



C/2024/894

6.2.2024

**Opinion of the European Economic and Social Committee on the 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**

(COM(2023) 395 final — 2023/0272 (COD))

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Rapporteur: **Jarmila DUBRAVSKÁ**

Referral	European Parliament, 11.9.2023 Council, 26.7.2023
Legal basis	Articles 192(1) and 304 of the Treaty on the Functioning of the European Union
Section responsible	Section for Agriculture, Rural Development and the Environment
Adopted in section	2.10.2023
Adopted at plenary	26.10.2023
Plenary session No	582
Outcome of vote (for/against/abstentions)	187/3/3

## 1. Conclusions and recommendations

1.1. The European Economic and Social Committee (EESC) endorses the Commission's goal of safeguarding people's health and lives and helping protect the environment.

1.2. The Committee therefore welcomes the ban on dental amalgam to enter into effect on 1 January 2025 and proposes introducing a strict ban as there are many alternatives which do not contain mercury. There is therefore no reason to continue using dental amalgam, even in exceptional circumstances, as by stopping its use we are protecting both patients' health and the environment.

1.3. Mercury-free alternative filling materials continue to be costlier for patients in certain Member States because some national healthcare systems cover dental amalgam but not alternative filling material. The EESC considers that phasing out amalgam, with no exceptions, will send an important signal to national healthcare systems to cover only filling materials which do not contain the toxic amalgam.

1.4. The ban on the use of amalgam in favour of suitable and appropriate alternatives can be put into effect by devising a form of financial compensation to be incorporated into the rules of individual health insurance companies. Accordingly, the EESC recommends that the Commission identify ways and means of financing safe, environmentally-friendly alternatives. Amalgam is already more expensive than the alternatives, given the costs of manufacture, the limited availability of raw materials, the requirement to install separators, and costs of storage and the safe removal of waste from dental offices.

1.5. Dental amalgam will continue to be necessary without a full ban. The Committee points out that in this case, due to the need to protect society and the environment at both EU and global level, it is essential to ensure a level playing field for all parties. It is unacceptable to impose a ban on the manufacturing and export of amalgam just for EU Member States, if amalgam can still be imported into the EU. Continued manufacture of amalgam within the EU will need to be authorised if it is still in use, even if only to a limited extent, so that the competitiveness of EU companies is maintained and measures are taken to ensure oversight of the manufacturing and quality of the amalgam supplied.

1.6. If the EU Chemicals Strategy for Sustainability and the Zero Pollution Action Plan are to be successful, it is key to involve the whole of society, including health insurance companies. In this way, these companies will contribute to protecting the environment.

1.7. The EESC recommends that steps be taken to pick up the pace as regards research into suitable alternatives to mercury-containing products.

1.8. The Committee regrets that no ban has been implemented to date on products deemed essential for civil protection and military uses and which continue to use mercury. Mercury contained in the above-mentioned products harms the environment and people's lives and health: it remains in the soil, gets into water and then is cycled back around, meaning that the damage it does to living organisms does not stop.

1.9. The Committee calls on the Commission to begin work on banning the manufacturing and use of mercury-containing products for military use at global level. This can help protect the environment and, most importantly, promote world peace.

## 2. Commission proposal

2.1. The European Commission has developed the Chemicals Strategy for Sustainability and the Zero Pollution Action Plan with an eye to health and the environment.

2.2. The proposal put forward by the Commission is connected to the strategy and action plan and is intended to find solutions to all issues relating to mercury, including its use in products, with a view to meeting the commitments under the Minamata Convention, which has now been ratified by 146 countries around the world <sup>(1)</sup>.

2.3. The aim of the proposal is to deliver on the EU's commitment to lead by example and ensure that hazardous chemicals banned in the EU are not manufactured for export and to meet the commitments to zero pollution and minimising the EU's external pollution footprint. This will entail amending relevant legislation.

2.4. Based on the Commission report on reviews <sup>(2)</sup> of the feasibility of phasing out the use of mercury in dental amalgam and other products, the Commission has submitted a proposal to phase out the use of dental amalgam and limit the manufacture and export of specific mercury-containing lamps.

2.5. As regards the use of dental amalgam, the Member States have already adopted legislation partially banning it: from 1 January 2018, use of dental amalgam has been banned for dental treatment of deciduous teeth and of vulnerable members of the population (i.e. children under the age of 15, and pregnant and breastfeeding women), except when deemed strictly necessary by the dental practitioner based on the specific medical needs of the patient.

2.6. As regards the use of mercury-added products, the ban covers the manufacture, import and export of the mercury-added products listed in Annex II <sup>(3)</sup> as from the phase-out dates specified therein (as from 31 December 2018 or 2020), except when they are deemed essential for civil protection and military uses or those used for research, calibration of instruments or as a reference standard.

