



Federal Ministry  
for the Environment, Nature Conservation  
and Nuclear Safety

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## **The German Government's National Action Plan for the Phase-down of Dental Amalgam**

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# 1 Introduction

Dental amalgam is the most frequent form in which mercury is used in the European Union. Its use is a significant source of environmental pollution, although national regulations have considerably reduced discharge into sewerage systems and watercourses. The signatories to the Minamata Convention, which include Germany, plan to progressively reduce the use of dental amalgam. The European Union and its Member States have transposed the Convention by adopting Regulation (EU) 2017/852 of the European Parliament and of the Council of 17 May 2017 on mercury (the EU Mercury Regulation).<sup>1</sup>

Key elements of this Regulation are restrictions on the use of dental amalgam in children and pregnant or breastfeeding mothers, and the mandatory use of separators to prevent amalgam entering the wastewater of dental practices.

Member States are also required to produce and publish a national plan setting out the measures they intend to take to further reduce the use of dental amalgam.

Discussions were held with the national umbrella organisations of dental practitioners and non-governmental organisations in order to collect information on the initial position and debate possible measures. The findings of the discussions have been incorporated into the National Action Plan.

The discussions involved the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU), the Federal Ministry of Health (BMG), the German Environment Agency (UBA), the German Dentists Association (BZÄK), the German Society for Environmental Dentistry (DEGUZ), the German Society for Tooth Preservation (DGZ), the German Society of Dentistry and Oral Medicine (DGZMK), the National Association of Statutory Health Insurance Dentists (KZBV) and the IG Umwelt Zahn Medizin (a consumer protection organisation that campaigns for environmentally friendly dentistry).

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<sup>1</sup> 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; <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0852>

## 2 The international context and statutory basis

### 2.1 The Minamata Convention

Under the Minamata Convention on mercury (Article 4(3) in conjunction with Annex A, part II), the Parties to the Convention must take measures to phase down the use of dental amalgam. The measures should take into account the Party's domestic circumstances and relevant international guidance and shall include two or more of the measures from the following list:

1. Setting national objectives aiming at dental caries prevention and health promotion, thereby minimising the need for dental restoration;
2. Setting national objectives aiming at minimising its use;
3. Promoting the use of cost-effective and clinically effective mercury-free alternatives for dental restoration;
4. Promoting research and development of quality mercury-free materials for dental restoration;
5. Encouraging representative professional organisations and dental schools to educate and train dental professionals and students on the use of mercury-free dental restoration alternatives and on promoting best management practices;
6. Discouraging insurance policies and programmes that favour dental amalgam use over mercury-free dental restoration;
7. Encouraging insurance policies and programmes that favour the use of quality alternatives to dental amalgam for dental restoration;
8. Restricting the use of dental amalgam to its encapsulated form;
9. Promoting the use of best environmental practices in dental facilities to reduce releases of mercury and mercury compounds to water and land.

### 2.2 The EU Mercury Regulation

The European Union has transposed the Minamata Convention by adopting Regulation (EU) 2017/852 (the EU Mercury Regulation). The Regulation stipulates *inter alia* that:

- ▶ From 1 January 2019 dental amalgam is only to be used in pre-dosed encapsulated form (Article 10(1) in conjunction with Article 10(5) of the EU Mercury Regulation; transposition of Annex A, part II, point viii of the Minamata Convention).
- ▶ Mandatory use of amalgam separators to collect and retain amalgam and teeth containing amalgam from used water in dental facilities from 1 January 2019. Separators installed from 1 January 2018 must provide a retention level of at least 95%. From 1 January 2021 all other separators must provide this retention level. All separators must be maintained in accordance with the manufacturer's instructions (Article 10(4) of the EU Mercury Regulation; transposition of Annex A, part II, point ix of the Minamata Convention).
- ▶ Dentists must ensure that amalgam waste is handled and collected by authorised waste management establishments or undertakings (Article 10(6) of the EU Mercury Regulation; Annex A, part II, point ix of the Minamata Convention).

