



Moving towards a

PHASE-OUT OF DENTAL AMALGAM IN EUROPE:

What dental practitioners need to know

BACKGROUND

WHY IS MERCURY IN THE ENVIRONMENT A PROBLEM?

Mercury is released into the environment from both natural sources and as a result of human activity; its properties mean that mercury can remain in environment for thousands of years. Mercury can travel long distances when airborne and large amounts also end up in seas and oceans meaning that mercury emissions have a global impact.¹

When mercury is released into the environment animals, humans, and the wider environment are exposed to its effects. Additionally, bacteria can convert mercury into its most toxic form: methylmercury, which builds up (bioaccumulates) in fish and seafood.¹ As a result, predators at the top of the food chain, including humans, can carry substantial amounts of mercury (biomagnification).

Approximately 41% of all water bodies in the EU exceed mercury concentration levels that were set to protect fish-eating birds and mammals. In some countries, mercury levels measured in biota were above safe limits in almost all bodies of surface water.¹

HOW DOES MERCURY AFFECT US?

Key properties of mercury:²

- Mercury can pass across the blood-brain barrier and through the placenta
- Methylmercury is particularly toxic, and it is easily absorbed in the digestive system of humans and transported freely throughout the body
- Exposure to mercury – even small amounts – is a threat to the development of children in utero and early life since their brains and nervous systems are still forming. Mercury may have toxic effects on the nervous, digestive, and immune systems, and can affect organs such as the lungs, kidneys, skin, and eyes
- Recent studies show that mercury exposure in older adults can increase the risk of cardiovascular disease and blood pressure problems¹

An extremely toxic and persistent metal, mercury is considered one of the World Health Organization (WHO)'s top ten chemicals of major public health concern.² Mercury has been detected in human blood, urine, milk, and hair.³ Human biomonitoring studies have shown that the consumption of fish is the largest source of dietary exposure to methylmercury for all age groups.⁴

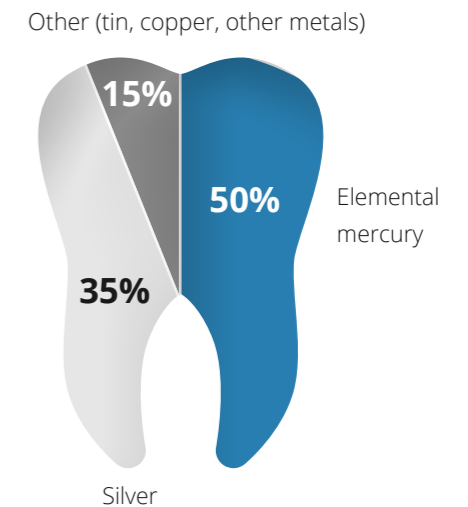
Foetuses are most susceptible to developmental effects due to mercury.² It is estimated that every year in Europe nearly 1.9 million babies are born with mercury levels above the safe limit recommended by recent evidence (equivalent to a concentration of 0.58 µg/g in hair). Of these, 200,000 babies have been exposed to levels above the WHO recommended maximum hair concentration of 2.5 µg/g.⁵

Another study shows that a considerable proportion of blood samples taken from both mothers and their children across Europe had mercury concentrations above the Human Biomonitoring (HBM) I value (5 µg/l) established by the German Human Biomonitoring Commission (12% of mothers and 4.4% of children).⁶ The HBM I value is the maximum concentration of a substance in human biological material at or below which there is no risk of adverse health effects, and therefore no need for action.

Methylmercury exposure in the womb can result from mothers' consumption of fish and shellfish. Methylmercury can adversely affect a baby's growing brain and nervous system.² The European Food Safety Authority (EFSA) has established 'safe levels', intended to protect consumers, particularly pregnant women, from adverse health effects posed by the possible presence of the main forms of mercury found in food. The likelihood of reaching such a level for methylmercury increases for consumers who frequently eat large quantities of fish especially large predatory fish.⁷

USE OF DENTAL AMALGAM CONTRIBUTES TO MERCURY POLLUTION

Dental amalgam is a compound of mercury (Hg, 43-54%) combined with other metals including silver, copper, and tin.



