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Deutsche Sozialversicherung  
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# Feedback from German Social Insurance dated 8 September 2023

## **Revision of the Mercury Regulation**

Draft regulation amending Regulation (EU) 2017/852 of the European Parliament and of the Council dated 17 May 2017 on mercury as regards dental amalgam and other mercury-added products subject to manufacturing, import and export restrictions

## I. Feedback

On 14 July, the European Commission presented a proposal for a regulation to revise the EU Mercury Regulation [COM(2023)395] with the aim of protecting EU citizens and the environment from toxic mercury. This will ban all forms of mercury in the EU, including the use, production and export of dental amalgam from 1 January 2025.

German Social Insurance (DSV) welcomes the goal of improving environmental and health protection. In Germany, strict regulations have been in place for decades regarding the dental use and disposal of dental amalgam. These have proven themselves and ensure safe handling. A complete ban on dental amalgam would therefore not be absolutely necessary.<sup>1</sup> 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. In contrast, the use of dental amalgam is considered safe because it is only used in pre-dosed and encapsulated form. However, for reasons of health and environmental protection, it is understandable that a complete ban on mercury is being sought. Despite precautions such as mandatory amalgam separators, mercury can still enter the environment today, e.g. under current conditions in crematoria.

However, a complete ban on dental amalgam from 1 January 2025 seems very ambitious in the view of the German Social Insurance (DSV).

In Germany, around 47 million dental fillings were billed to the statutory health insurance (SHI) funds in 2021<sup>2</sup>. Of these, 1.4 million were amalgam fillings – a meagre 3.2 per cent<sup>3</sup>. This shows that the usage of dental amalgam is already in sharp decline. Since 1 July 2018, a ban on dental amalgam has already been in force in Germany for deciduous teeth, children under the age of 15, and pregnant and breastfeeding patients<sup>4</sup>.

However, the use of dental amalgam demonstrates superior benefits to treatment alternatives for certain indications, and it is also more durable and long-lasting. At the same time, there is a lack of comprehensive scientific research on restorative

<sup>1</sup> DSV feedback on the impact assessment in the initial phase on the revision of the Mercury Regulation and repealing Regulation (EC) No. 1102/2008 of 1 April 2021. <https://dsv-europa.de/lib/2021-04-01-Feedback-Folgeabschaetzung-Amalgam.pdf>

<sup>2</sup> BZAEK/KZBV Yearbook 2022 Basic statistical data on SHI-accredited dental care, p. 90, [https://kzbv.de/static/flips/jahrbuch\\_2022\\_flip/](https://kzbv.de/static/flips/jahrbuch_2022_flip/)

<sup>3</sup> BZAEK/KZBV Yearbook 2022 Basic statistical data on SHI-accredited dental care, pp. 84-85, [https://kzbv.de/static/flips/jahrbuch\\_2022\\_flip/](https://kzbv.de/static/flips/jahrbuch_2022_flip/)

<sup>4</sup> Federal Ministry for the Environment, Nature Conservation, Nuclear Safety and Consumer Protection: National Action Plan of the Federal Government for the Gradual Reduction of Dental Amalgam, 10.07.2019: [https://www.bmu.de/fileadmin/Daten\\_BMU/Download\\_PDF/Chemikaliensicherheit/nationaler\\_aktionsplan\\_dentalamalgam\\_bf.pdf](https://www.bmu.de/fileadmin/Daten_BMU/Download_PDF/Chemikaliensicherheit/nationaler_aktionsplan_dentalamalgam_bf.pdf)

materials and their cost structure as an alternative to dental amalgam. From the German Social Insurance's point of view, it would make sense to award a research contract here.

The European Commission's impact assessment states that the cost difference between dental amalgam and mercury-free alternatives decreases as demand increases. This may be true for the material costs, but not for the doctor's fees, as the time required to place a composite filling, for example, is higher. These additional costs must be anticipated.

In order to ensure smooth implementation of the ban on dental amalgam, the timing should therefore be reconsidered and should not take place until 2030. Finally, the ban has contractual and supply policy implications in some Member States. In Germany, it is causing a fundamental health policy discussion about co-payment-free fillers in healthcare. They are part of the SHI catalogue of benefits, which needs to be further maintained.

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## About us

The German Federal Pension Insurance (DRV Bund), the German Social Accident Insurance (DGUV), the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband), the national associations for statutory health and long-term care insurance funds at the federal level and the Social Insurance for Agriculture, Forestry and Horticulture (SVLFG) have joined forces to form the "German Social Insurance - Working Group Europe" (Deutsche Sozialversicherung Arbeitsgemeinschaft Europa e. V.) with a view to their common European policy interests. The association represents the interests of its members vis-à-vis the bodies of the European Union (EU) as well as other European institutions and advises the relevant stakeholders in the context of current legislative projects and initiatives. As part of the statutory insurance system in Germany, health and long-term care insurance, pension insurance and accident insurance offer effective protection against the consequences of major risks to life.