The requirements of the Minamata Convention in relation to amalgam are thus implemented in the EU via the EU Mercury Regulation. In addition, the European Parliament and the Member States have agreed to introduce the following measures to reduce the use of dental amalgam:

- ▶ A complete ban on the use of dental amalgam in children under 15 years and pregnant or breastfeeding women from 1 July 2018 (Article 10(2) of the EU Mercury Regulation)
- ▶ Each Member State has until 1 July 2019 to produce a national plan detailing the measures it intends to implement to phase down the use of dental amalgam. Member States must make their national plans publicly available on the internet and transmit them to the Commission within one month of their adoption (Article 10(3) of the EU Mercury Regulation).

On the basis of these plans and other information the European Commission will by 30 June 2020 produce a report that explores the feasibility of completely phasing out the use of dental amalgam in the long term, and preferably by 2030 (Article 19(1)(b) of the EU Mercury Regulation).

## 2.3 National regulations and requirements

### Pre-dosed, encapsulated dental amalgam

**Since the early 1990s, the use of dental amalgam in pre-dosed encapsulated form has been recommended in various standards (including DIN EN 1641:2010-02 and DIN EN ISO 13897:2018-05 in their current versions). Use of non-encapsulated amalgam had all but ceased before the EU Mercury Regulation entered into force.<sup>2</sup>**

### Amalgam separators

The use of amalgam separators has been mandatory in Germany since the early 1990s. For dental practices it is regulated by Section 3 in conjunction with Annex 50 of the German Waste Water Ordinance (AbwV). The provisions include the requirement to store waste properly and ensure that it is recycled. Other rules on waste are contained in the Waste Catalogue Ordinance (AVV) and the Ordinance on Waste Recovery and Disposal Records (NachwV).

### Restrictions on the use of dental amalgam

**Various reports and position papers (including Bundesgesundheitsamt 1987, BMG et al. 1997<sup>3</sup>), RKI 2007<sup>4</sup>) have recommended that the use of amalgam fillings in pregnant and breastfeeding women and in children be subjected to special scrutiny or, as a preventive healthcare measure, be avoided altogether.**

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<sup>2</sup> Information from KZBV and BZÄK, 1 March 2019.

<sup>3</sup> Federal Ministry of Health (BMG); Federal Institute for Drugs and Medical Devices (BfArM); German Dentists Association (BZÄK); National Association of Statutory Health Insurance Dentists (KZBV); German Society of Dentistry and Oral Medicine (DGZMK); German Society for Tooth Preservation (DGZ) (ed.) (1997): Restaurationsmaterialien in der Zahnheilkunde [Restoration materials in dentistry].

<sup>4</sup> RKI (2007): Amalgam: Stellungnahme aus umweltmedizinischer Sicht. Mitteilung der Kommission "Methoden und Qualitätssicherung in der Umweltmedizin" [Amalgam: Statement from an environmental medicine perspective. Communication of the commission "Methods and quality assurance in environmental medicine"]. In: Bundesgesundheitsblatt, Gesundheitsforschung, Gesundheitsschutz 50 (10), pp. 1304–1307. DOI: 10.1007/s00103-007-0338-z.

### 3 Background

The German Environment Agency has established that the environmental quality standard for mercury in Biota laid down in the Surface Waters Ordinance (OGewV) is being exceeded at all measurement points in surface waters.<sup>5</sup>

In recent decades the paradigm shift towards a greater emphasis on prevention that has taken place in Germany has led to a significant improvement in the oral health of children and adolescents and, with a time lag, that of adults. In consequence the need for treatment of damaged teeth has fallen sharply.

At the same time, the proportion of dental amalgam in filling materials in Germany has been declining for some time and is now less than 10%. The trend is continuing downwards, because patients and doctors increasingly prefer amalgam-free materials. By comparison with other European countries, Germany is thus in the leading group with regard to reducing the use of amalgam.