The use of mercury in dental amalgam contributes to the accumulation of mercury in the environment globally; the European Commission's Scientific Committee on Health and Environmental Risks (SCHER) confirmed that amalgam poses environmental risks.⁸

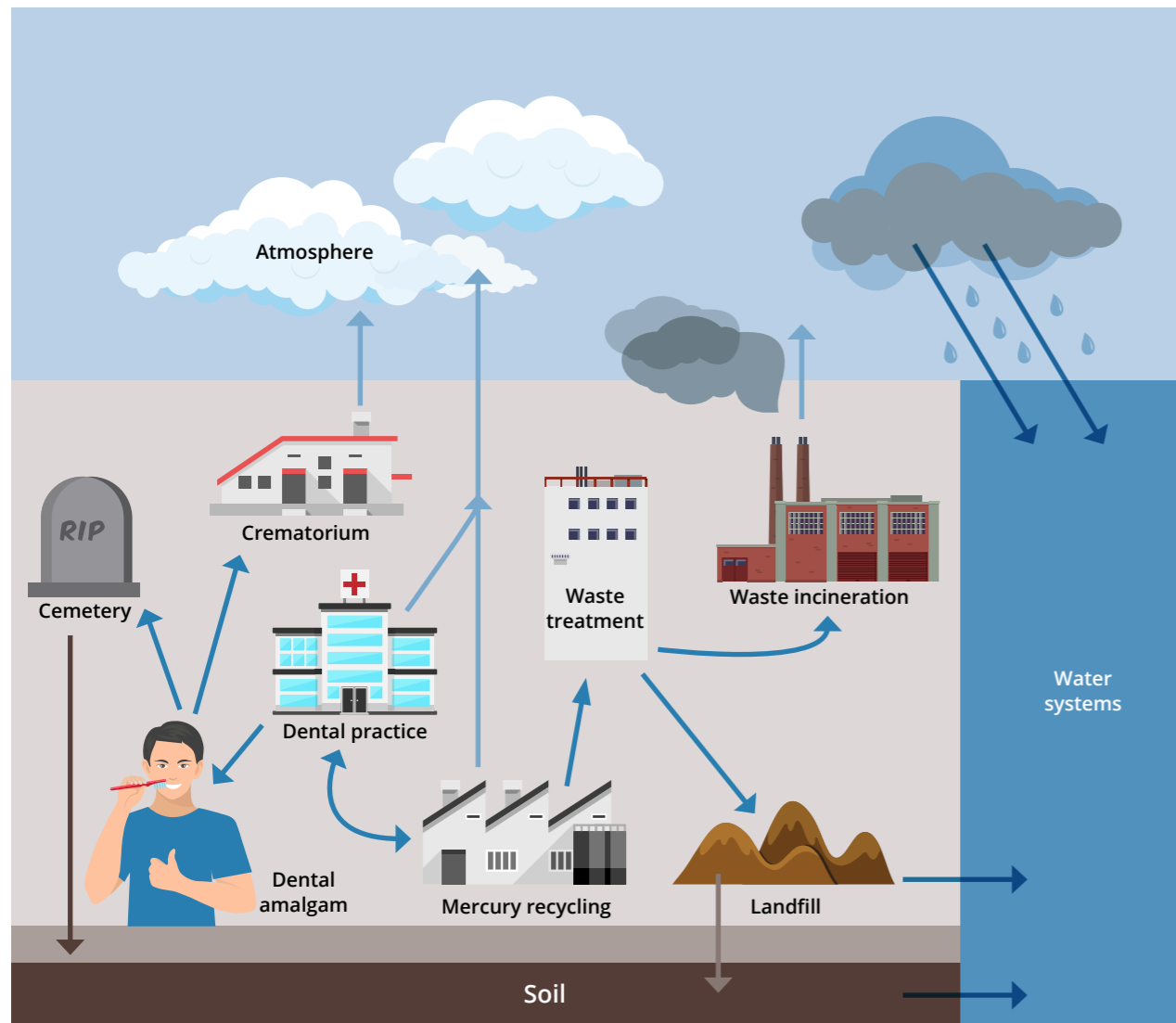
Dental amalgam is the largest use of mercury in the European Union and a significant source of pollution.⁹ The amount of dental mercury used in the EU in 2010 was estimated to range between 55 and 95 tonnes per year (t/y). Projected dental mercury use in 2025 is estimated to be 27-43t/y.⁹

