (EU) 2023/2417⁸.
- (14) As it is appropriate to prohibit the export from the Union of the remaining mercury-added lamps as soon as possible, and since some of those lamps are currently not covered by Part A of Annex II to Regulation (EU) 2017/852, they should, for the purposes of consistency, be included therein to prohibit their manufacturing and export as from the dates set out in Annex III to 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 CO₂ emissions from being released.

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) 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, 6.11.2023, ELI: <http://data.europa.eu/eli/dec/2023/2417/oj>).

- (15) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States but can rather, by reason of their scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.
- (16) 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, in Member States in which 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 the phase-out date of 1 January 2025, dental amalgam may be used for dental treatment until 30 June 2026. Member States shall provide, and make publicly available, reasoned explanations for making use of the 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 of this paragraph, the import and manufacturing of dental amalgam shall be allowed for specific medical needs as referred to in paragraph 2a, first subparagraph.’;

(2) 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 as referred to in Article 10(2a);

(g) information on the measures implemented on the basis of the Commission guidance on abatement technologies for emissions of mercury and mercury compounds 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 dental amalgam they imported or manufactured pursuant to Article 10(7), third subparagraph.’;

(3) Article 19 is amended as follows:

(a) in paragraph 2, the date ‘31 December 2024’ is replaced by ‘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) the implementation and impact of the guidance, developed by the Commission by 31 December 2025, on abatement technologies for emissions of mercury and mercury compounds from crematoria applied in Member States;

- (b) the need to maintain the exemption from the prohibition on 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 of patients dependent on amalgam fillings, and the need to maintain the derogation for the import and manufacturing of dental amalgam as referred to in Article 10(7), third subparagraph;
- (c) the developments under the 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 of the Conference of the Parties on the preparation of a report on cosmetics;
- (d) the need to phase out remaining mercury uses;
- (e) the need to expand the list of mercury waste sources set out in Article 11;
- (f) the need to expand the list of mercury compounds set out in Annex I, by adding, for example, mercuric azanide chloride (HgNH_2Cl).’;

(c) paragraph 3 is replaced by the following:

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

(4) 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 ...,

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 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 that are not included in entries 3 and 3a	31.12.2025’;

(2) the following entries are inserted:

Mercury-added products	Date from which the export, import and manufacturing of the mercury-added products are prohibited
‘4a. Tri-band phosphor lamps for general lighting purposes that are not included in entry 4, point (a).	31.12.2026
4b. Halophosphate phosphor lamps for general lighting purposes that are not included in entry 4, point (b).	31.12.2025
4c. Non-linear tri-band phosphor lamps.	31.12.2026
4d. Non-linear halophosphate phosphor lamps.	31.12.2025’;

(3) the following entry is inserted:

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