Dear Minister [*National Health Ministry/Department*],

**The *(CED Member Organisation)* and the Council of European Dentists (CED)[[1]](#footnote-1), of which we are a member, in the interest of patients feel responsible for accessible and high standard oral health care. Aware of this responsibility we are very concerned about a phase out of dental amalgam. However, we do support a phase-down of dental amalgam. The dental profession takes this commitment very seriously and is acting on it.**

We are writing to you on behalf of *(CED Member organisation)*, representing …. dentists in …., in connection to the European Commission’s planned revision of Regulation (EU) 2017/852 on mercury, and repealing Regulation (EC) No 1102/2008 (“Mercury Regulation”).

* **We strongly suggest that in view of the revision of the Mercury Regulation,** **all aspects of the impact of a phase out of dental amalgam be considered,** and the option of phasing down dental amalgam be revisited in order to ensure a fair and balanced discussion on this topic.
* **Alternative materials are no replacement**. Alternative materialshave been developed over recent years in an attempt to replace amalgam, e.g. resin-based materials or cements. However, they still have several shortcomings like increased costs, prone to further caries and reduced longevity especially in large cavities. Therefore, such materials can be used in many but not in all cases. Although the use of dental amalgam in dental care has been reduced throughout Europe, dental amalgam continues to be well established filling material for the restoration of decayed posterior teeth, due to its ease of use also in difficult clinical situations, durability, safety and cost-effectiveness.
* **Environmental concerns are met by amalgam separators.** Environmental concerns have been expressed related the release of mercury into the environment and are taken serious by the dental profession. In this regard, dental amalgam separators are reducing the release of mercury into the environment and the phase out of dental amalgam would not change the situation. Additionally, if there are environmental concerns in relation to mercury, similar concerns need to be extended to alternative materials, including 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.
* **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).
* **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, would likely 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 dental treatments not being carried out or not being carried out in time. The consequences would inevitably be an increase in dental diseases in parts of our population. **A general ban on, or ‘phase out’ of amalgam, would likely have social consequences,** especially for our national health system that is already under great strain, due to the COVID-19 pandemic.
* **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 organisation and delivery of health services and medical care*.*”* Overall, we would like to stress the importance of considering that **the EU’s environmental ambitions cannot be balanced against public health**. Taking into consideration that the TFEU is quite clear about the autonomy and responsibility of Members States on the organisation 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.
* **Governments should foster and ensure the phase up of effective dental caries prevention and health promotion programmes,** which will result in the phase down of the use of current restorative materials, including dental amalgam. Investment in prevention and attention to measures, for example, to restrict the use of dietary sugar will assist countries in reducing the level of dental caries and consequently the need for restorative treatment.

We would be glad to provide further information on this issue and therefore we would like to request a **joint meeting with you and the [*national Environment Ministry/Department*]** at your earliest convenience.

We look forward to your response.

Sincerely,

[A bibliography can be provided upon request.]

1. The CED is a European not-for-profit association representing over 340,000 dental practitioners across Europe through 33 national dental associations and chambers in 31 European countries. Established in 1961 to advise the European Commission on matters relating to the dental profession. The CED is registered in the Transparency Register with the ID number 4885579968-84. [↑](#footnote-ref-1)