

**FACT SHEET**  
**Dental amalgam**

**I. Facts**

a.) EU legal regulation in place

The EU has one of the most comprehensive and far-reaching bodies of legislation worldwide regulating mercury to protect human health and the environment. Regulation (EU) 2017/852 on mercury (“Mercury Regulation”) has restricted the use of mercury in most mercury-added products (MAPs).

The [Minamata Convention on Mercury](#) is an international treaty agreed in 2013 with the objective to “protect the human health and the environment from anthropogenic emissions and releases of mercury and mercury compounds”. The CED supports this Convention and believes that it is a sensible outcome that recognises the practicalities of improving oral health.

The Mercury Regulation is one of the key EU instruments transposing the Minamata Convention, which covers the whole mercury life-cycle, from primary mercury mining to final disposal of mercury waste.

Following the request in Article 19 of the Mercury Regulation, the European Commission has published a report on the use of mercury in dental amalgam and products (hereafter “European Commission report”) (1). This report is based on a study commissioned by the European Commission to the consultancy Deloitte entitled: “Assessment of the feasibility of phasing-out dental amalgam” (hereafter “Deloitte report”) (2). The final version of the report was published in June 2020.

In its report the Commission concludes that the phase-out of the largest remaining intentional use of mercury in the EU, dental amalgam, is technically and economically feasible before 2030.

b.) European Commission next steps

On 5 March 2021, the European Commission published its roadmap (3), for future restrictions on the use of mercury in the EU and its trade at international level. These restrictions shall be implemented by means of a European Regulation that will impose additional restrictions on mercury.

In accordance with the Commission report, the European Commission will assess the options concerning: (a) Phasing-out the use of dental amalgam in the EU, and (b) Prohibiting, if needed, the manufacture and export of certain mercury-added products (MAPs).

For dental amalgam, an impact assessment is planned to consider a phase-out over different timeframes and include the possibility of certain exceptions relating to specific categories of patients or medical specificities. The assessment will also address the implications a phase-out would have on mercury emission from crematoria and the potential need to regulate such emissions.

In the third quarter of 2021, the European Commission additionally plans a public consultation. The European Commission also plans a separate targeted consultation for key stakeholders

in a form of questionnaire(s). Stakeholder meetings will be organised to: present and discuss the main issues and options under consideration, and to present and discuss the main conclusions of the impact assessment.

The proposed Regulation, expected in the third quarter of 2021 with a view to adoption in the fourth quarter of 2022 by following the EU legislative process, is meant to contribute to the 'zero pollution' ambition within the *European Green Deal*.

In its report, the European Commission concludes that the phase-out of dental amalgam is technically and economically feasible before 2030. The upcoming European Commission initiative focuses on further restricting the remaining uses of mercury in the EU, especially in dental amalgam and certain other mercury-added products such as lamps and measuring devices, and their international trade.

#### c.) CED actions

According to the CED, the prudent way forward is to continue the pathway of active and positive efforts to phase down the use of dental amalgam, while looking into the development of a similarly effective and universally applicable substitute material and continued research into the short and long term impact of current range of alternative restorative materials. CED considers that the pace it is possible to phase down of the use of dental amalgam continues to be dependent on the individual domestic circumstances of countries throughout the world.

CED representatives attended and contributed during the final stakeholder workshop: "Assessment of the feasibility of phasing-out dental amalgam" on 30 January 2020 in Brussels. The concerns expressed by the CED, however, have not been adequately taken into account.

CED acted swiftly to provide feedback to a first version of the "Assessment of the feasibility of phasing-out dental amalgam" report by Deloitte (4) by commenting on some of the inaccuracies, assumptions and misinformation contained in the draft report and appendix (5).

Following the publication of the final report by Deloitte and the European Commission, the CED replied to these two reports (6).

## II. Lobby Member States' ministries for continuing the 'phase down' of dental amalgam

Lobbying ministries on the national level is important because the European decision-making process involves the European Parliament together with the Council of the European Union (which is made of the governments of the 27 EU countries).

Therefore, in parallel to actions on an EU level, CED members are encouraged to approach their national health ministries favoring a 'phase down' of dental amalgam rather than a 'phase out' while the following arguments could be envisaged.

- **Dental amalgam continues to be well established filling material and there is as yet no substitute material with equal advantages.** Alternative materials have been developed over many years. It is incorrectly considered that some of these can universally replace amalgam, e.g. resin-based materials or cements. However, despite considerable progress in recent developments, available alternative materials still have several shortcomings. These include increased costs of the materials themselves; the additional time take to place materials in teeth where dental amalgam would previously have been used, the increased risk of secondary

caries and reduced longevity especially in large cavities. Therefore, such materials can be used in many but not in all cases. Dental amalgam continues to be a well-established filling material for the restoration of decayed posterior teeth, due to its ease of use in difficult clinical situations, durability, safety and cost-effectiveness. This has been demonstrated by countless clinical studies.

