

Developing national plans for phasing out dental mercury

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Introduction

As the range of chemicals affecting human health and environment continues to grow, mercury remains a particular concern. In Europe, mercury pollution costs €5.1 billion a year.¹

Mercury has traditionally been an important chemical for the healthcare sector, used in devices such as thermometers and sphygmomanometers. However, considering the threat it poses to human health and the environment, Health Care Without Harm (HCWH) Europe has been working for many years to promote mercury-free healthcare by providing technical and policy guidance in support of the switch to mercury-free alternatives.

In recent years, HCWH Europe's work has focussed on the phase-out of dental amalgam, which contributes to the accumulation of mercury in the environment globally and is the largest use of mercury in the European Union and a significant source of pollution.²

In line with the EU Mercury Regulation, EU Member States are required to develop national plans to phase out mercury-containing dental amalgam (this regulation has its foundations in of the international Minamata Convention). To assist Member States in developing plans that are in line with the latest scientific research and offer an adequate level of protection to human health and the environment, HCWH Europe has created this guidance document and set of recommendations. Some common steps and measures suggested in the guidance are based on those proposed in the 2015 WHO Guidance on Developing National Strategies for Phasing Out Mercury-Containing thermometers and sphygmomanometers in health care.³

Whilst it is recognised that not all EU Member States will take the same approach to meeting the requirements, the measures suggested below are intended to inform health ministries, environmental ministries, and other stakeholders about key considerations that should be taken into account in the process. A background to the legislation, relevant supporting information, and good practice examples are provided.

By phasing out dental amalgam, countries can significantly reduce patients and dental staff's expose to mercury, whilst simultaneously reducing mercury emissions and minimising harm to the environment.

Legislative background

The Minamata Convention on Mercury is a UN global treaty to protect human health and the environment from the adverse effects of mercury; it was adopted at the diplomatic conference in Japan in October 2013, and by mid-December 2018 101 countries had ratified it, including the EU.⁴

Dental amalgam is among the products listed in Annex A of the Convention as a mercury-added product that needs to be regulated.

Provisions of Minamata Convention on Mercury

Annex A, Part II: Products subject to Article 4, paragraph 3

Dental amalgam

Measures to be taken by a Party to phase down the use of dental amalgam shall take into account the Party's domestic circumstances and relevant international guidance and shall include two or more of the measures from the following list:

1. Setting national objectives aiming at dental caries prevention and health promotion, thereby minimising the need for dental restoration.
2. Setting national objectives aiming at minimising its use.
3. Promoting the use of cost-effective and clinically effective mercury-free alternatives for dental restoration.
4. Promoting research and development of quality mercury-free materials for dental restoration.
5. Encouraging representative professional organisations and dental schools to educate and train dental professionals and students on the use of mercury-free dental restoration alternatives and on promoting best management practices.
6. Discouraging insurance policies, and programmes that favour dental amalgam use over mercury-free dental restoration.
7. Encouraging insurance policies and programmes that favour the use of quality alternatives to dental amalgam for dental restoration.
8. Restricting the use of dental amalgam to its encapsulated form.
9. Promoting the use of best environmental practices in dental facilities to reduce releases of mercury and mercury compounds to water and land.

On 17 May 2017, the EU institutions formally adopted the new Regulation on Mercury, which was published on 24 May 2017 (Regulation (EU) 2017/852).²

The EU Mercury Regulation seeks to align and enforce EU law with the provisions of the Minamata Convention. Article 10 of the Regulation addresses the issue of dental amalgam. The EU regulation applies as of 1 January 2018.

By 1 January 2019, Member States should have already implemented the following **key provisions relating to dental amalgam**:

- Article 10(1): 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.
- Article 10(2): 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.
- Article 10(4): 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:
 - (a) amalgam separators put into service from 1 January 2018 provide a retention level of at least 95 % of amalgam particles;
 - (b) 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.

- Article 10(5): 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.
- Article 10(6): 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.

The key provision of the Mercury Regulation on Mercury (as required by Article 10(3)) is that **by 1 July 2019, Member States will have to set out a national plan with measures for a phase-down of dental amalgam**. Member States must make their national plans publicly available on the Internet and transmit them to the European Commission within one month of their adoption.

In June 2018 the European Commission launched a study on the *Assessment of the feasibility of phasing out dental amalgam*.⁵ By 30 June 2020, the Commission shall report on the feasibility of a phase out of the use of dental amalgam in the long term, and preferably by 2030, as required by Article 19(1)(b) of the EU Mercury Regulation. Article 19(3) also requires the Commission, if appropriate, to present a legislative proposal together with its report.