Of the total amount of mercury used by dentists in the EU (~75t/y on average) approximately 56t/y ends up in patients' teeth, of which approximately 17t/y is used to make new fillings and 39t/y of 'new' mercury is used to replace old fillings.⁹

Approximately 20t/y of wasted mercury from amalgam ends up as solid waste, whilst 16t/y is emitted to the air, and 46t/y is discharged in wastewater (including 38 tonnes of removed amalgam from old fillings). In 2010, mercury emissions from dental amalgam in human remains were estimated to be 3.6 tonnes.⁹

Considering that approximately 75% of the 500 million EU inhabitants have dental fillings, it is estimated that 1,500 tonnes of mercury is currently contained in the bodies of people living in the EU.¹





INTERNATIONAL AND EU LEGISLATION ON MERCURY

The International Convention on Mercury, or "Minamata Convention"¹¹ (named after Minamata, Japan - the location of the worst ever case of mercury pollution) was signed in October 2013 and entered into force in August 2017. Its objective is to protect the human health and the environment from anthropogenic emissions and releases of mercury and mercury compounds. It covers all aspects of the mercury life cycle including the "phase down of dental amalgam use".

EU MERCURY REGULATION

A 2012 study commissioned by the European Commission concluded that the most efficient and effective way for the EU to meet its objectives concerning mercury use in dental amalgam would be to phase out its use and for the Member States to better enforce environmentally safe waste management.¹²

In the EU public consultation on the ratification and implementation of the Minamata Convention, the majority of respondents (61-86%) favoured immediate full prohibition of mercury use in dentistry, while only 12-23% expressed a preference for a gradual phase-down.⁹

On 17 May 2017, the EU institutions formally adopted the new **Regulation on Mercury (Regulation (EU) 2017/852)**.¹³ Article 10 of this regulation addresses the issue of dental amalgam, its key provisions and deadlines are:

- From 1 January 2019**, dental amalgam shall only be used in pre-dosed encapsulated form. The use of mercury in bulk form by dental practitioners shall be prohibited.
- From 1 July 2018**, dental amalgam shall not be used for dental treatment of deciduous teeth, of children under 15 years, and of pregnant or breastfeeding women, except when deemed strictly necessary by the dental practitioner based on the specific medical needs of the patient.
- By 1 July 2019**, each Member State shall set out a national plan concerning the measures it intends to implement to phase down the use of dental amalgam. Member States shall make their national plans publicly available online and shall transmit them to the Commission within one month of their adoption.
- From 1 January 2019**, operators of dental facilities in which dental amalgam is used or dental amalgam fillings or teeth containing such fillings are removed, shall ensure that their facilities are equipped with amalgam separators for the retention and collection of amalgam particles, including those contained in used water. Such operators shall ensure that:
 - Amalgam separators put into service from 1 January 2018 provide a retention level of at least 95% of amalgam particles.
 - from 1 January 2021**, all amalgam separators in use provide the retention level specified in point (a).

Amalgam separators shall be maintained in accordance with the manufacturer's instructions to ensure the highest practicable level of retention.
- Capsules and amalgam separators complying with European standards, or with other national or international standards that provide an equivalent level of quality and retention, shall be presumed to satisfy the requirements set out in paragraphs 1 and 4.
- Dental practitioners shall ensure that their amalgam waste, including amalgam residues, particles and fillings, and teeth, or parts thereof, contaminated by dental amalgam, is handled and collected by an authorised waste management establishment or undertaking. Dental practitioners shall not release directly or indirectly such amalgam waste into the environment under any circumstances.

