ANNEX 8

EU and International law on Mercury
in respect of dental amalgam and mercury-added products

Current EU law addresses the use of metallic mercury (hereinafter "mercury") and mercury compounds (hereinafter "mercury compounds") in a comprehensive manner. The key Union legal instrument is Regulation (EU) No 2017/852 on Mercury (hereinafter ‘Mercury Regulation’), which covers the whole life cycle of mercury from primary mercury mining to the final disposal of mercury as waste and transposes the Minamata Convention on Mercury (hereinafter ‘Minamata Convention’) into EU law.

Mercury is classified under EU chemical legislation as a hazardous substance with the following characteristics: Reproductive toxicity (Cat. 1B), Acute toxicity (Acute Tox. 2), Specific target organ toxicity – repeated exposure (STOT RE1), Hazardous to the aquatic environment (Aquatic Acute 1 and Aquatic Chronic 1). Mercury compounds are also classified as hazardous substances. Additionally, mercury is listed as a priority hazardous substance under EU water law.

Considering the level of hazardousness of mercury to both human health and the environment, this substance is not only addressed in the Mercury Regulation, but also in provisions established in other EU instruments setting specific controls on inter alia mercury air and water emissions, including from industrial installations, the temporary storage of mercury waste and the mercury content in seafood.

For the purpose of this document and in view of the scope of application of this initiative, this Annex focuses on existing EU provisions on dental amalgam and mercury-containing lamps as set in the Mercury Regulation, Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (hereinafter ‘RoIS Directive’).

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and the Minamata Convention. This Annex addresses also the Report of the Commission established under Art. 19(1) of the Mercury Regulation (hereinafter ‘Commission Review Report’), as its conclusions are part of the basis upon which this document is developed\textsuperscript{10}. At last, this Annex touches also upon Decision MC-4/3 adopted at the fourth Conference of the Parties to the Convention (March 2022)\textsuperscript{11} since this will also trigger amendments to Annex II (Part A) to the Mercury Regulation.

I. EU ACQUIS AND INTERNATIONAL LAW ON DENTAL AMALGAM USE

The use of dental amalgam in the EU is primarily regulated under Art. 10 of the Mercury Regulation. Firstly, this provision defines a set of measures aiming at promoting and hastening the \textit{phase down} of amalgam use and at reducing amalgam-related mercury emissions. They include the prohibition to use mercury in bulk form by dental practitioners, the obligation for Member States to develop a national phase down plan and for dental practices to be equipped with amalgam separators to collect dental amalgam waste. Secondly, Art. 10 sets a \textit{partial phase-out} on the use of dental amalgam since it prohibits it since 1 January 2018 for treatment of deciduous teeth and for vulnerable population groups (children below the age of 15, pregnant or breastfeeding women).

The use of dental amalgam is also subject to specific provisions under the Minamata Convention. Like the Mercury Regulation, the Minamata Convention sets rules on both the phase-down and phase-out of the use of dental amalgam. Regarding \textit{phasing-down}, Art. 4(3) and Annex II to that Convention requires Parties to take at least two measures, including, for instance, the establishment of national objectives to minimise the use of dental amalgam, the promotion of research and development on mercury-free alternatives and of environmental best practices within dental facilities. Concerning \textit{phasing-out}, Parties agreed at the fourth Conference of the Parties to the Convention (March 2022) to prohibit dental amalgam use for the same vulnerable population groups as under the Mercury Regulation. This prohibition shall enter into force on 28 September 2023.

As requested under Article 19(1)(b) of the Mercury Regulation, the Commission reported on the feasibility of a total phase-out preferably by 2030, taking into account above-mentioned national phase down plans and whilst fully respecting Member States' competence for the organisation and delivery of health services and medical care. Whilst it concludes that such a phase-out is economically and technically feasible, the \textit{Commission Review Report} highlights that additional information and assessment (e.g. further data on associated mercury emissions) are still necessary to enable the Union to make a well-founded legislative proposal to address the remaining use of dental amalgam. Such complementary information and assessment are contained in the relevant sections of this Staff Working Document.


