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Assessment of the feasibility of phasing-out dental amalgam

Final report (under Framework Contract No. ENV.C.4/FRA/2015/0042 – Service request 15)

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Abbreviations

General abbreviations	
AFR	Annual Failure Rate
AgNP	Nanoparticle of silver
AA	Annual average
BAT	Best Available Techniques
BPA	Bisphenol A
EEA	European Environment Agency
EFSA	Environmental Food Safety Authority
EPA	Environmental Protection Agency
EU	European Union
EU28	EU 28 Member States (Including UK)
EU27	EU 28 Member States (Including UK without Croatia)
EQS	Environmental Quality Standards
EU	European Union
g	Gramme
Mercury	Mercury
MAC	Maximum Allowable Concentration
mg	Miligramme
mg/l	Miligramme/litre
µg/l	Microgramme/litre
N/A	Not applicable
n.a.	Not available
NAP	National Action Plan
OSPAR	Oslo-Paris Convention
PEC	Predicted Environmental Concentrations
SCENIHR	Scientific Committee on Emerging and Newly Identified Health Risks
SCHER	Scientific Committee on Health and Environmental Risk
t	Tonnes
TWI	Tolerable Weekly Intake
WHO	World Health Organization
WFD	Water Framework Directive
Country abbreviations	
AT	Austria
BE	Belgium
BG	Bulgaria
CY	Cyprus
CZ	Czech Republic
DE	Germany
DK	Denmark
EE	Estonia
EL	Greece
ES	Spain
FI	Finland
FR	France
HR	Croatia
HU	Hungary
IE	Ireland

IT	Italy
LT	Lithuania
LU	Luxembourg
LV	Latvia
MT	Malta
NL	Netherlands
PL	Poland
PT	Portugal
RO	Romania
SE	Sweden
SI	Slovenia
SK	Slovakia
UK	United Kingdom

1. Executive summary

Introduction

Dental amalgam is a dental filling material composed of 50% mercury in the elemental form mixed with an alloy of metals (silver, tin, copper, etc.). It has been used as a dental filling material for centuries to fill dental cavities caused by tooth decay and to restore tooth surfaces. It is not tooth-coloured and it cannot adhere to remaining tooth tissues. Its mechanical properties, such as strength, integrity, durability and suitability for large cavities, make it a restorative material that is still widely used in some EU Member States for certain types of restorations.

Mercury, a metallic element, is a persistent pollutant and a toxic compound for humans and the environment, which exists in different forms on earth (elemental, inorganic and organic). Mercury emissions from dental amalgam and other sources are distributed in the environment and can be taken up by the general human population via food (especially fish consumption), water and air. Mercury is a heavy metal released to the environment by natural sources (earth's crust, volcanic emissions, geothermal activities) and additional anthropogenic activities (coal-fired power stations, manufacturing processes, residential coal-burning for heating and cooking or waste incinerators)[1]. For humans, mercury is a potent neurotoxin inducing permanent brain and kidney damage in adults and affecting foetal and early childhood development. Currently, **dental amalgam is the largest remaining use of mercury in the EU**.

Legislative background

Several legislative developments have been taken place both at the EU and international levels. Most recently, the EU adopted **Regulation (EU) repealing Regulation 1102/2008 on Mercury** (Mercury Regulation) in 2017 to align EU legislation with **the Minamata Convention on Mercury**, which had been adopted in 2013. The Minamata Convention was adopted to address the long-range transfer properties of mercury that cannot be reduced to acceptable levels through domestic policies alone. Dental amalgam is among the list of mercury-added products and services to be regulated by the Minamata Convention. With some exceptions, the Mercury Regulation requires Member States to ban dental amalgam use in dental treatments of deciduous teeth, of children under 15 years and of pregnant or breastfeeding women. In addition, it requires Member States to establish specific National Action Plans (NAPs) to phase down dental amalgam and to establish effective management of dental amalgam waste in dental facilities. Article 19(1)(b) of the Regulation tasks the Commission to report to the European Parliament and to the Council on the outcome of its assessment regarding:

"**the feasibility of a phase-out of the use of dental amalgam in the long term, and preferably by 2030**, taking into account the national plans referred to in Article 10(3) and whilst fully respecting Member States' competence for the organisation and delivery of health services and medical care".

Objectives of the study

The objective of the study is to **assist the Commission in assessing the feasibility of a phase-out of dental amalgam preferably by 2030**, as required by Article 19(1)(b).

The feasibility assessment was based on an extensive review and use of existing evidence that exists both at the EU and Member State levels. Nevertheless, certain data gaps exist and, for this reason, the assessment is based on a number of assumptions. The assumptions impose certain limitations particularly in the following areas: the use

[1] WHO, 2017. Mercury and health (https://www.who.int/news-room/fact-sheets/detail/mercury-and-health)

of dental amalgam and alternative materials; the market for dental amalgam and alternative materials; the safety of mercury-free materials; and the life cycle of mercury deriving from the use of dental amalgam.

Policy options

The present assessment considers a phase-out for all Member States over different timeframes. In this context, the following policy options are assessed:

- No additional policy action at the EU level (BaU): Under this scenario, the EU would not take any additional measures. However, Member States would implement their phasing down or phase-out strategies based on their National Action Plans. A complete phase-out would apply only for specific categories of patients as per Article 10 (2) of the Mercury Regulation.
- Option 1 (OP1): A complete phase-out by 2025
- Option 2 (OP2): A complete phase-out by 2027
- Option 3 (OP3): A complete phase-out by 2030

The phase-out in OP1, OP2 and OP3 would not be applied only on the use of dental amalgam in restoration, but also the manufacturing and import of dental amalgam (including encapsulated items). **Nevertheless, it must be highlighted that a phase-out does not refer to a complete ban.** Certain exceptions that relate to specific categories of patients or medical specificities, based on the experience in SE, are assumed to be allowed.

Note that other policy options for the phase out of dental amalgam have been examined and excluded from further analysis at an early stage. One of them, that deserves to be highlighted, looked at a phase-out of dental amalgam in Member States at different timeframes, depending on their current uses. Under these options, a longer timeframe for a phase-out would be allowed in Member States where the share of dental amalgam restorations is still high. This longer timeframe would be granted to allow a smooth implementation of actions that are required for a phase-out (e.g. development of required skills for all dentists and restructuring of the reimbursement schemes). However, this option was excluded as it could distort the functioning of the internal EU market.

Technical feasibility

To date, evidence has shown that mercury-free materials exhibit satisfactory mechanical properties, with a lower cavity preparation requirement for composites as well as aesthetically better results compared to dental amalgam. However composite and glass ionomer might exhibit lower durability than dental amalgam in the long term. Despite several studies and reviews having been conducted, **comparing the performance of composite materials with dental amalgam would require additional evidence and it currently remains inconclusive**. Therefore, at least for composite materials, these differences are not deemed to be significant, at least in countries where a ban of mercury-free materials has improved the performance of mercury-free fillings due to enhanced skills during the restoration process. Over time, the differences in the longevity of the materials has reduced significantly due to improvements in the materials used and in restoration skills. Glass-ionomer cement restorations appear to show superior retention levels when compared with resin-based composite restorations in follow-ups after between one and five years.

Safety concerns exist in relation to the safety profile of mercury-free materials particularly in relation to the release of Bisphenol A (BPA) from some dental materials and to toxicological aspects due to the presence of up to 60% of nano-sized filler particles within composites. Use of the existing mercury-free materials allow a phase-

out of dental amalgam, which is feasible despite the biocompatibility concerns in relation to BPA and nano-sized filler particles. However, scientific literature has shown so far that hazards related to mercury-free materials cannot be excluded. Regarding the environmental safety of mercury-free materials, the issue of their complexity also makes their assessment difficult. Therefore, data gaps **arising from the lack of comprehensive studies on mercury-free materials and substance behaviour require additional research that would provide a better overview of alternative safety profiles.**

Demand of dental amalgam and other filling materials

The estimated annual demand at the EU28 (including the UK) level amounts to be **between 26.8 t and 58.3 t Hg/year in 2018 (average 42.6 t/Hg year)**. This represents a significant drop in the use of dental amalgam, on average by approximately 43% compared to the previous estimate provided by the study of BIO Intelligence Service (55 t – 95 t/Hg year in 2010).

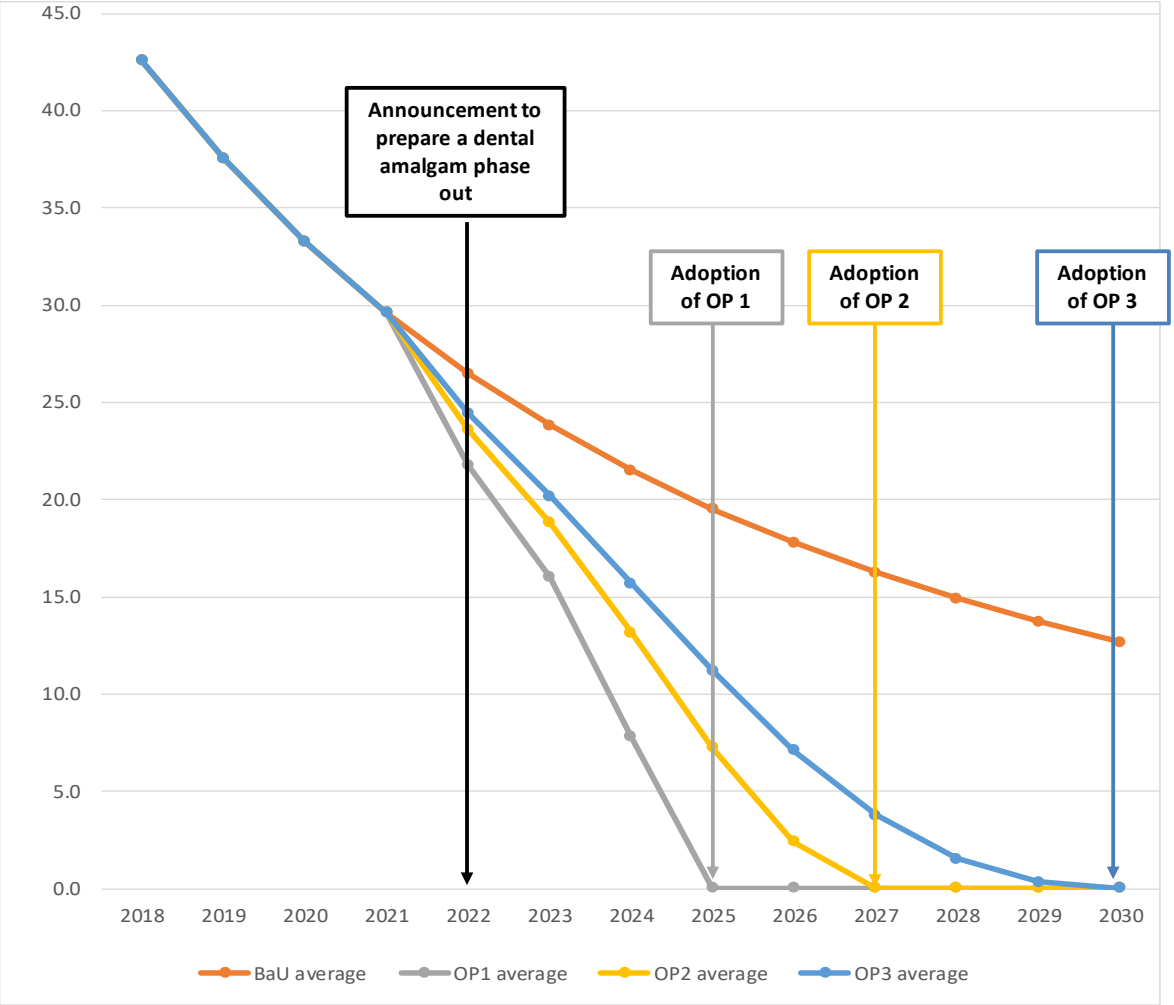
Broadly, the Member States are grouped into three categories, based on the share of dental amalgam restorations compared to total restorations:

- Group 1- High share of dental amalgam use (above 30%): BG, HR, RO, SI
- Group 2- Medium share of dental amalgam use (between 10% and 30%): CZ, LT, LV, PL, SK, IE, UK, FR, CY, EL, MT
- Group 3- Low use of dental amalgam (below 10%): AT, BE, DE, PT, HU, IT, DK, EE, ES, FI, LU, NL, SE

Particularly for the Member States with a low use (Group 3), all of the countries use dental amalgam in less than 7% of the total number of restorations. This group represents almost half of the Member States (13 out of 28). At the EU level, the share of dental amalgam restorations is estimated to be between **10% and 19%.**

The implementation of OP1, OP2 and OP3 would require a substantial reduction of use of dental amalgam as shown in the figure below. Based on an analysis of the historical trends, in the BaU scenario, a linear decrease is assumed for the whole period between 2018 and 2030. Assuming that a decision to propose a legislative act to phase-out dental amalgam at the EU level is made in 2022, OP1 would require an accelerated decrease before the year of the implementation of the dental amalgam phase-out (2025). The same applies for the other scenarios but, due to the longer timeframe of their implementation (2027 for OP2 and 2030 for OP3), the phase-out would be implemented with a lower annual reduction rate. As shown in the figure it is estimated that dental amalgam use will remain the same until 2021, while the reduction for the policy scenarios will start to appear in 2022, the year when the proposal for a phase-out is assumed to be made. It is therefore assumed that the proposal will be submitted before the end of 2022 while the communication process prior to the submission is also expected to cause a decrease in the use of dental amalgam.

Figure 1: Estimated amounts of dental amalgam produced under BaU, OP1, OP2 and OP3



Comparison of impacts

A comparison of the impacts for each of the three policy options and the different impact categories and indicators is presented in the table below. The comparison is carried out at the accumulative level (for the period between 2018 and 2030) against the BaU scenario. In the BaU scenario the results are presented also accumulatively for the same period.

Table 1: Inventory and summary of impacts per policy scenario

Impact indicators	**Comparison of policy options (compared to the BaU until 2030)**			
	BAU	**OP1**	**OP2**	**OP3**
Environmental impact indicators				
Mercury use in EU	195.8 t – 423.6 t (until 2030)	119.5 t – 257.7 t (reduction by 76.3 t – 257.7 t)	131.9 t– 284.4 t (reduction by 63.9 t – 139.2 t)	144.1 t – 310.4 t (reduction by 72.7 t – 113.2 t)

Quantities of dental amalgam waste produced (sludge collected from amalgam separators)	110.7 t - 239.5 t (until 2030)	101.8 t - 220.1 t (reduction by 8.9 t – 19.4 t)	103.5 t - 223.7 t (reduction by 7.2 t – 15.8 t)	104.9 t - 227.3 t (reduction by 5.8 t – 12.3 t)
Hg emissions to air / to water / to soil within the EU (total bioavailable discharges)	77.9 t - 142.6 t (until 2030)	70.1 t - 125.7 t (reduction by 7.8 t – 16.9 t)	71.0 t- 127.5 t (reduction by 6.9 t – 15.0 t)	71.7 t - 129.3 t (reduction by 6.2 t – 13.3t)
Economic impact indicators				
Revenues of EU dental filling manufacturing	18,755 - 19,284 million EUR (until 2030)	19,154 - 19,470 million EUR (Increase by 186 - 398 m EUR)	19,079 - 19,435 million EUR (Increase by 151 - 324 m EUR)	19,011 - 19,403 million EUR (Increase by 119 -256 m EUR)
Revenues for dentists	271,538 - 271,971 million EUR (until 2030)	271,992 - 272,254 million EUR (Increase by 284 - 494 m EUR)	271,884 - 272,179 million EUR (Increase by 209 - 346 m EUR)	271,786 - 272,110 million EUR (Increase by 140 - 248 m EUR)
Hg abatement costs for dentists		-	-	-
Hg abatement costs for crematoria		0	0	0
Hg abatement costs for public authorities		-	-	-
Direct costs borne by patients		+	+	+
Administrative costs		0	0	0
Social impact indicators				
Jobs in EU manufacturing industry		+	+	+

Health conditions	++ (dental amalgam) ? (alternative materials)	++ (dental amalgam) ? (alternative materials)	++ (dental amalgam) ? (alternative materials)
Other criteria			
Hg emissions to air / to water / to soil outside the EU	-	-	-
Hg use outside the EU	-	-	-
Degree of uncertainty/risk	Low	Low	Low
Technical feasibility	High	High	High

'+++': very beneficial effect; '++': substantial beneficial effect; '+': slight beneficial effect; '-': negative effect, '--': substantial negative effect; '---': very negative effect; '0': no effect; '?': unknown effect

Conclusions

The general conclusion of the assessment is that dental amalgam use is decreasing, and a general phase-out is both technically and economically feasible, but with some disruption of the insurance systems in the Member States that are currently using high amounts of dental amalgam and with reimbursement schemes that tend to favour dental amalgam restorations.

Between the last assessment of dental amalgam use in 2010 and today, the use of dental amalgam has dropped by an estimated 43%. Progressive substitution of dental amalgam with mercury-free materials has occurred even without a policy intervention (i.e. before the Mercury regulation came into effect) as patients, in general, prefer mercury-free fillings. Nevertheless, without a phase-out, significant amounts of dental amalgam are still expected to be used in the coming years. This use will prolong the associated environmental and health impacts associated with the current use of dental amalgam. This prolongation is arguably unnecessary given the technology for a full substitution already exists and is advancing. Dental amalgam might be still required in specific medical cases that do not allow substitution with mercury-free materials. Nevertheless, based on the experience in Sweden where certain exceptions are allowed, such cases appear to be very rare (i.e. only one case in 2017 and none in 2018).

From a legislative perspective the continuation of dental amalgam use could hinder and perhaps reduce the effectiveness of other legislation and measures that target the impacts of mercury, most notably the Water Framework Directive 2000/60/EC which classifies mercury as a priority hazardous substance (requiring cessation or phasing out of discharges, emissions and losses) and also Directive 2008/105/EC that sets environmental quality standards for mercury. EU legislation has already set the basis for the ban of mercury on a number of products (e.g. thermometers, batteries and blood pressure monitors) where alternatives exist. From an international perspective, the phasing-out of dental amalgam would be a strong signal towards the implementation of the objectives of the Minamata Convention and perhaps gradually set the paradigm for

a phase-out at the international level. Given the transboundary nature of mercury, the latter would further decrease the risk of mercury pollution at EU level.

Should such a general phase-out be considered, it would be important to (1) better understand whether exceptions to a general prohibition may be needed to take account of patients with special medical needs and, (2) assess whether accompanying measures would be required to reduce the risk of substitution of dental amalgam with fillings containing toxic substances.

In parallel to a phase-out of dental amalgam, efforts to prevent tooth decay should continue. Prevention is in general one of the key measures promoted in the National Action Plans and is regarded as effective in reducing the number of both dental amalgam and mercury-free fillings.

2. Background and objectives

This is the final report on a project for the European Commission on an assessment of the feasibility of phasing-out dental amalgam.

The sections below provide some key background information in relation to the use of dental amalgam and outline the key environmental and health concerns that gradually led to the adoption of EU and international legislation. They also provide an outline of these legislative developments and their links to the objectives of the present study.

2.1 Introduction

Mercury is a heavy metal released to the environment by natural sources (earth's crust, volcanic emissions, geothermal activities) and additional anthropogenic activities (coal-fired power stations, manufacturing processes, residential coal-burning for heating and cooking or waste incinerators)[2]. Around 1,540 million tonnes of mercury have been released by human activities up to 2010, with 73% released after 1850[3]. This metallic element is a persistent pollutant and a toxic compound for humans and the environment, which exists in different forms on earth (elemental, inorganic and organic). Mercury emissions from dental amalgam and other sources are distributed in the environment and can be taken up by the general human population via food (especially fish consumption), water and air.

For humans, mercury is a potent neurotoxin inducing permanent brain and kidney damage in adults and affecting foetal and early childhood development. The toxicity of mercury varies with the form of mercury, the route of exposure and the dose[4].

Concerning the geographical distribution of global atmospheric mercury emissions, almost 40% come from East and Southeast Asia, 18.5% from South America and 16% from Sub-Saharan Africa, while the EU represented 3.5% of global mercury emissions in 2015[5]. In the same year the EU emitted between 67.2 and 107 tonnes of mercury, fuel combustion being the main source (60%), followed by industries (29%) and sources associated with mercury-added products (11%). In the European Union (EU), mining activities to extract raw mercury ceased in 2003[6], but due to its volatility and persistence, mercury remains widely spread in ecosystems: mercury and methylmercury are contained in sediment and water but also in organisms (algae and insects)[7].

Dental amalgam has been used as a dental filling material for centuries to fill dental cavities caused by tooth decay and to restore tooth surfaces. **It is a dental filling material composed of 50% mercury in the elemental form mixed with an alloy of metals (silver, tin, copper, etc.)**. It is not tooth-coloured and it cannot adhere to remaining tooth tissues. Its mechanical properties, such as strength, integrity, durability and suitability for large cavities, make it a restorative material that is still widely used in some EU Member States for certain types of restorations.

[2] WHO, 2017. Mercury and health (https://www.who.int/news-room/fact-sheets/detail/mercury-and-health)
[3] Streets et al., 2017. Total mercury released to the environment by human activities. Environmental science and technology, 51(11), pp 5969-5977
[4] Bernhoft R. A. (2012). Mercury toxicity and treatment: a review of the literature. Journal of environmental and public health, 2012, 460508. doi:10.1155/2012/460508
[5] UNEP (2018), Global Mercury Assessment 2018
[6] European commission, 2013. Questions and answers on EU Mercury Policy (http://europa.eu/rapid/press-release_MEMO-13-871_en.htm)
[7] Žižek, et al., 2007. Bioaccumulation of mercury in benthic communities of a river ecosystem affected by mercury mining", Science of the Total Environment 377:407-415

Currently, **dental amalgam is the largest remaining use of mercury in the EU**. For this reason, as described in the following section, the EU has taken legislative actions targeting the use of dental amalgam and the treatment of waste from dental facilities.

2.2 Key legislative developments on dental amalgam use

In 2009, the UNEP Governing Council adopted Decision 25/5 and initiated a multilateral discussion on the threats posed to human health and the environment by the emissions and releases of mercury and mercury compounds[8]. To reduce mercury levels in the environment and to limit human exposure, the European Commission adopted the **EU Mercury Strategy** in 2005[9]. This strategy led to the adoption of the **Mercury Export Ban Regulation (EU) 1102/2008** in 2008[10] to prohibit mining and to ban exports of mercury and its compounds in the EU as of March 2011. The EU also banned mercury-containing thermometers, batteries and blood pressure monitors. Moreover, Member States are required to apply best available techniques (BAT) to reduce mercury emissions from industrial activities.

The EU tabled a proposal for a **Regulation (EU) repealing Regulation 1102/2008 on Mercury[11]** in 2016 to align EU legislation with the **Minamata Convention** on Mercury, which had been adopted in 2013[12]. This international convention was adopted to address the long-range transfer properties of mercury that cannot be reduced to acceptable levels through domestic policies alone. Dental amalgam is among the list of mercury-added products and services to be regulated by the Minamata Convention. It calls on the signatory countries to promote caries prevention; ensure proper treatment of dental amalgam waste to minimise leakages to the environment; and to minimise the use of dental amalgam. By the beginning of June 2019, the convention had been signed by 128 signatories and ratified by 118 parties including the EU and 24 Member States[13].

Notably, in addition to **Regulation (EU) 2017/852 on Mercury[14]**, dental amalgam is also regulated by several horizontal legislative documents that do not focus specifically on the use of dental amalgam. Notably **Regulation 2017/745 concerning Medical Devices (Medical Devices Regulation)** regulates the placing on the market or putting into service of medical devices for human use and accessories for such devices[15]. The scope of this regulation covers both dental amalgam and mercury-free materials. The Medical Devices Regulation classifies medical devices according to the area of the human body where the device performs, where it is introduced or applied and whether there is a systemic absorption of the substances composing the device or of the products of metabolism in the human. the regulation covers all filling materials and does not focus specifically on amalgam. It includes provisions to ensure the safety of all filling materials

[8] Decision 25/5 of the Governing Council of the United Nations Environment Programme (UNEP) (https://web.unep.org/globalmercurypartnership/governing-council-decision-255-mandates)
[9] Communication from the Commission to the Council and the European Parliament, COM (2005). Community strategy concerning mercury
[10] Regulation (EC) No 1102/2008 of the European Parliament and of the Council of 22 October 2008 on the banning of exports of metallic mercury and certain mercury compounds and mixtures and the safe storage of metallic mercury (Text with EEA relevance) (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32008R1102)
[11] 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 (Text with EEA relevance.) (https://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX:32017R0852)
[12] Minamata Convention on mercury, Text and annexes, UN (2017) (http://mercuryconvention.org/) UN Environnent, 2017. Minamata convention on mercury, text and annexes. (http://www.mercuryconvention.org/Portals/11/documents/Booklets/COP1%20version/Minamata-Convention-booklet-eng-full.pdf)
[13] The Minamata Convention has been signed by all 28 Member States but not ratified by the following ones: Greece, Italy, Poland and Spain. (http://www.mercuryconvention.org/Countries/Parties/tabid/3428/language/en-US/Default.aspx)
[14] 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)
[15] Regulation 2017/745 on the use of medical devices, COM (2017) (https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0745&from=EN)

for human health. Dental restorative materials belong to class II a, which requires manufacturers to assess the biocompatibility and the risks of unintended side effects. Manufacturers are required to be audited regularly by a third party.

Mercury emissions from dental surgeries are also subject to EU water legislation. The **Water Framework Directive 2000/60/EC** (WFD) classifies mercury as a priority hazardous substance[16]. As a result, Member States are obliged to take measures to cease or phase-out its emissions, discharges and losses. In addition, **Directive 2008/105/EC sets environmental quality standards** in the field of water policy for certain priority substances including mercury and its compounds[17].

2.3 Environmental and health concerns of dental amalgam use

In line with the Mercury Strategy, the European Commission requested the opinion of two scientific committees in 2008: the **Scientific Committee on Health and Environmental Risks (SCHER)**[18] and the **Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR)**[19]. Their opinions were updated in 2015.