MERCURY RELEASES FROM DENTAL AMALGAM⁹

IN DENTAL PRACTICES

- Release to air/water/waste
- During preparation/use of new amalgam (surplus amalgam)
- During removal of old amalgam fillings
- Loss or extraction of teeth with amalgam fillings

OUTSIDE DENTAL PRACTICES

- Mercury from dental amalgam is released in the oral cavity as inhalable mercury vapour, dissolved after oxidation, or suspended in saliva as amalgam particles
- Deterioration of amalgam fillings due to chewing, hot beverages, and corrosion (mercury in human waste)
- Cremation/burial of people with amalgam fillings (release to air/soil/water)



SWEDEN

In 1999, the Swedish Parliament decided that patients should no longer be reimbursed for the cost of amalgam fillings under the national healthcare system. As a result, the cost of amalgam for patients became comparable to the cost of composites. Since 2009, there has been a general ban on mercury in Sweden that includes dental amalgam. Meanwhile, the cost of mercury-free restorations has continued to decline with new technologies, and further training and experience of dental practitioners.¹⁴



DENMARK

The sale of mercury has been forbidden in Denmark since 1994, but an exemption was initially granted for mercury in dental amalgam. A subsequent 1999 recommendation of the Danish health authority stipulated that amalgam fillings should not be placed in front teeth, “milk teeth”, or generally used for dental care of children. They also recommended that mercury-free alternatives should be the first choice for new fillings, except where: 1) it is not possible to keep the area dry, 2) it is difficult to access the cavity, 3) there is a particularly large cavity, or 4) the distance to the proximate tooth is too great. By 2013, amalgam was used in only 5% of restorations in Denmark.¹⁴



THE NETHERLANDS

In the 1990s the Netherlands experienced a major shift away from amalgam after consultation with the dental sector, which eventually embraced the use of mercury-free dental restorations. Consequently, the average use of amalgam in the 2000s was around 7% of all dental restorative fillings, dropping to less than 1% by 2011.¹⁴

IMPLICATIONS OF THE MERCURY REGULATION FOR DENTAL PRACTITIONERS IN THE EU

As of 1 January 2018, **releasing amalgam waste into the environment is prohibited under any circumstances.**¹³ Dentists are responsible for ensuring that any amalgam waste released is collected separately and managed in an environmentally safe manner.

On 1 July 2018, **an EU-wide dental amalgam phase-out for vulnerable populations entered into force.**¹³ This phase-out applies for pregnant or breastfeeding women, and children under 15 years old (unless deemed strictly necessary by the practitioner on the ground of special medical needs).

After 1 January 2019, **dental facilities using dental amalgam or removing dental amalgam fillings must ensure that they are equipped with amalgam separators** for the retention and collection of amalgam residues, including dental amalgam particles and those contained in used water.¹³

Amalgam separators shall provide a retention level of at least 95% of amalgam particles, and be maintained accordingly. **Dental practitioners are also obliged to use pre-dosed encapsulated dental amalgam - the use of mercury in bulk shall be prohibited.**

It is already prohibited to use amalgam for the most vulnerable populations in all EU countries; mercury-free alternatives are therefore no longer optional for these patients. Dental practitioners are invited to not only implement these requirements but to also contribute to overall EU and global objectives towards phasing out mercury emissions, releases, and exposure.

When striving to meet these regulatory requirements and a phase-out of dental amalgam, it is also important to consider the following:

PROS & CONS OF DENTAL AMALGAM

Advantages

- + Durability: Amalgam can last at least 6-10 years
- + Strength: Can withstand chewing forces
- + Expense: Upfront costs may be less expensive than composite fillings

Disadvantages

- Health: Amalgam fillings release low levels of mercury in the form of a vapour that can be inhaled
- Destruction of tooth structure: Amalgam placement requires larger cavities to be prepared, often with excessive removal of tooth material
- Cracks and fractures: Amalgam can potentially increase the risk of cusp fractures, as teeth expand and contract in the presence of hot and cold liquids. Amalgam (in comparison with other filling materials) may experience a wider degree of expansion and contraction and lead to a higher incidence of cracks and fractures
- Allergic reactions: Approximately 1% of the population are allergic to mercury in amalgam restorations
- Corrosion: Amalgam fillings can corrode or tarnish over time and leave a grey hue to the surrounding tooth structure and the gum
- Poor aesthetics: Amalgam fillings don't match the colour of natural teeth
- Environment: High environmental cost





