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**Subject:** Clarification on the EU proposal to replace Regulation (EU) 2017/852 of the European Parliament and of the Council on mercury

Dear Mr McGuigan,

With regard to yesterday's hearing on the Phase out of dental amalgam, we would like to clarify some points presented by the BDA. We very much appreciate your dedication to this issue, yet we encourage you to consider these arguments of the civil society:

"Phase down is recognised internationally,.. at COP5 a proposal to phase out dental amalgam by 2030 was rejected."

Actually, 34 countries worldwide have already banned the use of dental amalgam, declared no longer to use it or replaced it in the public health system. By January 2025, this number is expected to rise to 56 countries. 2 further countries have stopped the Import. <https://environmentalmedicine.eu/mercury-free-dentistry-for-planet-earth/>

It is correct that there was no agreement on the proposal to phase out dental amalgam by 2030 at COP5. However, it was not rejected, but will be discussed further at COP6 in November 2025.

"There is more need for research"

Research into alternative materials has been sufficiently done. The last comprehensive study was actually the impact assessment for the European Commission, which was reviewed by the Regulatory Scrutiny Board on 14 December 2022, i.e. after the pandemic. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52023SC0396>

Information on the availability of alternative materials was also compiled for COP4 of the Minamata Convention ([https://minamataconvention.org/sites/default/files/documents/working\\_document/4\\_5\\_DentalAmalgam.English.pdf](https://minamataconvention.org/sites/default/files/documents/working_document/4_5_DentalAmalgam.English.pdf)) and WHO provided an overview of the availability of alternatives in 2022 (<https://iris.who.int/handle/10665/352480>).

"Decay-prevention is one of the three legs that underpin the Minamata convention."

The Minamata Convention rather examines whether a product containing mercury can be replaced to regulate it. Only for dental amalgam there was a list of 9 phase down measures in the 2013 version, among those decay prevention was one of the options that is least likely to contribute to an effective reduction in the use of dental amalgam.

Why has the EU brought forward the phase-out by 5 years?

On the use of dental amalgam, the Impact Assessment concluded that the preferred policy option is to introduce an EU-wide obligation to phase-out the use of dental amalgam as from 2025, given that (i) it would lead to the greatest environmental and health benefits, including in terms of reductions in mercury emissions from crematoria, (ii) this timeframe is implementable as demonstrated by those Member States that have already phased out or plan to phase out dental amalgam use and the overall declining trend in dental amalgam use, (iii) the cost difference between dental amalgam and mercury-free alternatives is expected to narrow with greater demand and innovation, (iv) it would ensure a uniform phase-out across all Member States and hence place the Union in a first-mover leadership role in relation to future international negotiations within the Minamata Convention and the Unions future market competitiveness, (v) this prohibition would contribute to meeting the objectives set out under the EGD, the Zero Pollution Action Plan and the Chemicals Strategy for Sustainability

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The BDA has an obvious financial interest in maintaining the use of amalgam in NHS care. With around 7% of dental amalgam use in Northern Ireland (comparing the consultation statements with the figures from 2015 in the BDA position paper) dentists are currently generating substantial income from the around 90% of treatments using alternatives via private services (alternative fillings for incisors reimbursed by NHS factored in).

Their fear is that phasing out dental amalgam might lead to NHS introducing alternative materials at lower reimbursements than can be claimed via private billing. Moreover, the demand for these services might increase.

Yet there are nowadays cost-effective and time-saving materials that can be introduced to ensure satisfactory NHS coverage, such as those introduced in Poland in 2022 (Glassionomers and Compomers replaced dental amalgam in the public health services). Amalgam has also been replaced in all European public reimbursement systems for children, pregnant and breastfeeding women.

When evaluating an appropriate reimbursement for a satisfactory filling by Public Health Services, it needs to be borne in mind that there has been significant technical development in the alternatives and that they are now more effective and less time consuming to process than amalgam, especially when considering that for a proper amalgam filling patients have to visit the dentist twice, as amalgam has to harden for 24 hours before grinding.

Governments have to decide where to draw the red line. Currently the society is bearing the costs for the environment pollution and health-effects for the use of dental amalgam - an injustice that needs to be stopped.