Member States are encouraged to consider including a complete phase-out of dental amalgam into their national strategy, should the incoming Commission decide to present a legislative proposal to phase out dental amalgam.

Facts & findings

Member States should consider the following when developing their national strategies:

- Dental amalgam is the only mercury-added product subject to a phase-down. All other mercury products addressed in the Minamata Convention and the EU Mercury Regulation are subject to a ban or phase-out i.e. a ban to take effect at a later date. Member States should therefore be aware that, in the longer-term, restrictions in mercury sourcing and trade (Article 3 of the Minamata Convention) are likely to have an impact on the availability and cost of mercury and consequently dental amalgam.
- It is highly unlikely that all dental practices will become compliant with the requirements of EU waste legislation in the short term without further enforcement actions from public authorities.⁶ Amalgam separators are not a viable control measure if not maintained properly, and some Member States' reports indicate that even some of the mercury collected may end up in waste incinerators or landfills, rather than recycling. A significant quantity of mercury used in dentistry (estimated at over 1,000 tonnes for the entire EU population) will not be collected via separators and will probably ultimately end up in the environment (e.g. in soil via burial, or directly to the atmosphere following cremation). Installing pollution control devices on crematoria is by far the most costly mercury emissions abatement measure.⁷
- A comprehensive study by the European Commission recognises that **prohibiting the use of mercury in dentistry, combined with improved hazardous waste management is the best environmental practice** for dental facilities.⁸
- Whilst mercury-free alternatives appear to be more expensive than dental amalgam, the environmental costs caused by mercury amalgam (e.g. waste management) are not factored into its purchase cost. If these externalities were to be included, it has been shown that **the market price of an average amalgam restoration would be equal to or higher than the price of a composite restoration.**^{9,10}

Rather than implementing expensive waste management measures in perpetuity, it would be far more cost-effective to simply avoid handling mercury in dental restorations.

Some dental practitioners may not be fully aware of the seriousness of the environmental impacts caused by dental amalgam or the extent of societal benefits of reducing mercury emissions. Nor are patients fully aware of the advantages and disadvantages associated with different filling materials, many are not aware that mercury is present in dental amalgam and the associated environmental impacts.⁶ Alternative mercury-free filling materials are available and are widely used in many European countries; estimations from 2012 show that they comprise approximately 66% of tooth restorations in the EU.⁸

In Denmark, Norway, and Sweden, mercury in dentistry has effectively been banned whilst Finland, Hungary, The Netherlands, and Switzerland have implemented measures that have reduced the use of mercury in dental restorations to very low levels.¹¹

The cost of dental amalgam restorations for patients differ significantly between Member States, mostly due to differences in labour costs and insurance reimbursement schemes. A major component of the labour cost is the time required to place alternative fillings - partially due to a lack of adequate training for dentists. The WHO also recognises that staff training is a major component for success in using mercury-free alternatives.⁶

The progressive substitution of dental amalgam with mercury-free materials is not expected to induce major socio-economic changes in the dental fillings industry since almost all dental amalgam manufacturers already produce mercury-free filling materials as well.⁶

In fact, switching to quality mercury-free alternatives is expected to increase competitiveness within the EU dental filling industry, whilst decreasing costs borne by dentists for amalgam waste management and costs borne by citizens (via taxes) related to mercury pollution abatement. At the same time, occupational health risks for dental personnel and public health risks due to indirect mercury exposure from dental amalgam are expected to significantly decrease.⁶

If mercury is not phased out the current use of dental amalgam will continue to impact the environment: a large part of the associated environmental emissions would occur during a period of 10-15 years after the placement of the amalgam, but the actual environmental impacts (adverse effects to ecosystems) and possible indirect human health effects will continue to occur for several decades.

