



Position Paper

in Support of phasing out dental amalgam
in Northern Ireland by 2025 as foreseen
by the revised European Mercury regulation and the Windsor Framework.

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The EU measure to stop the use and export of amalgam does not qualify for using the Stormont Brake. It has no significant adverse impact on everyday life in Northern Ireland neither is the EU measure a most exceptional circumstance requiring the Stormont Brake to be used as a matter of last resort. On the contrary, the Northern Irish Society will benefit from phasing out dental amalgam.

Background

On 8 February 2024, the European Council and European Parliament reached a provisional agreement on a proposal to revise the 2017 Mercury Regulation, which would phase out the use of dental amalgam and prohibit its manufacturing, import and export. This agreement is pending at the time of writing (April 2024), ahead of formal adoption by the European Council. The provisional agreement is foreseeing:

1. 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.
2. Introduce an eighteen-month derogation for 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. Member states would have to justify their use of the derogation and notify the European Commission within 1 month after the entry into force of the Regulation of the measures they intend to implement to achieve the phase out of dental amalgam by 30 June 2026.
3. From 1 January 2025, the export of dental amalgam shall be prohibited.
4. From 1 July 2026, the import and manufacturing of dental amalgam shall be prohibited and by way of derogation, only be allowed for specific medical needs.
5. A review of the exemptions for the use of dental amalgam will be performed by the European Commission by 31 December 2029, 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.

A ban on dental amalgam has been in place since July 1st 2018, for children under 15 and pregnant and nursing mothers. The EU regulation is only extending what the Northern Ireland's dentists have been subject to for nearly five years already to the rest of the population.

On 14 March 2024, the British Dental Association (BDA) called on the NI Assembly to utilise powers available to it and apply the Stormont Brake so that a proposed amended Mercury Regulation and a ban on dental amalgam from 1 January 2025 will not directly apply to Northern Ireland.

The EU is phasing out dental amalgam by 2025 for good reasons

On the use of dental amalgam, the Impact Assessment (undertaken between July 2021 and December 2022) 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 European Green Deal, the Zero Pollution Action Plan and the Chemicals Strategy for Sustainability.

The Society of Northern Ireland will benefit from the phase out by 2025

Dental amalgam still represents the largest remaining intentional use of mercury in the EU and North Ireland. It leads to adverse human health effects and mercury emissions, in particular during placement by dental practitioners and via excretion, cremation or burial of people fitted with dental amalgam. The continued use of dental amalgam is therefore a practice that contributes to the continuous build-up of mercury in the environment and excessive and unsustainable amounts of mercury in fauna, flora and habitats.

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. Alternative dental filling materials are "Available, Effective & Affordable."

Mercury-free fillings will become accessible for the low-income population

Currently Patients have to pay £80 - £150 for alternative fillings, instead of £8 - £20 for dental amalgam, although it is sometimes questionable whether the cost is actually reflecting the workload and material cost. For example, for a properly placed dental amalgam filling, patients have to visit the dentist twice, as the surface can only be polished after 24 hours, whereas composite fillings can be placed in one visit only.

The material cost only plays a minor role. The cost for an amalgam capsule is about £1 and composites are about twice as expensive, as stated by the BDA and the price difference is expected to decrease with further request.

The processing and durability of filling materials in particular have improved significantly over the past decades, so that a wide range of time-saving, single-layer materials can nowadays be used for basic care.

If the current composite fees for children up to 15 years of age of £21.64 - £47.96 were applied to the whole population, this could be ensured with these same materials. For a large part of the population, it would be a great financial relief. Dentists could still continue to sell multi-layer composites with colour matching as higher quality fillings based on current private fees.

The BDA itself suggested in its consultation that the Scottish model, which is similar to implementing the current composite fees for children up to 15 years to the whole population, would be a quick solution.

When looking at NHS costs, this shouldn't be overly challenging, especially when considering that adults in NI bear 80% of the costs themselves and the Minister for Health has just announced a £9.2m funding boost. Surely the expenditure will outweigh the environmental and health impact costs of dental amalgam.

In Poland, where the public health system covers 100% of the cost of fillings, dental amalgam was replaced in 2022 by glass ionomer cements, higher density glass ionomer cement and resin-reinforced glass ionomer cement.