The SCHER assessed the risk to the environment related to mercury releases from dental amalgam use; the effects that mercury releases from dental amalgam into the environment could cause on human health; and the environmental risks caused by dental amalgam compared to the use of mercury free alternatives. Based on the available studies and on three scenarios of dental amalgam use, the SCHER concluded that the share of emissions of mercury from dental amalgam represents a very minor contribution to total human exposure from soil and air. Concerning the concentration of methylmercury in fish coming from dental amalgam use, the assessment has a high degree of uncertainty. A risk assessment for surface water based on three scenarios showed that, under best local conditions (efficient dental amalgam separators in all clinics, correct dentist density, and minimal mercury use), the "calculated concentrations are far below the acceptable level in fish as well as the WFD threshold for secondary poisoning". Nevertheless, **the risk of secondary poisoning due to methylation of mercury cannot be excluded.**

The SCENIHR assessed the safety for patients and practitioners and the performance of both dental amalgam and mercury-free alternative materials. It recognised the efficiency of dental amalgam, especially for specific types of restorations. In addition, a review of the toxicology of elemental and inorganic mercury from dental amalgam and its potential health effects (local adverse effect in the oral cavity, systemic adverse effects, etc.), showed that there is a low risk of adverse health effects of using dental amalgam. To this end, the SCENIHR concluded that "current evidence does not preclude the use of either amalgam or alternative materials in dental restorative treatment. However, the choice of materials, dental amalgam or alternatives, should be based on patient characteristics". The patient characteristics refer to age (e.g. young children) or specific conditions (e.g. pregnant women, people with allergies, etc.). Except for patients with allergic reactions, the SCENIHR concluded that there is no general justification for clinical removal of dental amalgam restorations. Neither committee was able to reach a final conclusion regarding the relevance of additional regulatory

[16] Directive 2000/60/EC, establishing a framework for Community action in the field of water policy, COM (2000) (https://eur-lex.europa.eu/eli/dir/2000/60/oj)
[17] Directive 2008/105/EC on environmental quality standards in the field of water policy, COM (2008)
[18] SCHER, 2014. Opinion on the environmental risks and indirect health effects of mercury from dental amalgam (http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_165.pdf)
[19] SCENIHR, 2015. Scientific opinion on the Safety of Dental Amalgam and Alternative Dental Restoration Materials for Patients and Users.(https://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_046.pdf)

measures to restrict or to phase-out dental amalgam. **Nevertheless, based on these scientific reports, the EU applied the precautionary principle[20].**

SCENIHR concluded that mercury-free materials (composite resins, ceramics, glass ionomers cements and gold alloys) also have clinical limitations and toxicological hazards. In relation to the hazards, according to SCHER, the emissions of alternatives to the environment and the associated ecological risks are low. **However, both committees recognised that more experimental, clinical and epidemiological research is required on mercury-free materials.**

Earlier, in 2012, a study conducted by BIO Intelligence Service concluded that phasing-out dental amalgam is one of the most effective options for protecting human health and the environment when all environmental and socio-economic aspects are considered[21].

Mercury from dental amalgam is released to the environment (air, water and soil) mainly through leakages from dental surgeries, cremations and burials. According to the SCHER report, there are certain limitations imposed by the available scientific information to assess the environmental risks and indirect health effects from the use of dental amalgam in the EU. For this reason, the risks were assessed through different scenarios. In the worst-case scenario and in specific local conditions, the Predicted Environmental Concentration (PEC) can be above the annual average and Maximum Allowable Concentration (MAC) Environmental Quality Standard (EQS) for mercury in water, resulting in a risk of secondary poisoning due to methylation.

Dental amalgam is recognised by dentists and by the SCENIHR report to be an effective restorative material in terms of strength and longevity. It is often a material of choice for certain types of restorations, especially in posterior teeth. However, the environmental risks cannot be ignored even if a precise measurement is not possible. These risks are present in all stages of the dental amalgam life cycle, from the placement of dental amalgam to the removal and disposal.

In relation to the potential health effects, the exposure of the general population to mercury occurs mainly due to mercury accumulated in fish and through inhalation (organic mercury, methylmercury) as well as due to direct exposure to dental amalgam (elemental mercury, inorganic mercury). In addition, mercury is released from natural deterioration of amalgam fillings (chewing, brushing, etc.). Dental personnel and patients with amalgam fillings are two groups with higher exposure levels; they are directly exposed to mercury, especially during placement and removal.

Exposure assessments are subject to significant variations due to differences in systemic availability of mercury after inhalation and ingestion. Individual factors influence mercury-release from dental amalgam fillings (such as gum chewing, tooth brushing, etc.). All exposure measurements are also subject to uncertainty (due to fish consumption, etc.) and may not reflect the true mercury concentrations in the target organs. In addition, there is evidence that there is risks of adverse effects (allergies, neurological diseases, etc.) caused by dental amalgam restorations but according to the SCENIHR, the risk of adverse health effects is low. Except for patients with allergic reactions, there is no general justification to clinically remove dental amalgam fillings from restored teeth. However the risks of dental amalgam and the risks of alternative materials requires additional scientific evidence (few data are available for alternatives and the composition is not always known). According to SCHENIHR, under

[20] According to the European Commission, the precautionary principle is detailed in Article 191 of the Treaty on the Functioning of the European Union. It aims at ensuring a higher level of environmental protection through preventative decision-taking in the case of risk.(https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM%3Al32042)

[21] BIO Intelligence Service (2012), Study on the potential for reducing mercury pollution from dental amalgam and batteries (http://ec.europa.eu/environment/chemicals/mercury/pdf/review_mercury_strategy2010.pdf)

environmental and health precautions, mercury-free materials should be the first choice for primary teeth in children and pregnant women, etc.) and their use should take into account protection of health and the environment.

The present study reviewed more than 100 scientific articles and other publications published from 2015 onwards, to identify additional evidence that addresses the environmental and health concerns in relation to the use of dental amalgam. The review did not reveal any notable deviations from the conclusions from the SCENIHR and the SCHER reports. In contrast, additional information was identified in relation to potential environmental and health risks of the use of mercury-free materials and particularly the use of composites. A full summary of the outcomes of the review is provided in Appendix C and the potential risks in relation to the use of alternative materials is outlined in section 3.5.

2.4 Regulation (EU) 2017/852 on mercury

As a response to the environmental and health concerns of dental amalgam use, in 2017 **Regulation (EU) 2017/852**[22] was adopted. The Regulation requires Member States to establish specific National Action Plans (NAPs) to phase down[23] dental amalgam by 1 July 2019. A list of specific restrictions under Article 10 includes:

- As from **1 July 2018**, Member States are required to ban dental amalgam use in dental treatments of deciduous teeth, of children under 15 years and of pregnant or breastfeeding women, except when deemed strictly necessary by the dental practitioner based on the specific medical needs of the patient.
- By **1 July 2019**, each Member State must set out and publish on the internet a national plan on measures to phase down the use of dental amalgam.
- As from **1 January 2019**, dental practitioners are no longer allowed to use dental amalgam in bulk, but only in pre-dosed encapsulated form to prevent exposure of the patient and the practitioner.
- As from **1 January 2019**, all dental facilities dealing with dental amalgam (use of amalgam and/or removing dental amalgam fillings) must be equipped with amalgam separators ensuring the retention and collection of amalgam particles with a view to preventing their release into wastewater systems. Separators have to maintain a minimum retention level of 95%; immediately in the case of new separators and by 1 January 2021 in case of existing separators.
- Dental practitioners must ensure that their amalgam waste (e.g. amalgam residues, particles, fillings and teeth, or parts thereof, contaminated by dental amalgam) is handled and collected by authorised waste management establishments or undertakings (no direct or indirect release into the environment).

Furthermore, Article 19(1)(b) of the Regulation tasks the Commission to report to the European Parliament and to the Council on the outcome of its assessment regarding:

"**the feasibility of a phase-out** of the use of dental amalgam in the long term, and preferably by 2030, taking into account the national plans referred to in Article 10(3)

[22] Regulation (EC) No 2017/852 on Mercury, and repealing regulation (EC) No 1102/2008 (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0852)

[23] According to the World Dental Federation (FDI), phase down is "a task to reduce the use of dental amalgam through increased prevention, health promotion, and research on advanced restorative materials and techniques – maintaining or improving adequate clinical performance". (https://www.fdiworlddental.org/resources/policy-statements/dental-amalgam-phase-down)

and whilst fully respecting Member States' competence for the organisation and delivery of health services and medical care"

2.5 Objectives of the study

The objective of **the study is to assist the Commission in assessing the feasibility of a phase-out of dental amalgam preferably by 2030**, as required by Article 19(1)(b).

In particular, the study examined the current situation in relation to the use of dental amalgam in the EU. It further assessed the technical and economic feasibility of its phase-out. The potential social and environmental implications of such a phase-out are also assessed. For this reason, the study aimed at collecting information on the current use of dental amalgam and the alternatives, as well as on the implications of the organisation of health services in all EU Member States and the existing or planned measures to phase down the use of dental amalgam.

In this respect, the report assesses the effects of a potential phase-out of dental amalgam by 2030 on different market players and on the environment. Note that a **"phase-out" is not interpreted in this report to correspond to a complete ban, as certain exceptions are assumed to be allowed, following for example the Swedish and Danish models** (see section 3.4.1).

2.6 Methodological limitations and key assumptions

To fulfil the objectives of the study, the project team performed extensive data collection that included a review of scientific articles and reports, as well as EU-wide data collection through an online survey and interviews with selected experts at EU and Member State level. The survey was sent to 256 stakeholders (academics, dentists, dental association, Member State authorities, etc.). Responses were provided in writing (either through the online questionnaire or in word format) by 74 stakeholders from 23 countries[24]. The number of responses per country varied and, for some countries, no response was received. The information in this report has been updated based on the National Action Plans (NAPs) submitted by Member States[25]. Further expert opinions and information were collected during and after a stakeholder consultation workshop that was carried out in Brussels on 30 January 2020.

The estimates provided in the study are therefore based on an extensive review and use of existing evidence that exists both at EU and Member State levels. Nevertheless, certain data gaps exist and, for this reason, the assessment is based on a number of assumptions. The key limitations and assumptions are described in the following section and are further detailed in Appendix D.

2.6.1 Limitations

There are certain limitations imposed due to a number of data gaps, particularly in the following areas:

- **Use of dental amalgam and alternative materials**: Data on the use of dental amalgam and alternative materials is available only in specific Member States and in most cases this information is partial (e.g. referring only to restorations covered by the national health systems).

[24] The questionnaire is provided in Appendix F
[25] To date (March 13 2020), the following NAPs have been submitted by AT, CY, BG, CZ, DE, DK, ES, FI, IE, LT, LV, NL, SI, SK and the UK

- **Market for dental amalgam and alternative materials**: Data on the sales, imports and exports of filling materials are not collected at EU or Member State levels.
- **Safety of mercury-free materials**: There is a limited number of studies carried out in the EU or internationally on potential presence and the associated risks of hazardous components in alternative materials (e.g. BPA and nano-particles).
- **The life cycle of mercury deriving from the use of dental amalgam**: Although the different pathways for mercury from dental amalgam to environmental media (i.e. air, soil, water and groundwater) are well known, the exact flows are difficult to estimate.

To this end, certain assumptions were applied to fill these data gaps. The assumptions derive from previous studies, which overall, contain a certain level of uncertainty in their estimates. The paragraphs below outline the key assumptions and approaches in the current study. In spite of these limitations, applying the key assumptions below, we consider the findings to be robust, because (fully or partially) data on the use of dental amalgam was available in about half of the EU Member States. In addition, the assumptions were provided to the participants of a workshop that was organised in the context of the present study and any concerns were addressed in the present report. Uncertainties are addressed through the provision of ranges in the quantitative estimates instead of absolute figures.

2.6.2 Key assumptions

As explained in the sections above, the current use of dental amalgam (as well as the number of restorations with mercury-free materials) and trends in each Member State, was estimated based on data that is available for 14 out the 28 Member States (see section 3.2). The estimates were based on the correlation of the population with countries where data was available. The reference country for Member States with no available data was set based on certain criteria including the restrictions in place concerning the use of dental amalgam, historical data for the country and the overall trends in the use of dental amalgam. Similarly, the market aspects that relate to the sales of filling materials were calculated based on use of dental amalgam. As regards the flows of dental amalgam in the environment, the main source for the assumptions was the BIO intelligence Study that was carried out in 2012. These assumptions were updated based on expert opinion and more recent evidence.

3. Feasibility assessment

This chapter describes the **problems associated with the use of dental amalgam**, as well as the current situation and projections in relation to the use of restoration materials. The key drivers and barriers as well as the technical feasibility of a potential phase-out of dental amalgam are also described. Further, based on the evidence collected, this chapter includes an assessment of the **socio-economic and environmental aspects** as well as the likely evolution of the impacts in the absence of any further EU policy to restrict the use of dental amalgam.

In all steps of the assessment, the current scientific knowledge and uncertainties on possible health and environmental risks of dental amalgam and alternative materials are taken into account, particularly in the assessment of policy options. It must be noted that a **risk assessment of dental amalgam and the alternative restoration materials is not in the scope of this study.**

3.1 Problem definition

The overarching problem is the continuous build-up of mercury in the EU's environment causing excessive amounts of mercury in fish and seafood consumed by humans and an unsustainable amount of mercury in Europe's environment, resulting in health risks for fauna, flora and habitats. The more specific problem is the continuous intentional use of mercury in dentistry, which is contributing to the build-up of above-mentioned mercury in the environment.

The sections below discuss these problems in the context of a potential phase-out of dental amalgam.

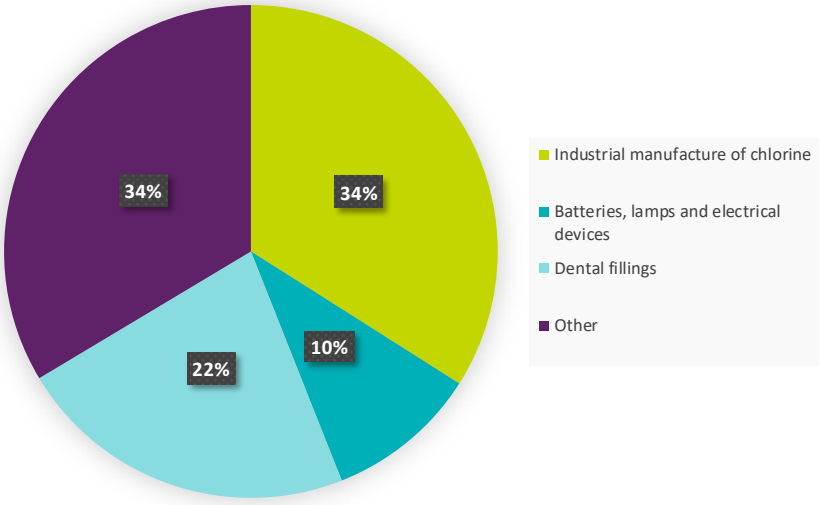
3.1.1 Intentional uses of mercury

Mercury has long been used in industrial activities, such as silver and gold mining, where it was employed to separate precious metals from other unwanted materials. For instance, during the mid-nineteenth century Gold Rush, many thousands of tonnes of mercury were released into the environment in California alone[26].

Today, mercury is used mainly in small-scale gold mining and vinyl chloride[27] production, which make up 37% and 26% of global mercury use respectively (largely driven by East and South East Asia); dental fillings, batteries and lamps represent other major fields of application. However, in the EU the distribution of mercury in the economy is quite different from the global scale. As shown in Figure 2, in 2015, in Europe 85 t were used in the industrial manufacture of chlorine, 56 t in dental fillings, 25 t in batteries, lamps and electrical devices, and 84 t in other sectors, totalling some 250 t overall (this represents 5% of the global amount and compares to some 2,400 t used in East and South East Asia)[28]. Since then, the EU has taken additional action to prohibit use of mercury in chlor-alkali plants, in production of polyurethane, in button-cell batteries, and to reduce allowed content of mercury in lamps. Furthermore, market penetration of LED lamps has reduced the market share of mercury lamps. Dental amalgam is now the largest EU use of mercury.

[26] Alpers et al., 2005
[27] Vinyl chloride is used to produce plastic products, one of the most prominent being polyvinyl chloride (PVC). Demand for vinyl chloride is particularly driven by developing countries.
[28] UN Environment (2017), 'Global mercury supply, trade and demand', United Nations Environment Programme, Chemicals and Health Branch

Figure 2. EU mercury consumption by activity in 2015[29]



One of the main reasons for these differences with the global data is that in the EU mercury is no longer used in small-scale mining (except for French Guyana), and its application in vinyl chloride production is limited to one plant in Slovakia, which will phase out its use by 2022. The use of mercury in industrial chlorine manufacture in the EU was also prohibited at the end of 2017, leading to dental fillings now being the main application[30].

3.1.2 Build-up of mercury in air, water and soil

Air

Mercury is naturally emitted into air from various sources such as volcanoes, erosion and natural fires. However, current global levels of mercury in the atmosphere are about 500% above natural levels[31]. Its accumulation in the air in Europe is largely influenced by external sources, as it is estimated that mercury emissions from outside Europe contribute about 50% of the anthropogenic mercury deposited annually within the continent, of which 30% originates in Asia[32,33]. Globally, the most prominent sources of mercury emissions to air are small-scale gold mining (37%), coal combustion (24%) and non-ferrous metal production (13%)[34]. Most estimates indicate that global mercury emissions to the atmosphere stand at 2,000 – 2,500 t per year, with a persistence of up to 2 years, before deposition into water or soil[35]. Mercury emissions to air in the EU were around 200 t in 1990 and around 60 t in 2016[30]. While in the first decade of the 21st century, emissions in Europe and North America have been decreasing, emissions in other regions such as Asia, Africa and South America have followed the opposite trend. This contraction in atmospheric mercury deposition observed in Europe is in the order of 1-2%, and further reductions of about 20-30% are expected under the "Current

[29] UN Environment (2017), 'Global mercury supply, trade and demand', United Nations Environment Programme, Chemicals and Health Branch
[30] European Environment Agency (2018) "Mercury in Europe's environment. A priority for European and global action", https://www.eea.europa.eu/highlights/mercury-pollution-remains-a-problem
[32] UNEP (2018), Global Mercury Assessment, https://wedocs.unep.org/bitstream/handle/20.500.11822/27579/GMA2018.pdf?sequence=1&isAllowed=y
[33] UNEP (2018), Global Mercury Assessment, https://wedocs.unep.org/bitstream/handle/20.500.11822/27579/GMA2018.pdf?sequence=1&isAllowed=y
[34] These emissions do not arise from mercury employed in the processes themselves, but rather because this is present in fuels and raw materials used. These are classified as "unintentional releases".
[35] https://www.des.nh.gov/organization/commissioner/pip/factsheets/ard/documents/ard-28.pdf

Policy" scenario (i.e. no policy changes)[36]. More stringent limits on industrial emissions allowed European mercury emissions to be cut by 71% between 1990 and 2016, and further reductions are expected due to increased uptake of Best Available Techniques imposed by the Industrial Emissions Directive.

Water

Around 40% of the EU's surface water bodies are currently assessed as contaminated with dangerous levels of mercury[37]. This mercury deposited in water poses a greater danger to human health than that deposited in air and soil, as water can store mercury for longer periods and because, under certain conditions, mercury in water can be converted into methylmercury[38] [39]. Data on historical and future mercury releases into water are much less advanced than for air, but an approximate assessment of global mercury emissions to oceans in 2018[40] concluded that global emissions from anthropogenic emissions in 2015 were around 54.6 t. The main activities contributing to this level were waste management and discharges; non-ferrous metal production; and coal-fired power plants. It is estimated that the European contribution of mercury emissions to freshwater is around 8 t[41]. Forecasts predict that mercury emissions to water, although already much lower than in other regions, will consistently and significantly decrease. For instance, reductions have already been observed in the mercury content in European fish in Northern Europe and in wastewater coming from dentistry[42].

Soil and groundwater

Climate change has an effect on soil mercury content, as increased floods can lead to mercury release through erosion while increased rainfall will cause higher deposition of mercury from the atmosphere. In addition, mercury contained in permafrost is predicted to be released as this thaws over the coming centuries. Once mercury is deposited on land, it can enter the food chain, especially through food grown in water environments (e.g. rice). Deposited mercury has a long lifetime, especially when transformed into methylmercury, which can persist in soils for decades[43].

The anthropogenic mercury contamination in soil and groundwater may result in much higher concentrations compared to other environmental media, particularly in contaminated sites[44]. Unlike in water bodies, where mercury tends to accumulate over time, in soils, mercury tends to accumulate until an event (e.g. erosion, floods) causes its release. Globally, it is estimated that there are approximately 10,000 t of mercury in vegetation, 863,000 t in the active layer of the soil, 793,000 t in permafrost and 454,000 t in other types of soil[45].

[36] UNEP (2018), Global Mercury Assessment.https://wedocs.unep.org/bitstream/handle/20.500.11822/27579/GMA2018.pdf?sequence=1&isAllowed=y
[37] EEA (2018) European waters. Assessment of status and pressures 2018. Report No 7/2018
[38] Methylmercury is formed from inorganic mercury by the action of microbes that live in aquatic systems. People are exposed to methylmercury when eating fish and shellfish that contain this compound or when inhaling mercury vapour. In pregnant women, methylmercury can adversely affect a baby's brain and nervous system. Similar effects can be observed in adult population (World Health Organization).
[39] UNEP (2018), Global Mercury Assessment, https://wedocs.unep.org/bitstream/handle/20.500.11822/27579/GMA2018.pdf?sequence=1&isAllowed=y
[40] UNEP (2018), Global Mercury Assessment, https://wedocs.unep.org/bitstream/handle/20.500.11822/27579/GMA2018.pdf?sequence=1&isAllowed=y
[41] AMAP/UNEP, 2008. Technical background report to the global atmospheric mercury assessment.
[42] UNEP (2018), Global Mercury Assessment, https://wedocs.unep.org/bitstream/handle/20.500.11822/27579/GMA2018.pdf?sequence=1&isAllowed=y
[43] EEA (2018) European waters. Assessment of status and pressures 2018. Report No 7/2018
[44] UNEP (2019), Technical information report on mercury monitoring in soil, available at: https://wedocs.unep.org/bitstream/handle/20.500.11822/30818/Soil_report.pdf?sequence=1&isAllowed=y
[45] UNEP (2019), Technical information report on mercury monitoring in soil, available at: https://wedocs.unep.org/bitstream/handle/20.500.11822/30818/Soil_report.pdf?sequence=1&isAllowed=y

3.1.3 Intentional use of mercury in dentistry

As described in section 2.3, dental amalgam is a combination of alloy particles and mercury that contains about 50% of mercury in the elemental form.

The alloy is not tooth-coloured; the amalgam cannot adhere well to remaining tooth tissues, so dentists often have to drill out relatively large holes in the teeth to securely fasten the filling. According to findings of the present study, the placement of dental amalgam fillings is no longer taught in several dental schools in the EU. Instead, the placement of mercury-free materials is taught (composite resins, ceramics, glass ionomers cements and gold alloys). However, dental amalgam is still in use due to its comprehensive mechanical properties, but also because some senior dentists have not received the required training in dental schools or through post-study training[46].

Overall, the use of mercury-free materials is increasing with a simultaneous decrease in the use of dental amalgam. The increased use of alternatives is due both to their superior aesthetic properties but also due to health concerns related to the use of dental amalgam particularly for certain groups of population (i.e. pregnant women and children)[47].

Any changes in the use of dental amalgam would affect a wide range of economic operators. This includes importers and exporters; manufacturers; waste handlers and recyclers; as well as the dentists. From a health perspective, the use of dental amalgam can affect not only dental professionals but also the wider population, which is exposed to mercury above the natural background level. Certain population groups such as high-level fish consumers, women of childbearing age and children are more vulnerable to exposure.

3.1.4 Risk to the environment (fauna/flora)

Mercury from dental amalgam is released into the environment (soil, atmosphere, water) via dental practices (surplus of amalgam or tooth extraction); deterioration in the mouth; burial or cremation; and waste management. Releases from waste treatment activities depend on the type of waste treatment applied, and on whether or not dental amalgam waste is mixed with non-hazardous waste or is managed as medical waste with specific collection and treatment of the waste from amalgam separators. Mercury released into the environment can reach the water compartment directly, either through sewage or wastewater. It can also contaminate water indirectly through atmospheric mercury deposition (carried by snow, rain, etc.) into the water cycle, and from surface water (oceans, lakes, rivers) to groundwater. In the atmosphere, mercury remains stable with a relatively long residence time (up to 2 years). It can be transported across long distances and redistributed by deposition to soil, air and water.

3.1.5 Risk to human health (bioaccumulation and biomagnification)

The release of mercury from anthropogenic sources, including dental amalgam, induces a progressive increase in the amount of mercury in the environment. Mercury, as a persistent substance, enters and circulates in the water cycle for several years.

Under anaerobic conditions, in soil or water, bacteria can metabolise inorganic mercury to a highly potent neurotoxin, methylmercury. In contaminated ecosystems, methylmercury can then bioaccumulate in organisms, especially plants and fish that are tolerant to a high amount of mercury. Levels of mercury in fish vary by species and their environment.

[46] Evidence collected in the context of the present study show that in at least some Member States, restoration with dental amalgam is no longer in use

[47] European Commission (2016), Commission Staff Working Document Impact Assessment Ratification and Implementation by the EU of the Minamata Convention on Mercury

Methylmercury introduced into the food chain via plants or fish can be ingested by humans. The mercury concentrations in organisms, including humans are affected by two major amplification processes: bioaccumulation that refers to the increase of mercury concentrations along the lifetime of an individual and; biomagnification that is defined as the increment of mercury concentration between the successive consumer levels of the food chain[48]. In humans, these processes can lead to toxic effects (nervous system damage in adults and neurological development damages in infants)[49].

For example, between 1932 and 1968, a devastating incident occurred in Minamata, Japan. A large amount of mercury was released from industrial wastewater from a chemical factory in Japan. Mercury was converted to methylmercury via bacteria and bioaccumulated and biomagnified in shellfish and fish. The contaminated fish was consumed by the local population of Minamata leading to deterioration of their health. Specifically, the contamination affected the central nervous system (this effect was also called Minamata disease) and eventually caused an increased awareness of the risks of exposure to mercury and particularly methylmercury.

3.1.6 Failure of WFD EQS

The Water Framework Directive (2000/60/EC) identifies mercury as a Priority Hazardous Substance. The Environmental Quality Standards Directive (2013/39/EU) sets maximum allowable concentration for mercury and its compounds at 0.07 µg/l in surface water bodies and at 20 µg/kg wet weight in biota[50].

The EEA State of Water Report highlights that in the 2nd River Basin Management Plans (2015-2021) only 38% of surface water bodies (e.g. rivers, lakes and coastal waters) were reported to be in good chemical status; 46% of water bodies failed to achieve good chemical status; and for 16 % of surface water bodies their status is unknown[51]. Mercury is one of the few substances responsible for a widespread failure to achieve good chemical status with 24 countries reporting water body failures for mercury. Some countries, such as Sweden, report that all of their surface water bodies are failing to achieve good status due to mercury[52].

Across Europe mercury (alongside brominated diphenylethers) is also responsible for failure to achieve good chemical status in the highest number of water bodies: out of a total of 111,062 surface water bodies, 45,973 are not achieving good status for mercury equating to about 41% of all surface water bodies in Europe[53]. If the widespread pollution by ubiquitous priority substances[54], including mercury, were omitted, the proportion of water bodies failing to achieve good chemical status would fall to 3% (as opposed to 46% for all such ubiquitous priority substances).

According to the EEA State of Water Report, atmospheric deposition leads to contamination with mercury in over 45,000 water bodies failing good chemical status

[48] Pouilly M. et al (2013), Trophic Structure and Mercury Biomagnification in Tropical Fish Assemblages, Iténez River, Bolivia, https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0065054

[49] According to the US Agency for Toxic Substances and Disease Registry (ATSDR) when mercury is swallowed, only a small amount (less than 0.01%) will be absorbed by the body unless the stomach or intestines, are diseased. However, when mercury is breathed most (about 80%) of the mercury enter the bloodstream directly from your lungs, and moves to other parts of the body, including the brain and kidneys where it can be accumulated for weeks or months.