#### Prevention and dental health

In the course of the paradigm shift that has taken place in dentistry in recent decades away from treatment in favour of prevention there has emerged a detailed network, funded by health insurance schemes, of preventive dentistry facilities and individual and group prophylaxis. 82% of all children, 72% of young adults and 90% of younger senior citizens regularly make use of the preventive measures covered by statutory health insurance (Jordan and Micheelis 2016<sup>6</sup>).

The prevention network is being constantly expanded, as the following measures illustrate:

- ▶ Since 1 July 2018, disabled and care-dependent people covered by statutory insurance have been entitled to special prevention services that cater for their needs.<sup>7</sup>
- ▶ Since 1 July 2019, check-ups for children between six months and three years have also been covered by the health insurance funds.<sup>8</sup>

The expansion of prevention has played a significant part in reducing the incidence of caries and improving dental health in all population groups. This is evidenced by the German oral health studies that have been conducted since 1989. The latest study in the series is the fifth (DMS V), which describes the situation in 2014 (Jordan and Micheelis 2016). Of particular interest are the findings on the prevalence of caries:

- ▶ 81.3% of all children (age 12) now have no caries. In 1989/1992 the figure was only 13.3%.
- ▶ Children now have on average 0.5 carious, missing or filled teeth. This is a fall of almost 90% since 1989/1992. In 1983 the figure was as high as 10.8. However, children of low social status still have twice as many affected teeth as children of middle and high social status.

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<sup>5</sup> [www.umweltbundesamt.de/publikationen/die-wasserrahmenrichtlinie-deutschlands-gewaesser](http://www.umweltbundesamt.de/publikationen/die-wasserrahmenrichtlinie-deutschlands-gewaesser), pp. 58/59

<sup>6</sup> Jordan, R.; Micheelis, W. (2016): Fünfte Deutsche Mundgesundheitsstudie [Fifth German oral health study]. Published by Institut der Deutschen Zahnärzte (IDZ) (IDZ-Materialienreihe, 35).

<sup>7</sup> Article 22a SGB V in conjunction with the guidelines of the Federal Joint Committee (G-BA) of dentists and health insurance funds on measures to prevent dental disease in care-dependent people and people with disabilities of 19 October 2017

<sup>8</sup> Guidelines of the Federal Joint Committee (G-BA) of dentists and health insurance funds on screening for dental, oral and jaw diseases of 17 January 2019

- ▶ Among younger adults (age 35-44), the number of teeth affected by caries has fallen from 16.1 in 1997 (the first time this age group was surveyed) to 8.6 in 2014. The improvement in children's dental health is having an impact here, although of necessity with a time lag.
- ▶ Among younger seniors (age 65-74), a similar trend is observable from 1997 to 2014, with the number of affected teeth falling from 23.6 to 17.7 over that period. Seniors now have on average 16.9 teeth of their own (1997: 10.4). Only 12.4% of all seniors are toothless (1997: 14.8%). However, the social differences here are considerable (3.8% of people of high social status vs. 16% of people with low status).
- ▶ In terms of care (tooth restoration and replacement), the social differences are only small.

Among the G7 countries Germany leads the way, with the lowest incidence of caries in children and toothlessness in seniors.

### **The state of filling practice**

The number of treatments of carious teeth can to some extent be determined from the yearbooks of the National Association of Statutory Health Insurance Dentists (KZBV) – most recently for 2017 (KZBV 2018<sup>9</sup>). These record only services paid for via primary and alternative health insurance funds (statutory health insurance, SHI) via the associations of SHI-accredited dentists (in accordance with the BEMA Assessment Standards for Dental Services). In other cases treatment is provided under private health insurance (PHI) or paid for directly by patients (in accordance with the GOZ Scale of Fees for Dentists).