Less mercury will pollute the environment

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.

Less health risk for consumer, dentists and dental assistants

A recent investigation by the U.S. Food and Drug Administration (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 and dental assistants 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.

The EU Medical Devices Regulation only allows carcinogens, mutagens or reprotoxic substances to exceed 0.1% by mass (dental amalgam contains 50% reprotoxic mercury) based on a scientific justification, but the current SCENIHR opinion from 2015 is outdated and last concluded that further research is needed, particularly on the possible neurotoxicity of mercury from amalgam and the effects of genetic polymorphisms.

The global trend is towards phasing out dental amalgam

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, demonstrating that alternatives are effective, available and affordable. No adverse clinical effects were reported. By January 2025, this number is expected to rise to 56 countries and 2 further countries have stopped the Import.

For example, Bolivia, Croatia, Denmark, Ecuador, Finland, Gabon, Indonesia, Italy, Japan, Lithuania, Moldova, Nepal, Norway, Peru, Philippines, Poland, Russia, Slovakia, Sweden, St. Kitts and Nevis, Suriname, Uruguay, and Vietnam among others, have phased out amalgam use, announced plans for phasing out amalgam use, or use de minimis amounts of amalgam. (<https://environmentalmedicine.eu/mercury-free-dentistry-for-planet-earth/>)

The Minamata Convention will discuss in November 2025 weather to phase out dental amalgam by 2030 and to exclude or not allow by taking measures as appropriate, the use of dental amalgam in government insurance policies and programmes. Current Obligations under the Convention are:

- to take two or more out of nine phase down measures
- exclude or not allow, by taking measures as appropriate, the use of mercury in bulk form by dental practitioners
- exclude or not allow, by taking measures as appropriate, or recommend against the use of dental amalgam for the dental treatment of deciduous teeth, of patients under 15 years and of pregnant and breastfeeding women, except when considered necessary by the dental practitioner based on the needs of the patient.
- Parties that have not yet phased out dental amalgam shall:
Submit to the secretariat a national action plan or a report based on available information with respect to progress they have made or are making to phase down or phase out dental amalgam every four years as part of national reporting.

The supply of dental amalgam is drying up in the EU

There are serious doubts as to whether dental amalgam will continue to be available due to the increased requirements of the EU Medical Devices Regulation, which also apply in NI.

Apart from the need for a scientific justification for exceeding the CMR threshold (see above), manufacturers have to declare for the first time 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 consumer can prove exceeding releases.

Numerous manufacturers have therefore already withdrawn from the European business. <https://environmentalmedicine.eu/manufacturers-exiting-the-amalgam-business-in-europe/>

Due to the EU-wide phase-out by 1 January 2025, it is expected that most manufacturers will refrain from renewing their expiring certificates by 26 May 2024, as extending the approval until 31 December 2028 will no longer be profitable.

From December 2028 at the latest, 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.**

In addition, the safety of alternative filling materials is further improving due to the increased requirements of the new Medical Device Regulation.

There is no alternative to phasing out dental amalgam in Northern Ireland

The national action plan to phase down dental amalgam is not resolving the problem. Focussing on prevention means to keep dental amalgam forever as there will always be tooth decay. Dental amalgam needs to be phased out for good reasons:

1. Dental Amalgam will no longer be available.
2. Dental Amalgam pollutes the environment and poses a health risk
3. New alternatives are as time saving or even more time saving and effective as dental amalgam
4. At least since the phase out of dental amalgam for children, pregnant and breastfeeding women, dentists are trained in using alternatives
5. Numerous countries show that there are no adverse health effects from phasing out dental amalgam.

Only dentists are benefitting from keeping dental amalgam by selling alternatives as a special more expensive treatment - an immoral business based on the NHS reimbursing a toxic material. Aesthetic and safe alternatives should become standard. The interests of around 700 dentists should not take precedence over the interest of the current society and the future generation.

Like in Norway and Sweden there will be exceptions for patients that need dental treatment under general anaesthesia or are allergic to components in mercury-free fillings. Exceptions, which in Norway or Sweden 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.