[50] DIRECTIVE 2013/39/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 12 August 2013 amending Directives 2000/60/EC and 2008/105/EC as regards priority substances in the field of water policy

[51] EEA (2018) European waters. Assessment of status and pressures 2018. Report No 7/2018

[52] European Commission (2019). COMMISSION STAFF WORKING DOCUMENT European Overview - River Basin Management Plans. SWD(2019) 30 final, February 2019

[53] European Commission (2019). COMMISSION STAFF WORKING DOCUMENT European Overview - River Basin Management Plans. SWD(2019) 30 final, February 2019

[54] Other ubiquitous, persistent, bioaccumulative and toxic substances causing failure to meet good chemical status next to mercury are pBDEs, tributyltin and certain polycyclic aromatic hydrocarbons (benzo(a)pyrene, benzo(g,h,i)perylene, indeno(1.2.3-cd)pyrene, benzo(b)fluoranthene and benzo(k)fluoranthene). Mercury is the most common. Out of some 111 000 European water bodies identified in an EEA report No 18/2018, more than 45 000, across 24 Member States, are failing to reach good chemical status due to mercury pollution.

while inputs from urban wastewater treatment plants (UWWTP) lead to contamination of over 13,000 water bodies with mercury and other heavy metals[55]. Whilst dental amalgam seems to have little influence on atmospheric deposition, it appears to be the main contributor to releases of mercury from UWWTP to water bodies. It must be noted however, that inputs from urban wastewater treatment plants is a less significant factor in achieving good environmental status of water, when compared to atmospheric deposition[56]. Currently, atmospheric deposition affects 38% of surface water bodies, with mercury being the main pollutant responsible for failure to achieve good chemical status[57]. The EEA state of the Environment reporting states that diffuse pollution remains a problem in Europe due to both historical and current emissions of mercury to the atmosphere and subsequently surface waters[58].

3.1.7 Mercury mobilisation/transport/dispersal (EU and international)

Mercury is a global pollutant, as airborne mercury can be transported over long distances (i.e. across continents) depending on the speciation of mercury emissions and reaction pathways, before being deposited on the Earth's surface.

Across different areas of the EU, the origin of atmospheric mercury deposition can differ substantially[59]. Currently it is estimated that European emissions contribute up to 60% in certain areas, while in others (e.g. the Mediterranean), the atmospheric deposition originating from sources in Europe corresponds to only 20% or less of the total deposition. This significant transboundary component of mercury indicates that addressing the problem requires action at the global level together with measures implemented at EU level.

Despite this transboundary nature of mercury, in the last two decades only the EU and a few other countries (e.g. Norway, Switzerland, the USA, Canada and Japan) have implemented restrictions and other measures that aim to decrease or cease the use of mercury and eventually the contribution to the global pool of mercury. In fact, in several countries in Asia the exact opposite trend has been observed with increases of mercury pollution in several Asian countries due to their industrialisation[60].

3.2 Current demand for dental amalgam and other filling materials

This section provides an estimate of dental amalgam use in 2018. The data on the use of dental amalgam and alternative materials is available, fully or partially, for only 14 Member States. This information was obtained primarily from direct consultation with Members States or from their National Plans. Specifically estimates on the use of dental amalgam was provided only by BE, CY, CZ, DE, ES, FI, FR, HU, IE, IT, NL, PT, SE and SI. Further details are provided in Appendix D, page 288.

In addition, with the exception of IT and NL, the existing data on the use of dental amalgam corresponds only to the restorations that are covered by national reimbursement schemes; thus this estimate is conservative. According to the National

[55] EEA (2018) European waters. Assessment of status and pressures 2018. Report No 7/2018
[56] European Commission (2016), Commission Staff Working Document Impact Assessment Ratification and Implementation by the EU of the Minamata Convention on Mercury
57 COMMISSION STAFF WORKING DOCUMENT EVALUATION of the Council Directive 91/271/EEC of 21 May 1991, concerning urban waste-water treatment, available at: https://ec.europa.eu/environment/water/water-urbanwaste/pdf/UWWTD%20Evaluation%20SWD%20448-701%20web.pdf
[58] EEA (2020), State of the Environment reporting 2020, available at: https://forum.eionet.europa.eu/nrc-state-environment/library/soer-2020-working-place-eionet/external-review-of-the-soer2020/4.4.-key-trends-europe-and-european-countries-including-outlooks
[59] European Commission (2016), Commission Staff Working Document Impact Assessment Ratification and Implementation by the EU of the Minamata Convention on Mercury
[60] European Commission (2016), Commission Staff Working Document Impact Assessment Ratification and Implementation by the EU of the Minamata Convention on Mercury

Action Plan of the Czech Republic, for example, most patients prefer mercury-free materials when a restoration is not reimbursed by the health system. It therefore appears that even patients that do not have access to a national health system prefer mercury-free materials. The National Action Plan of CZ assumes that the vast majority of the dental amalgam fillings that are reimbursed by the national reimbursement schemes, correspond to the total amount of these fillings. Nevertheless, evidence shows that in other countries (DE and IE), some dental amalgam restorations are done in private facilities and payed for by individuals, rather than being reimbursed. For this reason with the exception of IT and NL the number of dental amalgam restorations **refers to the treatments covered by the reimbursement schemes and is considered as a minimum value**. Nevertheless, it is also assumed that dental amalgam restorations also performed when patients cover at their own expenses these restorations. **As there is no data on the number of non-reimbursable dental amalgam restorations (that correspond to the maximum usage), these are estimated based on different assumptions that are applied in Member States depending on their national situation**. The assumptions are described in Appendix D, Table 181.

While data on the weight of mercury in dental amalgam used (in the EU or in the Member States) does not exist, the volume of mercury is calculated based on the assumption that, on average, for each restoration **850 mg** of mercury is used[61].

Additional information on the methodology and assumptions used are provided in Appendix E.

The estimated annual demand for dental mercury per Member State, using this approach, is shown in Figure 3 below. At the EU28 level, it amounts to **between 26.9 t and 58.3 t Hg/year in 2018 (average 42.6 t/Hg year).** In general, the minimum estimate of the range corresponds to the dental amalgam restorations where the costs are covered by the national schemes, whereas the maximum estimate assumes that dental amalgam restorations also take place when the cost is covered by the patients.

This represents a significant drop in the use of dental amalgam, on average by approximately 43% compared to the previous estimate provided by the study of BIO Intelligence Service (55 t – 95 t/Hg year in 2010)[62].

Broadly, the Member States are grouped into three categories, based on the share of dental amalgam restorations compared to total restorations:

- Group 1- High share of dental amalgam use (above 30%): BG, HR, RO, SI
- Group 2- Medium share of dental amalgam use (between 10% and 30%): CZ, LT, LV, PL, SK, IE, UK, FR, CY, EL, MT
- Group 3- Low use of dental amalgam (below 10%): AT, BE, DE, PT, HU, IT, DK, EE, ES, FI, LU, NL, SE

Particularly for the Member States with a low use (Group 3), all of the countries have dental amalgam used in below 7% of the total number of restorations. This group

[61] This amount was assumed in the BIO Intelligence Service (2012) Study on the potential for reducing mercury pollution from dental amalgam and batteries that assumed that the amount of 600mg of mercury is used per restoration. In addition, according to Agdembo, A. O.; Watson, P. A.; Rokni, S. (2004): Estimating the weight of dental amalgam restorations, the use of mercury ranges between 480 and 710 mg, thus also corresponding to approximately 600 mg. However, these estimates do not include the amount of mercury that is wasted. According to an expert opinion provided in the context of this study it is estimated that approximately 30% of mercury is wasted during the restoration process. This increases the average amount of mercury per filling to 850 mg with approximately 250 mg being wasted.

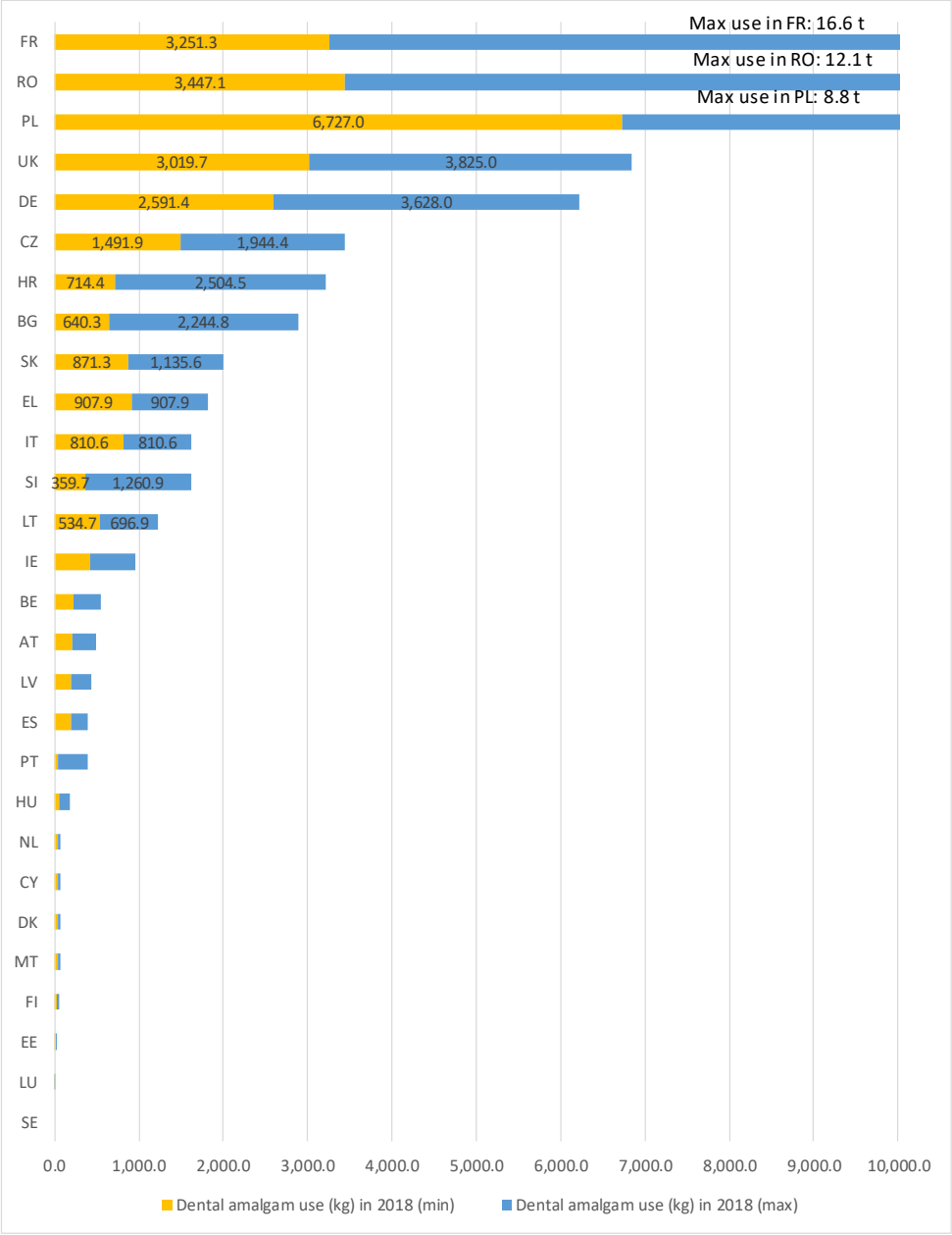
[62] BIO Intelligence Service (2012), Study on the potential for reducing mercury pollution from dental amalgam and batteries (http://ec.europa.eu/environment/chemicals/mercury/pdf/review_mercury_strategy2010.pdf)

represents almost half of the Member States (13 out of 28). At the EU level the share of dental amalgam restorations is estimated to be between **10% and 19%.**

In absolute terms, the highest user of dental amalgam is FR (3.3 t – 16.3 t) and the lowest user is SE, where the use of dental amalgam has been banned. At the per capita level, RO uses the highest amount of dental amalgam (up to 618.7 mg). At the other end of the scale is SE, where dental amalgam is no longer used, followed by LU with up to 1.77 mg per capita used in 2018. At the EU level the average per capita use ranges between 52 mg and 114 mg.

It must be noted however that significant uncertainties exist on the estimates of FR, RO and PL as no information is available for these Member States. A conservative approach is followed for these countries as indicated by the assumptions applied in these countries (Appendix D, Table 181).

Figure 3: Total dental amalgam use per Member State (kg, 2018)



Type of dental amalgam used

Article 10 (1) of the Mercury Regulation requires that, from 1 January 2019, "dental amalgam shall only be used in pre-dosed encapsulated form" while the "the use of mercury in bulk form by dental practitioners shall be prohibited". Although evidence from IE indicates that some mercury in bulk form might have been still in use in 2018, the requirement in relation to the use of an encapsulated form of dental amalgam is generally stipulated in the NAPs. It can therefore be assumed that the amount of bulk mercury still used in the EU market is negligible.

Production, imports and exports

No data was provided through the stakeholder survey (and none was identified in the literature) on the imports and exports of dental amalgam or of mercury-free materials.

PRODCOM[63] (community production) provides estimates of imports and exports as well as production under the relevant NACE 2 code[64]. However, this code is highly aggregated, as it does not only include dental filling materials (the data is provided in Appendix D).

The BIO Intelligence Study assumed (based on precedent studies) that 40% to 50% of dental amalgam produced in the EU was exported whereas 20% to 30% of the demand was imported. However, no current data are available to support these estimates. In addition, since 2010, the EU as well as the global demand of dental amalgam has changed significantly both in terms of amounts and forms (i.e. the import, export and sale of bulk mercury has been banned in the EU). In addition, according to an expert opinion provided in the context of the present study, **currently there is no production of dental amalgam** in the EU. All dental amalgam is understood to be imported to the EU and repackaged.

Number of dental amalgam and mercury-free restorations

Only a few Member States collect data on the number of restorations performed with mercury-free materials. In the present study, data on the number of mercury-free restorations were provided by BE, CZ, FI, HU, IE, LV and SI, only for restorations performed covered by the national health systems. Information on the total number of restorations is available only in IT, DE and NL. The estimates were then extrapolated for other Member States.

The estimates are based on data transferred from one country to another with similar socio-economic characteristics by also taking into account of any restrictions on the use of dental amalgam. Specifically, the countries have been grouped based on the following criteria:

- Possible restrictions in place concerning the use of dental amalgam (legal restrictions or recommendations by national authorities)
- Overall trends in the use of dental amalgam
- Economic wealth

These criteria are applied in Member States where estimates on the use and demand of dental amalgam or mercury-free materials do not exist. Further information on the assumptions and calculation methods is provided in Appendix D, 288.

[63] Prodcom provides statistics on the production of manufactured goods carried out by enterprises on the national territory of the reporting countries. The term comes from the French "PRODuction COMmunautaire" (Community Production).

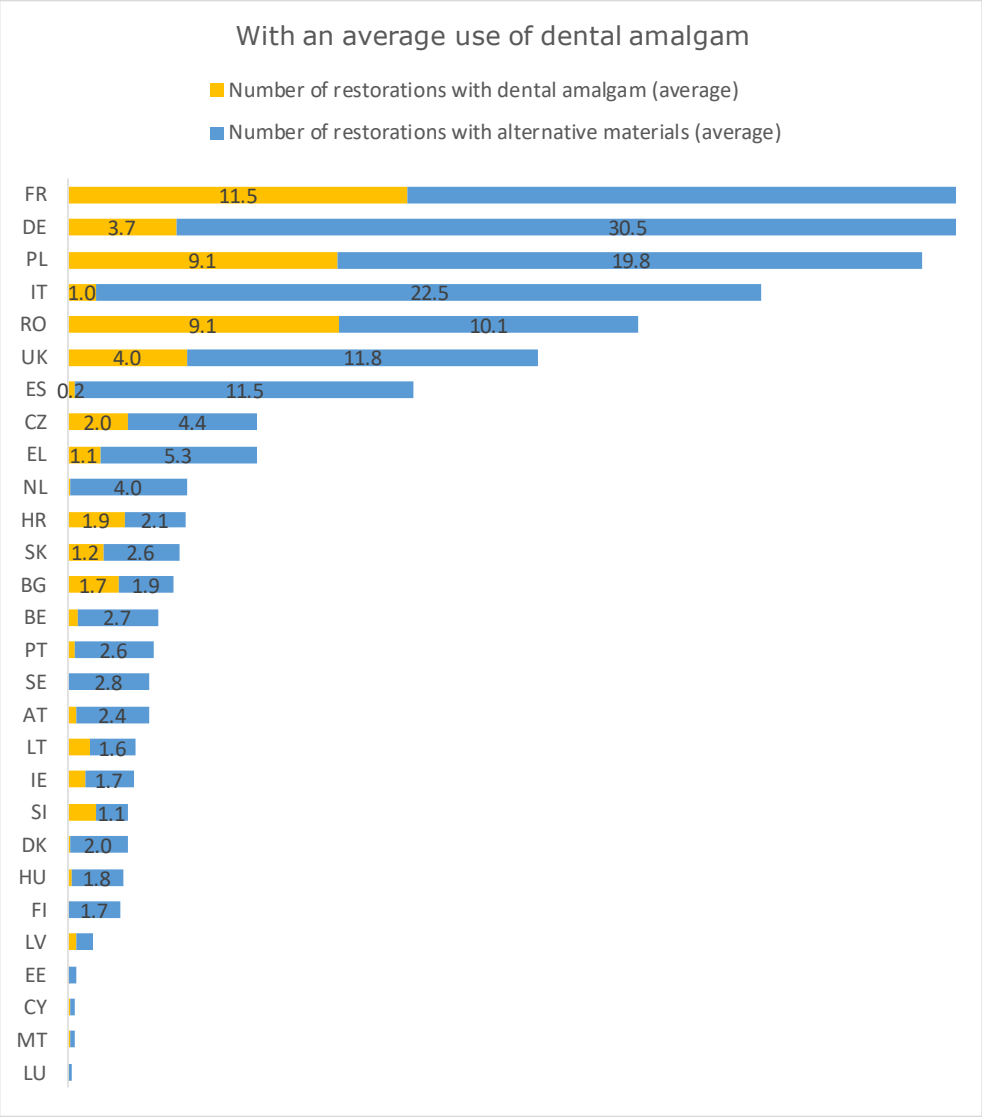
64 32505010 - Dental cements and other dental fillings; bone reconstruction cements

Figure 4 below shows the total number of restorations per Member State, with an average estimated use of dental amalgam. The figures illustrating the number of restorations with reactively a minimum and a maximum use of dental amalgam are presented in Appendix D (Figure 20).

FR has potentially the largest number of restorations, both in terms of the total number and the restorations performed with the use of dental amalgam. Nevertheless, it must be highlighted that there are no available data for FR other than the share of dental amalgam restorations in 2011 (25%). This is assumed to be the maximum current share of amalgam use in the country (see also Appendix D). The estimates in DE and IT reflect the current situation with a higher certainty as estimates on the number of restorations were provided for both countries in the context of the current study. DE is estimated to have a lower number of restorations than FR. According to estimates provided by an expert in the context of the present study, in DE the number of restorations dropped significantly due to preventive measures. Such evidence does not exist for FR or other Member States and therefore it is assumed that the total number of restorations is higher than in DE even though the population in the country is lower[65].

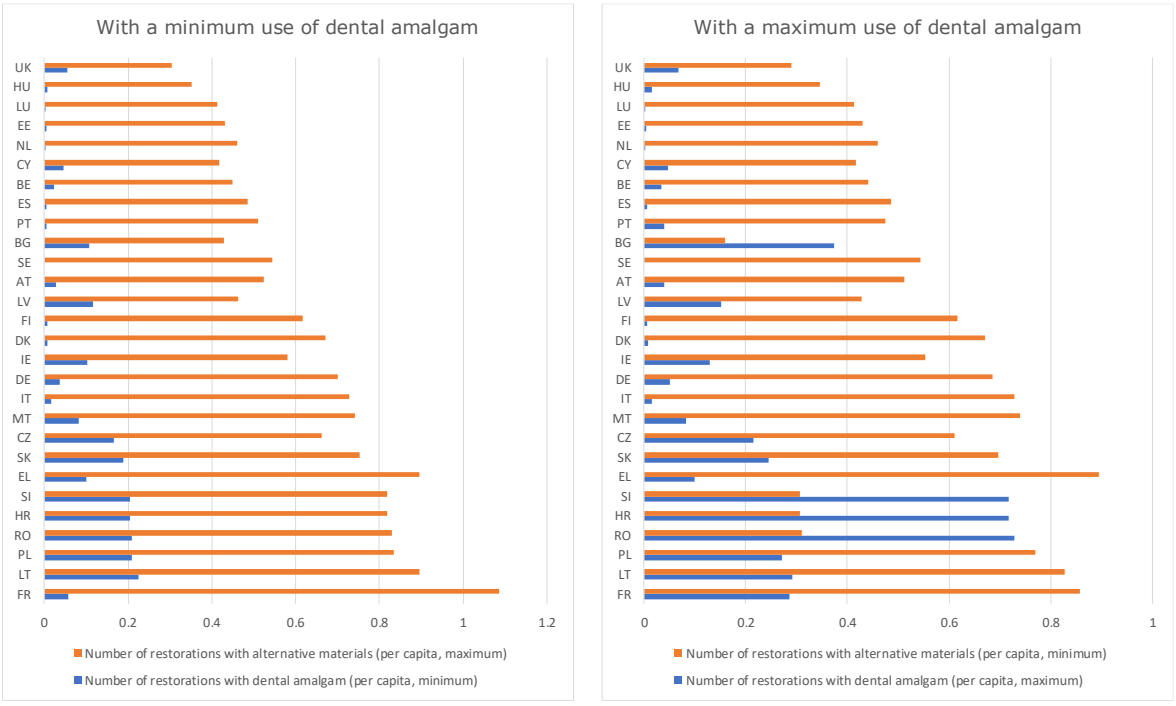
[65] According to Eurostat, the population in FR, in 2018 was 66.9 million and in DE 88.2 million

Figure 4: Number of restorations per filling material per Member State with an average use of dental amalgam (million, 2018)



The total and average (i.e. per 1,000 inhabitants) estimated number of restorations, by material, per Member State is provided in Figure 5. The estimates are provided with both a minimum and a maximum estimated use of dental amalgam restorations. In these estimates, the most commonly used alternatives to dental amalgam were considered, namely composite resins, glass ionomer cements, compomers and ceramics.

Figure 5: Number of restorations per filling material per Member State (per 1000 inhabitants per year)



In 2018, from the approximately 372 million dental restorations carried out annually at the EU28 level, approximately 32 – 69 million restorations are estimated to be carried out with dental amalgam (10% - 19% of the total) and 304.1 – 341.1 million with mercury-free materials (81% - 90% of the total). Therefore, the vast majority of the restorations are carried out with mercury-free materials regardless of whether the minimum or maximum estimated amount of dental amalgam is taken into account. The estimates indicate a significant proportional increase of mercury-free materials when compared to the BIO study which estimated that in 2010 the share of mercury-free restorations was 66%.

It must be noted that as the available information refer to restorations reimbursed by the national schemes only (except DE and IT), for the rest of Member States it was assumed that the total number of restorations covered is equal to the estimates of the BIO Intelligence Service study (2012). In this context, the total number of restorations performed with the use of dental amalgam and alternative-free materials is similar to the total number of restorations of the BIO Intelligence study (approximately 375 million restorations). Specifically, the present study estimates that the total number of restorations is equal to the 373 million restorations due to the update of the estimates in IT and DE as well as the introduction of HR (which was not included in the BIO study). The total number of restorations in HR was estimated based on the population correlation with SI.

Regarding the specific type of mercury-free materials most commonly used, data was only available for IE and PT (see also Appendix E). In PT, of all mercury-free materials, composites are preferred in most cases (approximately 90%). In the rest of the cases, resin-modified glass ionomer cements are used. In addition, data from the Portuguese primary health care suggests that, in health centres, the percentage of dental restorations with amalgam was 7.6%. From the remaining restorations, 86.3% were performed with composite resin and 6.1% of dental restorations were made with glass

ionomer cement. Therefore, data both from PT and IE suggest **that composites are by far the most used type of material in mercury-free restorations.**

Trends in the use of dental amalgam

The information collected in the context of the present study indicates a **consistent declining trend in the use of dental amalgam in favour of mercury-free materials**. This gradual decrease in amalgam use in the EU is consistent with the results of the survey carried out in the context of the present study as well as with interviews carried out with dental professionals in different Member States (see also Appendix D).

As regards the existing evidence on the number of restorations **covered by the national reimbursement schemes**, in BE the share of dental amalgam restorations reimbursed by the national health systems decreased from 100% in 2006 to 20% in 2014 and 7% in 2018. In CZ, which according to the 2010 estimates of the BIO study was one of the highest users of dental amalgam, the use of dental amalgam has dropped by approximately 22% between 2013 and 2016 (on average 7% per year). Similarly, in IE, between 2013 and 2018 the use of dental amalgam has been dropping by 5.1% per year. In DE, in 2013, it was reported that dental amalgam represented 10% of total restorations and by 2018 this was 5%. In SI, between 2013 and 2018, the use of dental amalgam has dropped by approximately 20%.

As regards the existing evidence on the **total number of restorations** (i.e. covered by both the national reimbursement schemes and paid for by patients at their own expense), in NL the use of dental amalgam represents approximately 0.5%. In IT, the use of dental amalgam is dropping by approximately 12% per year. In addition, in SE the use of dental amalgam has been banned since 2009, whereas in FI and EE the use is less than 1%. DK has also seen a large reduction, as the share of total restorations that were with dental amalgam dropped from 22% in 2007 to only 1.7% in 2017. In addition, according to a survey carried out in ES the current use of dental amalgam represents approximately only 1% of the total restorations. In addition to these quantitative decreases, qualitative evidence on the decrease of dental amalgam used also exists for AT, BG, CY, EL, FI, FR and LT (see Appendix D, page 298).

Despite the existence of evidence for a decreasing trend in the use of dental amalgam, both for reimbursable and non-reimbursable restorations, **historical quantitative data** on the use of dental amalgam is only available for certain Member States. These estimates are provided in the following table. It must be noted that the average change increased in 2018 due to the implementation of Article 1(2) of the Mercury Regulation, which bans the use of dental amalgam. It requires that dental amalgam not be used for treatment of deciduous teeth, of children under 15 years and of pregnant or breastfeeding women except in some specific cases.

Table 2: Trends in the use of dental amalgam (annual changes)

Country	Average change between 2014 and 2017	Change between 2017 and 2018	Annual average change
BE	-15.5%	-22.6%	-19.0%
CZ	-7.0%	-10.0%	-8.5%
NL	-18.4%	-20.3%	-19.4%
IE	-4.6%	-9.6%	-7.1%
SI	-3.1%	-5.5%	-4.3%

Based on these trends, the evolution of the use of dental amalgam and alternative materials until 2030 was estimated assuming that no further policy intervention will take place but that current policies continue to be implemented and specifically, the following:

- The ban of dental amalgam use as of 1 July 2018 that applies on "dental treatment of deciduous teeth, of children under 15 years and of pregnant or breastfeeding women, except when deemed strictly necessary by the dental practitioner based on the specific medical needs of the patient" (Article 10 (2) of the Mercury Regulation).
- The implementation of NAPs that call for a phase-down (see also Appendix B and F).
- Reduction measures promoted at the international or industry levels (e.g. Minamata Convention and the Berlin Declaration[66]).

