european center for environmental medicine

Feedback
to the
Inception Impact Assessment on the Revision of Regulation (EU) 2017/852 on mercury, and repealing Regulation (EC) No 1102/2008

The timely phase-out of amalgam in Europe is of great importance, as it accounts for a significant proportion of total emissions in Europe and contributes to the adding to the existing stock of mercury in the environment in the EU and worldwide. Water bodies in Europe are in poor condition, the circular economy of wastewater or sewage sludge is hindered, and the population is taking mercury up by the food.

Even though half of the mercury enters Europe through the atmosphere from outside, Europe must lead by example and prevent its own emissions. Dental amalgam accounts for by far the largest share of "intentional" use in Europe and especially since alternative filling materials are available and affordable, amalgam should be phased out in Europe by 2025 at the latest.

Mercury Emissions from the Use of Dental Amalgam

The impact assessment to the Proposal of the Commission for a Regulation on Mercury in 2017 described the significant contribution of mercury emissions from dental amalgam to the environment:

The European Union's emission inventory reported a **total emission of 56.9 tons in 2014**. It was stipulated that the air emission from the all life cycle phases of dental amalgams represented between **20% and 30% of the overall mercury emissions to air**. Dental amalgam also accounted for **33% of all emissions to surface waters** and **67% of emissions from municipal wastewater treatment**.[1]

Since then, the use of mercury in **products** such as **batteries, lamps and thermometers**, or in **industrial processes** such as the **chlor-alkali process** has been regulated and emissions from the energy sector have continued to decline. It is therefore reasonable to assume that the proportion of mercury emissions from the use of dental amalgam has not decreased, despite the decline in its own use.

The Assessment in 2020 of the feasibility of phasing-out dental amalgam, calculated that about **12-24 tons** of mercury are still made bioavailable due to dental amalgam.[2] As a comparison, coal-fired power plants and waste incineration plants have emissions per plant close to the threshold of 10 kg/year. Dental amalgam accounts nowadays for by far the largest share of "intentional" use in Europe and despite legal and other precautionary measures, mercury from dentistry is inevitably released into the environment.

The continued use of mercury in dentistry contributes to the adding to the existing stock of mercury in the environment in the EU and worldwide.

Due to the high cost of mercury emissions, amalgam is currently "more expensive than most, possibly all, other filling materials when environmental costs are factored in." [3]

Zero Pollution Strategy

Continued use of dental amalgam may hinder and potentially reduce the effectiveness of other legislation and policies:

(a) The EU Water Framework Directive, which classifies mercury as a priority hazardous substance and requires that waters in the EU should be in "good ecological" and "good chemical status" no later than 2027;[4]
(b) The EU Water Reuse Regulation, which aims to reduce water scarcity for agricultural irrigation from 2023 as a result of climate change, and to guarantee a high level of protection for the environment and human and animal health with minimum requirements; [5]
(c) The EU Circular Economy Action Plan,[6] which calls for a review of the Wastewater Treatment and Sewage Sludge Directives to apply circular economy practices to the management of wastewater and sewage sludge.

The Assessment of the feasibility of phasing-out dental amalgam concluded that a phase-out of dental amalgam before 2030 is both technically and economically feasible.

Alternative Filling Materials

Alternative mercury-free filling materials are reliable and available, as demonstrated by the growing number of European countries that have significantly phased down or completely eliminated the use of amalgam in dentistry:[7]

(a) Norway, Sweden and Moldova have banned amalgam without exceptions;
(b) In Finland, Denmark, the Netherlands, Luxembourg, Estonia, Spain, Italy and Switzerland the use is below 2%;

Finland, Ireland, Slovakia, Czech Republic, Croatia and Hungary have announced to adjust the government reimbursement schemes to alternative fillings in the coming years or by 2025 at the latest.

Italy has announced to phase out dental amalgam by 2025; Finland, Ireland, Slovakia and the Czech Republic by 2030.