In 2017 50.5 million fillings were recorded in the SHI sector. The figure has been falling steadily since 1991, when it was 84.4 million. When adjusted for the number of people insured, cases have fallen by 46% since 1991. Extrapolated figures for people who are privately insured can be taken from the statistical yearbook of the German Dentists Association (BZÄK 2018b<sup>10</sup>). These show that in 2016 around 5.17 million fillings were performed for privately insured people. For SHI and PHI patients combined, the number of fillings performed in 2016 is therefore around 56 million.<sup>11</sup>

The number of filled teeth in Germany is estimated at 471 million. This figure is expected to fall to 407 million by 2030.<sup>12</sup>

### **The state of dental amalgam use in Germany**

There are currently no reliable statistics on the use of amalgam or other filling materials in Germany; the only available information comes from scattered comments and statements that cannot be attributed to any primary source.<sup>13</sup> Collating this information indicates that the market share of amalgam has fallen from around 70% in 1985 to 5% in 2017 (Figure 1). The downward trend is continuing. A phase-down of amalgam use commenced in the 1980s. It should be noted that these figures relate to the cost-based share of total market volume. Because dental amalgam costs less per filling than composite materials, the percentage of fillings involving dental amalgam may be higher than the market share.

<sup>9</sup> National Association of Statutory Health Insurance Dentists (KZBV) (ed.) (2017/18): Jahrbücher 2017/18 [Yearbooks 2017/18]. Basic statistical data on contractual health care

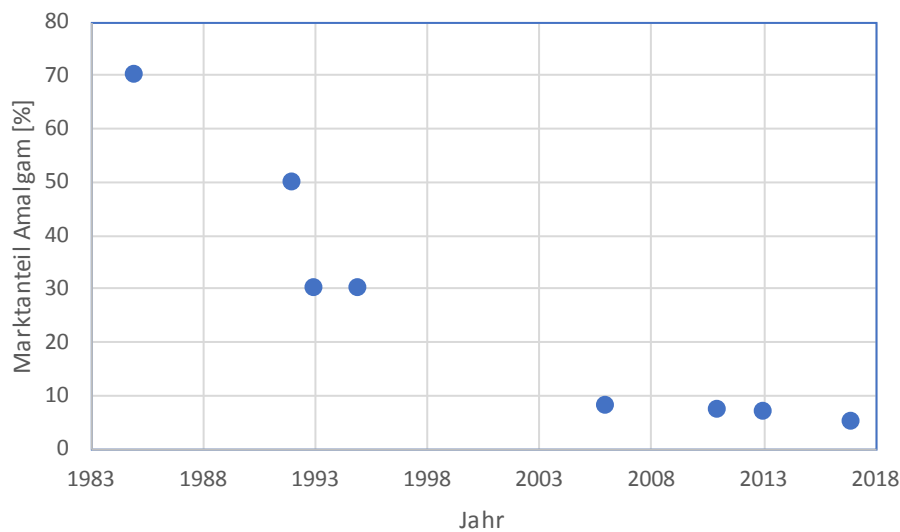
<sup>10</sup> German Dentists Association (BZÄK) (ed.) (2018b): Statistisches Jahrbuch der BZÄK 2017 | 2018 [Statistical yearbook of the BZÄK 2017 | 2018]. The 2019 yearbook with figures for 2017 is not yet available.

<sup>11</sup> In 2016 50.8 million fillings were invoiced in the SHI sector (KZBV 2017).

<sup>12</sup> Information from KZBV and BZÄK on the basis of data from the Institute of German Dentists (IDZ) of 1 March 2019

<sup>13</sup> Badzio and Hahn 2000, Kommission Umweltmedizin 2007, Staehle 2007, Wolf 2016, Bundesregierung 2018.

Figure 1: The market share of amalgam as a percentage of all filling materials



### Options for treating cavities

Practising dentists can choose from a number of different materials that can be used in dental treatment. The dentist assesses on a case-by-case basis which option provides the best balance between appropriate care and avoidance of risks (e.g. as a result of allergies). The guidelines of the professional dental associations help the dentist reach a decision.

Regardless of the assessment of the dentist performing the treatment, patients can request that alternative materials be used. If they are a member of a statutory health insurance scheme and have not taken out additional cover, this may incur additional costs that they will need to pay themselves.

The most commonly used materials are described briefly below. The list makes no claim to be complete.