THE REAL COST OF DENTAL AMALGAM

Mercury-free alternatives appear to be more expensive and this may act as a barrier to their introduction in the market. This is an erroneous perception, however, as the environmental costs caused by mercury amalgam use (e.g. waste management) are not factored into its purchase cost.⁹ If these externalities were to be included, it has been shown – based on the example of the US market – that the market price of an average amalgam restoration would be equal to or up to 15% higher than the price of a composite restoration.¹⁵ This is further supported by another study which shows that due to the high costs of dental mercury pollution, amalgam is now recognised as “more expensive than most, possibly all, other fillings when including environmental costs.”¹⁶

USE OF MERCURY-FREE ALTERNATIVES

Mercury-free, cost-effective, and durable alternative materials to dental amalgam have already been successfully used for many years in the EU and in countries with early mercury bans. For example, as reported in 2007, Swedish dentists began using different types of composites (i.e. polymer resin-based materials) as alternatives to amalgam. Other materials include ceramics, porcelain, glassionomers, combinations of materials (e.g. “compomers” that are modified composites) and prefabricated ceramic cones, (which are pressed into composite fillings to reduce shrinkage of the filling).¹⁷

Many dentists across Europe already work successfully with mercury - free alternatives: they comprise approximately 66% of tooth restorations in the EU.⁹ The evolution of new materials and training of dental professionals to work with these alternatives has led to dentistry practices where dental amalgam is no longer needed. Alternatives are more aesthetic and do not require the removal of healthy tooth material to make space for amalgam fillings. Dentists and patients can now have a choice of high quality fillings and affordable filling materials - well regarded as tooth replacement material.

Currently the most commonly used alterna-

tives to dental amalgam are composite resins, glass ionomer cement, compomers, composites, bulk-fill-composites, sealants and dental porcelain.⁹ Composites have become the material of choice for tooth restoration due to caries, trauma, and tooth wear.

WASTE MANAGEMENT

According to the 2015 EU Manual of Dental Practice, 22 out of 28 Member States already have binding legislation that requires the use of amalgam separators.¹⁸ Yet despite the large amounts of mercury used in dentistry in the EU and the threats posed to the environment and human health by mercury, the EC estimated in 2016 that only 69% of waste produced from dental amalgam was managed as hazardous waste.⁹

There is clearly an issue regarding proper use of equipment - adequate attention must be given to regular removal of collected mercury and maintenance of amalgam separators. Amalgam separators should be maintained in accordance with manufacturer’s instructions to ensure the highest practicable level of retention.

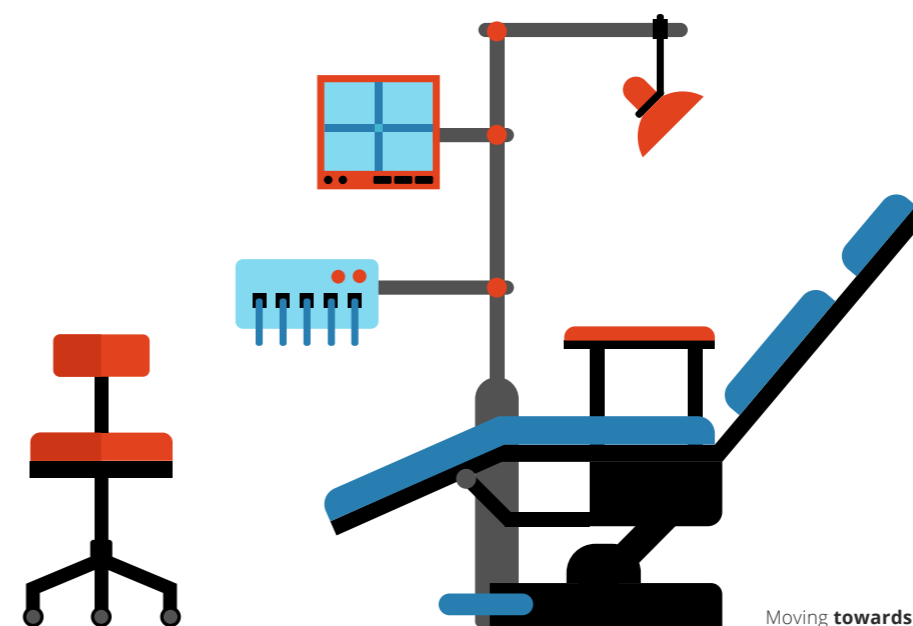
From 1 January 2021, all amalgam separators must provide a retention level of at least 95% of amalgam particles - this could mean that many dental