Examples of best practice

Under Article 4 of the Minamata Convention, Parties (signatory nations) are required to phase down the use of dental amalgam, taking into account domestic circumstances and relevant international guidance such as the UN Environment Programme report, *Lessons from Countries Phasing Down Dental Amalgam Use*. Published in March 2016, this report identifies various measures taken by countries which have effectively eliminated or significantly reduced the use of amalgam.⁷

When planning their amalgam phase-down, Nordic countries experienced some initial resistance from the dental industry and this was largely because they were:

1. Unaware of the environmental impacts of mercury from amalgam, and the social benefits of reducing mercury emissions
2. Initially reluctant to invest in new equipment required to reduce mercury pollution or to support mercury-free fillings

3. Initially unconvinced of the durability of alternative filling materials
4. Unfamiliar with the application of mercury-free techniques

Norway, Sweden, Denmark, The Netherlands, and Finland have all demonstrated that restricting amalgam use in children is an effective initial phase-down step. Additionally the product substitution principle, which mandates the use of mercury-free products, wherever possible is also an important step. Some countries modified or strengthened legislation and regulation. Norway and Sweden, for example, introduced step-by-step legislation that allowed time for industry and for dental practitioners to adapt to the new restrictions or guidelines.

In curricula, Danish dental schools actively collaborate in amalgam phase-down efforts, whilst Dutch dental schools stopped teaching the placement of amalgam between 1995 and 2005, on a voluntary basis. Whilst Sweden withdrew financial support for mercury amalgam fillings from the national dental insurance service, and the cost to the patient was subsequently equal to if not higher than a composite restoration, resulting in a near full phase-out of the use of dental amalgam.

The key measures taken by Nordic countries were:

- Consultations with the dental sector
- Raising public awareness about the presence of mercury in dental amalgam
- Modifying and strengthening legislation
- Adherence to the precautionary approachⁱ and the product substitution approachⁱⁱ
- Improving oral healthcare, preventing caries, and minimally invasive treatments
- Adapting insurance schemes
- Reducing environmental releases

The acceptance, performance, and use of mercury-free dental restorative materials has grown in these countries. The reduction of amalgam-use results from a desire to preserve as much of the tooth structure as possible, preference for more natural tooth coloured fillings, awareness of environmental impact, and other concerns associated with releases of mercury.

Governments that actively promoted reductions in amalgam-use observed more rapid progress toward phase down. Likewise, when phasing down dental amalgam, countries noted that initial investment was required to train dentists and purchase equipment, but ultimately this was not significant or lasting barrier to and amalgam phase-down.

ⁱ Precautionary measures should be taken in the face of threats to environmental and/or human health even if some cause and effect relationships are not fully established scientifically.

ⁱⁱ Products should, wherever possible, be replaced with alternatives that have a lesser impact on the environment.

Sweden reduced the use of dental amalgam in children from 30% in 1991 to 1.5% in 1995, subsequently banning amalgam fillings for all young adults. Likewise, Norway began a process to phase down amalgam use in the late 1990s, and amalgam use in children was reduced by 90% between 1995 and 2002.

While it is recognised that Member States should implement approaches to phasing out dental amalgam that are specific to their needs and context, there are some common steps and examples that should inform the process.

Key recommendations

When developing a National Plan with measures to a phase down/out dental amalgam planning (as per Article 10(3) EU Regulation on Mercury), HCWH Europe recommends the following steps for Member States:

1. Establish a coordinating body, and develop and implement a stakeholder engagement strategy:

- Identify all relevant Ministries (e.g. Environment, Health, etc.) and stakeholder groups (e.g. dentists, dental associations, dental colleges, physicians, patient groups, environmental organisations, insurers, manufacturers, legal, etc.). Stakeholder engagement is critical to the success of the overall plan strategy and should begin at the earliest point possible.
- Form a coordinating inter-sectoral body to facilitate input and coordination of the National Plan (such as a National Amalgam Advisory Committee, or working group).
- Define management and oversight arrangements to develop and implement National Plans and interventions.
- Establish a process for engaging stakeholders (their roles, responsibilities, timelines, frequency of meetings, etc.).

2. Situation assessment and inventory

- Establish an accurate and up-to-date data inventory of quantity of dental amalgam-use (both public and private), related mercury emissions, and dental amalgam restoration costs (conduct an inventory of manufacture, trade, and use of dental amalgam).
- Review existing policies and practices related to the handling, storage, and disposal of dental amalgam material (including amalgam waste in dental facilities). Identify areas requiring further support for capacity building.
- Assess availability and costs of mercury-free dental restorative material fillings and related supporting services. Confirm the supply & demand chain and quantity of mercury-free dental restorative material fillings used.
- Identify the quantity of dental amalgam that needs to be phased out and an estimation of associated costs. Assess challenges and opportunities for balancing dental insurance schemes.