Norway has impressively worked out for the Minamata Convention the advantages of phasing out dental amalgam for society. And by the way, there is no mention of more tooth extractions in the report and Sweden, which banned amalgam in 2009, also reported no adverse clinical effects. [https://minamataconvention.org/sites/default/files/documents/submission\\_from\\_government/Norway3\\_DentalAmalgam.pdf](https://minamataconvention.org/sites/default/files/documents/submission_from_government/Norway3_DentalAmalgam.pdf)

When the BDA expressed the opinion that dental amalgam might still be needed for special cases, I would like to remind you that this is foreseen by the EU Regulation. Also in Norway and Sweden there were exceptions for patients that needed dental treatment under general anaesthesia or were allergic to components in mercury-free fillings. Exceptions, which were withdrawn after some years.

Countries like Moldova, the poorest country in Europe, directly implemented a ban on dental amalgam use without exceptions in 2020.

Please take our position paper on the European Commission's Proposal for Phasing out Dental Amalgam by January 2025 into consideration. [https://environmentalmedicine.eu/wp-content/uploads/20230272COD\\_PositionPaper\\_DA\\_EnvMedNetwork-.pdf](https://environmentalmedicine.eu/wp-content/uploads/20230272COD_PositionPaper_DA_EnvMedNetwork-.pdf)

If there will be an investigation, we would welcome to be invited for consultation.

Yours sincerely,

Florian Schulze

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# Position Paper on the European Commission's Proposal for Phasing out Dental Amalgam by January 2025

11. October 2023

**The European Network for Environmental Medicine welcomes the Commission's proposal to phase out the use of dental amalgam and ban its production and export by January 1, 2025. We have been advocating for amalgam phase-out for years.**

With an average of 0.6 grams per filling and a total use of 40 tons of mercury per year dental amalgam is the largest remaining use of mercury in the EU and contributes significantly to environmental pollution. Only by phasing it out by 2025 the release of about 10 tons of mercury into the environment by 2030 can be avoided. Any further use is unnecessary and contributes to already elevated concentrations.

The current environmental conditions are alarming. In the atmosphere, mercury concentrations are 500% higher than natural levels and in oceans they are 200% higher. 40% of surface waters in the EU are contaminated with mercury, posing a risk to birds and marine mammals that feed on contaminated fish or shellfish (EEA 2018) and putting the human consumption of fish at risk. A study revealed, that in Europe, one in three newborns are born every year to mothers with exceeded mercury level which is associated with a loss of intelligence, because mercury is passed from exposed mothers through the placenta (DEMOCOPHES project Bellanger et al 2013).

A continued use of amalgam might hinder and reduce the effectiveness of current and upcoming EU legislation and policies, like the EU Water Reuse Regulation, for agricultural irrigation from **2023**, the Water Framework Directive, for waters in good ecological and chemical status from **2027** or the Circular Economy Action Plan, for the reuse of sewage sludge in agriculture.

Since about 50% of the anthropogenic mercury detected in the EU originates from outside European borders, the EU is also dependent on the international reduction of mercury emissions negotiated under the Minamata Convention, for which it must lead by example. Worldwide, over thirty countries have already phased out the use of amalgam. An EU-wide regulation is therefore preferable to national legislation.

## **Mercury fillings are more expensive than alternatives**

Mercury from dentistry contributes to polluting our water and air and poisoning the fish we eat and vegetables we grow. Because of the high environmental and health costs associated with mercury emissions, amalgam is more expensive than most, possibly all, filling materials (Hylander 2006). Costs that are borne primarily by taxpayers, often without being aware of the reasons.

Mercury from dentistry inevitably enters the environment: when new fillings are placed or old ones removed in dental offices, at the end of life of people with amalgam fillings (through cremation or burial), and during the progressive decomposition of amalgam fillings in the mouth through chewing, drinking hot beverages, and corrosion (through mercury excreted by humans).

It enters wastewater from dental clinics despite safety precautions because amalgam separators filter only part of the clinics wastewater and are often not properly maintained. From the excess amalgam from processing (about 60%), mercury still enters the environment in large quantities during waste treatment, even when properly disposed of. An "environmentally sound" management of amalgam is illusory.

Yet there are already sufficiently proven, cost-effective, safe, equally durable, and more tooth-friendly amalgam alternatives, as demonstrated by the experience in Sweden, where no adverse clinical effects were observed after the phasing out of dental amalgam in 2009. An experience shared by countless mercury-free dentists across Europe.

Information from the dental lobby might be driven by financial interests. In some countries dentists want to continue selling alternatives as a special more expensive treatment compared to amalgam and not aesthetic and safe alternatives to become the standard. But the time for processing and the material cost do not justify any higher price for alternatives like composites, compomers or Glass Ionomers. It's a Business and the Government has to decide where to draw the red line. Currently the society is bearing the costs for the environment pollution and health-effects - an injustice that has to be stopped.