practitioners will need to install new equipment to fulfil these criteria.

The cost of amalgam separators is very much dependent on the size of dental office, the number of separators required, as well as the model installed. Additionally, the amount of wastewater discharged determines the needs for maintenance and replacements (e.g. of traps and filters). Adequate attention has to be given to regular removal of the collected mercury and maintenance of the separator as improper use or poor maintenance will decrease its efficiency.

A report for the European Commission in 2008 estimated that the cost of amalgam separators was between €400-500 per year, including installation, servicing, and in-situ evaluation of filter efficiency and accreditation, based on information from Denmark.¹⁹ In 2016, the US Environmental Protection Agency estimated the average cost of a single amalgam separator and affiliated services to be approximately \$800 USD per year.²⁰

It is important to understand that **only dental facilities using dental amalgam or removing dental amalgam fillings will have to be equipped with amalgam separators and pay for the associated waste management.**



RECOMMENDATIONS: HOW DENTAL PRACTITIONERS CAN BECOME RESPONSIBLE PARTNERS IN THE PHASE-OUT OF DENTAL AMALGAM IN EUROPE

Dentists should take responsibility for the environmental impacts of their work and contribute as individuals and as associations to EU and global objectives to ultimately end the use of dental amalgam. Specifically, dental practitioners and associations can:

- 1. Offer mercury-free alternatives:** Whilst adhering to stringent best practice in terms of waste management when removing old amalgam fillings, dentists should offer proven mercury-free alternatives to all patients who require new fillings.
- 2. Centralise clinics with separators:** To relieve dentists from the burden of installing and maintaining expensive separators, designate centralised clinics to be equipped with separators, where patients with dental amalgam fillings could be sent for amalgam-related dental work.
- 3. Contribute to research for mercury-free materials:** Dental practitioners, with their experience, should further contribute to research on mercury-free and safer materials. Such research could not only assist the EU but also the global community. Unlike dental amalgam, mercury-free materials have been subject to continuous technical improvements in the past years and this trend is expected to continue.

- 4. Influence insurance schemes:** Dental practitioners should put pressure on public and private insurance systems to cover mercury-free alternatives. These systems need to adapt and favour mercury-free dental fillings. Due to the high costs of dental mercury pollution, amalgam is now recognised as more expensive than most, possibly all, other fillings when environmental costs are considered.
- 5. Increase awareness and education:** Professional organisations and dental schools must look ahead towards a mercury-free future; dental professionals and students should be trained on the use of mercury-free dental restoration alternatives. Update dental school curricula to promote mercury-free dentistry.

The most important way dentists can help Europe transition to a mercury-free environment is to stop using amalgam – a step that will be appreciated by your patients and communities as we all strive to protect our planet for future generations.

WITH THANKS TO:

- Elena Lymberidi-Settimo - The European Environmental Bureau Zero Mercury Campaign: www.eeb.org/work-areas/industry-health/zero-mercury-campaign
- Florian Schulze - IG Umwelt Zahn Medizin: www.ig-umwelt-zahnmedizin.de
- Charlie Brown and Sylvia Dove - World Alliance for Mercury-Free Dentistry: www.mercuryfreedentistry.net

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