II. EU ACQUIS AND INTERNATIONAL LAW ON MERCURY-ADDED PRODUCTS (MAPs)

1. The placing on the EU market and import into the EU of MAPs

The placing on the market and import of MAPs is regulated at Union level by means of several legal instruments, including e.g. Regulation (EC) 1907/2006 REACH\(^1\), Regulation (EC) 1223/2009 on cosmetic products\(^2\) and Directive (EC) 2006/66 on Batteries Directive\(^3\). The concerned products are prohibited from being placed on the market and imported when their mercury content exceeds a certain limit ranging from zero (e.g. thermometers, barometers) to a specific maximum limit (e.g. 0,007 % in eye products)\(^4\). In this regard and as stated earlier, this Annex addresses in particular the RoHS Directive that regulates the mercury content in lamps.

Whereas neither the Mercury Regulation nor the Minamata Convention addresses the placing on the (EU or international) market of MAPs, both instruments address their manufacturing, import and export.

2. The manufacturing, import and export of MAPs

2.1 The Mercury Regulation

Art. 5 of the Mercury Regulation provides that the manufacturing and international trade of the MAPs listed in its Annex II (Part A) are prohibited as from the dates specified therein (1 January 2019 or 1 January 2021). Currently, Annex II contains nine entries covering certain MAP, including (i) batteries or accumulators, (ii) switches and relays, (iii) cosmetic products, (iv) pesticides, biocides and topical antiseptics, (v) a set of non-electronic measuring devices, (vi) specific compact fluorescent lamps (CFLs), (vii) specific linear fluorescent lamps (LFLs) and (viii) high pressure mercury vapour lamps and (ix) certain cold cathode fluorescent lamps (CCFLs) and external electrode fluorescent lamps (EEFLs).

Hence, the Mercury Regulation complements above-mentioned EU legal instruments that prohibits the placing on the market and import of those MAPs.

2.2 The Minamata Convention and Decision MC-4/3

Similarly, Art. 4(1) and Annex A (Part I) to the Minamata Convention prohibits since 1 January 2021 the manufacture, import and exports of the MAPs, which are listed in Annex II (Part A) to the Mercury Regulation. This similarity in scope stems from the instrumental role

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\(^4\) For more information on identified existing mercury-added products and associated EU legislation, see the inventory developed by the Commission in accordance with Art. 8(7) of the Mercury Regulation, available at: [https://circabc.europa.eu/ui/group/19e66753-84ca-4e4e-a4a1-73bdfb368fc2/library/d198684c-0834-4f20-9682-de66553ed066/details](https://circabc.europa.eu/ui/group/19e66753-84ca-4e4e-a4a1-73bdfb368fc2/library/d198684c-0834-4f20-9682-de66553ed066/details)
played by the EU in the course of the negotiations on the establishment of the Minamata Convention.

The scope of application of the Minamata Convention regarding MAPs has recently been extended by means of Decision MC-4/3. In particular, Parties agreed to prohibit the manufacturing, import and export of eight additional MAPs as from 1 January 2026, including:

(i) CFL.i for general lighting purposes that are ≤ 30 watts with mercury content not exceeding 2.5 mg per lamp burner,
(ii) CCFLs and EEFL of all lengths for electronic displays, that are not yet included in Annex II (Part A),
(iii) Melt pressure transducers, transmitters and pressure sensors,
(iv) Mercury vacuum pumps,
(v) Tire balancers and wheel weights,
(vi) Photographic film and paper,
(vii) Propellant for satellites and spacecraft,
(viii) Strain gauges to be used in plethysmographs

The adding of those MAPs to Annex A (Part I) to the Minamata Convention was fully supported by the EU. In such case, Article 20 of the Mercury Regulation provides that the Commission is empowered to adopt delegated acts in order to amend e.g. Annex II (Part A) to that Regulation to align it with decisions adopted by the Parties to the Minamata Convention. However, for the sake of legal practicability and clarity, the relevant complementary MAPs covered by Decision MC-4/3 will be included in Annex II (Part A) to the Mercury Regulation by means of this initiative.