Composite fillings and glass ionomer cements allow for less destruction of the tooth and thus longer survival of the tooth itself through minimally invasive procedures. [8] Composite restorations today last as long or longer than amalgam fillings.[9]

Modern alternative filling materials are cost-efficient and time-saving to use. In Finland, Denmark, Ireland, Belgium, the Czech Republic, Cyprus and Malta, the reimbursements by the public health care system for alternative fillings are equivalent to those of dental amalgam.[10]

Global Impact

Globally, mercury is anthropogenically released into the atmosphere, mainly from gold mining and coal-fired power plants, and is dispersed across borders. The Global levels in the

atmosphere today are about 5 times higher than natural levels. More than half of the mercury deposited in Europe comes from mercury emissions in other parts of the world.

The environmental quality standard for mercury is currently exceeded at all monitoring sites in surface waters in Germany.[11] Almost all fish exceed the environmental quality objectives of the Water Framework Directive; in the river basins Elbe, Danube and Rhine by a factor of 5-16.[12]

Fish and shellfish are the main sources of methylmercury exposure for humans. According to an EU study (2012), one in three newborns in Europe already show elevated mercury levels, which are associated with loss of intelligence. [13]

Political Measures

For these concerns, the European Union is particularly depending on the regulations under the Minamata Convention, the UN-treaty on mercury to reduce the emissions internationally. However, in order to demand further action at the conferences of the parties, the EU is obliged to lead by good examples.

Ending the use of amalgam fillings internationally would significantly reduce emissions of mercury from dentistry especially in countries with lower mercury disposal standards and even have a positive impact on reducing the use of mercury in ASGM, by inhibiting the practice of miners to obtain mercury on the open market under the guise of using it in dentistry.[14]

Provided that the upcoming discussion on the adoption of a general amalgam phase-out at the COP4 of the Minamata Convention is postponed from November 2021 to 2022 (due to the corona pandemic), we call on the European Commission to complete the part of the impact assessment on amalgam before COP4 in order to being able to obtain a strong mandate for the negotiations.

A general phase-out of the use of amalgam in Europe should be decided for 2025 at the latest. The precautionary principle and “Do no harm first”-principle should be invoked. Cost-effective, durable and easy-to-process alternatives are available.

The technical advantages of mercury-free alternatives are described in our submission to the Minamata Convention. (attached below)

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[1] COWI/ICF, Support to assessing the impacts of certain amendments to the Proposal of the Commission for a Regulation on Mercury Final Report 18 July 2017; Page 3; The European Union's emission inventory report for the period 1990-2014 under the UNECE Convention on Long-Range Transboundary Air Pollution reported total emissions of 56.9 tons in 2014. Dental amalgam also accounts for 33% of all emissions to surface waters and 67% of emissions from municipal wastewater treatment.
https://ec.europa.eu/environment/chemicals/mercury/pdf/Final%20Report_KH0617141ENN.pdf

[2] Deloitte et al., Assessment of the feasibility of phasing-out dental amalgam, report prepared under contract to the Directorate-General Environment of the European Commission, 17 June 2020. *The release occurs at various stages of its use, particularly 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 (mercury excreted by humans).*

[3] Lars D. Hylander & Michael E. Goodsite, Environmental Costs of Mercury Pollution, 368 (2006) 352-370.

[4] Water Framework Directive - Germany's waters 2015, https://www.umweltbundesamt.de/sites/default/files/medien/1968/publikationen/final_broschure_wasserrahm_enrichtlinie_bf_112116.pdf

[5] REGULATION (EU) 2020/741 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 May 2020 on minimum water reuse requirements, https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:32020R0741&from=EN

[6] Communication from the Commission: A new Action Plan for the Circular Economy - Towards a cleaner and more competitive Europe,COM (2020) 98 final, 11.3.2020.

