

## **Bonn Declaration on Dental Amalgam** (2021)

**The undersigned demand a decision from the Federal Government to generally phase out the use of amalgam fillings in dentistry<sup>1</sup> by 2025 at the latest and to adjust the reimbursements of the statutory health insurance funds to alternative filling materials, for the following reasons:**

1. Dental amalgam is a dental filling material consisting of 50% elemental mercury.
2. Mercury is one of the most harmful substances of global concern. It is especially toxic to the development of children's brains, damages the central nervous system,<sup>2</sup> kidney,<sup>3</sup> cardiovascular<sup>4</sup> and immune systems.<sup>5</sup> It is persistent and accumulates in the body. Mercury burden is passed from mothers to children through the placenta and breastfeeding.<sup>6</sup>
3. Despite legal and other precautionary measures, mercury from dentistry is inevitably released into the environment. In a European comparison, Germany is in the top group in the use of amalgam and thus also in the generation of mercury emissions in dentistry.<sup>7</sup>
4. EU-wide, about 12-24 tons of mercury (about 20% - 40% of total emissions<sup>8</sup>) are bioavailable due to dental amalgam, i.e. emitted to air, discharged to surface water, disposed of in solid waste and/or released to groundwater.<sup>9</sup> Since the use of mercury in products such as batteries, lights and thermometers or in industrial processes has been regulated, amalgam accounts for by far the largest share of "intentional" use in Europe. In amalgam fillings of EU citizens, an estimated 1500 tons of mercury are still stored.<sup>10</sup>
5. Globally, mercury is anthropogenically released into the atmosphere, mainly from gold mining and coal-fired power plants, and is dispersed across borders. 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.<sup>11</sup>
6. Once elemental mercury enters water bodies, bacteria can convert it to methylmercury, a highly toxic form that accumulates in fish, shellfish, and animals that eat fish. The environmental quality standard for mercury is currently exceeded at all monitoring sites in surface waters in Germany.<sup>12</sup> 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.<sup>13</sup>
7. 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.<sup>14</sup>
8. Because of these concerns, 128 countries negotiated a legally binding treaty, the Minamata Convention on Mercury, which entered into force in August 2017. The Minamata Convention requires each nation to reduce all uses and releases of mercury, including from dental amalgam.

9. The Minamata Convention states that Parties are “Aware of the health concerns, especially in developing countries, resulting from exposure to mercury of vulnerable populations, especially women, children, and, through them, future generations.”<sup>15</sup>
10. In 2017, the European Union adopted a ban on the use of amalgam in children and pregnant and breastfeeding women (as of July 2018), required member states to develop strategies to further reduce amalgam use by 2019, and decided to conduct a feasibility study on generally phasing out the use in the EU.<sup>16</sup> This study concluded in 2020 that a phase-out of dental amalgam before 2030 is both technically and economically feasible.<sup>17</sup>
11. 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."<sup>18</sup>
12. 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;<sup>19</sup>
  - (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;<sup>20</sup>
  - (c) The EU Circular Economy Action Plan,<sup>21</sup> 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.
13. European chemicals policy stipulates that products with toxic ingredients should always be replaced by products with less toxic ingredients<sup>22</sup> and there is extensive evidence that mercury is far more toxic than any chemicals in mercury-free alternatives.<sup>23</sup>
14. The EU Medical Device Regulation (MDR)<sup>24</sup> requires sound evidence of the biocompatibility<sup>25</sup> of dental filling materials from May 26, 2021. Special requirements also apply to the approval and labeling of fillings containing carcinogens, mutagens or reprotoxic substances (CMRs). Approvals from before May 26, 2021, will lose their validity by May 26, 2025, at the latest.