- **Individual assessments can only be made by dentists.** Dentists are best placed to identify patients' individual oral health needs, offer choices of a range of options to their patients and seek valid consent for the treatment they provide
- **The safety of dental amalgam and alternative materials.** Safety of dental amalgam and alternative materials has been investigated and evaluated in independent scientific reviews and by national and international scientific expert panels including those from the EU (SCENIHR). It was concluded that current evidence does not preclude the use of amalgam in dental restorative treatment for members of the general population who do not present with allergies towards materials components or severe renal diseases. This was confirmed by a recent evaluation of the International Association for Dental Research (IADR). Additionally, alternative materials, although not free of toxicological concerns, can be used for restoring teeth. However, the choice of material should be based on patient characteristics.
- **Environmental concerns are met by amalgam separators.** Environmental concerns have been recognised in relation to the release of mercury into the environment and are taken seriously by the dental profession. In this regard, dental amalgam separators, as required in Regulation (EU) 2017/852 on mercury are significantly reducing the release of mercury into the environment and the phase out of dental amalgam would not change the situation, as was delineated in the Deloitte report.  
Additionally, if there are environmental concerns in relation to mercury, similar concerns need to be extended to alternative materials, and should also include concerns about their disposal. The CED has repeatedly expressed concerns regarding a lack of available information on mercury-free materials, as well as the safety profile and biocompatibility of certain materials. In this regard, further research is needed.
- **Dentistry has been reducing amalgam use. Over the last 10 years use of amalgam has declined (natural phase-down)** – due to patient choice for aesthetic reasons, profession's awareness of the need to reduce the use of amalgam and its approach to moving to alternative materials. According to the Deloitte Report, the use of amalgam decreased by 43% during the recent decade. A further annual decline of 12% was estimated.
- **Burden on national health reimbursement systems.** We can take as fact that **the choice for a phase-out by means of regulatory action in Member States where mercury fillings are still in use, is likely to affect national reimbursements - and health care financing schemes.** A complete phase out of

dental amalgam poses a threat to such services and threatens to widen oral health inequalities. The alternative materials currently available are considerably more expensive, which could lead to patients delaying or declining restorative dental treatments. The consequences would inevitably be an increase in dental diseases in parts of our vulnerable populations and/or an increase in the extraction of otherwise restorable teeth. Additionally, the global spread of the SARS-CoV-2 virus and the declaration of the COVID-19 pandemic has led to far-reaching implications for all sectors of our societies, including dentistry. Providing interventional treatment in dentistry requires aerosol generating procedures to be carried out. Many countries require a 'fallow' period to follow this during which a surgery has to stay empty. At an individual level, this means that the volume of dentistry provision has reduced as a result of the additional infection prevention and control measures that are needed in restorative dental practice and is likely to continue to be reduced for the foreseeable future. More than ever before, swift, straightforward restorative solutions are required so that patients can be seen and treated in a timely fashion. In summary, the pandemic, had led to a real potential for destabilisation of health economies with the unintended consequence of increases in untreated disease levels or patients forced into the reductive choice of extraction rather than restoration on economic grounds. It is more than ever important that decisions about dental materials are made carefully to avoid the risk of unintended consequences.

- **The EU's environmental ambitions must not over-ride critical public health imperatives. The balance must be properly assessed.** The proposed Regulation is meant to contribute to the *European Green Deal*. The European Green Deal aims to protect, conserve and enhance the EU's natural capital, and protect the health and well-being of citizens from environment-related risks and impacts. Putting public health at the heart of the transition to sustainability is crucial, as the EU also plays a fundamental role in protecting the health of its citizens and in improving healthcare. To maintain and protect public health, the phase down of amalgam needs to be accompanied by the development of a similarly effective and universally applicable substitute material and continued research into the short- and long-term impact of current range of alternative restorative materials (see also below).
- **The principle of subsidiarity must be respected.** Article 168 (7) of the Treaty on the Functioning of the European Union (TFEU) establishes that the "*Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organization and delivery of health services and medical care.*" Taking into consideration that the TFEU is quite clear about the autonomy and responsibility of Member States on the organization and delivery of health care services, regulatory action for a phase-out would mean that the European Commission is in breach of its obligation towards its Member States as laid down in Article 168 TFEU. Article 168 TFEU enables the European Commission to complement national policies of Member States on oral health prevention measures. Alongside already existing European regulation on reducing mercury

and taking into account the fact of progressive substitution of dental amalgam with alternative materials, prevention policies (within the national context) could be the better and more effective strategy, with in the end the same result.

- **A need for increased oral disease prevention efforts**. As dental decay is entirely preventable, governments should increase oral disease prevention efforts to reduce the need for any kind of restorative material in the first place, as the global pervasiveness of oral diseases will continue to slow the phase-down. Investment in prevention and attention to measures, for example, to educate about and restrict the use of dietary sugar, will assist countries in reducing the level of dental caries. Dental decay remains a common and expensive non-communicable disease for society and affected individuals. A substantial part of the economic burden posed by this disease, however, could be averted by means of prevention.
- **A need for increased research and surveillance efforts**: as has been pointed out by many international expert panels, e.g. from the EU (SCENIHR), but also in the text of the Minamata Convention, the urgent need for enhanced research into alternative materials is warranted. Despite many new developments during recent year, so far, no real amalgam replacements have been developed. Further research is needed on new biocompatible and environmentally friendly restorative materials and approaches that are proven to have equal or improved clinical longevity and cost-effectiveness when compared with dental amalgam (durable, accessible, affordable).

## **Bibliography of selected references**

- (1) European Commission, Report from the Commission to the European Parliament and the Council on the reviews required under Article 19 (1) of Regulation 2017/852 on the use of mercury in dental amalgam and products. Accessible [here](#).
- (2) Deloitte, Assessment of the feasibility of phasing-out dental amalgam- Final Report. Accessible [here](#).
- (3) European Commission, Roadmap: Mercury – review of EU law. Accessible [here](#).
- (4) Deloitte, Assessment of the feasibility of phasing-out dental amalgam (under Framework Contract No. ENV.C.4/FRA/2015/0042 – Service request 15) Workshop background document (6 February 2020). Accessible [here](#).
- (5) CED response to the Workshop Background - Assessment of the feasibility of phasing out dental amalgam. Accessible [here](#).
- (6) CED reply to the Report from the European Commission on the reviews required under Article 19(1) of Regulation 2017/852 on the use of mercury in dental amalgam and products and Final report on the assessment of the feasibility of phasing-out dental amalgam. Accessible [here](#).