[7] National Action Plans to Phase Out the use of Dental Amalgam in the EU https://environmentalmedicine.eu/news/national-action-plans-to-phase-out-the-use-of-dental-amalgam-in-the-eu/

[8] European Commission Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), Final opinion on the safety of dental amalgam and alternative dental restoration materials for patients and users (29 April2015), p.69 http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_046.pdf

[9] DGZ, DGZMK, Recommendations for composite restorations in the posterior region, Oct.2016. Survival rates of composite restorations in the posterior region (1990-2015) - long-term clinical studies with at least 4 years of observation. https://secure.owidi.de/documents/10165/1373255/kompositszblang.pdf/7b1a34a7-ae85-4ace-bc83-0b31bd094fbd

[10] Deloitte et al., Assessment of the feasibility of phasing-out dental amalgam, report prepared under contract to the Directorate-General Environment of the European Commission, 17 June 2020. Page 303

[11] Answer of the Federal Government to a small question in the Bundestag of July 12, 2018 - Drucksache 19/3065 - Impacts of amalgam use in dentistry on humans and the environment; https://polit-x.de/de/documents/1083252/bund/bundestag/drucksachen/antwort-2018-07-23-auf-die-kleine-anfrage-drucksache-193065-auswirkungen-der-amalgam-nutzung-in-der-zahnmedizin-auf-mensch-und-umwelt

[12] Federal Environment Agency, Frequently asked questions about mercury, as of 04.05.2016, https://www.umweltbundesamt.de/themen/gesundheit/umwelteinfluesse-auf-den-menschen/chemische-stoffe/haeufige-fragen-zu-quecksilber#wie-kommt-das-quecksilber-in-die-umwelt-

[13] European study on the environmental impact of mothers and children, Democophes 2012, http://www.eu-hbm.info/euresult/media-corner/press-kit

[14] *According to the International Pollutants Elimination Network (IPEN), there is concern that in countries with ASGM, the use of mercury in dental amalgam acts as a "cover" for the illegal trade in mercury destined for ASGM. Policing national borders to prevent illegal mercury imports would be greatly assisted by the phase out of dental amalgam.*
IPEN submission on review of Annex A and B of the Minamata Convention, http://www.mercuryconvention.org/Portals/11/documents/meetings/COP4/submissions/IPEN_submission_Annex_A_B.pdf

Technical Advantages of Mercury-Free Dentistry

1. Availability and Feasibility of Non-Mercury Alternatives

The availability of superior non-mercury alternatives has enabled the virtual phase out of amalgam use in entire countries in Europe. For example, Sweden[1] and Norway[2] have phased out amalgam use. Finland[3], the Netherlands[4], and Denmark[5] use amalgam for only 1% of all fillings. In fact, according to the latest report, fully 70% of the EU Member States – 17/27 – are reported to have less than 10% amalgam use or have filed phase out plans.

The use of non-mercury alternatives to amalgam is not only feasible; it is supported by the European public, recognized by industry, and already practiced by many dentists. The European Commission's' online public consultation resulted in over 85% support for phasing out amalgam.[6] The manufacturers are focused on alternatives, having even hosted a conference themed "The Demise of Amalgam". The majority of dentists practice mercury-free dentistry, and all dentists (certainly all under age 70) know how to use mercury-free fillings.

A recent survey of the market shares of mercury-free fillings in Germany (Annex I) impressively shows how modern and user-friendly alternative products for permanent fillings have been established on the market while the number of fillings per year continue to decline. [7]

Clearly and indisputably, the non-mercury alternatives to amalgam are available and feasible.

2. Mercury-free fillings are more minimally-invasive than amalgam

It is well-established that amalgam damages healthy tooth matter, weakens tooth structure, and fractures teeth:

- "However, some significant disadvantages are associated with amalgam that are not encountered with resin based composite. These include…strict preparation requirements for depth and mechanical retention; and its non-adhesive nature."[8]

Mercury-free materials like composite offer the invaluable benefits of preserving tooth structure and strengthening teeth:

The majority of cavities are small and can be filled time-saving with single layer composites, compomers or glass-ionomers

The majority of cavities are small cavities of one or two surfaces (statistically 70% in Germany in 2018[9]) which can be fast and easily filled by using minimal invasive single-layer composites, composer or glass ionomers.

