

**Statement from German Social Insurance about the impact assessment in the initial phase of the revision of the Mercury Regulation and repealing Regulation (EU) No. 1102/2008**

In order to implement the United Nations Minamata Convention, the global agreement on mercury, the EC submitted an impact assessment in the initial phase for the revision of the Mercury Regulation and repealing Regulation (EU) No. 1102/2008 on 5th March 2021. It also intends to ban the use of dental amalgam by 2030 for environmental and health protection reasons. It is considering different options for the phasing out over different time periods and exemptions related to specific patient categories or special medical aspects. The aim is to reduce the use of mercury as much as possible worldwide for environmental reasons.

German Social Insurance welcomes the aim to improve environmental and health protection in connection with dental amalgam. However, this objective can also be achieved by lesser means, such as stricter regulations covering the use of dental amalgam. From German Social Insurance's point of view it makes sense to use dental amalgam only in encapsulated and pre-dosed forms. This is already a practical reality in Germany. The mandatory equipment for dental facilities throughout Europe with amalgam separators for retaining and collecting amalgam particles is also appropriate for preventing mercury from entering the environment. The use of amalgam separators has been mandatory in Germany since the early 1990s.

From the point of view of occupational health and safety, there is no reason to demand the continuation of this technique and the use of amalgam. On the other hand, the use of dental amalgam is considered safe because it is only used in pre-dosed and encapsulated form. With the use of encapsulated dental amalgam and amalgam separators in dental facilities, the environmental and health protection goals of the European legislators are realised. Therefore, a complete ban on the use of dental amalgam does not appear to be absolutely necessary.

Improved oral health has led to more than 40 percent fewer fillings being used today than in 1991, and the use of dental amalgam has declined accordingly. Those with private health insurance are also increasingly demanding plastic fillings. It can be assumed that this trend will continue and that the share of amalgam fillings in the total number of fillings will continuously decrease even without an amalgam ban. With the mandatory labelling of amalgam fillings in the invoicing of contractual dental services, which was introduced on 1st January 2021, it will be possible to substantiate this trend in terms of figures.

However, there are indications that using amalgam as a filling material has a superior benefit to other treatment alternatives. It is also resistant and durable. A complete abandonment of dental amalgam would mean giving up these advantages. For this reason, amalgam should continue to be available as an option among various filling materials in the future, in the interest of both patients and those paying their premiums. The EU already has one of the world's most comprehensive regulatory frameworks covering mercury to protect human health and the environment. In our view, a complete ban on dental amalgam should not be the aim of the European regulations revision.