### Dental amalgam

Dental amalgam – an alloy of mercury, silver, tin and copper – was for many years the preferred material for treating cavities in the posterior region. Its advantages are that it is easy to work with, lasts a long time despite masticatory forces and prevents secondary caries effects. It is therefore particularly recommended for fillings in the posterior teeth that are exposed to masticatory forces (BZÄK and KZBV 2018<sup>14</sup>). Because amalgam does not adhere to the tooth substance, it is often necessary to remove additional healthy substance in order to enable a mechanical bond between amalgam and tooth.

### Composites

Composites consist of an organic polymer that is combined with inorganic fillers. Polymerisation of the monomeric source materials (curing) takes place during the treatment, usually by means of photo induction (ultraviolet laser). Composites were initially recommended mainly for the anterior teeth, where a tooth-coloured filling is desirable (BZÄK and KZBV 2009<sup>15</sup>). There is now also evidence

<sup>14</sup> National Association of Statutory Health Insurance Dentists (KZBV) (ed.) (2017/18): Jahrbücher 2017/18. [Yearbooks 2017/18] Basic statistical data on contractual health care.

<sup>15</sup> German Dentists Association (BZÄK); National Association of Statutory Health Insurance Dentists (KZBV) (ed.) (2009): Das Dental Vademecum [The dental vademecum]. 10th edition. Cologne.



of successful use in side and chewing surfaces in the posterior region (Federlin et al. 2016<sup>16</sup>). Frequently, too, it is now possible to use composites in situations in which inlays used to be indicated. Bulk-fill composites are a relatively new development: they can be applied in thicker layers and thus involve less work (Tauböck and Attin 2016<sup>17</sup>), but there are as yet comparatively few studies of their longevity. The findings so far suggest that their life is comparable to that of classic composites (Pfeifer 2017).

Composites are of limited usefulness in situations in which the cavity is hard to access, such as in the contact surfaces between posterior and anterior teeth. They are not recommended for use in the event of strong parafunctions (non-natural use of the teeth, e.g. bruxism), poor oral hygiene and high caries risk. Their use is also contra-indicated in cases of relevant intolerance.

The application of composites can be gentler on the tooth substance than the use of amalgams. Once the carious substance has been removed, there is no need for further undercuts in healthy tooth substance of the sort that provide mechanical bonding when amalgam is used. In this respect composites are superior to amalgams (Federlin et al. 2016<sup>15</sup>).

There is constant further development of composite materials to improve workability and longevity.

### **Glass ionomer cements, compomers, giomers**

Glass ionomer cements (GICs) are produced by mixing calcium alumino-fluorosilicate glass and polyacrylic acid. The mixture reacts in two stages, resulting after about 24 hours in the formation of a cross-linked water-insoluble aluminium polycarboxylate complex. GICs bond direct to the dentine and need no additional bonding agent. However, their mechanical strength is significantly less than that of composites. They are therefore recommended only as an alternative material in the cervical tooth region and as temporary filling material before other materials are used (Frankenberger and Krämer 1999<sup>18</sup>). They are also used in the temporary treatment of children's milk teeth because they are easy to apply and long-term durability and aesthetics are less important. Depending on the product, the release of fluoride can suppress secondary caries effects. Because they are inexpensive to use, glass ionomer cements fulfil an important role in developing countries. Performing atraumatic restorative treatment with these products requires only manual instruments; this facilitates low-threshold access to dental treatment, especially in areas without health care facilities or without an electricity supply (Frencken 2009).

Compomers and giomers are mixtures of composites and glass ionomer cements. Chemically and aesthetically they resemble composites; they share with glass ionomers the properties of being easy to work with (although giomers need light-curing), fluoride release but also a short life. They are typically used to treat milk teeth. Attempts are being made to develop materials that have a longer life.

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<sup>16</sup> Federlin, M.; Blunck, U.; Frankenberger, R.; Knüttel, H.; Reichl, F. X.; Schweikl, H. et al. (2016): S1-Handlungsempfehlung (Langversion). Kompositrestaurationen im Seitenzahnbereich [S1 Recommendations for action (long version) Composite restorations in the posterior dental region]. German Society for Tooth Preservation (DGZ); German Society of Dentistry and Oral Medicine (DGZMK); German Society for Restorative and Regenerative Tooth Preservation (Leitlinien Zahnmedizin [Guidelines on dental medicine]).