Since the use of these materials is less invasive and allows a longer survival of the tooth, they should be **the first choice for small cavities.**

This also complies with the World Dental Federation which recommended in September 2018 to reduce and if possible, avoid the use of amalgam particularly in lesions that are suitable for other restorative materials, especially in first restorative treatment and young patients. [10]

Using amalgam causes large cavities reducing the healthy tooth structure and poses a greater challenge to the dentist when they have to be replaced. The consistent use of the minimally invasive therapy from the beginning would therefore reduce the number of large cavities in the long term.

In any case, even large cavities can nowadays be handled just as well with alternative materials as with amalgam.

A further assessment of the feasibility and benefits of non-mercury alternatives to dental amalgam is attached with images (Annex II)

3. Mercury-free fillings can be placed as fast as amalgam

It generally does not take dentists any more time to place a composite than it does an amalgam:

- According to a 2012 BIOIS report prepared for the European Commission, "it has been shown that the time needed to carry out a Hg-free [mercury-free] restoration has reduced significantly as dentists have gained more experience in the handling of Hg-free materials, so that there is currently no (or minor) time difference to perform Hg-free restorations compared to amalgam."[11]

As mentioned before, small cavities can be fast and easily filled by using minimal invasive single-layer composites, compomers or glass ionomers.

For **large cavities with three or four surfaces,** even in the masticatory load-bearing posterior region dentists have nowadays the choice between several modern non-metallic alternatives or a combined technique with a comparable lifetime to amalgam.

A standard technique is the combination of glass ionomer cement and composites. It saves material costs, reduces shrinkage stress and increases marginal seal. The self-adhesive glass ionomer cement replaces the missing dentin as a cavity base and the composite covers the base to increase the durability. This cost-effective and durable combination of glass ionomer cements and composites is suitable for medium to large cavities with sufficient enamel limitation in the posterior region.

Another alternative to traditional incremented composites are the new generation of optimized bulk fill composites. Given that these new composites are placed in-bulk, restoring the complete cavity or most of it, depending on the type of bulk-fill composite, the placement is time-saving and therefore cost-effective.

Direct composite restorations in the posterior dentition have become an indispensable element of modern dentistry. The performance of these restorations has been conclusively proven in many clinical studies. This procedure is usually carried out in a layering technique. Aside from the possibilities that highly aesthetic composites offer in the application of polychromatic multiple-layer techniques, there is also a great market demand for the simplest and quick and therefore economical composite- based materials for posterior teeth. These products are offered in the category of bulk-fill composites.

4. Mercury-free fillings can last as long – or longer – than amalgam

According to the current guideline of the DGZ (Deutsche Gesellschaft für Zahnerhaltung, German society for tooth preservation) on composite restorations in the posterior region from 2016, alternative restorations can be successfully used in the posterior region according to the current data situation for the restoration of class I and II cavities[12]. The results of a comprehensive review have shown that the annual failure rate of composite fillings in the posterior region (2.2%) is statistically not different from that of amalgam fillings (3.0%)[13]. For not only time-consuming high-end restorations for the posterior region, but also a simpler, faster and therefore more cost-effective basic restoration, bulk fill composites with optimized curing depths have been available on the market for some time now. They allow clinically acceptable posterior fillings to be placed in a more economical procedure than the 2 mm layering technique with traditional hybrid composites[1415].

The following table shows the survival rates of composite restorations in the posterior region in long-term clinical studies with at least a 4 years observation periods (1990-2015)[16]
(AFR = Annual Failure Rate)