Like in Poland, amalgam can simply be replaced by glass ionomer cement, compomer or composite. In Poland, it was actually the dentists who called for the phase-out because they no longer wanted to expose themselves and their employees (mainly women in childbearing age) to mercury in their clinics.

### **Amalgam manufacturers fail to meet requirements for approval**

In addition, the safety of filling materials is further improving due to the increased requirements of the new Medical Device Regulation (MDR). Mercury-free products have already received MDR certificates, which is not the case for amalgam capsules.

It is expected that amalgam capsules will not be able to meet the requirements of the MDR, as for the first time manufacturers will have to declare the release rate of mercury under all possible circumstances, such as poor processing, age of the filling, contact with other metals or habits such as grinding teeth, chewing, drinking hot drinks or brushing teeth. The problem for manufacturers with this specification are potential compensation claims if higher releases are proven.

Numerous manufacturers have therefore already withdrawn from the amalgam business. Of the few manufacturers who still have valid certificates under the old Medical Device Directive (MDD), only Madespa (Spain) is based in the EU.

When these certificates also expire in May 2024 at the latest, they can be extended under certain conditions without further testing following a recently agreed extension of the transitional period until December 2028. One condition is a signed agreement for an MDR assessment which is quite expensive.

It can therefore be assumed that the number of approvals for the sale of amalgam in Europe will be further reduced in 2024. From December 2028, sales should cease completely and only stocks may be sold off. There is no point in continuing to offer amalgam in public health systems when it's no longer available.

### **Mercury amalgam poses a health risk**

The further approval of dental amalgam also depends on the opinion of the European Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), as the MDR only allows carcinogens, mutagens or reprotoxic substances to exceed 0.1% by mass on scientific justification and dental amalgam contains 50% reprotoxic mercury. SCENIHR last concluded in 2015 that further research is needed, particularly on the possible neurotoxicity of mercury from amalgam and the effects of genetic polymorphisms.

A recent investigation by the U.S. Food and Drug Administration (FDA) confirms these doubts about the safety of amalgam. After a review of recent studies (from 2009-2019), the FDA concluded in 2020 that dental amalgam poses a risk to vulnerable populations, affecting all women who are planning to become pregnant, pregnant and breastfeeding women, children, people with pre-existing neurological

disease such as Multiple Sclerosis, Alzheimer's disease, or Parkinson's disease, and patients with impaired kidney function or known allergies to amalgam.

Studies have shown that dentists who work with amalgam also have significantly higher mercury levels in blood and urine. Especially for female dentists of childbearing age, amalgam poses a high risk. It accumulates in the body and passes through the placenta during pregnancy, which may affect the development of the unborn child.

Even if dental amalgam is no longer approved in the near future, the Commission's proposal to phase out the use of amalgam by January 2025 due to environmental and health reasons is preferable. This is the only way to provide planning security for Member States and to address the transition of the statutory health insurance funds to the reimbursement of alternative materials in a timely manner. It should also be borne in mind that the Commission proposal provides for exemptions that will have to expire when the availability of amalgam ends.

### Member states are ready to phase out amalgam use by 2025

The European trend toward reducing the use of dental amalgam underscores that Europe is ready for the transition to mercury-free dentistry by January 2025: **Sweden** has banned amalgam in 2009, **Denmark** and **Lithuania** have banned it with few limited exceptions; **Italy** adopted a plan to phase it out by 2025; the **Romanian** Dental Association has agreed to phase out the use of dental amalgam by 1 July 2025; **Poland** has withdrawn dental amalgam from the public program in 2022, effectively phasing it out; **Croatia** and the **Czech Republic** adopted a plan to facilitate uniform reimbursement for dental fillings regardless the material by 2025; in **Finland** and **Slovakia**, a composite restoration already costs the patient the same as an amalgam restoration; **Ireland**, **Slovenia** and **Hungary** will alter its insurance to favor mercury-free fillings in the coming years, in **Spain**, **Finland**, **Estonia** and the **Netherlands**, the use of dental amalgam is already below 1% and in **Germany**, the use of amalgam has decreased from 3.2% in 2021 to 2.4% in 2022.

**We support the Commission's proposal for the 2025 amalgam phase-out a) to best protect environment and health, b) not to jeopardize the Green Deal goals for a toxic-free environment, c) to take a lead in the Minamata Convention negotiations, d) to give Member States planning certainty, taking into account that amalgam does not meet the requirements of the new Medical Devices Regulation e) as sufficient affordable and effective alternatives are available, and f) as Member States have demonstrated that this timeframe is feasible.**

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