- Comprehensively assess national and institutional capacity to support phase-out activitiesⁱⁱⁱ (consider any existing national measures and plans due by July 2019 and specificities of national health services, including the extent to which they fund use and removal of dental amalgam).
- Undertake a legal review/gap analysis for developing legislation to support phase-out of dental amalgam use.
- If possible, the situation assessment and dental mercury inventory should be aligned with other national activities related to the implementation of the Minamata Convention and the EU Mercury Regulation.

3. Strategy development, capacity building, and implementation

- Set a phase-out strategy with clear goals, timelines, and short, medium, and long-term targets; include clear and measurable performance indicators to monitor and evaluate progress implementing the strategy. Provisions should be made for regular review and, if needed, modification in case of unforeseen issues.
- Define specific interventions and supporting activities, agreed by all stakeholders that are coherent with existing policies and capacities, especially those related to waste management and disposal of mercury. If non-existent or inadequate, consider establishing or improving them - they are integral to the phase-out process.
- Reach an agreement on roles and responsibilities for delivery of the above in relation to time-bound targets and measurable indicators. Agree on resources (technical and financial) available and required to implement the plan.
- Establish a monitoring framework to facilitate reporting on delivery of interventions and any unforeseen or unexpected issues/impacts.
- Modify or strengthen appropriate national regulations and policies to support phase-out of dental amalgam use.
- Modify government programs and insurance coverage to favour mercury-free alternatives.^{iv}
- Raise awareness amongst dental practitioners and dental associations about the environmental impacts of dental amalgam and the social benefits of reducing mercury emissions - this will be crucial in ensuring real progress.^v

ⁱⁱⁱ A phase-out in vulnerable groups (mandated by July 2018) is an important first step towards a full phase-out. The several existing examples of successfully switching to mercury-free dental materials serve as models to be replicated elsewhere.

^{iv} Affordable alternatives need to be made available either via incentives, fostering competition, or lowering import duties and taxes on mercury-free alternatives. Public and private insurance systems should favour mercury-free dental fillings.

^v Knowledge, attitudes, practices and beliefs of dental practitioners should be considered when designing awareness-raising and capacity-building efforts at the start of a phase-out. Promote awareness amongst the dental sector about its responsibilities in fulfilling the Minamata Convention and EU Mercury Regulation. It is incumbent on policy-makers to produce and disseminate information relating to dentists' concerns over potential implications of a phase-out.

- Increase public awareness about mercury in dentistry^{vi} and in particular the environmental and health issues associated with dental amalgam. Communications initiatives (e.g. brochures, letters, and stakeholder meetings) are crucial.
- Develop a programme for necessary training of key stakeholders (e.g. dentists, customs, government purchasing officers) to support phase-out of dental amalgam.
- Conduct data-gathering and information sharing on mercury-free dental restorative filling materials. Promote and support additional research on mercury free materials.
- Review and update dental schools' training curriculum to emphasise and promote mercury-free dentistry.^{vii}
- Improve (if necessary) mercury pollution management.^{viii} Develop and issue guidelines covering all aspects of safe handling and storage, and environmentally sound collection and disposal of dental mercury (requirements for transport, labelling, and safe handling might also be specified).

4. Monitoring and reporting

- Monitor/gather data on the accurate quantity of mercury used for dental purposes. The quantity of alternative materials (e.g. registration system) should also be monitored, as this can be an indicator of their uptake.
- Monitor results of interventions and supporting activities with subsequent reporting to the designated entity responsible, verifying compliance with delivery of agreed interventions^{ix} and recording the number of dental facilities with substitution or replacement activities. Monitor the availability of mercury-free alternatives following the implementation of the phase-out strategy and related substitution activities as applicable as well as monitoring change in policies and practices of dental facilities and staff, for example as a result of training and awareness activities.
- Detect and report, as relevant, unforeseen issues/impacts related to the implementation of the strategy.
- Adjust the strategic approach as needed and in agreement with partners/stakeholders and consider lessons learned.

^{vi} Common terms such as “silver” filling in English, or “plombage” in French, (derived from the word for lead) are misleading; people are generally unaware that amalgam contains approximately 50% mercury.

^{vii} Dental schools should develop curricula for dental students to use mercury-free alternatives and provide continuing education for dentists. Both current and future dentists must be educated about amalgam's impacts on the environment.

^{viii} It is highly unlikely that 100% of dental practices become compliant with the relevant requirements of EU waste legislation without any further enforcement actions from public authorities. To unburden dentists from the costs of expensive separators, patients requiring procedures/extractions with dental amalgam filling(s) could be sent to centralised clinics equipped with separators.