Author	Year	Observation period (years)	Compositgroup	AFR (%)
Manhart et al. (not yet published)	2016	10	Bulkfill Composit Hybridcomposit	1.8
Pallesen and Van Dijken [17]	2015	30	HybridComposit light-curing 2 Hybridkomposite chemically curing	1.4 1,1/0,8
Pallesen and Van Dijken [18]	2015	27	2 Hybridcomposites light-curing Hybridkomposit chemically curing	1,7/1,8 1,4
Van Dijken and Pallesen [19]	2013	6	Hybridcomposit Nano-Hybridcomposit	1,7 2,3
Van Dijken and Pallesen [20]	2011	7	Hybridkomposit without Lining Technik Hybridkomposit with Lining Technik	2,3 2,0
Da Rosa Rodolpho et al. [21]	2011	22	Hybridcomposit (70vol% Filler) Hybridcomposit (50vol% Filler)	1,5 2,2
Manhart et al. [22]	2010	4	Bulkfill Composit Hybridcomposit Kompomer Underfilling	2,7 0,6 0,2
Van Dijken [23]	2010	12	Hybridkomposit (closed sandwich technique) Hybridkomposit (only Class I Restauratioen)	0,2
Opdam et al. [24]	2010	12	Hybridcomposit Amalgam	1,68 2,41
Van Dijken et al. [25]	2009	5	Hybridcomposit Hybridkomposit with Präpolymerisaten (low shrinkage)	2,9 2,1
Lindberg et al. [26]	2007	9	Compomer/Hybridcomposit (Open Sandwich Technique) Hybridcomposit	1,0 1,37
Van Dijken et al. [27]	2005	4	Hybridcomposit Calcium aluminate cement	1,9 19
Pallesen and Quist [28]	2003	11	Hybridcomposit Composit-Inlays	1,5 1,5
Gaengler et al. [29]	2001	10	Hybridcomposit	2,58

5. Mercury-free fillings are safer than amalgam

Amalgam never faced the regulatory scrutiny that new dental materials go through: Amalgam came into use more than a century ago, before any effective government safety regulations for new medical devices existed. Many current regulatory schemes permit the continued use of this mercury-added product under "grandfather" clauses that excuse older products from meeting current regulatory standards (or any standards at all). Today, a new product this toxic would have to overcome far more regulatory hurdles well before it reached the market – and any serious health, safety and environmental concerns would be addressed during this rigorous process. As a result, any risky products – especially one comprised of a known neurotoxin—are unlikely to receive regulatory approval, well in advance of reaching the market. In Europe it is even more unlikely now that the new Medical Devices Regulation (MDR) (EU 2017/745)[30] is going into effect. MDR will enter into force on 26th Mai 2021 in all EU Member States, provide an optimised uniform regulation for the marketing of medical devices, and enhance the focus on product quality and safety. Detailed documentation, including raw materials, will be required. In conclusion, MDR will ensure the safety of new dental filling materials. If the manufacturer of a device has a current "approval", this remains valid for the time being, but **its validity ends at the latest on 27 May 2025**. There is reason to believe that dental amalgam would not meet these requirements.

Considering that amalgam consists of 50% mercury, it is no surprise that the industry was failing to introduce effective safety standards for products on the market. Usually, the safety is made transparent to consumers by applying uniform standards which are indicated on the package leaflet. In the case of dental amalgam, a standard for tolerable release rates of mercury was delayed for decades. Due to the Minamata Convention and the EU mercury regulation, standards for encapsulated and non-encapsulated amalgam fillings have finally been initiated (ISO 23325, ISO 20749 and ISO 24234). However, since these new standards refer to a purely mechanical test method of the corrosion resistance and accept a wear rate of 20%, they are not suited to prove the safety of amalgam. If the immersion procedure or the potentiostatic procedure (as had been defined in the now ignored Technical Specifications of ISO/TS 17988 Dentistry - Corrosion test methods for dental amalgam) had been applied, consumers would at least have had the opportunity to verify the quality of the filling by a saliva-, vapour- or tension test.