There are strong reasons why amalgam should no longer be approved under the requirements of the MDR if the following circumstances are adequately addressed:

- (a) Small amounts of mercury vapor are continuously released from amalgam fillings. Increased release rates depend on the quality and age of the filling, as well as contact with other metals and habits such as grinding teeth, chewing, drinking hot beverages, or brushing teeth;<sup>26</sup>
- (b) While small inhaled amounts may not be harmful to most people, long-term exposures may pose an increased health risk to vulnerable individuals and in those who have an impaired ability to excrete mercury;<sup>27</sup>

- (c) There are concerns about the potential for mercury to transform and accumulate in the body into other (more toxic) mercury compounds;<sup>28</sup>
  - (d) There are concerns about the effects of additional mercury from other environmental and/or dietary sources (e.g., fish) or combination effects by loads from a different exposure.<sup>29</sup>
15. 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:<sup>30</sup>
- (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%;
  - (c) Finland, Ireland, Slovakia, Czech Republic, Croatia and Hungary have announced that they will adjust the government reimbursement schemes to alternative fillings in the coming years.
16. 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.<sup>31</sup>
17. Composite restorations today last as long or longer than amalgam fillings.<sup>32</sup>
18. 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 amalgam.<sup>33</sup> In Germany, the rates for composites are still higher, but have not been adapted to technical developments since 1996.<sup>34</sup>
19. Consumers are often faced with significant additional costs for alternative filling materials since only amalgam is reimbursed by statutory health insurers for posterior teeth.<sup>35</sup> Low-income people have difficulties affording it.
20. At German universities, the processing of amalgam is barely taught in practice, but only theoretically.<sup>36</sup> The young generation of dentists can no longer meet the demand of health insurance companies to use amalgam as a standard material.<sup>37</sup>
21. A clear majority of 86% of the respondents in an EU survey (2014) spoke out in favor of a European phase out on the use of dental amalgam.<sup>38</sup>

**We therefore call on the German government to comply with the precautionary principle and environmental standards, to decide on a general phase-out of the use of dental amalgam<sup>39</sup> by 2025 at the latest, and to adopt the reimbursements of the statutory health insurance funds to alternative filling materials.**

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<sup>1</sup> Possibly with exceptions for patients for whom such treatment is mandatory because of specific medical needs.

<sup>2</sup> Minamata Convention on Mercury

<https://www.mercuryconvention.org/Portals/11/documents/Booklets/COP3-version/Minamata-Convention-booklet-Sep2019-EN.pdf>

<sup>3</sup> 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), p.36, 43,75:

[http://ec.europa.eu/health/scientific\\_committees/emerging/docs/scenihr\\_o\\_046.pdf](http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_046.pdf)

<sup>4</sup> Wendy Mckelvey and Emily Oken, Mercury and Public Health: An Assessment of Human Exposure (2012)

<sup>5</sup> Mergler D, Anderson HA, Chan LH, et al. Methylmercury exposure and health effects in humans: a worldwide concern. *Ambio*. Feb 2007, 36(1): 3-11.

<sup>6</sup> Ha, Eunhee; Basu, Niladri; Bose-O'Reilly, Stephan; Dórea, José G.; McSorley, Emeir; Sakamoto, Mineshi; Chan, Hing Man, Current progress on understanding the impact of mercury on human health, (2017)

<sup>7</sup> 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.

<sup>8</sup> 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.

<sup>9</sup> 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).*

<sup>10</sup> EEA Report No 11/2018, Mercury in Europe's environment: A priority for European and global action, <https://www.eea.europa.eu/publications/mercury-in-europe-s-environment>

<sup>11</sup> ebd.

<sup>12</sup> 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>

<sup>13</sup> 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->

<sup>14</sup> European study on the environmental impact of mothers and children, Democophes 2012,

<http://www.eu-hbm.info/euresult/media-corner/press-kit>

<sup>15</sup> <https://www.mercuryconvention.org/Portals/11/documents/Booklets/COP3-version/Minamata-Convention-booklet-Sep2019-EN.pdf>

<sup>16</sup> EU Mercury Regulation 2017/852, <https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:32017R0852&from=EN>

<sup>17</sup> REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL on the review of the use of mercury in dental amalgam and in products pursuant to Article 19(1) of Regulation 2017/852

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<https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:52020DC0378&from=EN>

<sup>18</sup> Lars D. Hylander & Michael E. Goodsite, Environmental Costs of Mercury Pollution, 368 (2006) 352-370.

<sup>19</sup> Water Framework Directive - Germany's waters 2015,

[https://www.umweltbundesamt.de/sites/default/files/medien/1968/publikationen/final\\_broschure\\_wasserrahm\\_enrichtlinie\\_bf\\_112116.pdf](https://www.umweltbundesamt.de/sites/default/files/medien/1968/publikationen/final_broschure_wasserrahm_enrichtlinie_bf_112116.pdf)

<sup>20</sup> 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>

<sup>21</sup> 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.

