EU submission on dental amalgam

The EU is pleased to share with the Minamata Convention Secretariat a study it has commissioned to gather information on the feasibility of phasing out dental amalgam. The final report[1] of the study provides the basis for the assessment of the technical and economic feasibility of a phase out of dental amalgam and documents its environmental implications.

The study collected information on the use of dental amalgam and mercury-free alternatives, implications for the organisation of health services in EU Member States and dental amalgam phase down plans established by Member States under Article 10(3) of Regulation 2017/852 on mercury[2].

Extensive data collection included the review of scientific articles and reports, EU-wide data collection through an online survey and interviews. A workshop gathering experts from EU Member States and stakeholders (dentistry organisations, NGOs) organised in January 2020 validated the preliminary findings of the study, and provided additional input to improve the modelling and conclusions.

Whilst the whole report may be of relevance to the Minamata intersessional process on dental amalgam, a short summary is provided below.

Trends of the use of dental amalgam

Dental amalgam has been used as a restorative material for centuries, in order to fill cavities caused by tooth decay and to repair tooth surfaces. It is an alloy of mercury and other metals (e.g. silver, tin, copper).

Dental amalgam is the largest remaining use of mercury in the EU. The estimated annual demand for dental amalgam (EU28) amounted to 27-58 t of mercury in 2018. This represents a significant decrease, by approximately 43%, compared to the previous estimate 55-95 t of mercury a year in 2010[3]. It is estimated that in 2018, approximately 372 million dental restorations were carried out in EU28. Of these, only between 10% and 19% would have used dental amalgam. This share however varies significantly among Member States.

Increasing consumer awareness of the environmental and associated indirect health effects of dental amalgam, as well as more desirable aesthetics of alternative materials, appear to be main drivers for the decreasing use of dental amalgam.

Dental amalgam use is expected to decrease by approximately 70% between 2018 and 2030. The use in 2030 would be approximately 8-17 t of mercury.

Economic feasibility

The progressive substitution of dental amalgam with mercury-free materials (such as e.g. composite resins, ceramics, and glass ionomer cements) is already taking place. The overwhelming majority of EU manufacturers (95%) produce mercury-free materials, which represent a major share of the market.

[1] Study on assessment of the feasibility of phasing out dental amalgam.
[2] Regulation (EU) 2017/852 of the European Parliament and of the Council of 17 May 2017 on mercury, and repealing Regulation (EC) No 1102/2008 (OJ L 137, 24.05.2017).
[3] Bio Intelligence Service (2012), Study on the potential for reducing mercury pollution from dental amalgam and batteries.

The difference between the prices of dental restorations per type of material is relatively small due to improvements in mercury-free restoration techniques. Furthermore, the price difference between dental amalgam and mercury-free materials has decreased.

Technical feasibility

Given the high use of mercury-free materials across the EU, it can be assumed that the vast majority of dental facilities in the EU already have the equipment required for mercury-free restorations and that most, if not all dentists, master the necessary techniques.

Evidence has shown that mercury-free materials exhibit satisfactory mechanical properties, with a lower cavity preparation requirement for composites[4] as well as better aesthetics[5]. Four main factors influence the longevity of a filling: the material, the method of restoration, the dentist's skills and the patient's dental hygiene. Mercury free materials are nowadays of good quality, effective restoration methods are widely available and dental schools are increasingly teaching the necessary skills. Dental hygiene should continue improving thanks to public health communication. Hence, the longevity of restorations should further improve.

Dentist representative organisations have however expressed concerns regarding a lack of available information on mercury-free materials, as well as the safety profile and biocompatibility of certain materials, some of which contain Bisphenol A (BPA) and nano-sized particles (particles with a size from 1 to 100 nm). Due to a lack of comprehensive scientific evidence, the potential direct and indirect impacts of mercury-free materials remain uncertain. Available scientific reviews concluded that release of BPA from certain dental materials was associated with only negligible health risks[6] and exposure to BPA is within the Tolerable Daily Intake[7]. However, the 2015 BPA risk assessment by the European Food Safety Authority, which reduced the Tolerable Daily Intake for BPA from 50 to 4 µg/kg bw/day, is currently under review.

Environmental aspects

Dental amalgam causes significant emissions of mercury to air, water and soil.

Emissions to air were estimated[8] to be 19 t over the dental amalgam life cycle (2012, EU27[9]). Emissions to water[10] by dental clinics were estimated to be 3 t (2010, EU27), which will reduce as the Regulation mandates dental practices to be equipped with high level retention dental amalgam separators.

The presence of mercury in wastewaters is problematic for the residues (sludge) from urban wastewater treatment plants. Depending on the type of wastewater treatment, mercury may end up

[4] Mulligan, S., et al. "The environmental impact of dental amalgam and resin-based composite materials." *British Dental Journal* 224.7 (2018): 542.
[5] Milosevic, Milos. "Polymerization mechanics of dental composites–advantages and disadvantages." Procedia Engineering 149 (2016): 313-320.
[6] SCENIHR, 2015. Scientific opinion on the Safety of Dental Amalgam and Alternative Dental Restoration Materials for Patients and Users.
[7] Bisfenol a i dentala material socialstyrelsen, 2015.
[8] BIO Intelligence Service (2012), Study on the potential for reducing mercury pollution from dental amalgam and batteries.
[9] Does not include Croatia that joined the EU in 2013.
[10] Mercury passes from the dental clinics through waste water treatment plants. Treatment technologies employed reach different removal efficiencies, and mercury, as other heavy metals tend not degrade but to adsorb in sludge. (Pistocchi et al. 2019; Hargraeves et al. 2016).

in sludge from wastewater plants. Mercury emissions from dental amalgam to soil, estimated at 8 t (2010, EU27), are primarily due to the spreading on land of such sludge.