Amalgam's known risks keep increasing while no harm from mercury-free fillings has been found in half a century: No study has proven that mercury-free fillings pose a risk – and new developments make it even less likely that they ever will. For example, the share of hybridfiller and organic matrix in a composite filling is today 15-25% organic matrix and 75-85% inorganic filler. The share of hybrid fillers can actually exceed 86% without containing nanoparticles[31]. This high proportion increases the strength of the filling while reducing the potential release of the organic matrix. However, new research has concluded that amalgam's mercury poses even more risks than were known at the time of SCENIHR's 2015 opinion. For example, *Bjorkman et. al.* (2018) found that "The results from this study support the hypothesis of increased risk of perinatal mortality of children born by women with many amalgam fillings."[32] And *Yin et. al.*(2016) "found that dental surface restorations significantly contributed to the blood concentrations of THg and IHg in both periods of study, as well as MeHg in 2011–2012, after adjusting covariates such as age, education, race/ethnicity, gender, smoking, and fish consumption history" – meaning that it is now clear that amalgam's elemental mercury can convert to methylmercury in the human body and put people (especially individuals already exposed to other sources of methylmercury like high fish diets) at

even more risk, especially if they are already exposed to other sources of methylmercury (like high fish diets or mercury-based skin creams).[33]

While mercury poses many risks to both health and the environment, **the European Center for Environmental Medicine would like to direct the Secretariat's attention specifically to the problem of amalgam use in people with kidney impairments** because so many studies, governments, and industry sources – especially in the European Union, but also beyond – have warned against the use of amalgam in people with kidney impairments.

Kidney disorders affect millions of Europeans. According to the European Renal Association-European Dialysis and Transplant Association (ERA-EDTA), 10% of Europeans are affected by chronic kidney disease.[34] This means that approximately "70 million Europeans (850 million people worldwide)[35] have lost some of their kidney function and are at high risk of becoming dependent on renal replacement therapies (dialysis or transplantation)."[36] Making the problem even worse, many people – especially low-income individuals with less access to healthcare – do not even realize they have a kidney impairment because the disease has few "alarm signals" until it reaches an advanced stage and there is a lack of public awareness about the disease. [37] The ERA-EDTA says this lack of awareness extends to the medical community. These facts raise particular problems for amalgam use:

- With so many people who have undiagnosed kidney impairments (or who will develop kidney disease later), how can dentists ensure that they are not using amalgam in this vulnerable population?

- If even medical doctors are unaware of kidney disease, how can dentists – who are not licensed or trained to practice medicine – be depended upon to decide which patients with kidney impairments, with undiagnosed kidney impairments, or with higher risk of developing kidney impairments should receive amalgam?

Below are examples of studies, governments, and even industry warning against amalgam use in people with kidney impairments, indicating that use of non-mercury alternatives to amalgam would be a clear benefit to the health of this vulnerable population.

Studies support the conclusion that dental amalgam should never be used in people with kidney impairments:

- *European Commission Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), Final opinion on the safety of dental amalgam and alternative dental restoration materials for patients and users (29 April 2015), http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_046.pdf, p.36, 43, 75:*
  The European Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) explained that "decreased kidney function (decreased renal clearance) is likely to decrease the ability to eliminate mercury and other substances via the urine." [38] It concluded that "use of amalgam restorations is not indicated in primary teeth, in patients with mercury allergies, and persons with chronic kidney diseases with decreased renal clearance."[39]

- *Barregard L, Fabricius-Lagging E, Lundh T, Mölne J, Wallin M, Olausson M, Modigh C, Sallsten G., Cadmium, mercury, and lead in kidney cortex of living kidney donors: Impact of different exposure sources. Environ Res. 2010; 110(1): 47-54:*

As explained in the abstract, Barregard *et al.* (2010) found that "Kidney Hg increased by 6% for every additional amalgam surface, but was not associated with fish consumption…. Dental amalgam is the main determinant of kidney Hg."[40]

- *Wael I. Mortada, Mercury in dental restoration: Is there a risk of nephrotoxicity, J. NEPHROL (2002), http://www.ncbi.nlm.nih.gov/pubmed/12018634:*
  Mortada *et. al.* (2002) explained that "A total of 101 healthy adults (80 males and 21 females) were included in this study. The population as grouped into those having amalgam fillings (39 males and 10 females) and those without (41 males and 11 females). Hg was determined in blood, urine, hair and nails to assess exposure. Urinary excretion of beta2-microglobulin (beta2M), N-acetyl-beta-D-glucosaminidase (NAG), gamma-glutamyltransferase (gammaGT) and alkaline phosphatase (ALP) were determined as markers of tubular damage. Albuminuria was assayed as an early indicator of glomerular dysfunction. Serum creatinine, beta2M and blood urea nitrogen (BUN) were determined to assess glomerular filtration….From the nephrotoxicity point of view, dental amalgam is an unsuitable filling material, as it may give rise to Hg toxicity…in these exposure conditions, renal damage is possible…"[41]