2.3 The 2020 Commission Review Report

As requested under Article 19(1)(c) of the Mercury Regulation, the Commission reported on the environmental benefits and feasibility of a further alignment of Annex II to the Mercury Regulation with relevant Union legislation regarding the placing on the market of MAPs. Considering the intrinsic link between EU law on mercury and the Minamata Convention and given that some of the MAPs prohibited from being placed on the market are still manufactured in the EU for export to third countries, the Commission Review Report identifies two possible approaches.

- The first approach would make the concerned MAPs subject to a unilateral EU ban on manufacturing and international trade by adding them to Annex II (Part A) to the Mercury Regulation. According to the Commission Review Report, the environmental

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16 ‘CFL.i’ means compact fluorescent lamps with integrated ballast.
17 Those MAPs are already prohibited from being manufactured, imported and exported from the EU in accordance with Annex II (Part A)(entry 9(f) to the Mercury Regulation.
18 Supra n° Council Decision (EU) 2021/727 of 29 April 2021 on the submission, on behalf of the European Union, of proposals to amend Annexes A and B to the Minamata Convention on Mercury, regarding mercury-added products and manufacturing processes in which mercury or mercury compounds are used (OJ L 55 of 5.5.2021, p. 23).
19 Supra n° 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).
impacts of such a ‘unilateral ban’ could be either positive or negative depending on the extent to which EU production would be substituted by production in third countries.

- The second approach would focus on the Union’s effort to negotiate and agree at global level on an extension of the list of MAPs referred to in Annex A (Part I) to the Minamata Convention. Once such an extension would be adopted by the Parties to the Convention, it would then be transposed in Annex II (Part A) to the Mercury Regulation by means of a legislative proposal or by means of a Delegated Act, in accordance with Art. 19(3) or 20 of that Regulation.

The successful applicability of this second option depends not only on the EU’s policy objectives but primarily on the uncertain level of ambition of the other Parties to the Minamata Convention. This is one of the key the reasons why the preferred option identified in this document in respect of problem area 2 consists, as a first step, of amending unilaterally Annex II (Part A) to the Mercury Regulation to align it with provisions set out under RoHS prohibiting the placing on the market of several mercury-containing lamps, and, as a second step, of pushing for an agreement at Minamata level to extend again the scope of application of Art. 4(1) and Annex A (Part I) to the Convention to align it with the then amended Annex II (Part A) to the Mercury Regulation.

3. **To align Annex II (Part A) to the Mercury Regulation with relevant RoHS restrictions on mercury-containing lamps.**

Without prejudice to the legal obligation to complement Annex II (Part A) to the Mercury Regulation with the seven MAPs covered by above-mentioned Decision MC-4/3, this initiative aims also, for the purpose of implementing Art. 19(1)(c) and (3) of the Mercury Regulation, at aligning Annex II (Part A) to the Mercury Regulation with the relevant restrictions set out under RoHS. The objective is to ensure below listed MAPs, which are already prohibited from being placed on the market and imported in the EU in accordance with RoHS, are also made subject to a ban on manufacturing and export by adding them to Annex II (Part A) to the Mercury Regulation. As explained in this Staff Working Document, this initiative focuses on the three types of mercury-containing lamps for general lighting purposes accounting for the most important intentional mercury uses in products alongside dental amalgam.