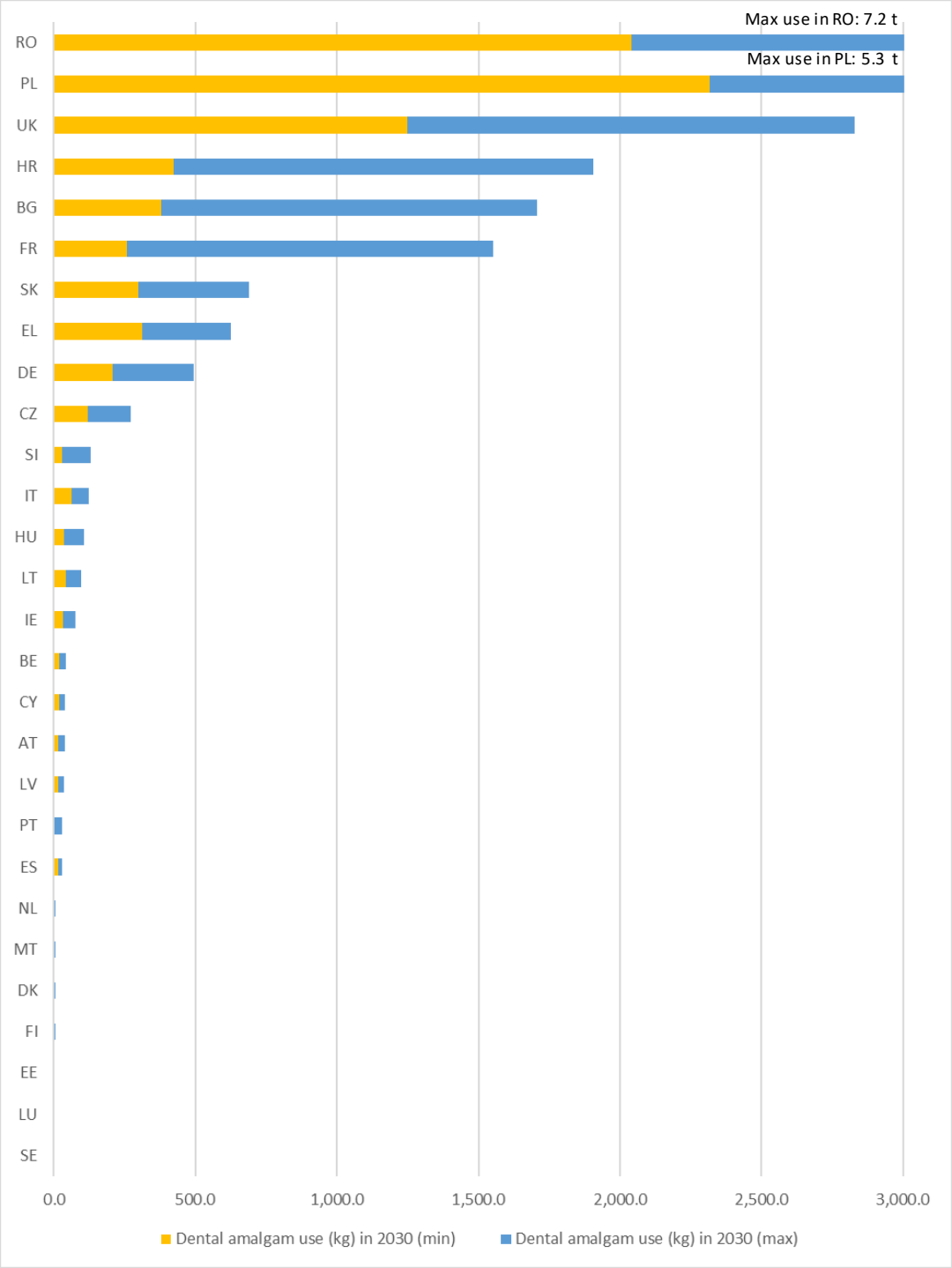
As in the case of the estimation of the dental amalgam use in 2018, it was assumed that each Member State will follow the trends of a reference country. The reference countries are provided in Appendix E. It was further assumed that each trend will correspond to the average of the trends between 2014 and 2017 and the trend between 2017 and 2018. This is based on the assumption that the average trend away from use of dental amalgam after 2017 will increase due the ban of the use of dental amalgam in certain categories of patients but it will not be as high as the trends between 2017 and 2018, as all restorations will cease in these categories after 2019. Nevertheless, an increased trend away from amalgam (compared to the levels until 2017) can be expected due to the implementation of the National Action Plans that will implement measures for a phase down or phase-out of dental amalgam beyond the measures which restrict use by 2018.

According to these estimates, if no further policy measures are implemented, the use of mercury in dental amalgam will decrease from 26.8 t - 58.3 t in 2018 to 12.4 t - 26.7 t in 2025, 10.2 t - 22.3 t in 2027 and 7.9 t-17.5 t in 2030. Therefore, the use of mercury in dental amalgam is expected to decrease by approximately 70% between 2018 and 2030. Therefore, **without additional policy measures, a significant use of dental amalgam is still expected**, mainly in the Group 1 countries but also Group 2 countries that currently have a medium use of dental amalgam, particularly those with large populations and thus higher numbers of dental restorations.

The quantitative estimates on the use of dental amalgam in 2030 are illustrated in Figure 6 below.

[66] 2017: Berlin Declaration: After a gathering at a two-day Pan-European Summit to plan the end of amalgam, environmental and consumer NGOs, dental associations, Members of the national parliaments and the European Parliament, academics, and industry issued the "Berlin Declaration to End Amalgam Use in Europe in 2020, available at: https://www.ig-umwelt-zahnmedizin.de/wp-content/uploads/Berlin-Declaration-to-End-Amalgam-Use-in-Europe-on-1-July-2022.pdf

Figure 6: Estimate of dental amalgam use without policy intervention (kg, 2030)



This estimate assumes that the total number of dental restorations will remain stable until 2030, whereas in practice this might change because of two reasons: a) changes in the quality and effectiveness of the dental treatment in different counties (particularly in relation to the preventive measures and treatment of any unmet needs) and b) differences on the performance, and particularly the longevity between dental amalgam and mercury-free restorations.

The following general assumptions can be made with regards to the correlation of improvements in the **effectiveness of the dental care systems in different Member States** and the number of restorations:

- The oral health prevention policies that are applied by Member States may gradually decrease the need for dental restorations, regardless of restoration material. Simultaneously, these policies might increase the longevity of natural teeth in elderly people and thus the need for restorations might increase. According to recent study by the Irish Environmental Protection Agency (EPA), due to fluoridation of water and improved dental care, adults in Ireland have fewer missing teeth but also more teeth with fillings as a result[67].
- In some Member States, there are large unmet needs for dental restorations. Nevertheless, if access to dental health care (for example due to enhanced dental services towards the population with a lower income) increases, this is expected to lead to a larger number of dental restorations.

Overall, caries prevention and the promotion of oral health in general is stipulated in the NAPs and is one of the actions put forward in the Minamata Convention[68]. However, at present, there is not sufficient information to establish relevant correlations between these aspects and future dental restoration needs.

The **longevity of fillings** can affect the indirect costs of dental amalgam substitution with mercury-free materials over the long term. A shorter average lifetime of a dental filling requires more frequent restorations. There is a multitude of factors that affect the longevity including the type of filling material and the quality of the placement when composites are concerned.

A number of studies suggest that the **performance of composite fillings is equal or superior to dental amalgam restorations**. The BIO Intelligence Service Study referred to previous studies indicating diverging views on the differences in their lifetime. According the World Health Organisation (WHO), amalgam fillings used to have a longer average lifetime than composite fillings[69]. However according to the organisation, 'recent data suggest that RBCs (resin-based composites) perform equally well as amalgam' and 'composite resins have been reported to last 12-15 years'. In addition, according to an expert opinion provided in the context of the present study, amalgam fillings tend to corrode, expand and crack the teeth. According to the same expert, after a few years cracks in the enamels around the filling start to appear. The SCENIHR concluded that dental restorative treatment can be adequately ensured by amalgam and alternative types of restorative material. They also concluded that the longevity of restorations of mercury-free materials in posterior teeth has improved with the continuing development of these materials and the practitioner's familiarity with effective placement techniques. The SCENIHR also concluded that some recent studies from the Netherlands, Sweden and Denmark showed very good long-term clinical effectiveness for posterior resin composite restorations with equal and better longevity than for amalgam.

Another important aspect in relation to the performance of filling materials is the **preservation of the underlying tooth** and the functioning of the dentition as a whole. A focus is placed on keeping open future options for restorations given that the current

[67] EPA Research (2020), Study on Usage and Waste Management of Amalgam Dental Fillings and Mercury-free Alternatives

[68] The Minamata Convention, Annex A, Part I sets out nine measures to phase down the use of dental amalgam, one of which is the "setting national objectives aiming at dental caries prevention and health promotion, thereby minimizing the need for dental restoration"

[69] According to WHO, Future Use of Materials for Dental Restoration, the average lifetime for amalgam fillings was 10-15 years for dental amalgam fillings and 5-8 years for composites

restorations will fail in the future and will need to be replaced, repaired or adjusted. In this context, the focus is not achieving the strongest restoration possible "but rather a restoration that is compatible with the mechanical, biological, and optical properties of underlying tissues" [70]. This approach is also put forward by the Norwegian Directorate for Health and Social Affairs that states in its guidelines that the selection of a restoration material shall be based on a minimal removal of dental tissue. The guidelines further state that glass ionomer cements and composites require less removal of tooth tissue than amalgam to gain retention, as they bind themselves to dental tissue[71]. The SCENIHR also states that "amalgams may be seen to be inferior to the alternatives" given the aesthetics and non-adhesive character of mercury-free materials[72]. According to SCHENIHR, dental amalgam requires the preparation of larger cavities that are often associated with excessive tooth tissue removal. The World Health Organization (WHO) also states that adhesive resin materials (such as composites) cause less destruction and allow a longer survival of the tooth[73].

In relation to the **reparability features**, mercury-free restorations and particularly composites can be restored with a partial replacement when they fail[74]. Composites permit minimal invasive approaches for localised repair. Therefore, the consequences of a total restoration replacement – that include an increase in the depth and width of the cavity – for the replacement of failed fillings are avoided with the use of composites[75]. Another study concluded that composite fillings have a higher success rate than dental amalgam fillings when repaired. Specifically, the annual failure rate (AFR) after 4 years for repairs of dental fillings was respectively 9.3% for dental amalgam[76] and 5.7% for composite fillings.

Other studies suggest that the performance of **dental amalgam is in general superior to the mercury-free restorations**. A recent study that assessed 3.5 million restorations in the UK concluded that, overall, dental amalgam has better performance compared to other restoration materials as the failure rate is overall lower compared to both composites and glass ionomers in different. Nevertheless, this study focused only on the UK, which is characterised by a high share of dental amalgam restorations. This high usage might affect the development of the required skills that affect the longevity of mercury-free fillings (as it is very sensitive to the quality of the intervention). At the global level, according to the WHO, dental amalgam and composites have a similar failure rate (around 2.2%), whereas other Mercury-free materials have a higher failure rate; glass ionomers have the highest failure rate at 7.6%. In addition, a study published by the American Journal of Dentistry77, determined that 'the failure of amalgam restorations occurs more frequently in primary teeth, especially in small children, due

[70] NJM Opdam, R Frankenberger, and P Magne (2016) From 'Direct Versus Indirect' Toward an Integrated Restorative Concept in the Posterior Dentition. Operative Dentistry: September 2016, Vol. 41, No. S7, pp. S27-S34

[72] SCENIHR, 2015. Scientific opinion on the Safety of Dental Amalgam and Alternative Dental Restoration Materials for Patients and Users.(https://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_046.pdf)

[73] World Health Organization (2011), Future Use of Materials for Dental Restoration, http://www.who.int/oral_health/publications/dental_material_2011.pdf, pp.16, 27, 29

[74] JJM Roeters, ACC Shortall, and NJM Opdam (2005), Can a single composite resin serve all purposes?, BRITISH DENTAL JOURNAL 199, 73 - 79 (2005),

[75] Christopher D. Lynch, Kevin B. Frazier, Robert J. McConnell, Igor R. Blum and Nairn H.F. Wilson, Minimally invasive management of dental caries: Contemporary teaching of posterior resin-based composite placement in U.S. and Canadian dental schools

[76] Niek J.M. Opdam, Longevity of repaired restorations: A practice based study, Journal of Dentistry 40 (2012) 829 – 835,

[77] Reinhard Hickel et al. (2005) Longevity of occlusally-stressed restorations in posterior primary teeth, American Journal of Dentistry, Vol. 18, No. 3 (http://www.amjdent.com/Archive/2005/Hickel%20-%20June%202005.pdf)

to moisture contamination of the cavities during condensation'. The age of the children at the time of placement is therefore a major factor in restoration longevity.

Table 3: Survival of restorations per type of material in the UK[78]

Type of treatment	Survival (%) at			
	1 year	5 years	10 years	15 years
Amalgam	91	66	51	41
Composite resin	87	59	43	34
Glass ionomer	84	53	37	28

In addition, according to a recent study published by the Irish Health Research Board, there is inadequate evidence upon which to assess the performance of composite resins and glass-ionomer restorations and compare those with dental amalgam restorations including in relation to restoration failure rates[79]. Nevertheless, according to the same study and based on the results of a 2015 review, existing evidence suggests that dental amalgam restorations in posterior permanent teeth last longer when compared with composite resin restorations. In addition, dental amalgam restorations are associated with the presence of fewer secondary caries.

Based on the review of studies on the performance of different restoration materials the comparison of the longevity of mercury-free fillings (and particularly composites) and dental amalgam restorations is inconclusive. There are **four main factors that influence the longevity of a filling**: the material used, the method of restoration, the skills of the dentist and the dental care performed by the patient himself. The quality of composite materials and the restoration methods are nowadays (in general) of good quality, so the longevity of restoration mainly depends on factors related to the patient and the skills of the dentist[80]. Evidence from Sweden suggests that, as the skills of the dentists with mercury-free restorations improve, their longevity will become equal to dental amalgam restorations. In addition, according to the review of the evidence, mercury-free materials cause a lesser destruction of the tooth tissue and can be repaired more easily when compared to dental amalgam restorations.

Even if the evidence is in general inconclusive, it is concluded that that **the longevity of mercury-free fillings is no longer a factor with significant effect** on the overall difference between dental amalgam and mercury-free restorations in terms of the amount of replacements. This is based on the assumption that any difference on the longevity of the materials will be further reduced significantly following a gradual higher use and experience in the use of mercury-free materials which is sensitive to the quality of the intervention. In addition, evidence exists as regards the better performance of mercury-free materials in relation to the health of tooth tissue and the reparability aspects.

Drivers of and barriers to the declining trends

The study survey included a question on the most significant drivers and barriers for a prospective reduction in dental amalgam use (see Appendix F). The paragraphs below

[78] British Dental Journal, Volume 224 NO. 12. June 22 2018
[79] Health Research Board (2020), Measures to reduce the clinical need for dental amalgam
[80] Kopperud E. et al (2016), Fyllningars hållbarhet mest beroende av patient och operator, available at: https://www.tandlakartidningen.se/wp-content/uploads/2017/04/Simen-E-Kopperud-et-al.pdf

present the results of this survey question, together with some key remarks concerning the situation in specific Member States.

The figure below illustrates the main drivers behind a reduction of the use of dental amalgam, as identified by the respondents to the questionnaire. The numbers in the figures show the respective responses for each of the drivers and barriers. **Increasing consumer awareness of the environmental and associated indirect health effects of dental amalgam has been identified as the main driver for decreased use of dental amalgam.**

The promotion of mercury-free materials through both guidelines and fiscal measures, together with enhanced training of dentists on the use of such materials, has also been identified as a significant driver. The improvement of the durability of the alternative materials and closing the gap between the share provided by the reimbursement schemes on dental amalgam and mercury-free materials were not considered as significant drivers for a decrease in the use of dental amalgam.

Figure 7: Drivers for the reduction of dental amalgam use (number of responses)

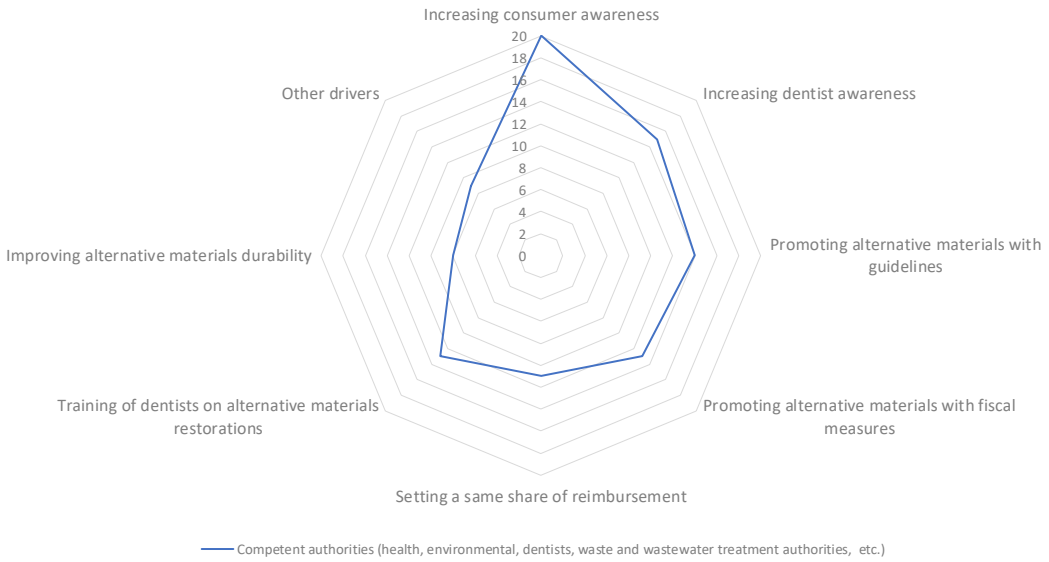
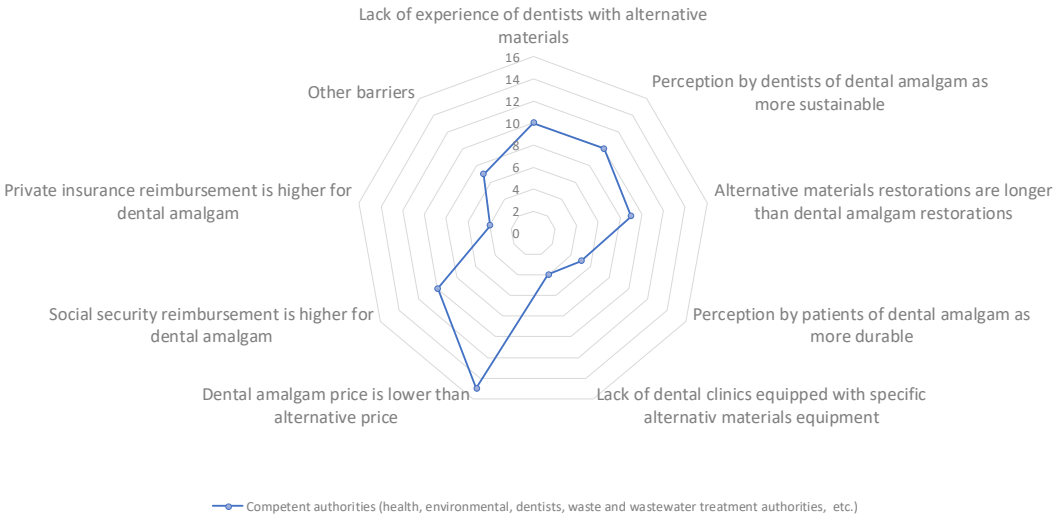


Figure 8: Barriers to the reduction of dental amalgam use



As regards the barriers (see Figure 8), the fact that **the cost of dental amalgam restorations** (due to a higher amount of time required to perform them, and not due to the cost of materials) **is relatively low compared to the price of alternatives is considered as the most significant barrier**. Similarly, the higher reimbursement values for dental amalgam restorations (in some cases) also acts as a key reason for dental amalgam still being in use. Other aspects that relate to potential differences in the durability of dental amalgam restorations were considered as less important.

3.3 Evolution of socio-economic and environmental effects

This section provides an overview of the economic, social and environmental aspects that relate to the use of dental amalgam. The economic aspects relate to the costs that are borne by the different actors, namely dentists, wastewater treatment facilities, solid waste facilities, crematoria and patients. From a social perspective, the focus is on the expenses of patients for dental treatment and the national reimbursement schemes as a whole.

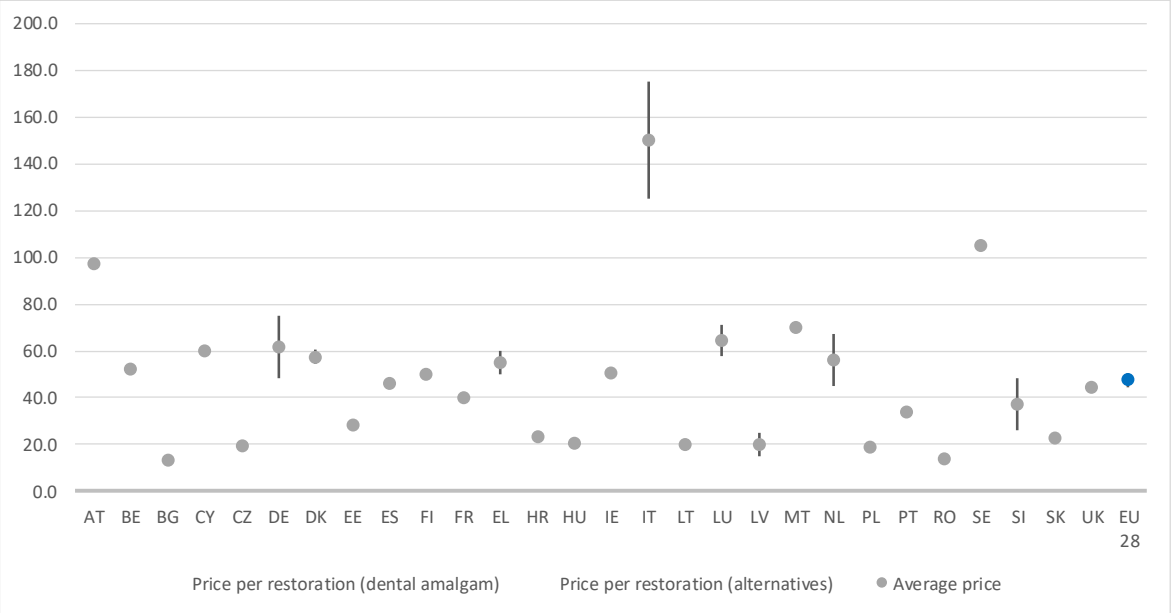
The environmental concerns are associated with the use of dental amalgam use through the various stages of its life cycle. The environmental effects concern the emissions of mercury to air, water and soil through dental facilities, and wastewater treatment plants and solid waste treatment facilities.

Costs for patients and national reimbursement schemes

Figure 9 below provides an estimate of the restoration prices in the EU28 Member States for both dental amalgam and mercury-free restorations. The estimates are based on data available in 16 Member States. The estimates for the remaining 12 Member States were provided based on reference countries, based on the health price indices provided by Eurostat [81]. The detailed results of this approach are provided in Appendix D.

[81] Eurostat, Harmonised index of consumer prices (HICP), available at: https://ec.europa.eu/eurostat/web/hicp/data/database

Figure 9: Prices of restorations with dental amalgam and mercury-free materials (EUR, 2018)



In most countries, where data is available for both dental amalgam and mercury-free materials, the differences in the prices of the restoration are not significant. For some Member States (BE, CY, CZ, DK, FI, IE, MT and the UK) the prices are equal or approximately so. Significant differences appear in SI and LT. **Nevertheless, it must be highlighted that in most cases the prices indicated refer to the reimbursable costs (i.e. caps), and not to the actual prices charged to the patients.** In IT where in general the price of restorations are not reimbursed, the difference between dental amalgam restorations and mercury-free materials is significant. In addition, according to expert opinion, in DE the additional price of composite restorations ranges between 20 to 80 EUR. However, in CY where reimbursement of dental fillings is also not provided, the prices are the same, regardless of the restoration material. In addition, the prices of mercury-free materials refer primarily to composite and glass-ionomers. The cost with the use of ceramics can reach up to 570 EUR per filling. Nevertheless, evidence collected in the context of this study indicates that ceramics are used in a very limited number of restorations (see section 3.2).

More significant differences are found in the reimbursement schemes. The national health systems in some countries provide 100% reimbursement to patients (e.g. AT, and CZ). In other Member States, it is common for patients to purchase (or receive from their employer) a complementary insurance to have full reimbursement in their restorations (e.g. FR, ES, IT and HU). There are also cases where the reimbursement varies, depending on specific groups of the population such as children (e.g. DE, ES, LV, NL, PL) or other groups (e.g. Chernobyl victims in LV or patients over 63 years old in EE). In GR, MT and IT dental care is provided for free only in public hospitals and health centres. Therefore, if patients chose private dental surgeries, they must pay the price of restoration themselves. As also indicated by the case of IT and DE, the cost differences between dental amalgam and mercury-free restorations might be significant. **This indicates that patients are required to cover the price differences themselves.** Additional details on the structure of the reimbursement schemes in different countries is provided in Appendix E.

In addition, based on information collected, in only a few Member States the share or the amount of reimbursement is not affected significantly by the restoration material, regardless of whether the filling is dental amalgam or a mercury-free material (e.g. in BE). Member States tend to differentiate the reimbursed amount based on whether a restoration is performed on anterior or posterior teeth or on the existence of allergies that do not allow a restoration with the use of dental amalgam (e.g. AT and DE). Overall there is no differentiation on the price of restorations per material for the population categories defined under the dental amalgam ban of Article 10(2) of the Mercury Regulation (i.e. children under 15 years and of pregnant or breastfeeding women). **This indicates that a large share of adult patients in the EU are required to cover any price differences between dental amalgam and mercury-free restorations at their own expense.**

It appears that the main reason that dental amalgam is still used relates to the cost differences between dental amalgam and mercury-free restorations. Nevertheless, the evidence collected in the context of this study indicates that these differences are shrinking. The same applies for the differences on the coverage of the reimbursement schemes at least for the population categories covered by Article 10(2) of the Mercury Regulation. **Historically, dental amalgam was favoured by the national health systems, but this trend appears to be shifting towards an equal share of reimbursement, regardless of the choice of restoration material.** This already occurs for the population categories listed under Article 10(2) of the Mercury Regulation for which the use of dental amalgam has been banned. A further shift towards a same share of reimbursement is also expected to result from the phasing-out or phasing down measures stipulated in the NAPs. For example, SK plans to reduce the reimbursement of amalgam fillings even though they are the cheapest filling material.

The reimbursement schemes, together with the prices of dental restorations (see Figure 9) greatly affect dental patients. In the Business as Usual (BaU) scenario of the present study (see section 3.4 for the description of the options), it is assumed that any changes **in the selected dental filling materials will affect the costs incurred by dentists for performing the restorations and it is assumed that any changes in such costs will be passed on to dental patients or the reimbursement schemes (i.e. depending on the respective coverage provided)**. However, the difference in the cost of materials is small; therefore, the main factor affecting the price differences are the differences in the labour costs. As experience from Sweden showed, the skills of dentists in handling mercury-free filling materials are improving, and this reduces the restoration times for mercury-free materials, to levels that are comparable to the restoration time required to handle dental amalgam materials. In addition, in at least 16 Member States for which data is available, there is no significant difference in the coverage of the reimbursement schemes between dental amalgam and mercury-free restorations (except for CZ and DE). In addition, the ban of the use of dental amalgam on the population categories laid down in Article 10(2) of the Mercury Regulation is already causing a shift towards mercury-free materials.