- *Ritchie KA et. al., Mercury vapour levels in dental practices and body mercury levels of dentists and controls, British Dental Journal (2004), https://www.researchgate.net/publication/8118038_Mercury_vapour_levels_in_clinical_practices_and_body_levels_of_dentists_and_controls:*
  Ritchie *et al.* (2004) found that the urinary mercury levels found in dentists can be over four times that of the control group: "A large and highly significant difference was found between urinary mercury levels of dentists and controls, with the geometric mean urinary mercury for dentists being 4.17 times that for the control group (95% CI = 3.36 to 5.19)....There was, amongst dentists, a significant correlation between the number of amalgam fillings they placed and removed in a week and urinary mercury concentration ($r = 0.38$, $P < 0.001$, and $r = 0.29$, $P<0.001$)."[42] It also found that dentists were significantly more likely than non-dentist control subjects to report having disorders of the kidney: "....dentists were significantly more likely to have suffered from kidney disorders (6.5%) than control subjects (0.6%),...".[43]

Governments – in the EU and beyond – support the conclusion that dental amalgam should not be used in people with kidney impairments:

- *European Commission, Final Report: Review of the Community Strategy Concerning Mercury (October 2010), https://ec.europa.eu/environment/chemicals/mercury/pdf/review_mercury_strategy2010.pdf , p.187:*
  According to a report prepared for the European Commission, in Germany "It is recommended not to use dental amalgam on children, pregnant and nursing women, people with kidney problems, when in contact with other metals, such as braces, and in people with mercury sensitivity."[44]

- *Ministero della Salute (Italy), Divieto di utilizzazione, importazione e immissione in commercio, sul territorio italiano degli amalgami dentali non preparati sotto forma di capsule predosate e precauzioni ed avvertenze da riferire nelle istruzioni per l'uso degli amalgami dentali posti in commercio in Italia. (G.U. Serie Generale , n. 261 del 09 novembre 2001), http://www.trovanorme.salute.gov.it/norme/dettaglioAtto?id=14407&completo=true*

"evitare per prudenza la posa e la rimozione dell'amalgama in pazienti con allergia per l'amalgama, gravidanza, allattamento, bambini sotto i sei anni d'eta', pazienti con gravi nefropatie" (translated as "prudently avoid the installation and removal of the amalgam in allergy patients, pregnancy, breastfeeding, children under six years of age, patients with severe kidney disease)[45]

- *Health Canada, The Safety of Dental Amalgam, https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/dhp-mps/alt_formats/hpfb-dgpsa/pdf/md-im/dent_amalgam-eng.pdf:*
  According to Health Canada's Position Statement on Dental Amalgam, "Amalgam should not be placed in patients with impaired kidney function."[46]

- *National Health & Medical Research Council, Dental Amalgam – Filling You In (2002), https://web.archive.org/web/20040611002357/http://www.health.gov.au/nhmrc/publications/pdf/d18.pdf:*
  Australia's National Health and Medical Research Council brochure *Dental Amalgam – Filling You In* warned people with kidney impairments to avoid amalgam: "Very small amounts of mercury are released from the surface of dental amalgam fillings, mainly as mercury vapour. Grinding teeth, chewing and tooth-brushing all increase the amount of mercury released. Some of the vapour is breathed out, but some is breathed in, or dissolves in saliva and is swallowed. In this way, some mercury can reach the rest of the body and accumulate in certain organs, particularly the kidneys….Because high levels of mercury exposure may affect the kidneys, people with kidney disease may be more concerned than others to minimise exposure to mercury."[47]

Industry supports the conclusion that dental amalgam should never be used in people with kidney impairments:

- *Professor Gottfried Schmalz, Webinar: What dentists need to know about the Minamata Convention on Mercury, https://www.fdiworlddental.org/news/20190501/webinar-what-dentists-need-to-know-about-the-minamata-convention-on-mercury (emphasis added)*
  "….the scientific advisory committee of the EU (SCENIHR) in 2015 concluded that current evidence does not preclude the use of amalgam for the general population with no allergy to amalgam components or *with no renal disease*."[48]

- *World Dental Federation (FDI), Policy Statement on Dental Amalgam Phase Down (September 2018), https://www.fdiworlddental.org/resources/policy-statements/dental-amalgam-phase-down (emphasis added):*
  "FDI supports the following practices in the phase down of dental amalgam….Reduce and if possible avoid the use of amalgam particularly in: lesions that are suitable for other restorative materials, especially in first restorative treatment and young patients; *patients with special medical conditions, such as severe renal disease* or patients with allergic reactions to amalgam or (erosive) lichenoid contact lesions in the oral mucosa; except when deemed necessary by the dental practitioner based on the specific needs of the patient. "[49]

- *Canadian Dental Association, Dental Amalgam FAQs, http://www.cda-adc.ca/en/oral_health/faqs/dental_amalgam_faqs.asp*
  "Can dental amalgam be safely used with every patient? No….Health Canada suggests that alternatives should be considered for patients with impaired kidney function. Although dental

amalgam itself is not linked to such conditions, there is evidence that total body burden of mercury is of particular concern with these patients."[50]

6. Mercury-free fillings are safer for the environment

A report by UNEP shows that, per capita, the European Union largest user of dental mercury in the world – consuming at least 90 tons in 2010.[51] While this is due in part to more universal dental care than is available in other regions, the stark reality is the E.U. is the #1 dental mercury polluter; as this AMAP/UNP report shows, all other regions consume significantly less dental mercury[52]:

Once in the environment, SCHER has confirmed that dental amalgam in the environment can methylate (forming the most toxic form of mercury, methylmercury), that as a result "the acceptable level in fish is exceeded" under some circumstances, and thus there is "a risk for secondary poisoning due to methylation."[53]

The use of Dental Amalgam is critical for the chemical status in water bodies

The European Environmental Agencies State of Water Report (2018)[54] highlights, that across Europe mercury is the main contributor for failure to achieve good chemical status in the highest number of water bodies: out of a total of 111,062 surface water bodies, 45,973 are not achieving good status for mercury equating to about 41% of all surface water bodies in Europe. If the widespread pollution by ubiquitous priority substances, including mercury, were omitted, the proportion of water bodies failing to achieve good chemical status would fall to 3% (as opposed to 46%).

Additionally, dental amalgam appears to be the main contributor to releases of mercury from urban wastewater treatment plants (UWWTP) to water bodies.

A report (BIOis 2012[55]) on behalf of the European Commission suggested to ban dental amalgam since it seems necessary to achieve mercury-related requirements of the EU legislation (the Water Framework Directive (2000/60/EC), Decision 2001/2455/EC and Directive 2006/11/EC on dangerous substances and Directive 2008/105/EC on priority substances).

Meanwhile, mercury-free composites and glass ionomers are safe for the environment:

- European Commission Scientific Committee on Health and Environmental Risks (SCHER): "Due to the low mammalian toxicity of these compounds, indirect risks to human health from release of the alternatives [to amalgam] without mercury are estimated as low."[56]

- According to a 2012 study by the Health Care Research Collaborative of the University of Illinois at Chicago School of Public Health, the Healthier Hospitals Initiative, and Health Care Without Harm, "there is no current evidence of significant personal or environmental toxicity" from the non-mercury alternatives.[57]

- A briefing note from EurEau says: **The available evidence suggests that microplastics at current concentration levels do not pose a risk to human health and waste water is not a source of microplastics.** Only a minor share of the total microplastics released from various sources enter waste water infrastructure. Conventional WWTPs can efficiently remove up to 80-95% of microplastics, mostly in the preliminary and primary treatment steps. [58]

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