

Feedback on EU 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 dental amalgam in Europe is of major relevance as the use of mercury in dentistry accounts for a significant share of total mercury emissions in Europe. The use of dental amalgam 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 large amounts of the mercury pollution come to Europe from outside via the atmosphere, 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/year** 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**³ – 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." ⁴

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;⁵
- (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;⁶
- (c) The EU Circular Economy Action Plan,⁷ 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:⁸

- (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. ⁹ Composite restorations today last as long or longer than amalgam fillings.¹⁰

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.¹¹

Global Mercury Pollution

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.¹² 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 5-16.¹³

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.¹⁴

Impact of 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.¹⁵

Provided that the upcoming discussion on the adoption of a general phase-out of dental amalgam 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 further emphasized in our submission to the Minamata Convention. (attached below)

01. April 2021

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; 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 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

⁴ Lars D. Hylander & Michael E. Goodsite, Environmental Costs of Mercury Pollution, 368 (2006) 352-370.

⁵ Water Framework Directive - Germany's waters 2015,
https://www.umweltbundesamt.de/sites/default/files/medien/1968/publikationen/final_broschure_wasserrahm_enrichtlinie_bf_112116.pdf

⁶ 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>

⁷ 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.

⁸ 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/>

⁹ 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.69
http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_046.pdf

¹⁰ 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>

¹¹ 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

¹² 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>

¹³ 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->

¹⁴ European study on the environmental impact of mothers and children, Democophes 2012,
<http://www.eu-hbm.info/euresult/media-corner/press-kit>

¹⁵ *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