^{ix} This includes monitoring facility-based measures to ensure that amalgam is stored in designated locations under required conditions. It may also include monitoring of waste collection, transport, disposal, and export. Traceability of mercury-containing products encompasses actions, measures, and procedures to identify and record all hazardous waste management activities to ensure that such waste is not used illegitimately or disposed of inappropriately. Routine monitoring and reporting can be combined with periodic visits or audits.

Additional resources/reading

- Swedish Chemicals Agency (2011). Mercury Phase-Out: A Study of the Experience of Swedish Companies. <https://www.kemi.se/global/pm/2011/pm-2-11-phase-out-of-mercury.pdf>
- Climate and Pollution Agency, Norway (2011). Norwegian experiences on phasing out the use of dental amalgam https://wedocs.unep.org/bitstream/handle/20.500.11822/13835/Presentation_of_Norwegian_experiences_on_phasing_out_amalgam.pdf
- Climate and Pollution Agency, Norway (2012). Review of Norwegian experiences with the phase-out of dental amalgam use <http://www.miljodirektoratet.no/old/klif/publikasjoner/2946/ta2946.pdf>
- WHO (2009). Future Use of Materials for Dental Restoration http://apps.who.int/iris/bitstream/handle/10665/202500/9789241500647_eng.pdf
- The World Alliance for Mercury-Free Dentistry: www.mercuryfreedentistry.net
- The European Environmental Bureau, Zero Mercury Campaign: www.eeb.org/work-areas/industry-health/zero-mercury-campaign

About HCWH Europe

HCWH Europe is a non-profit European membership organisation of hospitals, healthcare systems, healthcare professionals, local authorities, research/academic institutions and environmental and health organisations. It currently has 89 members in 26 countries from the WHO European region, including 17 EU member states.

HCWH Europe works to transform the healthcare sector worldwide so that it becomes more ecologically sustainable and a leading advocate for environmental health and justice across the globe. We bring the voice of healthcare professionals to the European policy debate about key issues such as chemicals, climate change and health, green building, sustainable procurement, pharmaceuticals, sustainable food and waste management.

www.noharm-europe.org

References

¹ WHO (2018). Healthy Environments for Healthier People. The WHO European Centre for Environment and Health (WHO ECEH). Available at:

<http://www.euro.who.int/en/health-topics/environment-and-health/noise/publications/2018/healthy-environments-for-healthier-people-2018>

² See: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0852>

³ WHO (2015). Developing National Strategies for Phasing Out Mercury-Containing thermometers and sphygmomanometers in health care, including in the context of the Minamata Convention on Mercury. Key considerations and step-by-step guidance. Available at:

https://www.who.int/ipcs/assessment/public_health/WHOGuidanceReportonMercury2015.pdf

⁴ See more at: www.mercuryconvention.org

⁵ The terms of reference of the study are available at:

<http://ec.europa.eu/environment/chemicals/mercury/pdf/20180619%20ToR%20DentalAmalgam%20phase%20out%20short%20version.pdf>

⁶ SWD/2016/017 final - 2016/023 commission staff working document impact assessment Ratification and Implementation by the EU of the Minamata Convention on Mercury. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=SWD:2016:17:FIN>

⁷ UNEP (2016). Lessons from countries phasing down dental amalgam use. UNEP Chemicals and Waste Branch, Geneva, Switzerland. Available at: <https://wedocs.unep.org/bitstream/handle/20.500.11822/11624/Dental.Amalgam.10mar2016.pages.WEB.pdf>

⁸ BIO Intelligence Service (2012). Study on the potential for reducing mercury pollution from dental amalgam and batteries, Final report prepared for the European Commission – DG ENV. Available at: http://ec.europa.eu/environment/chemicals/mercury/pdf/final_report_110712.pdf

⁹ Lars D. Hylander & Michael E. Goodsite (2006). Environmental Costs of Mercury Pollution. *Science of the Total Environment* 368, 352-370.

¹⁰ The real cost of dental mercury. Concorde (2012). Report prepared for the European Environmental Bureau (EEB), the Mercury Policy Project and Consumers for Dental Choice. Available at: http://www.zeromercury.org/index.php?option=com_phocadownload&view=file&id=158:the-real-cost-of-dental-mercury&Itemid=70

¹¹ EEA (2018). Mercury in Europe's environment – A priority for European and global action. European Environmental Agency Report No 11/2018. Available at: <https://www.eea.europa.eu/publications/mercury-in-europe-s-environment>