<sup>17</sup> Tauböck, T. T.; Attin, T. (2016): Bulk-Fill-Komposite - ein Update [Bulk-fill composites – an update]. In: Swiss Dent. J. 126, pp. 694–695.

<sup>18</sup> Frankenberger, R.; Krämer, N. (1999): Glasionomerzemente [Glass ionomer cements]. In: W.-M. Boer (ed.): Metallfreie Restaurationen [Metal-free restorations], 1 part 4. Balingen: Spitta Verlag.

## 4 Goal

The German government aims to work towards further reducing the use of amalgam in dental treatment and restricting it to essential special cases. A combination of various measures that are to be implemented in collaboration with relevant stakeholders in the healthcare industry will contribute to this.

An underlying principle is that full and effective medical care for all sections of the population should continue to be ensured, whichever further advances in or widespread achievement of the replacement of dental amalgam by mercury-free filling materials may be attained.

The measures are also intended to further reduce the release of mercury via sewerage systems into watercourses and thus improve the chemical status of water bodies.

## 5 National Action Plan

### 5.1 Measures

#### **Continuing to enhance prevention**

Preventive measures are pivotal and are the most important basis for improving oral health and hence for preventing restorative dental treatment. Germany has a comprehensive system of dental prophylaxis, especially for children and adolescents. Enhanced provision for disabled and care-dependent people has been added in the current decade. The German government will continue to pursue the path of a care system geared to the principles of prevention and tooth preservation that it embarked on in the 1980s. In the coming years it will place particular emphasis on the prevention of early childhood caries. In 2015 the German Bundestag adopted the Prevention Act, thereby extending dental early detection check-ups to children below the age of three. The German government will closely follow implementation of this move by the health insurance funds and dentists' umbrella organisations. Group dental prophylaxis for children and adolescents in day care facilities and schools is also to be further enhanced. This has been found to be particularly suitable for including those children and adolescents who are often hard to reach through other prevention services. The programmes to improve the dental health of disabled and care-dependent people that have been launched in recent years will also be developed further. The innovation fund in the statutory health insurance sector that promotes health care research projects and new forms of care will also fund projects to improve oral health, including the oral health of care-dependent people and people with a migration background.

#### **Education and training**

The curricula of colleges and universities that train dental personnel reflect the call to reduce dental amalgam. This mainly involves communicating information on the use of alternative filling materials.

#### **Informing patients and the public**

Patients are to be informed about the options for treating cavities. They must have the information needed to make an informed decision. In all the federal states there are patient advice facilities provided by the associations of statutory health insurance dentists and chambers of dentists, and the Independent Patient Advice Germany (UPD) scheme funded by the German government is also available to answer questions on dental treatment.

#### **Minimising release of dental amalgam into sewerage systems**

The use of separators to retain dental amalgam from the wastewater of dental practices has been mandatory in Germany since the early 1990s. The mercury content of sewage sludge has fallen considerably, but in some places it is still too high.

The German government is consulting with the responsible authorities at national and state level in order to establish how the provisions under water law to prevent the discharge of dental amalgam into wastewater are being implemented and whether release into the environment can be reduced.

## 5.2 Milestones

1. The reduction in the use of amalgam will be monitored at regular intervals. This will be achieved by working with dentists' umbrella organisations and professional associations to collate and publish the relevant data that can yield information on the proportion of fillings that are performed with amalgam. This is to happen for the first time in 2020.
2. The findings of the data collection process and the progress on measures in the other areas that have been mentioned will be discussed with government bodies, dentists' umbrella organisations and non-governmental organisations.
3. The German government is consulting with the responsible authorities at national and state level in order to establish how the provisions under water law to prevent the discharge of dental amalgam into wastewater are being implemented and whether release into the environment can be reduced.