The longevity of materials is also a significant aspect as it affects the frequency of filling replacements. Nevertheless, as mentioned above (see section 3.2), the performance of dental amalgam and mercury-free materials (particularly composites and glass-incomers) is assumed to be broadly equal due to inconclusive evidence.

Manufacturing of dental amalgam materials

Information available suggests that there are 63 dental fillings manufacturers in the EU of which three companies manufacture dental amalgam only (see the table below). These companies are located in CZ, IT and the NL (see table below). As highlighted in section 3.2 in the EU, the manufacturing is understood as import from non-EU

countries and repackaging. No information is available on the SME status of these companies.

Table 4 : Manufacturers of dental amalgam only

Company	Country
Bome s.r.o.	CZ
WORLD WORK SRL	IT
M&R Claushuis B.V	NL

Overall, there are more than 65,000 companies operating in the "Manufacture of medical and dental instruments and supplies" sector of which only 219 are large companies (equating to about 0.3%)[82]. At the same time, large companies accounted for 56% of total turnover in the EU in 2016. However, the share of the turnover that is associated with the manufacturing of filling materials, as well as the equipment that is required per type of material, is unknown.

In the EU, SMEs accounted for 99.7% of companies in the sector and 44% of its turnover. Information is available on Eurostat for CZ, IT and the NL suggesting a similar pattern except for NL, where large companies in this sector account for 13% of total turnover[83]. Further information is provided in Appendix D, page 302.

Revenues of manufacturers

The figure below provides an estimate on the annual revenues of the dental filling manufacturing sector in the EU that derive from the selling of the filling materials that are examined in the current study. Only 12 Member States produce filling materials including dental amalgam capsules and mercury-free materials. The full list of the companies is provided in Appendix D, page 302.

Annual revenues were estimated based on the number of restorations per dental material. As no data exists on imports and exports, it is assumed that the amounts produced are fully used in the EU. In addition, as explained in section 3.2, according to an expert consulted in the context of the present study, the amounts of dental amalgam produced in the EU may not correspond to actual manufacturing but repackaging of imported dental amalgam. Due to the uncertainties in data on imports and exports, the figures below need to be read with discretion.

It is estimated that if the amount of dental amalgam produced in the EU is equal to the demand (between 38.4 t and 83.3 t), the total revenues of EU manufacturers in 2018 ranging between 76.2–165.3 million EUR. The revenues of manufacturers of mercury-free materials ranges between 1,342-1,506 million EUR. The estimates of the revenues of manufacturers was based on the number of restorations per year that was multiplied by the prices of restoration materials (see Appendix D, Table 186).

[82] Source: Eurostat: Industry by employment size class (NACE Rev. 2, B-E) [sbs_sc_ind_r2]
[83] Source: Eurostat: Industry by employment size class (NACE Rev. 2, B-E) [sbs_sc_ind_r2]

Figure 10: Annual revenue of manufacturers of filling materials per Member State based on the estimated minimum use of dental amalgam (million EUR, 2018)

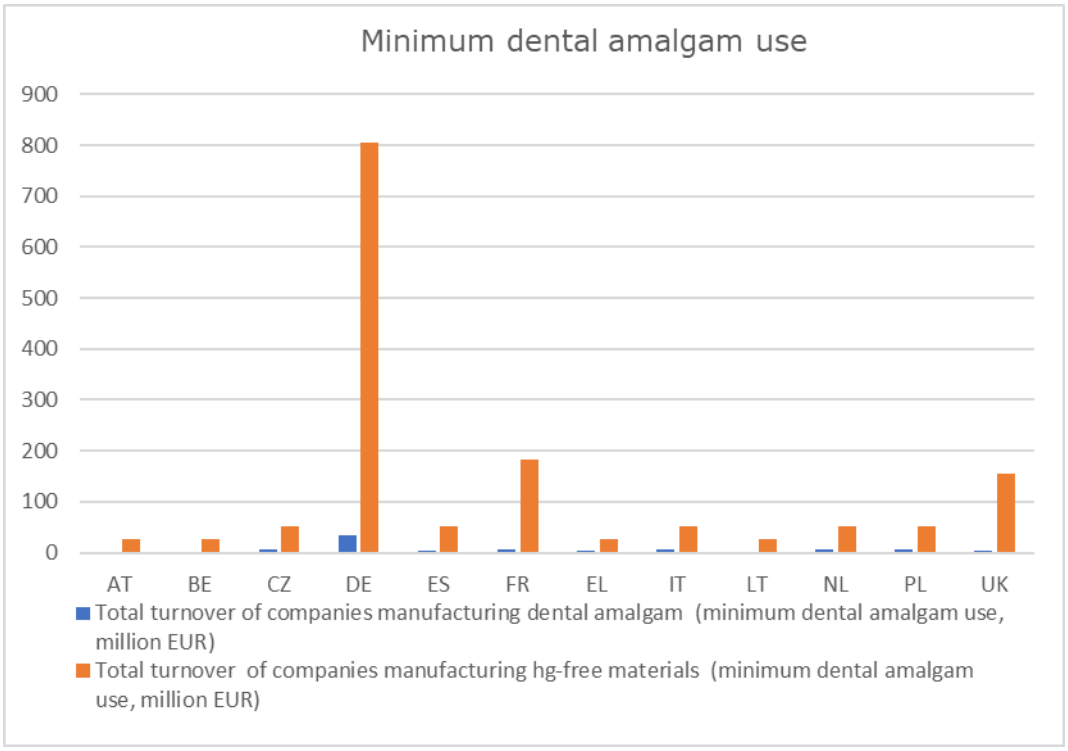
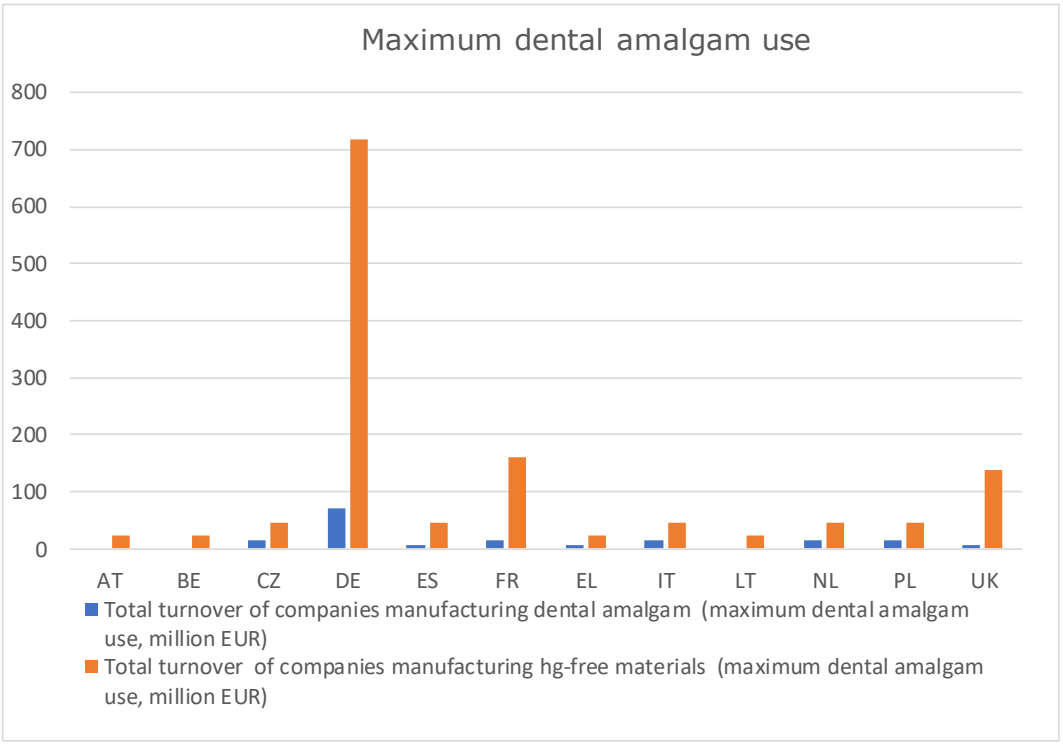


Figure 11: Annual revenue of manufacturers of filling materials per Member State based on the estimated maximum use of dental amalgam (million EUR, 2018)



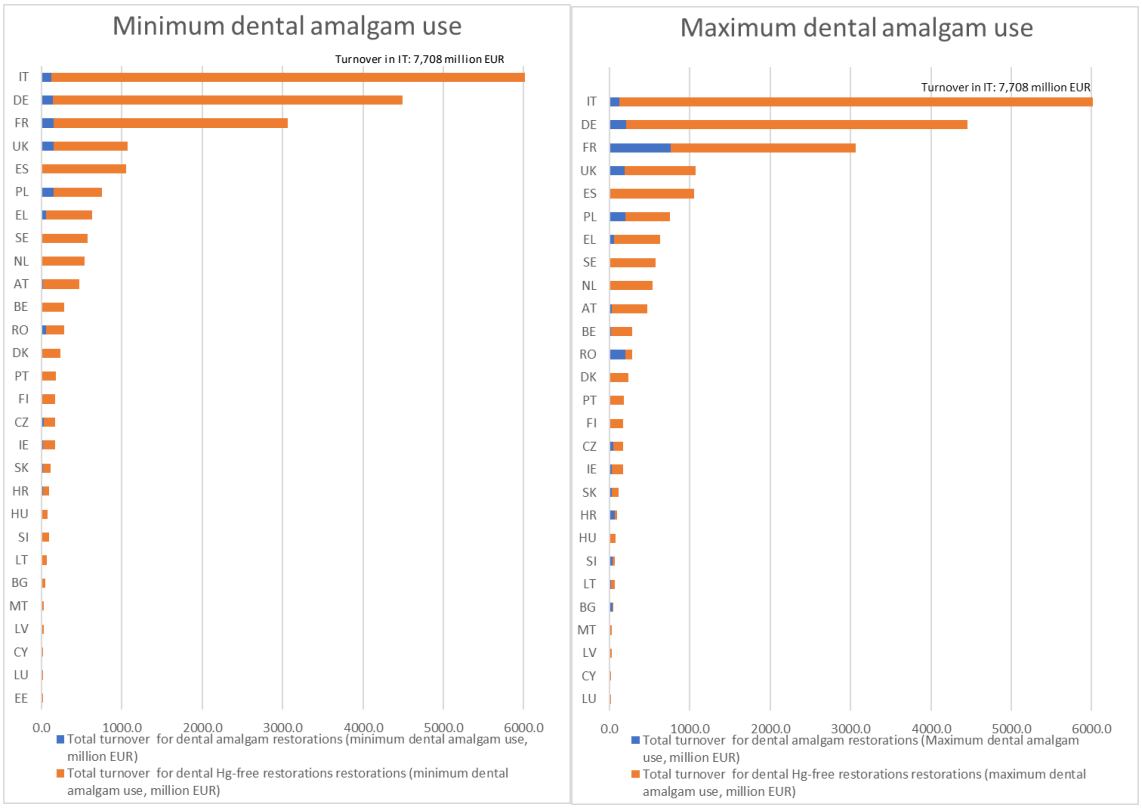
Revenues of dentists

In the EU28, in 2018 there were approximately 75 dentists for every 100,000 inhabitants on average. According to the BIO Intelligence Service Study, in 2009, the average number of dentists was 62 for every 100,000 inhabitants in the EU27. This indicates a gradual increase in the number of dentists.

The figure below presents an estimation of the total turnover of dentists per Member State. This estimate is calculated based on the number of restorations per material and the estimated cost of restoration per material and per Member State. Specifically, for each Member State the estimated number of restorations per type of material was multiplied by the average price of respectively dental amalgam and mercury-free restorations. Both the number of restorations, as well as the prices, greatly affect the estimations.

For this reason, the most populous Member States also appear to have significantly higher revenues. It must be noted, as also explained above, that the cost of restorations is known only for specific countries. The reason for this discrepancy is the fact that most price estimates refer to the reimbursable part of restorations. Overall, it can be assumed that the actual price difference is higher in most Member States than the difference presented in Figure 9. **Thus, the turnover of dentists, particularly from mercury-free restorations can also be assumed to be higher.**

Figure 12: Annual revenues of dentists per Member State with a minimum and a maximum use of use of dental amalgam (million EUR, 2018)



In relation to dental amalgam use, the costs that are incurred by dentists also relate to the installation and maintenance of amalgam separators. The regular collection and

treatment of amalgam waste as hazardous waste also constitutes a significant share of the cost as it occurs on a regular basis. Nevertheless, it is assumed that the costs that relate to the installation and maintenance of amalgam separators and the collection of waste are included in the fees and therefore they are passed to the patients and the reimbursement schemes.

Solid waste from dental amalgam

Dental amalgam as a hazardous waste must be treated and managed considering Directive 2008/98/EC[84], under which dentists are responsible for properly managing amalgam waste[85]. Proper mercury waste management implies minimisation, segregation, reuse and recycling of dental amalgam[86]. Minimisation involves not only the reduction of the use of hazardous material such as dental amalgam, but also the separation of non-hazardous waste from hazardous waste. To that end, in the EU, dental surgeries must be equipped with amalgam separators to retain and collect amalgam particles to avoid the discharge of dental amalgam into wastewater treatment plants[15].

Amalgam separators are devices installed on a vacuum line at dental surgeries. They filter out and collect solid mercury and other particles from wastewater (using different technologies such as centrifugation, filtration, sedimentation, etc.)[87], to reduce the amount of amalgam released to the sewage system.

According to the EU Manual of Dental Practice[88] published by the Council of European Dentists, 22 out of the 28 EU Member States already have binding legislation requiring the use of amalgam separators (except BG, EE, IE, IT, LT, PT and RO). Evidence collected from the study survey indicates that, in 16 Member States that provided data, all dental facilities are equipped with amalgam separators. Their efficiency as reported is 95% with the exemption of CZ where the average efficiency is estimated at 90%. It must be noted, however, that according to Article 10 of the Mercury Regulation, for separators installed after 2018, a retention level of 95% is required. For older separators, retention levels might be (much) lower but need to be upgraded by 1 January 2021. This will also affect the amounts of mercury from dental amalgam that are currently captured in amalgam separators.

In the present study, it is generally assumed that approximately 90% of dental clinics are equipped with amalgam separators as according to the EU Manual of Dental Practice, not all dental clinics in the EU were equipped with dental amalgam separators. It is further assumed that the average efficiency of the separators is 90%. A relatively low efficiency of separators is assumed as in certain cases the efficiency is lower due to poor maintenance. For example, evidence collected in the context of the present study suggests that in HU 40% of dental units are very old and their actual efficiency is significantly lower than the declared value.

Based on the assumptions described in Appendix D, page 314 (and illustrated in Figure 21), through this filtering process, **12.7 t – 27.4 t of mercury is estimated to be captured and collected from waste management contractors**. From this amount, about 80% is treated as hazardous waste and 20% as non-hazardous waste. An additional amount of **4.5 t - 9.8 t** derives from surplus mercury that is left over after the preparation of dental amalgam fillings. From this amount, about 70% is treated as hazardous waste and 30% as non-hazardous waste. Also an amount of **3.4 t - 7.3 t derives from lost and extracted teeth** and is treated as either hazardous waste

[84] Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32008L0098)
[85] World Health Organization (WHO) (2011), Future use of Materials for Dental Restoration.
[86] Daou et al. (2015), Current status of dental waste management in Lebanon.
[87] Center for Scientific Information, ADA Science Institute (2017), Amalgam separators and waste best management (ada.org).
[88] Council of European dentists (2015), EU Manual of dental practice (http://cedentists.eu/library/eu-manual.html).

(40%), non-hazardous waste (30%) or biomedical waste (30%). The treatment processes for each of these flows are based on findings of the BIO Intelligence Service study. Nevertheless, it is generally assumed that gradually all collected waste will be treated as hazardous waste as a result of Article 10(4) of the Mercury Regulation (see also section 3.5).

Based on information collected through the study survey, there are significant differences in the prices of dental amalgam separators, which in general range between 1,000 EUR and 3,000 EUR. The collection and treatment of dental amalgam waste also differs significantly as for each kg, costs range between 15.3 EUR in CZ to 60 EUR in DE. In CY, on average the collection of waste per amalgam separator is between 400 and 500 EUR per year. Significant price differences are also found within the same Member States. In some cases, the dental amalgam is collected without charge given that there can be a positive value from its treatment e.g. collection of the silver component of the amalgam. Even if the mercury does not have significant value (and is most often sequestered), the revenues from the recycling of the alloys can be higher than the costs of the collection and treatment.

Despite the drop in the use of dental amalgam and the increasing use and efficiency of amalgam separators, discharges are still occurring from historical use of dental amalgam (i.e. replacement of old fillings), dental amalgam that is trapped in pipes and possibly other sources that do not relate to the use of dental amalgam (e.g. pharmaceuticals, old thermometers, etc.).

From an economic perspective, it was stated by an expert in the context of the present study that the contamination of sewage sludge with mercury and the need to incinerate the sludge instead of using it in the agricultural sector, creates a cost increase for local wastewater treatment plants.

Mercury releases to water

As highlighted in the BIO Intelligence study, the removal of old amalgam fillings is the main source of dental amalgam released to wastewater via the clinic vacuum pump or similar systems. During the placement of new amalgam fillings, there is also some surplus of amalgam that is discharged to wastewater. In addition, the use of high-speed drills leads to mercury emitted to air or released to water during the replacement of old amalgam fillings and the placement of new ones.

The following paragraphs provide an estimate of the mercury emissions to water, air and soil. The estimates below, together with the assumptions, are outlined in Appendix D, page 314 and illustrated in Figure 21. **Overall, it is estimated that the amount of mercury that derives from current and historical dental amalgam restorations that are released to the water range between 3.5 - 7.6 t.** Of this, an amount of 3.0 t - 6.4 t derives from dental facilities and corresponds to the amounts of mercury that are not trapped in chairside filters or dental amalgam separators. An additional amount of 0.5 t - 1.2 t derives from releases during the treatment of solid dental amalgam waste, collected from dental amalgam separators.

Additional releases derive from the following sources:

- Accumulation of mercury in pipes in dental clinics from past restorations may also contribute to additional releases.
- Releases from the human body through faeces and urine can eventually end up in waste treatment plants and in sludge. Past evidence suggests that on average,

a person with dental amalgam restorations releases 27 - 190 micrograms Hg/24 h via faeces and 1.8 - 19 micrograms Hg/24 h via urine[89].

There is not sufficient data to quantify the amounts accumulated in pipes and associated releases or the releases from the human body.

Mercury releases to the air

A significant amount of mercury emissions to the air arise during cremations and during incineration of dental amalgam solid waste. A stabilisation of those types of emissions seems to have occurred since 2005[90]. Based on information collected from the study survey, the cremation rate of deceased people in the EU has been increasing. This is based on increasing trends reported in BE, DK, FI, LV, NL and UK. The share of crematoria equipped with mercury abatement technology is in general increasing. In addition, according to the BIO Intelligence Study, EU citizens now keep their teeth for a longer period due to improvements in dental treatment.

Currently, there is no specific legislation at EU level that requires Member States to install mercury abatement technologies in crematoria. The requirements at EU level are set only through the Oslo-Paris (OSPAR) Recommendation 2003/4, which recommends the use of Best Available Techniques (BAT) and could be applied to crematoria to prevent and control the dispersal of mercury to the environment[91]. Only 11 Member States are Parties to this convention[92]. The survey that was carried out in the context of this study indicates that at least HR, CZ and LT have not installed such technologies in their crematoria.

Based on information collected in the study survey it is estimated that currently there are approximately 1,000 crematoria in the EU28 with at least 3.2 million cremations being carried out annually. Overall, there is an increasing preference for cremation over burial. According to Eurostat, in 2018 5.3 million people died in the EU28. It is generally assumed that 60% of these people were cremated and the remaining 40% were buried (the assumptions are described in Appendix D).

A recent study published by the Irish Environmental Protection Agency[93], state that due to fluoridation and improved dental care, adults in Ireland have fewer missing teeth. However, they have more teeth with fillings as a result. Given that similar prevention measures have been applied in EU Member States, it can be assumed that a larger number of teeth filled with dental amalgam will be cremated.

If on average, the content of mercury in each deceased person is 1g and about half of the crematoria are equipped with abatement technologies, **it is estimated that the emissions of mercury from dental amalgam in crematoria are approximately 1.6 t.** Other sources of air emissions include releases from dental facilities during the dental restoration processes including drilling (0.2 t - 0.5 t) and releases from existing restorations (0.6 t – 1.3 t). The assumptions of this estimate are described in Appendix D, page 317.

[89] Skare Enqvist , sept /oct 1994. Vol. 49 (No 5) Archives of Environment Health

[90] BIO Intelligence Service (2010), Review of the Community Strategy concerning Mercury (http://ec.europa.eu/environment/chemicals/mercury/pdf/review_mercury_strategy2010.pdf).

[91] https://www.ospar.org/documents?d=35427

[92] The OSPAR signatories are Belgium, Denmark, the European Union, Finland, France, Germany, Iceland, Ireland, the Netherlands, Norway, Portugal, Spain, Sweden and the United Kingdom of Great Britain and Northern Ireland.

[93] Environmental Protection Agency Research (2020), Study on Usage and Waste Management of Amalgam Dental Fillings and Mercury-free Alternative:
http://www.epa.ie/researchandeducation/research/researchpublications/researchreports/Research_Report_307.pdf

Bioavailable dental amalgam

The following table shows the amounts of mercury released to air, water and soil as estimated in the previous sections (deriving both from the current and historical use of dental amalgam). Based on the assumptions described in Appendix D, page 314 (and illustrated in Figure 21), it **is estimated that in the EU, approximately 5.2 t – 9.4 t are emitted to air, 3.5 t – 7.6 t are discharged into water** and **3.1 t – 6.8 t end up as solid waste or in groundwater.** The aggregation of these estimates represent the total amount of mercury that becomes bioavailable (11.8 t – 23.8). In addition, it is estimated that the amount of 15.0 t– 32.5 t year **are sequestered or recycled**. The total estimates from the present study and the underlying assumptions in Appendix D.

Table 5: Estimated amounts of bio mercury treated and emitted from dental amalgam (2018)

Type of discharge/ treatment	Releases estimated in our study (t/y)
Treated mercury from dental amalgam	
Sequestered or recycled	15.0 – 32.5
Discharged mercury from dental amalgam	
Air	5.2 – 9.4
Water	3.5 – 7.6
Solid and ground water	3.1 – 6.8
Total emitted (bioavailable)	11.8 – 23.8

As also described in section 3.3, some releases of mercury from dental amalgam to the environment are converted into methylmercury, the most toxic form of mercury. Exposure to methylmercury is associated with health impacts, including the loss of IQ. A study demonstrated a loss of 0.18 IQ points for each part-per million of maternal hair mercury[94]. In fact, in 2013 the total annual benefits of mercury exposure prevention within the EU achieved through the EU regulations were estimated at around 650,000 IQ points per year[95]. In monetary terms, it was estimated that these benefits correspond to range between 9.25 and 9.5 billion EUR per year.

The contribution of dental amalgam to IQ losses due to exposure to mercury is not known. **Nevertheless, it can be assumed that the use of dental amalgam also contributes to IQ losses and is associated with significant costs, which are not estimated in the previous sections due to limited data.**

Employment

The total number of jobs associated with the production of dental fillings in the EU28, could not be estimated due to lack of data on employment in the industry, particularly on the share that is associated with dental amalgam and mercury-free restorations. The number of manufacturers of dental fillings in the EU28, with a breakdown by Member State and by type of filling materials, is presented in Appendix D, page 302. In addition, an estimate of the revenue of the manufacturers is provided in Figure 10. No information could be obtained on the number of jobs associated with dental waste management.

[94] Bellinger D et al (2016), Country-specific estimates of the incidence of intellectual disability associated with prenatal exposure to methylmercury, Environmental Research

[95] AMEC et al (2017), Study on the cumulative health and environmental benefits of chemical legislation, available at: https://op.europa.eu/en/publication-detail/-/publication/b43d720c-9db0-11e7-b92d-01aa75ed71a1/language-en

The progressive substitution of dental amalgam with mercury-free materials is not expected to create major socio-economic changes in the industry, since, if excluding 3 out of 61 companies, all manufacturers already produce mercury-free filling materials. In addition, according to an expert opinion (see Section 3.2), currently there is no production in the EU but only repackaging of dental amalgam imported from non-EU countries.

3.4 Policy objectives

The general objective of the Mercury Regulation is to significantly reduce the build-up of mercury in the EU's environment. The objective of this study is to understand whether EU action to further phase-out mercury dental amalgam use in dentistry is feasible.

3.4.1 Description of policy options

Different policy options for the phase-out of dental amalgam have been examined, some of them excluded from further analysis at an early stage. Among these were options that would allow a phase-out of dental amalgam in Member States at different timeframes, depending on their current uses. Under these options, a longer timeframe for a phase-out would be allowed in Member States where the share of dental amalgam restorations is still high. This longer timeframe would be granted to allow a smooth implementation of actions that are required for a phase-out (e.g. development of required skills for all dentists and restructuring of the reimbursement schemes). However, these options were excluded as it could distort the functioning of the internal EU market.

For this reason, the present assessment considers a phase-out for all Member States over different timeframes. In this context, the following policy options are assessed.

- No additional policy action at the EU level (BaU): Under this scenario, the EU would not take any additional measures. However, Member States would implement their phasing down or phase-out strategies based on their National Action Plans. A complete phase-out would apply only for specific categories of patients as per Article 10(2) of the Mercury Regulation.
- Option 1 (OP1): A complete phase-out by 2025
- Option 2 (OP2): A complete phase-out by 2027
- Option 3 (OP3): A complete phase-out by 2030

The phase-out in OP1, OP2 and OP3 would not only be applied to the use of dental amalgam in restoration, but also the manufacturing, export and import of dental amalgam (including encapsulated items).

Nevertheless, it must be highlighted that a phase-out does not refer to a complete ban. Certain exceptions that relate to specific categories of patients or medical specificities, based on the experience in SE, are assumed to be allowed. In 2009, a general ban on mercury came into force that better corresponded with the Swedish environmental quality objective for "a non-toxic environment". This ban allowed exceptions for certain categories of patients. Despite these exceptions, in 2017, dental amalgam was used only once for restoration in SE. In 2018, there were no restorations with dental amalgam and all exemptions were withdrawn.

The provision of a definition of the exceptions are not included in the scope of the present study. An assessment commissioned by the Danish Health Agency

recommended the limitation of dental amalgam restorations to the following cases only[96]:

- Lack of possibility of drying
- Difficult accessibility to the cavity
- Particularly large cavity
- Large distance to neighbouring tooth

In SE, before 2018 when a total ban was implemented, the use of dental amalgam was allowed only in the following exceptional cases[97]:

- Technical difficulties in the placement of alternative materials
- Adverse reactions to alternative materials
- In restorations done under general anaesthesia

The required amounts to perform these restorations in SE can reportedly be covered by stocks of encapsulated dental amalgam or imports from non-EU countries.

3.5 Technical feasibility

Before describing the expected impacts for each of the options, a summary **of key aspects with respect to the technical feasibility** of a phase-out of dental amalgam by mercury-free materials is provided below. This study considered the following materials: composite resins, glass ionomers cements (also in combination with composites, for medium to large cavities with sufficient enamel limitation in the posterior region). It must be noted that although prevention and promotion of dental health are important aspects that affect the number of restorations in general, these were not included in the scope of the technical feasibility assessment

Performance of restoration materials

As also assessed in section 3.2, to date, evidence has shown that mercury-free materials exhibit satisfactory mechanical properties, with a lower cavity preparation requirement for composites[98] as well as aesthetically better results compared to dental amalgam[99]. However, composite and glass ionomer might exhibit lower durability than dental amalgam in the long term[100] [101].