2.7. There are various options when it comes to air pollution by mercury. At present, mercury is captured in sorbents. This is a very expensive technology, particularly for individual operations owing to pressure losses and the costs incurred in disposing of hazardous waste.

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<sup>(1)</sup> Party profiles | Minamata Convention on mercury ([minamataconvention.org](http://minamataconvention.org)).

<sup>(2)</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), 17.8.2020.

<sup>(3)</sup> There are six types of products: batteries and accumulators, certain switches and relays, a range of mercury-containing lamps, including certain compact fluorescent lamps (CFLs) and linear fluorescent lamps (LFLs) for general lighting purposes, mercury-added cold cathode fluorescent lamps and external electrode fluorescent lamps (CCFLs and EEFLs) for electronic displays and high-pressure mercury vapour lamps (HPMV) for general lighting purposes, cosmetics (except some eye products), pesticides, biocides and topical antiseptics, and certain non-electronic measuring devices (e.g. thermometers, barometers).

2.8. At present a new innovative technology is available which uses a more modern, less costly method: the mercury is ionised, collected at the waste facility and subsequently re-used. This new method costs a fraction of the cost of the standard method, and enables mercury to be captured from the fumes <sup>(4)</sup>.

2.9. As regards the availability of technically and economically feasible mercury-free alternatives, further restrictions have been imposed, under the RoHS Directive <sup>(5)</sup>, on other mercury-added products, in terms of placing these products on the market and importing them. This proposal aims to phase out the manufacture, import and export of mercury-containing lamps, which are listed in the annex to the Regulation.

2.10. This proposal adapts EU law on mercury-added products and implements Decision MC-4/3 adopted by the Minamata Convention in March 2022 <sup>(6)</sup>.

### 3. General comments

3.1. Machines, equipment and chemicals have been part of human life and existence since the industrial revolution, when they started to be used intensively in pursuit of progress. However, good things have unfortunate consequences. In the case of chemicals, certain characteristics of elements which themselves can be safe for life, health and the environment are a problem. Mercury is a risk for health and the environment.

3.2. Mercury is a potent neurotoxin: it induces permanent brain and kidney damage, harms foetal development, damages organs, affects human reproduction and is toxic to aquatic life. Steps must therefore be taken to prevent it being released into water, air and soil. This can only be achieved by banning its use, import and export and replacing it with suitable alternatives as quickly as possible to avoid losing access to devices which use mercury.

3.3. The Committee endorses the proposed Regulation of the European Parliament and of the Council, which will amend and complete the 2017 Regulation. However, it has a number of reservations and comments regarding the proposal. The proposal for a Regulation will ensure consistency between the Mercury Regulation and the RoHS Directive, and thus contribute to achieving the EU's commitments under Flagship 8 of the Zero Pollution Action Plan <sup>(7)</sup> by phasing out the manufacture and export of mercury-containing lamps. These conditions and recommendations should be applied at global level, with reciprocal measures designed to safeguard life, health and the environment. This means that the ban on exports should be flanked by a ban of imports.

3.4. The Committee endorses the measures protecting the environment from the harmful effects of mercury, including a ban on imports, manufacture and exports, where there are suitable alternatives to this highly toxic element. The aim is to avoid interference with and restrictions on individuals in need of dental treatment, and on consumers who already have products containing mercury. The Committee considers however that the ban should be extended to other products in use in the EU and around the world, so that mercury is replaced by suitable and safe alternatives.

3.5. The EESC believes that with the proposal, which extends the ban on the use of dental amalgam to all population groups in the EU from 1 January 2025 (total ban) so that it can be used only in a few specific circumstances when deemed strictly necessary by the dental practitioner based on the specific medical needs of the patient, and with the ban on the manufacture and export of dental amalgam in the EU from 1 January 2025 and the ban on the manufacture, import and export of a further six mercury-added products, the EU is safeguarding people's health and the environment in Europe and around the world. The EU therefore needs to address the paradoxical situation facing the EU itself and third countries: most countries have ratified the Minamata Convention — even those which are major producers of mercury and mercury-containing products. The EU needs to address the import of any mercury-containing products into the EU by means of a ban.

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<sup>(4)</sup> Information about this technology can be found at the Czech National Intellectual Property Office: [https://isdv.upv.cz/webapp/resdb\\_print\\_detail.det?pspis=PUV/40735&plang=EN](https://isdv.upv.cz/webapp/resdb_print_detail.det?pspis=PUV/40735&plang=EN).

<sup>(5)</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>(6)</sup> MC-4/3 — Review and amendment of annexes A and B to the Minamata Convention on Mercury.

<sup>(7)</sup> Flagship initiative 8 — Minimising the EU's external pollution footprint.