<sup>22</sup> Chemicals Strategy for Sustainability Towards a Toxic-Free Environment, 2020

<https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf>

<sup>23</sup> Reichl et al. (2006), Cell death effects of resin-based dental material compounds and mercurials in human gingival fibroblasts <https://www.ncbi.nlm.nih.gov/pubmed/16691427> ;

Reichl et al. (2006) Cytotoxicity of dental composite monomers and the amalgam component Hg(2+) in human gingival fibroblasts. <https://www.ncbi.nlm.nih.gov/pubmed/16474958>

<sup>24</sup> REGULATION (EU) 2020/561 of the European Parliament and of the Council concerning medical devices <https://eur-lex.europa.eu/legal-content/DE/TXT/PDF/?uri=CELEX:32020R0561&from=EN>

<sup>25</sup> A major difference between the previous Medical Device Directive (MDD) and the Medical Device Regulation (MDR) is that the MDR in its current version has direct validity and effect in all EU member states. The MDR requires proof of biocompatibility of all dental filling materials. <https://www.johner-institut.de/blog/systems-engineering/biokompatibilitaet/>

The ISO 10993-17 standard, which is harmonized for regulatory approval, requires the specification of limits for each applicable exposure period as the patient dose, which represent the acceptable risks from medical devices under the conditions of intended use.

<sup>26</sup> Recommendations About the Use of Dental Amalgam in Certain High-Risk Populations: FDA Safety Communication, September 24, 2020 <https://www.fda.gov/news-events/press-announcements/fda-issues-recommendations-certain-high-risk-groups-regarding-mercury-containing-dental-amalgam>

<sup>27</sup> ebd.

<sup>28</sup> ebd., In 2016, a study of 15,000 subjects found that in people with more than 8 amalgam surfaces, the concentration of Hg and methylHg increased by 150%. Lei Yin, Kevin Yu, Simon Lin, Xiao Song, Xiaozhong Yu. Associations of blood mercury, inorganic mercury, methyl mercury and bisphenol A with dental surface restorations in the U.S. population, NHANES 2003–2004 and 2010–2012. *Ecotoxicology and Environmental Safety*, 2016; 134: 213 DOI: 10.1016/j.ecoenv.2016.09.001

<sup>29</sup> ebd., Chemicals Strategy for Sustainability for a Pollutant-Free Environment [https://eur-lex.europa.eu/resource.html?uri=cellar:f815479a-0f01-11eb-bc07-01aa75ed71a1.0002.02/DOC\\_1&format=PDF](https://eur-lex.europa.eu/resource.html?uri=cellar:f815479a-0f01-11eb-bc07-01aa75ed71a1.0002.02/DOC_1&format=PDF)

<sup>30</sup> 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/>

<sup>31</sup> 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](http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_046.pdf)

<sup>32</sup> 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>

<sup>33</sup> 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

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<sup>34</sup> Resolution of the Extended Evaluation Committee for Dental Services of 17.04.1996, <https://abrechnungsmappe.kzvb.de/kzvb/artikel?version=1&artikel=41>

*A note stated that composite exception positions will be reevaluated once they exceed 1% of all fillings, which has been the case since 2019 (4.5%).*

<sup>35</sup> Although the Federal Joint Committee does not explicitly require amalgam fillings as a standard material, most statutory health insurers are committed to the exclusive reimbursement of amalgam in posterior teeth (see web pages: [Barmer](#), [AOK](#), [DAK](#),...).

<sup>36</sup> Medizinischer Dienst des Spitzenverbandes Bund der Krankenkassen e.V.. (MDS), Amalgam: Toxicological and allergological risk assessment. Status: January 25, 2013, page 33 [https://www.amalgam-informationen.de/dokument/GKV\\_2013\\_Toxicologie\\_Allergologie\\_Amalgam.pdf](https://www.amalgam-informationen.de/dokument/GKV_2013_Toxicologie_Allergologie_Amalgam.pdf)

<sup>37</sup> ebd.

<sup>38</sup> Public Consultation on the Ratification by the EU of the Minamata Convention on Mercury, 2014 <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52016SC0017&from=EN>

<sup>39</sup> Possibly with exceptions for patients for whom such treatment is mandatory because of specific medical needs.