Evidence collected through interviews with dental professionals in the context of the present study points towards concerns on a potential phase-out of dental amalgam. Notably, it was pointed out that mercury-free materials might not be technically sufficient in certain cases, especially when the patient has a moisture control issue. Composite reportedly cannot tolerate any moisture contamination and such patients require more treatment in the long run if dental amalgam is not available. In addition, it was pointed out that mercury-free materials have not yet proven to be as durable as dental amalgam, but overall the views are divergent among professionals. Overall, dentists and other dental professionals highlight the significance of prevention and preventive dentistry.

[96] Danish Health Agency, Phasing-out of amalgam in dental care - clarifying options and recommendations
[97] Based on information received from an expert in the context of the present study
[98] Mulligan, S., et al. "The environmental impact of dental amalgam and resin-based composite materials." *British Dental Journal* 224.7 (2018): 542.
[99] Milosevic, Milos. "Polymerization mechanics of dental composites–advantages and disadvantages." Procedia Engineering 149 (2016): 313-320.
[100] British dental journal (June 22, 2018), volume 224 n°12
[101] Moraschini et al. (2015), Amalgam and resin composite longevity of posterior restorations: a systematic review and meta-analysis. Journal of dentistry, 43, 1043-1050.

Despite several studies and reviews having been conducted, comparing the performance of composite materials with dental amalgam would require additional evidence[102] and it currently remains inconclusive. As described in section 3.2 at least for composite materials, these differences are not deemed to be significant, at least in countries where a ban of mercury-free materials has improved the performance of mercury-free fillings due to enhanced skills during the restoration process. As also explained in section 3.2, over time, the differences in the longevity of the materials has reduced significantly due to improvements in the materials used and in restoration skills. Glass-ionomer cement restorations appear to show superior retention levels when compared with resin-based composite restorations in follow-ups after one and five years[103].

Restorations with alternative dental materials require additional equipment such as dental dams or light curing units, inducing technological investment costs for dentists if they were not already equipped[104]. The extent to which access to additional equipment is a barrier to feasible implementation of a phasing out is unknown. Nevertheless, given the high use of mercury-free materials across the EU, and based on expert opinion provided in the context of the present study, it can be assumed that only a very limited number of dental facilities in the EU are not already equipped with the required equipment.

All EU Member States already teach/practice with alternative materials, some especially focusing on those materials since amalgam fillings represent a relatively small share of total dental fillings in most Member States. Therefore, it is assumed that dentists with the required training, skills as well the required equipment to perform restorations with mercury-free materials are available in all Member States. In fact, in certain Member (LT and NL), students in dental schools are only trained to use mercury-free materials. There might be some practitioners in certain Member States that are trained to use dental amalgam only, but it can be assumed that these are small in number and most likely close to retirement. This assumption is based on a statement from an expert in CZ (where the use of dental amalgam remains relatively high). In addition, according to a survey conducted by the Irish EPA Research, in IE, 5% are not confident in their technical ability to place composites in unretentive cavities[105]. These dentists received their training prior to 1990 and may have received clinical training in the placement of composites for posterior teeth. Overall, 31% of dentists in IE have not received clinical training in the placement of posterior composite as part of their dental school training. However as only 5% are not confident in their technical ability and assuming that these dentists are close to retirement, it can be assumed that a further reduction of dental amalgam use will not affect the sector as a whole.

Safety profile of alternative materials

Regarding the safety profile of alternative materials to dental amalgam, the current study agrees with both SCENIHR and SCHER that data is lacking with respect to alternative materials[106] [107].

Dental restoration materials are medical devices regulated under Regulation 2017/745 which, requires dental manufacturers to assess the biocompatibility and the risks of

[102] Kean M. et al., "Measures to reduce the clinical need for dental amalgam, Evidence review", Health Research Board, Dublin, 2020.
[103] Kean M. et al., "Measures to reduce the clinical need for dental amalgam, Evidence review", Health Research Board, Dublin, 2020.
[104] Mulligan, S., et al. "The environmental impact of dental amalgam and resin-based composite materials." *British Dental Journal* 224.7 (2018): 542.
[105] EPA Research (2020), Study on Usage and Waste Management of Amalgam Dental Fillings and Mercury-free Alternatives
[106] SCHER, 2014. Opinion on the environmental risks and indirect health effects of mercury from dental amalgam (http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_165.pdf)
[107] SCENIHR, 2015. Scientific opinion on the Safety of Dental Amalgam and Alternative Dental Restoration Materials for Patients and Users.(https://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_046.pdf)

unintended side effects. Alternative materials (and related adhesive systems) are complex chemical mixtures some of which involve volatile monomers and organic solvents that may lead to toxicological issues[108]. However, information on the exact composition of alternative materials as well as extensive and rigorous risk assessment (including hazards, concentration, behaviour in the long run, metabolisation) are lacking, which makes it difficult for stakeholders to understand the alternatives' safety profile. Therefore, practical and effective implementation of Regulation 2017/745 regarding the safety of mercury-free materials could represent a challenge.

In the wider literature reviewed, particular attention has been given to Bisphenol A (BPA). The SCENHIR[109] pointed out the potential occurrence of BPA in dental care medical devices, not as a compound but rather as a contaminant or as the result of a degradation process within the material or in saliva. Indeed, concerns have been rising regarding BPA exposure associated with resin-based composite alternative materials such as methacrylate monomers (e.g. Bis-GMA, UDMA, TEGDMA…)[110] [111]. It seems that diffusion of monomers could result from the incomplete polymerisation, hydrolytic degradation of composites resins or introduction as a manufacturing contaminant, which could result in BPA exposure[112] [113].

Identified exposure scenarios highlight long-term oral exposure and short-term oral exposure related to dental material, as well as inhalation from dust during laying. The SCENHIR concluded that **release of BPA from some dental materials was associated with only negligible health risks**[114]. Some evidence has been found of exposure to BPA but is within the Tolerable Daily Intake[115]. However, these conclusions are based on the last BPA risk assessment by EFSA, which is currently under review.

Nevertheless, resins that are alternatives to Bis-GMA and Bis-DMA do exist. These include Uréthane DiMéthAcrylate (UDMA) based resins[116] and more recently alternative resins are based on siloranes[117] in place of methacrylates[118].

In addition, **concerns exist in relation to toxicological aspects due to the presence of up to 60% of nano-sized filler particles within composites**[119]. Indeed, it has been shown that the placement and removal of mercury-free materials are abrasive processes that produce dust particles involving various unpolymerised monomer nano-particles originating from the composite. The latter can lead to health risks for the exposed dental personnel who are then exposed to a higher risk of developing asthmatic diseases[120].

[108] SCENIHR, 2015. Scientific opinion on the Safety of Dental Amalgam and Alternative Dental Restoration Materials for Patients and Users.(https://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_046.pdf)
[109] SCENIHR, 2015. "The safety of the use of bisphenol A in medical devices"(https://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_040.pdf)
[110] Robberecht Lieven et al, 2016 « Le bisphénol A en Odontologie », Bio matériaux cliniques, vol n°1, Université de Lille (http://wala.elteg.net/id/media/bmc-1-2-p96-99.pdf)
[111] Mulligan, S., et al. "The environmental impact of dental amalgam and resin-based composite materials." *British Dental Journal* 224.7 (2018): 542.
[112] Mulligan, S., et al. "The environmental impact of dental amalgam and resin-based composite materials." *British Dental Journal* 224.7 (2018): 542.
[113] SCENIHR, 2015. "The safety of the use of bisphenol A in medical devices"(https://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_040.pdf)
[114] SCENIHR, 2015. Scientific opinion on the Safety of Dental Amalgam and Alternative Dental Restoration Materials for Patients and Users.(https://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_046.pdf)
[115] BISFENOL A I DENTALA MATERIAL SOCIALSTYRELSEN, 2015
[116] https://substitution.ineris.fr/sites/substitution-portail/files/newsletter/newslettersna_10_1216_v2b_gb_0.pdf
[117] Siloranes are a combination of siloxane and oxiranes. The silorane composites generate lower volume shrinkage and stress upon polymerization.
[118] SCENIHR, 2015. Scientific opinion on the Safety of Dental Amalgam and Alternative Dental Restoration Materials for Patients and Users.(https://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_046.pdf)
[119] Van Landuyt et al. (2013), Nanoparticle release from dental composites. Acta biomaterialia 10 365-374.
[120] Cokic, S. M., et al. "Release of monomers from composite dust." *Journal of dentistry* 60 (2017): 56-62.

Use of the existing mercury-free materials allow a phase-out of dental amalgam, which is feasible despite the biocompatibility concerns in relation to BPA and nano-sized filler particles. However, scientific literature has shown so far that hazards related to mercury-free materials cannot be excluded. **Therefore, data gaps arising from the lack of comprehensive studies on mercury-free materials and substance behaviour require additional research that would provide a better overview of alternative safety profiles.** For clarity, the available information on the hazards of mercury and dental amalgam is far more extensive than that for (potential) alternative materials used in dentistry.

The table in Appendix G provides a review of current hazard classifications under EU regulation (REACH and CLP data) associated with the main substances found in methacrylate-based resin composites matrix as well as BPA. The list in Appendix G is not exhaustive, as the regulation profile may evolve along with the development of new scientific evidence and hazard notifications by industry. The same applies to any restoration material, including dental amalgam. Siloranes, not shown in the Table, are substituted cyclosiloxanes. Several cyclosiloxanes have been classified as PBT or vPvB chemicals under REACH.

Regarding the **environmental safety** of alternative materials, the issue of their complexity also makes their assessment difficult. To what extent Regulation 2017/745 will address the environmental risk also remains to some extent undetermined. Mercury-free materials might involve the release of chemicals that are hazardous for the environment, such as BPA and several methacrylate monomers. BPA might be removed (to a certain extent) from wastewater by WWTPs[121] and (naturally) from sludge, but there is less information available on the fate of methacrylate monomers. Regulation 2017/745 considers risks to human health of CMR and endocrine disrupting substances (Annex I, Chapter II, section 10.4 "Substances", and section 14.7 "Safe disposal"). However, consideration of risks to the environment is not made explicit. The Regulation provides that further guidelines on "other endocrine disrupting substances" will be prepared by the Commission (section 10.4.4) but it is not specified whether the guidelines will address environmental hazards and impacts of endocrine disrupting chemicals. Similarly, "safe disposal of related waste substances by the user" should be described in the instructions for use of the device (section 14.7), but it is not specified whether these instructions would be based on an environmental risk assessment.

3.6 Analysis of impacts

This chapter assesses the potential direct and indirect environmental, social, and economic impacts of the policy options listed in section 3.4.1. The aim of the assessment is to provide clear information on the likely impacts of the policy options as a basis for comparing them against one another and the business as usual (BaU) scenario.

3.6.1 Environmental impacts

Quantities of dental amalgam produced

The figure below provides an overview of the projections of dental amalgam use under the BaU scenario as well as OP1, OP2 and OP3 between 2018 and 2030.

As shown by the figure, the decrease is expected to be substantial even under the BaU scenario given the historical decreasing trends that are expected to further continue, given the ban of the use of dental amalgam in certain population categories and based on Member State NAPs to phase down dental amalgam. Based on the trends presented in section 3.2 (explained in Appendix D, 298) it is estimated that under the BaU scenario the demand for dental amalgam will reach 12.4 t – 26.7 t in 2025, then 10.2 t – 22.3

[121] Zielinska M. et al., 2018, « Bisphenol A Removal from Water and Wastewater", Springer

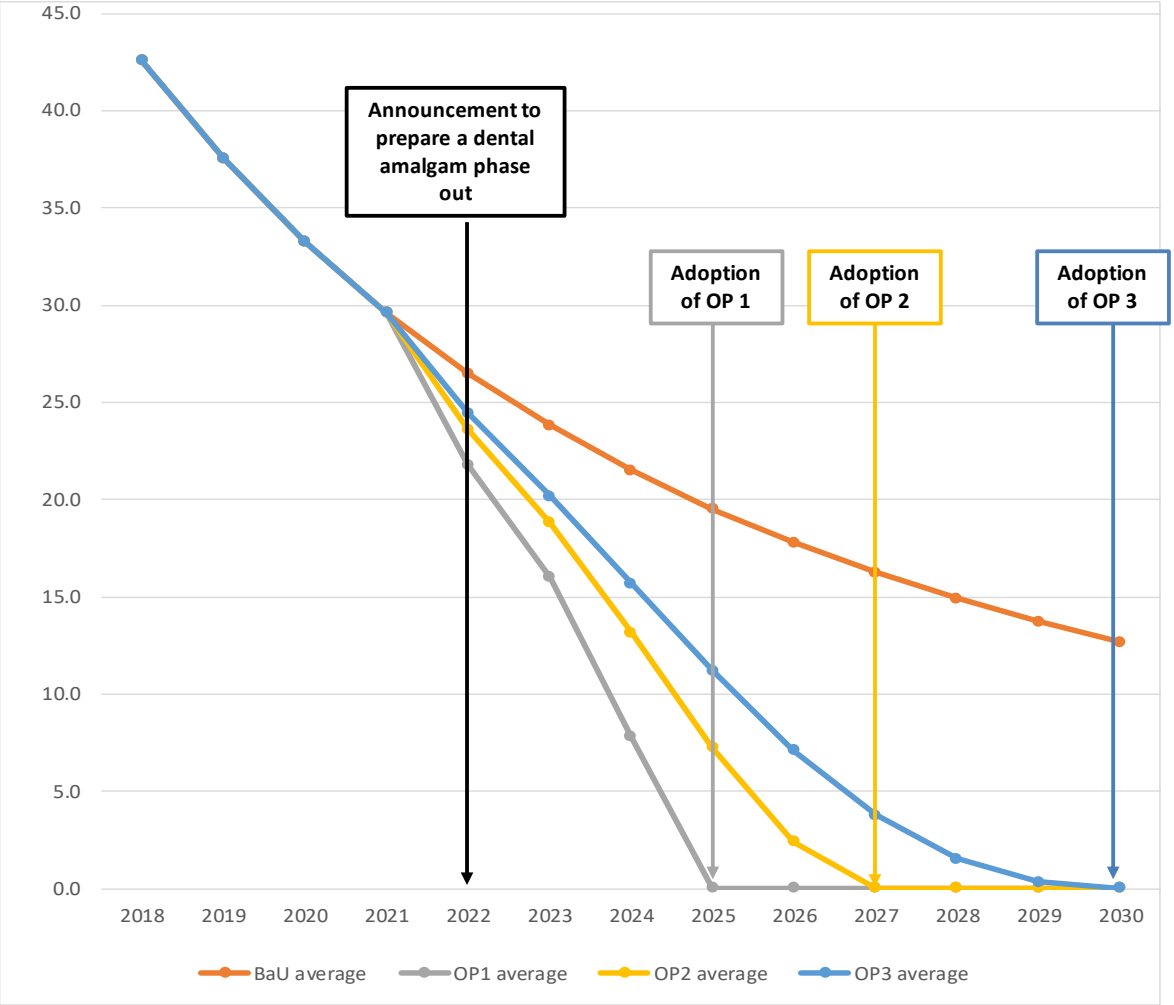
in 2027 and finally 7.9 t – 17.5 t in 2030 at the EU 28 level. Nevertheless, some substantial use is still expected, particularly in Group 1 countries and Member States with a large population (particularly in BG, HR, RO, SI as well as FR and the UK).

The implementation of OP1, OP2 and OP3 would require a substantial reduction of use of dental amalgam. The decrease that is assumed for each of the scenarios are included in the table below. In the BaU scenario, a linear decrease is assumed for the whole period between 2018 and 2030. The estimate of this decrease is detailed in Appendix D. OP1 would require a further decrease that will be accelerated before the year of the implementation of the dental amalgam phase-out (2025). The same applies for the other scenarios as it is generally assumed that the rate of the decrease will gradually accelerate. It is assumed that a decision to prepare a legislative act to phase-out dental amalgam at the EU level is made in 2022. Therefore, until 2021, the reduction rate for all 3 policy options is equal to the reduction rate of the BaU scenario. From 2023 onwards a sharp decrease is expected in all policy options until the phase-out becomes applicable (2025 in OP1, 2027 in OP2 and 2030 in OP3). The acceleration of the reduction rate is linear in all 3 policy scenarios, resulting in nearly no quantities of dental amalgam use in the year of implementation of the scenarios (very small amounts could still be used after the year of the implementation of the phase-out, in accordance with the allowed exemptions, but these are considered to be negligible).

Table 6: Average annual decrease of dental amalgam use per scenario

Scenario/ year	BaU	OP1	OP2	OP3
2018	-12%	12%	12%	12%
2019	-12%	12%	12%	12%
2020	-12%	12%	12%	12%
2021	-12%	12%	12%	12%
2022	-12%	-26%	-20%	-17%
2023	-12%	-26%	-20%	-17%
2024	-12%	-51%	-30%	-22%
2025	-12%	-99%	-45%	-29%
2026	-12%	0%	-67%	-37%
2027	-12%	0%	-99%	-47%
2028	-12%	0%	0%	-60%
2029	-12%	0%	0%	-77%
2030	-12%	0%	0%	-98%

Figure 13: Estimated amounts of dental amalgam produced under BaU, OP1, OP2 and OP3



It can be argued that certain Member States will require more time for the implementation of the options for instance, for the adaptation of their reimbursement schemes and perhaps for the retirement or retraining of dentists that might be skilled in the use of dental amalgam only. As assessed in section 3.5 on technical feasibility, only a limited number of dentists would be affected as dentists with no adequate skills are assumed to be small in number and close to retirement. In addition, based on information collected in the context of the present study (see section 3.5) only a very limited number of dental facilities are not equipped with the equipment required to perform mercury-free restorations (e.g dental dams or light curing units).

Quantities of dental amalgam waste produced

Regardless of whether dental amalgam is phased out or not, the use of amalgam separators in all dental facilities will still be required due to the existing amalgam fillings that will remain in people's mouths. Nevertheless, a phase-out would eliminate the discharges from the current use (mainly from the carved surplus amalgam remaining during placement).

Under the BaU scenario, the total waste captured in amalgam separators (to be collected and treated by specialised contractors) is estimated to amount to 12.7 t -27.4 t in 2018, 7.6 t – 16.3 t in 2025, 6.3 t - 13.6 t in 2027 and 4.8 t - 10.6 t in 2030. This estimate assumes a significant improvement in the coverage and efficiency of the dental amalgam

separators as a result of the implementation of Article 10 (4) of the Mercury Regulation that requires that, as of 1 January 2021, all Member States must ensure that facilities with amalgam separators attain a retention level of at least 95%. The underlying assumptions are described in Appendix D, page 314.

The implementation of the policy scenarios will result in a reduction of the collected waste due to the reduction of dental amalgam use. Nevertheless, a significant amount of waste will still be collected from amalgam separators, mainly due to the removal of historical dental amalgam fillings. Specifically, the collected amount under OP1 in 2025 is estimated at 6.0 t – 13.0 t, with 5.0 t – 10.8 t under OP2 in 2027 and 3.8 t – 8.4 t. The dropping amounts for collected waste occurs due to the gradual decrease of historical amalgam, which is expected to be higher in 2030 compared to 2025 and 2027.

Dental Hg emissions to air, water, soil and groundwater

The table below provides the estimated amounts emitted to the different environmental media in the different assessed timeframes for each of the policy scenarios. The table provides the average amounts of discharges that correspond to the average use of dental amalgam in the different years of implementation of the policy scenarios. All amounts in the table aggregate the annual treated and discharged amounts between 2018 and 2030. The aggregated amounts of the BaU scenario are presented in three different periods (i.e. between 2018 and 2025, 2027 and 2030). The estimates are also illustrated in the figures below.

Table 7: Average cumulative amounts of mercury per type of treatment or discharge per environmental medium and per scenario (tonnes)

Type of treatment or discharge	BaU			Options		
	2025	2027	2030	OP1 - 2030	OP2 -2030	OP3 -2030
Treated mercury from dental amalgam						
Collected from amalgam separators	129.2	150.0	175.1	160.9	163.6	166.1
Sequestered or recycled	176.0	204.7	239.3	209.7	216.2	222.3
Discharged mercury from dental amalgam						
Air	36.2	43.2	52.8	48.8	49.2	49.6
Water	31.9	35.8	40.4	37.0	37.6	38.1
Solid and ground water waste	13.5	15.1	17.0	12.1	12.4	12.8
Total emitted (bioavailable)	81.6	94.1	110.2	97.9	99.2	100.5

Figure 14: Average cumulative amounts of treated mercury from dental amalgam per scenario (tonnes)

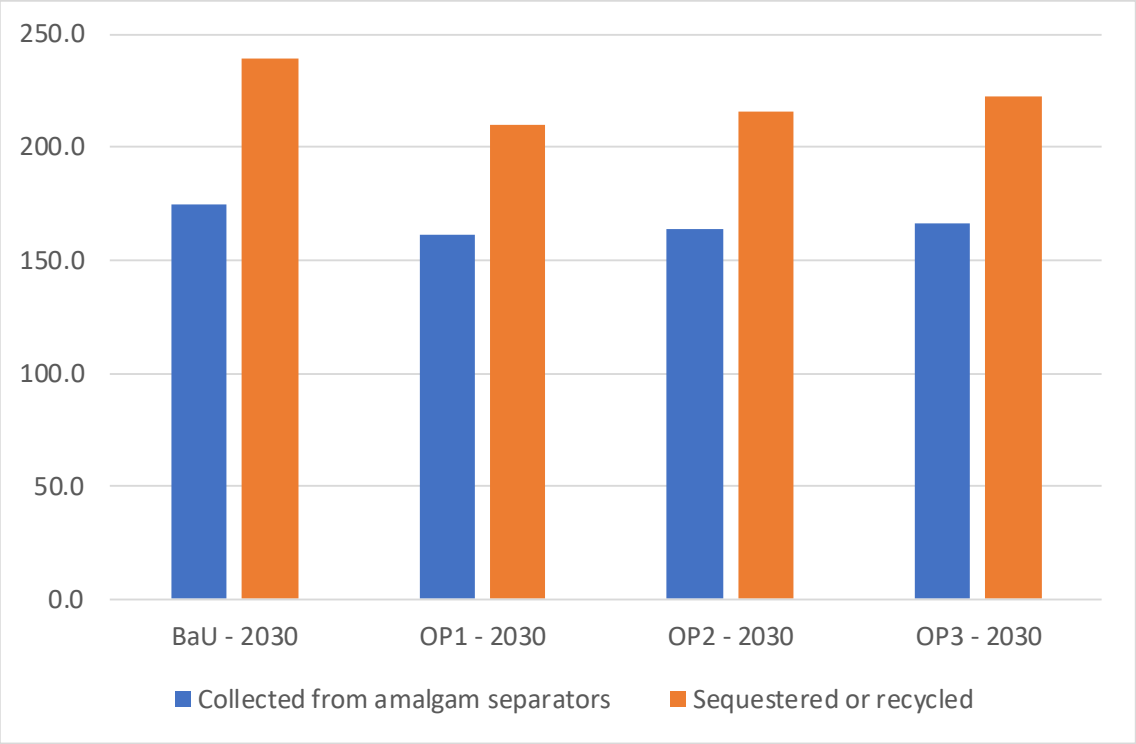
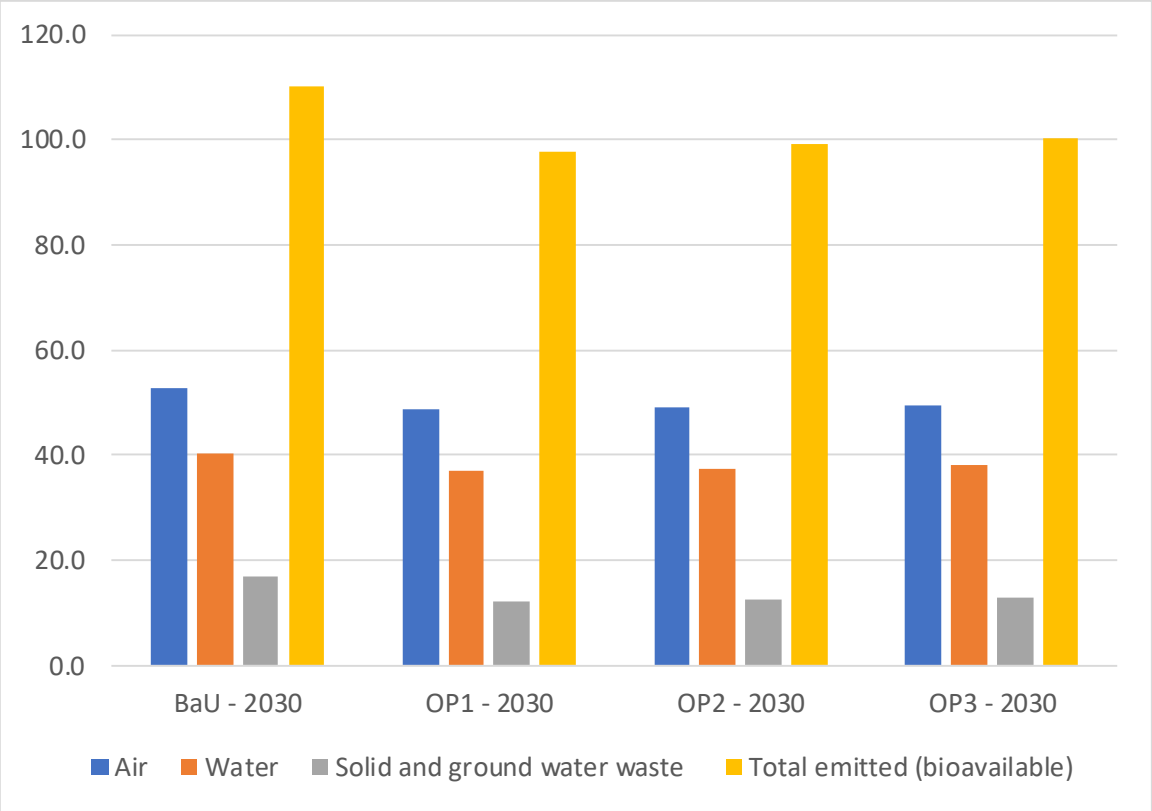


Figure 15: Average cumulative amounts of mercury from dental amalgam discharge per environmental medium and per scenario (tonnes)



As regards the policy options, under the same assumed improvements on the coverage and performance of dental amalgam separators and crematoria (see Appendix D), it is estimated that the cumulative amounts of mercury becoming bioavailable will be reduced between 2018 and 2030, on average for OP1 by 12.3 t, for OP2 by 11 t and for OP3 by 9.8 t. The exact amounts of mercury per treatment process or medium of discharge is presented in Table 8. Therefore, the reductions are significant but the emitted amounts under all policy scenarios are also estimated to be significant due to the continuous effects from the removal and treatment of historical dental amalgam. Due to these effects from historical dental amalgam the differences in the environmental impacts between the policy options are not significant during the assessed period (2018-2030). More significant reductions can be expected under these policy options after 2030 as the historical accumulation of dental amalgam in people's mouths will continue to decrease.