3.1 **The case of mercury-containing compact fluorescent lamps (CFLs) for general lighting purposes**

On the one hand, current Annex II (Part A) (entry 3) to the Mercury Regulation prohibits the manufacturing, import and export of the following CFLs:

- (a) CFL, i ≤ 30 watts with mercury content > 2,5 mg per lamp burner for general lighting purposes
- (b) CFL,ni20 ≤ 30 watts with mercury content > 3,5 mg per lamp burner for general lighting purposes

On the other hand, as a follow-up to the adoption of Commission Delegated Directive (EU) 2022/276 amending Annex III (entries 1, 1(a), 1(b), 1(c), 1(d) and 1(e) to the RoHS

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20 ‘CFL ni’ means compact fluorescent lamps without integrated ballast.
Directive, as from 24 February 2023, all CFLs for general lighting purposes can only be placed on the Union market and imported into the EU if they contain zero mercury content.

Hence, should the co-legislators agree on an alignment between the Mercury Regulation and RoHS regarding those lamps, it would imply that above-mentioned existing entry 3 of Annex II (Part A) to this Regulation would need to be amended in such a way as to provide that all CFLs (including all CFL.i and CFL.ni.) for general lighting purposes containing mercury would be prohibited from being manufactured in the EU, imported into the EU and exported from the EU. In this respect, it is to be noted that the amendment to Annex II (Part A) (entry 3)(a) will directly stem from the need to transpose above-cited Decision MC-4/3.

3.2 The case of mercury-containing linear fluorescent lamps (LFLs) for general lighting purposes - Triband phosphor LFLs

On the one hand, current Annex II (Part A) (entry 4)(a) to the Mercury Regulation prohibits the manufacturing, import and export of the following triband phosphor LFLs:

(a) Triband phosphor < 60 W with Hg content > 5 mg per lamp burner for general lighting purposes

On the other hand, as a follow-up to the adoption of Commission Delegated Directive (EU) 2022/284 amending Annex III (entries 2(a), 2(a)(1), 2(a)(2), 2(a)(3), 2(a)(4) and 2(a)(5)) to the RoHS Directive, as from 24 February 2023 or 24 August 2023, all triband phosphor LFLs for general lighting purposes can only be placed on the Union market and imported into the EU if they contain zero mercury content.

Hence, should the co-legislators agree on an alignment between the Mercury Regulation and RoHS regarding those lamps, it would imply that above-mentioned existing entry 4(a) of Annex II (Part A) to this Regulation would need to be amended in such a way as to provide that all triband phosphor LFLs for general lighting purposes containing mercury will be prohibited from being manufactured in the EU, imported into the EU and exported from the EU.

3.3 The case of mercury-containing halophosphate fluorescent lamps for general lighting purposes

On the one hand, current Annex II (Part A) (entry 4)(b) to the Mercury Regulation prohibits the manufacturing, import and export of the following halophosphate fluorescent LFLs:

(b) Halophosphate phosphor (LFLs) < 40 watts with mercury content > 10 mg per lamp burner for general lighting purposes

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On the other hand, Annex III (entries 2(b)(1) and 2(b)(2)) to the RoHS Directive prohibits, since 13 April 2012 and 13 April 2016, the placing on the market and import of (i) linear halophosphate phosphor lamps with tube diameter > 28 mm (e.g. T10 and T12) and (ii) all non-linear halophosphate phosphor lamps.

Hence, should the co-legislators agree on an alignment between the Mercury Regulation and RoHS regarding those lamps with a view to aligning Annex II (Part A) to the Mercury Regulation with the RoHS Directive as far as halophosphate phosphor lamps are concerned, above-mentioned existing entry 4(b) of that Annex will need to be amended in such a way as to provide that all halophosphate phosphor lamps will be prohibited from being manufactured in the EU, imported into the EU and exported from the EU.

4. **The specific case of the manufacturing, import and export of dental amalgam**

Under current EU and international law, there are no restrictions on the manufacturing, import and export of dental amalgam. Should the co-legislator agree on prohibiting the export of dental amalgam whilst allowing the continued manufacture and import for EU use only to cover specific medical needs of patients, the Mercury Regulation would need to be amended accordingly (either by means of an amendment to its Art. 10 or to its Annex II (Part A)).