3.6. The Committee believes that rules must be established and measures rolled out which will safeguard people's lives and health and the environment, while also taking care not to undermine the competitiveness of EU economic operators. The conditions and rules in place should therefore be reciprocal and apply both to manufacture and exports and to imports.

#### 4. Specific comments

4.1. The Committee regrets that no ban has been implemented to date on products deemed essential for civil protection and military uses. Research is therefore the key to rapidly identifying effective alternatives to mercury in this area as well. The main reason for this is to remove the harmful effects of mercury, which in the EU is classified as being toxic for reproduction, fatal if inhaled, causing damage to all organs through prolonged or repeated exposure and very toxic for aquatic life with long lasting adverse effects. The ban on the manufacture and use of mercury-containing products for military uses at global level would help protect the environment and, most importantly, promote peace in many parts of the world.

4.2. Many EU Member States have already banned dental amalgam or it is considered to be banned in many EU countries. For instance, in 2009 Sweden banned dental amalgam with a few exceptions which were also banned in 2018 <sup>(8)</sup>. The main advantage these days of mercury-free alternatives to amalgam, specifically Glass Ionomer Cement and compomers, is that they can be used even in tricky situations requiring rapid application and resistance to the patient's saliva. For children, uncooperative patients or people with hypersalivation, an alternative filling material would offer the same level of quality and functionality even in these conditions. Patient comfort is therefore no justification for continuing to authorise exceptions which are a threat to patients' health and to the environment.

4.3. Dental practitioners, who for various reasons continue to use dental amalgam for treatment, must be engaged in replacing amalgam if there is to be swift progress. One reason that they continue to use it is affordability for part of the population. Each Member State has its own health insurance scheme and thus its own methods for reimbursing dental treatment; that is one area regarding which we have reservations. The system of reimbursements by health insurance companies for treatment and fillings should focus on the safety of individual filling materials for the patient's health and the environment. Amalgam, which poses a risk, should not have a higher reimbursement threshold. At the same time, patients should be informed about the risks of using dental amalgam in fillings, not just for health but also in terms of its suitability for teeth: amalgam can be used in a limited number of treatments, but it expands which can lead to cracks in the enamel or cause the crown to break and have to be removed — the worst scenario for the patient in terms of aesthetics and functionality.

4.4. It is true that amalgam used to be a cheaper filling material than the alternatives. However, the end price for society as a whole was and still is high, given the overall environmental and health implications and the requirement that dental practitioners have a separator. Consequently, it is critical that a system be found to facilitate the use and affordability of substitutes for the entire population, such as a system of reimbursements by health insurance companies.

4.5. The Committee endorses the measures protecting the environment from the harmful effects of mercury, including a ban on imports, manufacture and exports, if there is a suitable alternative to this highly toxic element. It is key to ensure reciprocity of all measures, and so the ban referred to in Article 10(b) of the new Regulation should extend to imports of dental amalgam. If amalgam is manufactured in the EU, both the process and the quality can be rigorously checked. Amalgam imported with no regard to the origin of the mercury cannot provide adequate checks on the manufacturing process or the quality and so people who come under the exceptions will be exposed to significantly higher risk.

4.6. Effective checks must be carried out on imports into the EU of banned mercury-containing products, including dental amalgam and mercury-added products.

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<sup>(8)</sup> Measures to reduce the use of Dental Amalgam in Europe, European Network of Environmental Medicine, 20 August 2021.

4.7. If the EU Chemicals Strategy for Sustainability and the Zero Pollution Action Plan are to be successful, the import of dental amalgam into the EU must be banned along with its manufacturing and export. This ban should be made easier by the fact that most of the countries around the world have already ratified the Minamata Convention. Otherwise, amalgam will enter the human body in the event of dental treatment using imported amalgam. If it is not possible to impose a ban on imports, the Committee considers that limited manufacture must be authorised within the EU for use only when deemed strictly necessary by the dental practitioner based on the specific medical needs of the patient. This will ensure that there are comprehensive checks on the manufacturing, quality and amount of amalgam, and our environment will not be burdened by the high carbon emissions entailed by importing amalgam into the EU.

4.8. If mercury-added lamps and products are banned, then a ban will need to be imposed on imports into the EU market from third countries and steps taken to enforce that ban. The use of third-country based delivery services is a particular concern, as are illegal imports: the EU has to cope with illegal imports of almost every type of imported commodity.

4.9. The Committee urges the Commission to lose no time in proposing suitable alternatives to mercury in products which are still available on the EU market. Research institutes must be brought on board to explore products for civil protection and military uses or those used for research and calibration.

Brussels, 26 October 2023.

*The President*  
*of the European Economic and Social Committee*  
Oliver RÖPKE