Table 8: Cumulated differences between the BaU scenario and OP1, OP2 and OP3 on the average amounts of mercury per type of treatment or discharge per environmental medium (tonnes)

Type of treatment or discharge	Options		
	OP1 - 2030	OP2 -2030	OP3 -2030
Treated mercury from dental amalgam			
Collected from amalgam separators	-14.2	-11.5	-9.0
Sequestered or recycled	-12.3	-11.0	-9.8
Discharged mercury from dental amalgam			
Air	-4.0	-3.6	-3.2
Water	-3.4	-2.8	-2.3
Solid and ground water waste	-4.9	-4.6	-4.3
Total emitted (bioavailable)	-12.3	-11.0	-9.8

Evidence exists on the effect of a phase-out of dental amalgam and the concentrations of mercury measured in wastewater treatment facilities. Data provided by EurEau in the context of the present study indicate that the concentration of mercury in a WWTP in Upsala (SE) indicated a gradual reduction of mercury concentration from 2.43 mg of Hg per kg of sludge in 1989 to 0.47 mg in 2019 as a result of the phase-out in SE. The potential effects of other sources (e.g. deposited atmospheric mercury on soil, linkages from mercury thermometers, removal of historical dental amalgam fillings etc.) is unclear. However, given the constant decrease of mercury concentrations in sewage sludge during the period of the ban of dental amalgam in SE, it can be assumed the impact of this ban was significant.

3.6.2 Economic impacts

Impacts on SMEs

Data on the share of SMEs among the total number of companies that are affected directly by the use of dental amalgam (or mercury-free materials) cannot be estimated based on the available information. At least for the dental clinics, it can be assumed that the number of SMEs is small as the vast majority are micro enterprises operating with personnel that ranges between 1 and 2 dentists per clinic. A significant number of SMEs can be assumed in the wastewater management, restoration material manufacturing and funeral service sectors as well as in the service sector that specialises in the collection and treatment of amalgam waste from amalgam separators. A potential

phase-out of dental amalgam is not expected to have a significant economic impact on these sectors, except for the solid waste collection and treatment facilities. The implementation of OP1 would have a more significant impact on their revenues compared to OP2 and OP3 as it would reduce higher amounts of collected waste (see Table 8 above).

Competitiveness of EU dental fillings industry

Implementation of the ban on the use of dental amalgam as implied by OP1, OP2 and OP3 will affect patients, dentist practices and manufacturers of dental cements and fillings. In particular, the ban would adversely affect manufacturers of dental amalgam requiring them to increase production of mercury-free materials or to continue dental amalgam manufacturing only for export. The ban would accelerate the shift from the use of dental amalgam in dentistry towards mercury-free alternatives stimulating research and innovation and increasing competition between dental filling manufacturers.

Level of innovation in dental filling materials

The use of mercury-free alternatives has been growing in recent years and this trend is expected to continue. In turn, projected demand for mercury-free materials is expected to boost further investments in research and development (R&D) and innovation. Demand is anticipated to increase for composites and glass ionomers stimulating innovation and improving technical characteristics. Implementation of the amalgam phase-out proposed under OP1, OP2 and OP3, would accelerate research and innovation into alternative materials, likely improving their performance (e.g. longevity) and decreasing production costs, thereby making them more affordable.

Revenues of the dental fillings industry

In the BaU scenario, it is estimated that revenues from the manufacturing of dental filling materials will increase in all policy options. The cumulative revenues of the dental filling manufacturing industry per scenario by 2025, 2027 and 2030 are presented in the table below.

Table 9: Cumulative revenues of the dental filling manufacturing industry per scenario by 2025, 2027 and 2030 (million EUR)

Option	Cumulative revenues since 2018		
	2025	2027	2030
BaU	10,811 - 11,189	15,564 - 16,039	18,755 - 19,284
OP1	10,927 -11,243	15,863 - 16,179	19,154 - 19,470
OP2	10,877 - 11,220	15,788 - 16,144	19,079 - 19,435
OP3	10,856 - 11,210	15,726 - 16,115	19,011 - 19,403

This increase results from the gradual substitution of dental amalgam with mercury-free materials and is based on the changes of the share of dental amalgam and mercury-free restorations. This estimate assumes that the total number of restorations will remain the same regardless of the selection of the restoration material. Therefore, it is assumed that the longevity between the different types of materials is not different. However as described in section 3.2, the evidence of differences in the performance of dental amalgam and mercury-free restorations is inconclusive. Even if the performance of mercury-free materials is gradually improving due to enhanced skills of dentists, this assumption has a considerable level of uncertainty.

In addition, the use of dental amalgam will also drop significantly under the BaU and this trend will accelerate as a result of the implementation of the Member State NAPs.

Under these assumptions, the revenue will not change substantially between the BaU and the assessed policy options.

Revenues and costs of dentists

As in the case of the turnover of the dental filling industry, the cumulative revenues of dentists under the BaU scenario and the policy options was estimated based on the number of restorations per type of material. The cumulative revenues for each scenario and different timeframes are presented in the table below.

Table 10: cumulative revenues of dentists per scenario by 2025, 2027 and 2030 (million EUR)

Option	Cumulative revenues since 2018		
	2025	2027	2030
BaU	180,808 - 181,148	226,159 - 226,549	271,538 - 271,971
OP1	181,025 -181,287	226,508 - 226,771	271,992 - 272,254
OP2	180,926 - 181,219	226,401 - 226,696	271,884 - 272,179
OP3	180,874 - 181,182	226,310 - 226,632	271,786 - 272,110

The relatively small difference in the cumulative turnover, can be explained due to small differences in the prices between the dental restorations that are carried out with dental amalgam and mercury-free materials as well as the increasing share of mercury-free materials under the BaU scenario. Nevertheless, as explained in section 3.2 the actual prices might be significantly higher than those collected in the context of the present study. The latter represent in most cases the reimbursable amounts which in general are lower than those paid to the dentists.

A potential phase-out of dental amalgam is also expected to affect costs that are borne by dentists for the collection and treatment of waste from amalgam separators. This cost is estimated to range significantly between Member States as well as within countries. For example, in CZ the cost per kg of sludge from amalgam separators is estimated at 15 EUR and in DE at 60 EUR. According to an expert opinion, in DE the collection from some contractors is free of charge as the costs are covered by the revenues of the waste treatment facilities from the recovery of valuable metals from the alloys.

The amounts of waste from historical use will remain high within the assessed timeframe (i.e. up to 2030). In addition as per Article 10(2) of the Mercury Regulation, the effectiveness and monitoring of the performance of the dental amalgam separators as well as the collection and treatment of the collected waste will improve (see Appendix D for the assumptions on the relevant improvements). For this reason, the collected and treated amounts are expected to increase (see Table 8 above).

Direct costs borne by patients for dental restoration

The direct costs borne by the patients in the BaU scenario and under the policy options correspond to the revenues of dentists that are described in the paragraphs above. As also highlighted in the paragraphs above, the actual price difference between dental amalgam and mercury-free restorations might be significant[122]. It must be noted however, that a possible phase-out is expected to decrease the prices of mercury-free restorations, due to improved skills on placing mercury-free restorations and innovation. In addition, it can be assumed that the reimbursement schemes will be adapted to the phase-out and the mercury-free restorations will be fully or partially covered by the

[122] The data collected refer mainly on the reimbursable prices, but the actual prices might be higher if the national health systems do not fully reimburse these prices.

schemes. Nevertheless, this will have an impact on the schemes themselves. According to a calculation presented by the German Government to the Bundestag, banning dental amalgam would lead to an additional cost burden to the German public health system in the order of 1 billion EUR per year[123]. It is not known if this estimate considers a potential decrease in the prices of alternatives over time.

Hg abatement costs for crematoria

The use of dental amalgam has raised concerns on the emissions of mercury, particularly in the OSPAR countries. For this reason, in several facilities, certain abatement technologies have been installed to minimise such emissions. Regardless of whether dental amalgam will be phased-out or not, such technologies will still be required due to the large amounts of mercury accumulated in people's mouths. In addition, the abatement technologies are not installed for the control of mercury emissions only, but also for other pollutants. Therefore, it is assumed that implementation of the policy options will not have a significant impact on the costs associated with the installation and maintenance of abatement technologies in crematoria as, at least in OSPAR countries, such measures are already implemented.

The cremation rate of deceased people in the EU is increasing (see section 3.3). In addition, EU citizens now keep their teeth for a longer period due to improvements in dental treatment. Therefore, the amount of historical dental amalgam that is cremated has tended to increase. Due to these different parameters, it was estimated that EU mercury emissions from cremation will remain at a similar level to those in 2010 until 2025 (i.e. 1.9 t hg /year). Then, due to an increased preference for mercury-free materials, it is expected that gradually the amounts of mercury emissions from crematoria will drop. The trends in the installation of abatement technologies at crematoria are uncertain. Nevertheless, it can be assumed that an increasing number of crematoria, at least in Parties to the OSPAR Convention, will be equipped with such technologies. According to the second assessment on Recommendation 2003/4[124], the majority of these contracting parties have put in place regulations which control mercury emissions from crematoria which require crematoria to have emissions permits and a significant number apply mercury removal techniques Also at the EU regional level, HELCOM Recommendation 29/1[125] on the reduction of emissions from crematoria, which applies to three EU Member States (DK, FI, and SE), recommends that mercury emissions be kept below the limit value of 0.1 mg/Nm^3 in crematoria with a capacity exceeding 500 cremations/year. More recently, the German Engineers Association (VDI) published Guidance Document no. 3891 on BAT in Human Cremation Facilities (2013, confirmed in 2019)[126] stating that the typical mercury emission is between 0.0001 and 0.05 mg/m^3 if dust filters and/or sorbents are used (fixed bed or sorbent injection).

Administrative costs for public authorities

According to Article 14 of the Mercury Regulation, Member State Authorities are obliged to report annually on the implementation of the Regulation. The reporting obligations include the progress of implementation of their National Action Plans concerning the phase down of dental amalgam. Therefore, a prospective phase-out is not expected to impose additional monitoring and reporting requirements. It is assumed that the monitoring and reporting of the phase-out will be carried out simultaneously with the implementation and monitoring of the requirements on the efficiency and maintenance of amalgam separators. In addition, as the phase-out would allow certain exemptions,

[123] Bundesregierung (2018): Antwort der Bundesregierung auf die Kleine Anfrage der Abgeordneten Dr. Bettina Hoffmann, Dr. Kirsten Kappert-Gonther, Kordula Schulz-Asche, weiterer Abgeordneter und der Fraktion BÜNDNIS 90/DIE GRÜNEN – Drucksache 19/3065 –. In Bundestagsdrucksache (19/3065)

[124] OSPAR (2016), Implementation of OSPAR Recommendation 2003/4 on Controlling the Dispersal of Mercury from Crematoria, Second Overview assessment

[125] www.helcom.fi/Recommendations/en_GB/rec29_1/?u4.highlight=mercury ban

[126] https://www.vdi.de/richtlinien/details/vdi-3891-emissionsminderung-anlagen-zur-humankremation

the existing requirement to track and report on the amounts of mercury used in dentistry are expected to remain.

3.6.3 Social impacts

Jobs in EU manufacturing industry of dental filling materials

The available information does not allow quantification of jobs in the manufacturing industry under the BaU scenario. However, as the revenues are expected to increase slightly, it can be assumed that the number of jobs will also increase at low levels or remain the same assuming that the same number of employees are adequate for such a marginal increase. This is also due to the fact that according to an expert opinion provided in the context of the present study, there is no production of dental amalgam in the EU but only repackaging which is less labour-intensive. This increase is expected to be higher under OP1 as the increase would occur in 2025 whereas OP2 and OP3 would be implemented respectively in 2027 and 2030.

Health conditions

A phase-out of dental amalgam is expected to have both direct and indirect benefits for EU society. Given that the Mercury Regulation has already banned the use of dental amalgam for vulnerable populations (i.e. children below 15 years old, pregnant and breastfeeding women), the greatest expected direct benefits are lowering exposure of dental personnel to mercury. In addition, significant benefits are expected from the reductions of bioaccumulated mercury in the environment, which also in turn is expected to reduce the formation of methylmercury and hence have the potential to affect people (see section 3.6.1). These benefits are expected to be higher under OP1 as risks for dental personnel will cease sooner. The same applies for the releases of accumulated mercury as the releases of mercury from new dental amalgam fillings will cease immediately, as well as discharges from past fillings reducing more quickly.

Nevertheless, the potential health risks of mercury-free materials cannot be disregarded. As highlighted in section 3.5, there is a general lack of scientific evidence in relation to the use of alternative materials and substance behaviour. There are still concerns in relation to mercury-free materials, particularly in relation to the presence of nano-particles and bisphenol A (BPA). Due to lack of comprehensive scientific evidence, the potential direct and indirect impacts of mercury-free materials remain uncertain. In addition, as explained in section 3.5, the effect of Regulation 2017/745 on the environmental risks of restoration materials remains to some extent undetermined.

3.7 Summary and comparison

A comparison of the different policy options analysed, based on their respective environmental and socio-economic impacts, is presented in this chapter. Policy options are compared with regard to their potential for achieving the objectives previously set out with a minimum of undesirable side effects.

3.7.1 Inventory and summary of all impacts

A comparison of the impacts for each of the three policy options and the different impact categories and indicators is presented in the table below. The comparison is carried out at the accumulative level (for the period between 2018 and 2030) against the BaU scenario. In the BaU scenario the results are presented also accumulatively for the same period.

Table 11: Inventory and summary of impacts per policy scenario

Impact indicators	Comparison of policy options (compared to the BaU until 2030)			
	BAU	**OP1**	**OP2**	**OP3**
Environmental impact indicators				
Mercury use in EU	195.8 t – 423.6 t (until 2030)	119.5 t – 257.7 t (reduction by 76.3 t – 257.7 t)	131.9 t– 284.4 t (reduction by 63.9 t – 139.2 t)	144.1 t – 310.4 t (reduction by 72.7 t – 113.2 t)
Quantities of dental amalgam waste produced (sludge collected from amalgam separators)	110.7 t - 239.5 t (until 2030)	101.8 t - 220.1 t (reduction by 8.9 t – 19.4 t)	103.5 t - 223.7 t (reduction by 7.2 t – 15.8 t)	104.9 t - 227.3 t (reduction by 5.8 t – 12.3 t)
Hg emissions to air / to water / to soil within the EU (total bioavailable discharges)	77.9 t - 142.6 t (until 2030)	70.1 t - 125.7 t (reduction by 7.8 t – 16.9 t)	71.0 t- 127.5 t (reduction by 6.9 t – 15.0 t)	71.7 t - 129.3 t (reduction by 6.2 t – 13.3t)
Economic impact indicators				
Revenues of EU dental filling manufacturing	18,755 - 19,284 million EUR (until 2030)	19,154 - 19,470 million EUR (Increase by 186 - 398 m EUR)	19,079 - 19,435 million EUR (Increase by 151 - 324 m EUR)	19,011 - 19,403 million EUR (Increase by 119 -256 m EUR)
Revenues for dentists	271,538 - 271,971 million EUR (until 2030)	271,992 - 272,254 million EUR (Increase by 284 - 494 m EUR)	271,884 - 272,179 million EUR (Increase by 209 - 346 m EUR)	271,786 - 272,110 million EUR (Increase by 140 - 248 m EUR)
Hg abatement costs for dentists		-	-	-
Hg abatement costs for crematoria		0	0	0
Hg abatement costs for public authorities		-	-	-

Direct costs borne by patients	+	+	+
Administrative costs	0	0	0
Social impact indicators			
Jobs in EU manufacturing industry	+	+	+
Health conditions	++ (dental amalgam) ? (alternative materials)	++ (dental amalgam) ? (alternative materials)	++ (dental amalgam) ? (alternative materials)
Other criteria			
Hg emissions to air / to water / to soil outside the EU	-	-	-
Hg use outside the EU	-	-	-
Degree of uncertainty/risk	Low	Low	Low
Technical feasibility	High	High	High

'+++': very beneficial effect; '++': substantial beneficial effect; '+': slight beneficial effect; '-': negative effect, '--': substantial negative effect; '---': very negative effect; '0': no effect; '?': unknown effect

3.7.2 Comparison of impacts

While the BaU scenario (i.e. without any further policy at the EU level) assumes a gradual decrease in dental amalgam demand until 2030 (with the average annual reduction rate of 12%) the dental amalgam used will remain significant. Specifically, it is estimated that under the BaU Scenario, the total amount of dental amalgam that will be used in the EU28 (including the UK) between 2018 and 2030 will reach 195.8 t - 423.6 t in 2030. The consumption in 2030 will be lowered by about 19.0 t - 40.8 t, compared to current annual levels.

Nevertheless, the use of dental amalgam will still be high in certain Member States if accelerated actions are not taken, most importantly in BG, HR, RO, SI (Group 1 countries) as well as FR and the UK that have a large population. The implementation of OP1, OP2 and OP3 would therefore ensure that the use of dental amalgam will

practically cease in all Member States simultaneously (but within different timeframes), thus avoiding the release of significant amounts of mercury to the environment. Some amounts of dental amalgam will still be used in exceptional cases as in the model applied previously in SE or currently in DK (see section 3.4).

Nevertheless, even if any of the policy options are implemented, there will still be significant amounts of mercury emitted to the environment, deriving from the historical use of dental amalgam. Respectively, the total amounts of mercury released until 2030 will reach 70.1 t - 125.7 t under OP1, 71.0 t- 127.5 t under OP2 and 71.7 t - 129.3 t under OP3. These emissions are expected to cease within a timeframe that exceeds the current timeframe of the analysis (i.e. until 2030). Even if a specific estimate cannot be provided in the context of the present study, it can be argued that an earlier implementation of a phase-out will lead to higher avoided emissions from current uses as well as from historical uses in the long-term. Therefore, the implementation of OP1, which calls for a phase-out in 2025, is expected to result in the avoidance of larger amounts of mercury. Additional reductions can be expected in non-EU countries due to spill-over effects at the international level, derived from the knowledge exchange that already occurs in the context of the implementation of the Minamata Convention.

Also from an economic perspective, earlier implementation is expected to create larger benefits for the EU manufacturing industry and dentists. These benefits derive from relatively high prices of mercury-free materials and restorations, compared to dental amalgam[127]. In addition, as the manufacturing of dental amalgam might be limited to repackaging only, the replacement of this repackaging with an actual production of mercury-free materials is expected to have a positive impact both in terms of turnover increase and creation of jobs.

With regards to the price differences, evidence collected in the context of the present study shows that this difference is decreasing due to improvements on technical aspects and skills required for restorations with mercury-free materials (including impacts on time required for restorations). In contrast, costs are expected to increase for the national reimbursement schemes and perhaps the patients as well (if the reimbursement schemes are not adapted to reflect the price differences), again due to the differences in prices. These differences might be eliminated through a reduction of prices on the mercury-free materials (e.g. through enhanced skills and reduction of the time required for mercury-free restorations).

Especially in countries where the price differences are currently high, the costs for patients and the national schemes are expected to be high, at least for a certain amount of time until the improved skills on placing mercury-free restorations decreases the prices. During this transitional period, some additional costs are expected to be borne either by the patients or the reimbursement schemes (i.e. depending on the share of cost coverage of these schemes). Notably, in DE a phase-out of dental amalgam is estimated to cost 1 billion EUR per year. It is unknown whether this estimate considers a potential decrease over time in the price difference between dental amalgam and mercury-free restorations.

With regards to the costs for the installation and maintenance of abatement technologies (i.e. amalgam separators and abatement processes in crematoria), a potential phase-out is not expected to have a significant impact, as these technologies will still be needed to tackle discharges from historical uses of dental amalgam or because of existing legislative requirements. Nevertheless, a phase-out of dental amalgam might lead to the gradual development of mercury-free dental clinics. Such clinics will not be equipped with dental amalgam separators, but patients with dental amalgam fillings in their

[127] The data collected refer mainly on the reimbursable prices, but the actual prices might be higher if the national health systems do not fully reimburse these prices.

mouth will not be admitted. Overall, from an economic perspective an earlier phase-out under OP1 is feasible when considering the benefits for the dental filling industry and dental clinics. Nevertheless, as mentioned above for certain Member States where the difference of the actual prices of restorations per material is high, an early implementation might be challenging either for the patients or the reimbursement schemes. However, the incremental economic and health benefits (e.g. avoidance of IQ loss) that derive from a decrease of mercury releases to the environment will increase the health and wider economic benefits deriving from a phase-out. Such benefits are higher in OP1 which results in higher reductions of mercury releases from dental amalgam.

With regards to the social impacts, a prospective phase-out is not expected to lead to significant changes in the number of jobs. Only certain dentists that do not have the skills required to place mercury-free fillings might be impacted. Nevertheless, the number of such dentists can be assumed to be low, as this study indicates that many of them will be close to retirement (and so most would have retired by 2025-2030). In addition, in relation to the use of dental amalgam, a phase-out would lead to benefits at least for the dental personnel as any health risks that relate to the placement of dental amalgam fillings would be reduced significantly.

Society as a whole is also expected to benefit from a ban on dental amalgam due to the reductions of the amounts of mercury from dental amalgam that becomes bioavailable and thus can be converted to methylmercury with associated risks for human health. Therefore, from a social perspective, again OP1 is the preferred option. Nevertheless, particular attention should be directed towards the potential health and environmental risks of mercury-free materials, especially in relation to the potential discharges of BPA and nano-particles. Therefore, in parallel to a phase-out, accompanying measures may be required to reduce the risk of substitution of dental amalgam with fillings containing toxic substances.

4. Conclusions

The general conclusion of the assessment is that dental amalgam use is decreasing, and a general phase-out is both technically and economically feasible, but with some disruption of the insurance systems in the Member States that are currently using high amounts of dental amalgam and with reimbursement schemes that tend to favour dental amalgam restorations.

Between the last assessment of dental amalgam use in 2010 and today, the use of dental amalgam has dropped by an estimated 43%. Progressive substitution of dental amalgam with mercury-free materials has occurred even without a policy intervention (i.e. before the Mercury regulation came into effect) as patients, in general, prefer mercury-free fillings. Nevertheless, without a phase-out, significant amounts of dental amalgam are still expected to be used in the coming years. This use will prolong the associated environmental and health impacts associated with the current use of dental amalgam. This prolongation is arguably unnecessary given that technology for a full substitution already exists and is advancing. Dental amalgam might be still required in specific medical cases that do not allow substitution with mercury-free materials. Nevertheless, based on the experience in Sweden where certain exceptions were allowed, such cases appear to be very rare (i.e. only one case in 2017 and none in 2018).

From a legislative perspective, the continuation of dental amalgam use could hinder and perhaps reduce the effectiveness of other legislation and measures that target the impacts of mercury, most notably the Water Framework Directive 2000/60/EC which classifies mercury as a priority hazardous substance (requiring cessation or phasing out of discharges, emissions and losses) and also Directive 2008/105/EC that sets environmental quality standards for mercury. EU legislation has already set the basis for the ban of mercury on a number of products (e.g. thermometers, batteries and blood pressure monitors) where alternatives existed. From an international perspective, the phasing-out of dental amalgam would be a strong signal towards the implementation of the objectives of the Minamata Convention and perhaps gradually set the paradigm for a phase-out at international level. Given the transboundary nature of mercury, the latter would further decrease the risk of mercury pollution at the EU level.

Should such a general phase-out be considered, it would be important to (1) better understand whether exceptions to a general prohibition may be needed to take account of patients with special medical needs and, (2) assess whether accompanying measures would be required to reduce the risk of substitution of dental amalgam with fillings containing toxic substances.

In parallel to a phase-out of dental amalgam, efforts to prevent tooth decay should continue. Prevention is in general one of the key measures promoted in the National Action Plans and is regarded as effective in reducing the number of both dental amalgam and mercury-free fillings.

Appendix A Stakeholder list

Table 12: List of stakeholders that received the online questionnaire

Member state	Type of organisation	Name of organisation
AT-Austria	Amalgam separator manufacturer	Metasys AG, Austria
	Crematoria business	Benu
		Krematorium Wien
	Dental association	Österreiche Zahnärztekammer
	Funeral Services	Fachverband der Bestattung
		Himmelblau Bestattung
	Health authority	Sozial Ministerium
	Water treatment	Österreichische Vereinigung für das Gas- und Wasserfach
		Österreichischer Wasser- und Abfallwirtschaftsverband
BE-Belgium	Crematoria business	Crematorium Hofheide
	Dental association	Chambres Syndicales Dentaires asbl
		Council of European Dentists (CED)
		KREIOS bvba
		L'Union Francophone des Laboratoires Dentaires de Belgique
		SOBOR-BEVOR
		Union Francophone des Orthodontistes de Belgique
	Dental fillings manufacturer	Codema
		DMG Chemisch Pharmazeutische Fabrik GmbH
	Environmental agency	Zero Mercury Working Group
	Expert	University of Gent
	Funeral Services	Fédération Nationale des Unions Professionelles et Chambres Syndicales des Entrepreneurs des Pompes Funèbres de Belgique (FUNEBRA)
	Health Authority	Federal Agency for medicines and health products
	NGO	amalgaam.be
		European Environmental Bureau (EEB)
		Health Care Without Harm Europe
		IEB - Inter Environnement Bruxelles
	Other	Biological dentist, Cheop Health Center
	Waste treatment	DEME Environmental Contractors
		DEME Environmental Contractors
		INDAVER nv
		INDAVER NV
	Wastewater Treatment	AQUAWAL

Member state	Type of organisation	Name of organisation
		Aquafin NV
		EWTA- European Water Trade Association
		Fédération Belge du Secteur de l'Eau
BG-Bulgaria	Dental association	Bulgarian Dental Association
	Health authority	Vice-President of the Standing Committee of Dental Practice and Professional Defense
	Water treatment	Bulgarian Water Association
CY-Cyprus	Dental association	Cyprus Dental Association
	Env. authority	Ministry of Agriculture, Rural development and Environment
		Ministry of Environment
		IESC - Innovating Environmental Solutions Center
		IESC - Innovating Environmental Solutions Center
		Senior Environment Officer
	Funeral Services	G&P Melas Funeral Directors
	Health authority	Cyprus National Committee on Environment and Child's Health
		Cyprus Medical Association
		Cyprus Chemical & Pharmaceuticals Companies
	Insurance	Insurance Association of Cyprus (IAC)
	NGO	Federation of Environmental and Ecological Organizations of Cyprus
	Waste	Association of Hazardous Waste Management Companies (SEDEA)
		Advance Medical Waste Management
	Water treatment	Water Board of Nicosia
	Other	Association of Pharmaceutical Chemical Industries of Cyprus (FARCHIM)
CZ-Czech Republic	Dental association	Czech Dental Chamber
	Dental fillings manufacturer	Bome s.r.o.
		SAFINA, a.s
	Drinking water supply and wastewater treatmenr	SmVaK Ostrava a.s.
	Environmental national authority	Ministry of Environment
	Funeral Services	Sdruzeni Pohrebnictvi v Cr
	Health national authority	Ministry of Health
	NGO	ARNIKA ASSOCIATION
	Water treatment	Water Supply and Sewerage Association of the Czech Republic
DE-Germany	Amalgam separator manufacturer	Durr Dental
		DÜRR DENTAL AG
	Dental association	Bundeszahnartzekammer

Member state	Type of organisation	Name of organisation
		Bundeszahnartzekammer
		Bundeszahnrztekammer
		Federation of the European Dental Industry – FIDE
		PAIN-ESSEN
	Dental fillings manufacturer	3M ESPE
		Association of German Dental Manufacturers (VDDI e.V.)
		BBFU - Bundesverband der Beratungsstellen für Umweltgifte
		DENTSPLY DeguDent GmbH
		Dr. Ihde Dental GmbH
		Heraeus Kulzer Dental GmbH & Co. KG
		Kaniedenta Dentalmedizinische Erzeugnisse GmbH & Co. KG
		M & W Dental
		Merz Dental GmbH
		S&C Polymer GmbH
		Voco GmbH
	Dental NGO	IG Umwelt Zahn Medizin gUG
	Env. Authority	Federal Ministry for the Environment
		German environment Agency
	Funeral Services	RAL Gutegemeinschaft Krematorien
		Bundesverband Deutscher Bestatter e.V.
	NGO	BUND - Friends of the Earth Germany
		Deutsche Umwelthilfe e.V. - German Environment Aid
		Deutscher Naturschutzring (DNR)
		VHUE - Verein zur Hilfe umweltbedingt Erkrankter e.V.
		BUND - Friends of the Earth Germany
	Other	Department of Operative Dentistry and Periodontology, University of Regensburg
		EUROPEAN ACADEMY FOR ENVIRONMENTAL MEDICINE
		Universitätsklinikum Freiburg
		Dentist
		Universitätsklinikum Freiburg
		University of Regensburg
	Recycling and waste management	Enretec GmbH
	Expert	University of Munich
		Univeristy of Regensburg

Member state	Type of organisation	Name of organisation
		University of Freiburg
	Waste treatment	NQR Nordische Quecksilber Rückgewinnung GmbH
		NQR Nordische Quecksilber Rückgewinnung GmbH
		Begemann Milieutechniek B.V
		DELA GmbH
		DELA GmbH
		DELA GmbH
		Deutsche Steinkohle AG, Abt BA3 Umweltshudz
		GMR Gesellschaft für Metallrecycling mbH
	Water treatment	Bundesverband der Energie- und Wasserwirtschaft e.V.
		Deutche Vereinigung des Gas- und Wasserfaches
DK-Denmark	Amalgam separator manufacturer	Rash Dental ApS, Denmark
	Dental association	Aarhus University, Denmark
		Danish Dental Association
		Danish Dental Association
	Env. Authority	Ministry for Environment and Food, Chemical Divison
	Funeral Services	Danske Bedemaend
	Waste treatment	Kommunekemi a/s
		Kommunekemi a/s
	Water treatment	Danish Water and Wastewater Association
EE-Estonia	Dental association	Estonian Dental Association - Eesti Hambaarstide Liit
	Dental clinic	Lumen dental clinic
	Dental fillings manufacturer	Plandent
	Dental manufacturer	Dline
	Env. Authority	Ministry of Environment
	Funeral Services	Tallinna and Tartu Krematoorium
	Perm Rep	EU ENVIRONMENT DELEGATE
	Waste treatment	EJKL
	Water treatment	Eesti Vee-ettevõtete Liit
		Tallinnavesi

Member state	Type of organisation	Name of organisation
ES-Spain	Dental association	Spanish Dental Association
		APDENT -Asociación Profesional de Dentistas
		Spanish Dental Association
	Dental fillings manufacturer	Madespa S.A
	Environmental authority	Ministerio para la Transición Ecológica
	Funeral Services	PANASEF - Asociación Nacional de Servicios Funerarios
	Health authority	Ministerio de Sanidad, Consumo y Bienestar Social
	NGO	ECOLOGISTAS EN ACCION
		ECOLOGISTAS EN ACCION
		MERCURIADOS - Asociacion Espanola de Afectacos por Mercurio de Amalgamas Dentales y Otras
	Water supply and wastewater treatment and collection	Consorcio de Aguas Bilbao Bizkaia
	Water treatment	Asociacion Espanola de Abastecimientos de Agua y Saneamiento
FI- Finland	Dental association	Finnish Dental Association - Suomen
	Environmental authority	Finnish Environment Institute (SYKE)
	Funeral Services	Suomen Hautaustoimistojen Liitto r.y
	Health Authority	Minisgtry of Social Affairs and Health of Finland
	Water treatment	Finnish Water and Wastewater Works Association
FR-France	Crematoria businesses	Association Française d'Information Funéraire
	Dental association	Association Dentaire Française
		CNSD - Confration Nationale des Syndicats Dentaires
		CNSD - Confration Nationale des Syndicats Dentaires
	Dental fillings manufacturer	Dentoria SAS
		Specialities Septodont
		Dentoria SAS
		Specialities Septodont
		Zimmer GmbH
	Funeral Services	Confédération des Professionnels du Funéraire et de la Marbrerie (CPFM)
		Confédération des Professionnels du Funéraire et de la Marbrerie (CPFM)
	NGO	NGO Non au mercure dentaire
	Waste treatment	ALLIATECH ENVIRONNEMENT
		DRS FRANCE/SAGE EXPORT
		Duclos Environnement
		Mercure Boys manufacture (MBM)
		DRS FRANCE/SAGE EXPORT

Member state	Type of organisation	Name of organisation
	Water treatment	ASTEE
		Fédération Professionnelle des Entreprises de l'Eau
GR-Greece	Chemicals	General Chemical State Laboratory
		Hellenic Association of Chemical Industry (HACI)
	Dental association	Hellenic Dental Association
	Dental fillings manufacturer	DMP Dental Materials Ltd
	Drinking water and wastewater	DEYAL (Water and weverage municipal company of larissa)
	Env. Authority	Ministry of Environment & Energy
		Greece National Centre for Environment And Sustainable Development
		Ministry of Environment - Waste Management & Environmental Certification
		Ministry of Environment - General Environmental Policy
	Funeral Services	Association of Funeral Home
		Cremation Society of Greece
	Health	Ministry of Health
	Other	Aristotle University of Thessaloniki, Dpt. of Mechanical Engineering
		UNIVERSITY OF ATHENS
	University	Athens University
	Waste Treatment	Hellenic Recycling Agency
	Water treatment	Hellenic Union of Municipal Enterprises for Water Supply and Sewage
		EYDAP
		EYATH
HR-Croatia	Env. Authority	Ministry of Environment and Energy
	Health Authority	Croatian Institute for Public Health
HU-Hungary	Dental association	National Committee for Hungarian Dentistry
	Funeral Services	MATESZSZ c/o - Magyar Temetkezési Szolgáltatók Országos Szakegyesülete
	Health Authority	Ministry of Human Capacities - State Secretariat for Health
	Professional interest representation	Dental Section of the Hungarian Medical Chamber
	Water treatment	Hungarian Water Utility Association
IE-Ireland	Crematoria business	Mount Jerome
	Dental association	Irish Dental Association Ltd.
		Dental Council of Ireland
	Env. Authority	Department of Communications, Climat Action and Environment - Climate Adaptation, Soils, GMO's and Chemicals Division

Member state	Type of organisation	Name of organisation
		Department of Communications, Climat Action and Environment - Climate Adaptation, Soils, GMO's and Chemicals Division
		Department of Communications, Climat Action and Environment - Climate Adaptation, Soils, GMO's and Chemicals Division
		EPA (Environental Protection Agency)
		Department of Communications, Climat Action and Environment - Environment Advisory Unit
	Funeral Services	Irish Association of Funeral Directors (IAFD)
	Health Authority	Government - Department of Health
		Community Pharmacy, Dental, Optical and Aural Policy
	NGO	VOICE of Irish Concern for the Environment
	Water treatment	County and City Managers' Association
IT-Italy	Dental association	Associazuone Nazionale Dentisti Italiani
	Dental fillings manufacturer	Kerr
		Kerr Sales representatives (Firenze)
		Kerr Sales representatives (Milano)
		Kerr Sales representatives (Roma)
		Kerr Sales representatives (Torino)
	Env. Authority	Italian Ministry of the Environment, Land and Sea
	Funeral Services	Federazione Nazionale Imprese Onoranze Funebri (FeNIOF)
		Bologna Servizi Funerari (FeNIOF)
	Health Authority	Ministry of Health
	NGO	LEGAMBIENTE
	Other national authority	ENEA (Italian Nat Agency for new technologies, energy and sustainable economic dev)
	Waste treatment	Waste italia
	Water treatment	Federazione delle Impresse Energetiche e Idriche
		UTILITALIA
LT-Lithuania	Dental association	Lithuanian Dental Chamber
	Env. Authority	Pollution Prevention Policy Group
	Health Authority	Public Health Safety Conrol Unit
LU-Luxembourg	Dental association	Association des Medecins-Dentistes du Grand-Duch de Luxembourg
	Funeral Services	Erasmy Pompes Funèbres
		Pompes Funèbres Générales Paul Brandenburger Sàrl
	Health Authority	Direction de la Sante

Member state	Type of organisation	Name of organisation
	NGO	AKUT ASBL
	Water treatment	Association Luxembourgeoise des Services d'Eau asbl
LV-Latvia	Dental association	Latvian Dental Association
	Env. Authority	Environmental sector
	Health Authority	Health sector
MT-Malta	Dental association	Dental Association of Malta
	Health Authority	Oral Health Unit in the Department of Health Regulation of malta
	Water treatment	Water Services Corporation
NL-Netherlands	Water treatment	Aquaminerals
NO-Norway	Dental fillings manufacturer	Nordiska Dental AB
	Dental Institute	Nordic Institute of Dental Materials
	Env. Authority	Norwegian Environment Agency
	Other	Executive Secretary Arctic Monitoring and Assessment Programme (AMAP) Secretariat
		Norwegian Institute for Air Research (NILU)
	Water and wastewater	Norwegian Water
PL-Poland	Dental association	Polish Chamber of Physicians and Dentists
	Water treatment	Izba Gospodarcza "Wodociagi Polskie"
		MPWiK SA
PT-Portugal	Dental association	Portuguese Dental Association - Ordem dos Medicos Dentistas
	Environmental agency	Agência Portuguesa do Ambiente
	Funeral Services	Associação Portuguesa dos Profissionais do Sector Funerário (ASSPPSF)
	Waste treatment	CIRVER - INTEGRATED CENTER OF WASTE RECOVERY, VALORIZATION, TREATMENT AND DISPOSAL
	Water treatment	Associacao Portuguesa de Distribuicao e Drenagem de Aguas
		INSAAR - DEPARTAMENTO DE PLANEAMENTO E GESTÃO DO DOMÍNIO HÍDRICO INSTITUTO DA ÁGUA
RO-Romania	Dental association	RDAPP/AMSPPR Romanian Dental Association of Private Practitioners/Romanian Dental Association
	Environmental authority	Ministry of Environment
	Funeral service	Servicii funerare
	Waste treatment	FCC Environment România S.R.L.
	Water treatment	Romanian Water Association
SE-Sweden	Amalgam separator manufacturer	SIE Dental AB
		Sie Dental AB, Sweden
		SRAB, SWEDEN RECYCLING AB

Member state	Type of organisation	Name of organisation
		STENA MILJO AB
		Sweden Recycling AB
		Tekniska Verken i Linköping AB
	Dental association	Department of Dental Materials Science, Faculty of Odontology, Umea University, Sweden
		Swedish Dental Association
	Dental fillings manufacturer	Ardent AB
	Env. authority	Swedish Chemicals Agency-Kemi
		Swedish Chemicals Agency-Kemi
		Ministry of Environment
		Swedish Chemicals Agency-Kemi
		Swedish Environmental Protection Agency
		Swedish Environmental Protection Agency
		Swedish Environmental Protection Agency
		Swedish Ministry of the Environment
		Swedish Ministry of the Environment
		Swedish Ministry of the Environment
		Ministry of the Environment
		Ministry of the Environment
		Ministry of the Environment
		Swedish Chemicals Agency-Kemi
		Swedish Chemicals Agency-Kemi
		Swedish Chemicals Agency-Kemi
		Swedish Chemicals Agency-Kemi
		Swedish Environmental Protection Agency
		Swedish Environmental Protection Agency
		Swedish Environmental Protection Agency
	Funeral Services	Sveriges Begravningsbyraaers Foerbund
		SKKF
		SKKF
	Health authority	Medical Products Agency 'Läkemedelsverket' Medical Devices
		Medical Products Agency 'Läkemedelsverket' Medical Devices
		The Dental and Pharmaceutical Benefits Agency
		folkhalsomyndigheten

Member state	Type of organisation	Name of organisation
		Department of Oral Diagnostics, Faculty of Odontology, Malmö University, Malmö, Sweden
		Department of Oral Diagnostics, Faculty of Odontology, Malmö University, Malmö, Sweden
		Socialstyrelsen (The National Board of Health and Welfare)
		Health and Social Care Inspectorate (IVO)
	Other	IVL Swedish Environmental Research Institute
		KUNGLIGA TEKNISKA HÖGSKOLAN
		Stockholm University, Inst. of Applied Environmental Research
	Perm Rep	EU ENVIRONMENT DELEGATE
		EU ENVIRONMENT DELEGATE
		EU ENVIRONMENT DELEGATE
	Waste treatment	SAKAB AB
		SAKAB AB
		SAKAB AB
	Water treatment	Stockholm Vatten AB
		Swedish Water and Wastewater Association - Svenskt Vatten AB
		Tekniska Verken i Linköping AB
SI-Slovenia	Dental association	The Medical Chamber of Slovenia
	Funeral Services	Zale d.o.o., Javno Podjetje
	Health authority	Ministry of Heath
	Other	Department of Environmental Sciences
SK-Slovakia	Dental association	Slovak Chamber of Dentists
	Env. Authority	Slovakia Environmental Agency
		Ministry of the Environment of the Slovak Republic
	Funeral Services	Slovak Association of Funeral and Cremation Services
	Health Authority	Ministry of Health of the Slovak Republic
		Public Health Service of the Slovak Republic
		Public Health Service of the Slovak Republic
		Slovak Chamber of Dentists
	Water treatment	Asociacia vodarenskych spolocnosti
UK-United Kingdom	Crematoria businesses	Cremation society of GB
		Federation of British Cremation Authorities

Member state	Type of organisation	Name of organisation
	Dental association	Department of Health Chief Dental Office (2007 -) / Committee for Clinical Dental Academic Staff
		1. Postgraduate Dental Dean, Mersey Deanery 2. Restorative Dentistry
		1. University of Birmingham School of Dentistry 2. Restorative Dentistry to South Birmingham Health Authority (Teaching) 3. British Dental Association
		1. University of Sheffield UK 2. British Association for the Study of Community Dentistry
		British Dental Association
		British Dental Association (BDA)
		British Dental Association (BDA)
		British Dental Association (BDA)
		British Society for Oral and Dental Research
		Dental School University of Liverpool, UK
		The British Dental Trade Association
		University of Liverpool, Dental Materials, Cariology, Dental Education
	Dental fillings manufacturer	SS White Group
	Env. Authority	EU and International Chemicals, Department for Environment, food and rural affairs
	Expert	University of Birmingham
		University of Bristol
		Freelance writer
	Funeral Services	National Association of Funeral Directors (NAFD)
	Health Authority	Government - Department of Health
		Scottish Government
		NHS England
	NGO	Greenpeace International
		Mercury Madness
		World Alliance for Mercury-free Dentistry.
		Basel Action Network, Ban Mercury Working Group
		GROUND WORK - FRIENDS OF THE EARTH
		Natural Resources Defense Council
		TOXICS LINK
		Toxics Link - Basel Action Network

Member state	Type of organisation	Name of organisation
	Other	International Academy of Oral Medicine and Toxicology
		Lambert Metals International Ltd
		University of Oxford
		University of Oxford
	University	King's College London
	Waste treatment	Mercury Recycling Limited, UK
		Quicksilver Recovery Services Ltd
		Quicksilver Recovery Services Ltd
	Water and Sewage company	Dwr Cymry
	Water treatment	Water UK
EU	Dental association	Council of European Dentists (CED)
		European Dental Association (EDA)
		European Dental Student's Association (EDSA)
	Dental Authority	CED
	Env. Authority	EEB (European Environmental Bureau)
	Funeral Services	European federation of funeral services
		FIAT-IFTA - THE WORLD ORGANIZATION OF FUNERAL OPERATIVES
		International Cremation Federation
		The European Young Funeral Directors - EYFD
	NGO	ECOS
		European Consumers' Organisation (BEUC)
		European Environmental Bureau (EEB)
		European Public Health Alliance Environment Network
	Other	European Chemicals Agency (ECHA)
		European Topic Centre on Resource and Waste Management (ETC/RWM),
	Waste treatment	FEAD - European Federation of Waste Management and Environmental Services
		FEAD - European Federation of Waste Management and Environmental Services
		FEAD - European Federation of Waste Management and Environmental Services
	Water treatment	EUREAU - European Fedration of national Associations of Water and Wastewater Services
		European Water Association (EWA)
		European Water Association (EWA)

Appendix B Member State reports

Table 13: Respondents of the online questionnaire

Type of organisation	Name of organisation
Dental association	British Dental Association (BDA)
Dental association	Bundeszahnartzekammer
Dental association	Chambres Syndicales Dentaires asbl
Dental association	Federation of the European Dental Industry – FIDE
Dental association	Finnish Dental Association - Suomen
Dental association	Irish Dental Association Ltd.
Dental association	Polish Chamber of Physicians and Dentists
Dental association	University of Liverpool, Dental Materials, Cariology, Dental Education
Health authority	Ministry of Health
Environmental authority	Ministry of Environment
Water treatment	Asociacia vodarenskych spolocnosti
Water treatment	Danish Water and Waste Water Association
Waste management	INDAVER NV
Water treatment	Hungarian Water Utility Association
Water treatment	Unie van Waterschappen
Water treatment	Water Supply and Sewerage Association of the Czech Republic
Environmental authority	Ministry of Environment
Waste management	Advance Medical Waste Management

Type of organisation	Name of organisation
Health Authority	Public Health Safety Conrol Unit
Environmental authority	Pollution Prevention Policy Group
Environmental authority	Department of Communications, Climat Action and Environment - Climate Adaptation, Soils, GMO's and Chemicals Division
Environmental authority	Ministry of Environment
Health Authority	Ministry of Health
Health Authority	Oral Health Unit in the Department of Health Regulation of malta
Health Authority	Health sector
Environmental authority	Environmental sector
Environmental authority	Ministry of Environment - Waste Management & Environmental Certification
Dental Association	Hellenic Dental Association
Expert	University of Birmingham
Environmental authority	EEB (European Environmental Bureau)
Dental association	Spanish Dental Association
Health Authority	Minisgtry of Social Affairs and Health of Finland
Environmental authority	Ministry of Environment and Energy
Health Authority	Croatian Institute for Public Health
Health Authority	Ministry of Human Capacities - State Secretariat for Health
Waste management	BDE
Environmental authority	Swedish Chemicals Agency-Kemi
Environmental authority	Swedish Chemicals Agency-Kemi
Amalgam separator manufacturer	SRAB, SWEDEN RECYCLING AB

Type of organisation	Name of organisation
Dental association	Swedish Dental Association
Environmental authority	Swedish Environmental Protection Agency
Environmental authority	Swedish Ministry of the Environment
Water treatment	Swedish Water and Waste Water Association - Svenskt Vatten AB
Health Authority	Socialstyrelsen (The National Board of Health and Welfare)
Health Authority	Ministry of Heath
Water treatment	AQUAWAL
Water treatment	Aquafin NV
Water treatment	SmVaK Ostrava a.s.
Waste management	Enretec GmbH
Funeral service	RAL Gutegemeinschaft Krematorien
Water treatment	Consorcio de Aguas Bilbao Bizkaia
Water treatment	DEYAL (Water and weverage municipal company of larissa)
Dental association	Dental Section of the Hungarian Medical Chamber
Water treatment	Norwegian Water
Water treatment	MPWiK SA
Water treatment	Dwr Cymry
Expert	Individual expert
Expert	Individual expert

Austria

Introduction

Austria is a country of Central Europe with 8.8 million of inhabitants. The capital and largest city is Vienna. The country spent 37 117 million euros (10.4% of GDP) in healthcare in 2016[128].

Table 14 Key socio-economic and health data

General information	
Population (million):	8.8
GDP per capita (PPP, EUR):	2.2; 38,000
GDP per capita (rank in the EU):	7
Unemployment rate (%):	4.9
Minimum wage salary (EUR):	N/A
Number of dentists per hundred thousand inhabitants:	56.7 (2016)
Dental outpatient curative care (PPS per inhabitant):	222.02 (2016)
Dental outpatient curative care (Percentual share of total current health expenditure (CHE)):	5.8 (2016)

DENTAL AMALGAM USE, ALTERNATIVES AND TRENDS

Number of restorations per type material

Data on the annual number of restorations in Austria was not available, but dental fillings cost public insurances €174.69 million in 2016 (not including self-employed patients) according to the Austrian Court of Audit[129].

In 2014, the latest year for which data is available, the overall expenditure for dental treatment in Austria was €1,815.70 million, of which €888.60 million (equivalent to 49% of the total) were borne by the public sector (primarily public insurance)[130]. Hence, the overall cost of dental fillings including both publicly and privately funded fillings is likely higher, possibly in the order of magnitude of twice as high.

Data on privately funded cost was not available broken down by type of dental treatment (such as fillings, restorations).

[128] Eurostat (online data codes : hlth_sha11_hf, demo_gind and nama_10_gdp)
[129] Rechnungshof Österreich: Versorgung im Bereich der Zahnmedizin. Reihe BUND 2018/24. Available at: https://www.rechnungshof.gv.at/rh/home/home/Zahnmedizin.pdf
[130] Ibid.

Dental sector and effectiveness

Table 15 Quantitative data on the dental sector

	Number							
	2011	**2012**	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**
Dentists[131] (number)	N/A	N/A	4,853	4,893	4,906	4,954	5,009	N/A
Dental clinics[132] (number)	3,806	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Average turnover per clinic (thousand EUR)[133]	Ca €230,000	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Self-reported unmet needs for dental examination due to urbanisation (%)	N/A	N/A	1.4	0.4	0.4	0.5	0.5	N/A
Self-reported unmet needs for dental care due to financial reasons (%)	N/A	N/A	N/A	6.1	N/A	N/A	N/A	N/A

Some 5,000 dentists practice in about 3,800 dental clinics in Austria, generating an average turnover of some €230,000 per clinic (see table above). This suggests a prevalence of rather small dental practices with one or only a small number of dentists, as opposed to large clinics.

According to System of Health Accounts data[134], almost half (46%) of the total expenditure to dental practices is financed by social health insurance schemes. Almost all of the rest (50%) is recorded as household out-of-pocket payment[135].

Patients can seek advice about dental treatment (including restoration-related issues) from the insurances[136] and the federal and regional dentist associations ("Zahnärztekammer")[137].

[131] The term "dentists" refers to individual professionals.
Source: Statistik Austria (2018): Ärzte und Ärztinnen seit 1960 absolut und auf 100.000 Einwohner. Available at: http://www.statistik.at/web_de/statistiken/menschen_und_gesellschaft/gesundheit/gesundheitsversorgung/personal_im_gesundheitswesen/022350.html.
[132] The term "dental clinics" refers to establishments which offer dental treatment, including dental practices.
Source: Statistik Austria: Anzahl Unternehmen in Österreich per 31.12.2011 nach ÖNACE2008-Klasse Statistisches Unternehmensregister, Stichtag 31.12.2011. Available at: https://www.bmf.gv.at/budget/Unternehmen_Anzahl_OENACE_4Steller_20121107.xlsx)
[133] 870 million / 3,806 clinics = €230,000 (rounded to closest 10,000).
Sources:
Revenue and expenditure of the Austrian health insurance system for dental treatment and restoration in 2010 (closest year to 2011 for which this data was available). Source: 2017 Jahrbuch der GESUNDHEITSSTATISTIK. Herausgegeben von STATISTIK AUSTRIA. Wien 2019.
Number of dental clinics as of 31/12/2011. Source: Statistik Austria: Anzahl Unternehmen in Österreich per 31.12.2011 nach ÖNACE2008-Klasse Statistisches Unternehmensregister, Stichtag 31.12.2011. Available at: https://www.bmf.gv.at/budget/Unternehmen_Anzahl_OENACE_4Steller_20121107.xlsx.
[134] Table HCxHPxHF Current expenditure on health care by functions, providers and financing schemes in Austria, 2017 (in million euros). Available at: http://www.statistik.at/web_de/statistiken/menschen_und_gesellschaft/gesundheit/gesundheitsausgaben/index.html.
[135] Ibid.
[136] See e.g. https://www.ooegkk.at/cdscontent/?contentid=10007.705167&portal=ooegkkportal&viewmode=content.
[137] See e.g. http://www.zahnaerztekammer.at/patientinnen/.

Manufacturing companies of dental amalgam and alternative materials

No data on sales, turnover and employment associated with the manufacture of dental amalgam and alternative materials in Austria was available.

Extra-EU Imports and exports of dental amalgam and alternative restoration materials

Data on extra-EU trade of amalgam and alternative restoration materials was not available. However, it is known that dental amalgam accounted for the majority of 4 tonnes of mercury imports as of 2009[138]. At a mercury concentration of 500,000 mg/kg[139], this implies dental amalgam imports of up to 8 tonnes.

Table 16 Extra-EU Imports and exports per material

Imports/exports	Material	Amounts	Value	Destination / origin
Imports	Dental amalgam	Up to 8t	N/A	N/A
	Composite resins	N/A	N/A	N/A
	Glass ionomer cements	N/A	N/A	N/A
	Compomers	N/A	N/A	N/A
	Ceramics	N/A	N/A	N/A
Exports	Dental amalgam*	N/A	N/A	N/A
	Composite resins	N/A	N/A	N/A
	Glass ionomer cements	N/A	N/A	N/A
	Compomers	N/A	N/A	N/A
	Ceramics	N/A	N/A	N/A

Waste treatment from amalgam separators and water waste treatment facilities

Table 17 Quantitative data on water and solid waste from dental amalgam

[138] Umweltbundesamt (2009): RUSCH Ressourcenpotenzial und Umweltbelastung der Schwermetalle Cadmium, Blei und Quecksilber in Österreich. Available at: http://www.umweltbundesamt.at/fileadmin/site/publikationen/REP0229.pdf.
[139] Ibid.

Category	Mercury waste treatment					
	2013	2014	2015	2016	2017	2018
Share of dental chairs equipped with amalgam separators (%)	100%	100%	100%	100%	100%	100%
Share of waste from separators treated in specialized treatment facilities (%)	100%	100%	100%	100%	100%	100%
Average dental amalgam removal efficiency of separators (%)	>95%	>95%	>95%	>95%	>95%	>95%
Cost of collection and treatment of waste from separators per kg (thousand EUR)	N/A	N/A	N/A	N/A	N/A	N/A
Concentration of mercury in sewage sludge (µg/L)	N/A	N/A	N/A	N/A	N/A	N/A

In Austria, the Ordinance on Wastewater Emissions in the Medical Sector ("AEV Medizinischer Bereich") requires dental treatment facilities that process or remove amalgam to be equipped with separators which recover more than 95% of the amalgam from the wastewater[140].

Amalgam waste from dental practices are classified as hazardous waste with the code SN 35326 for mercury-containing waste, which can only be disposed of via authorised waste operators in compliance with Article 25 of Waste Management Act ("Abfallwirtschaftsgesetz 2002")[141].

Data on the cost of collection and treatment of this waste, the types of treatment facilities used by authorised operators for this waste, or the concentration of mercury in sewage sludge was not available.

Number of Cremations

Table 18 Quantitative data on cremations

Category	Air emissions from crematoria					
	2005	…	2011	…	2017	2018
Number of crematoria[142]	10	N/A	N/A	N/A	N/A	17

[140] Umweltbundesamt (2009): RUSCH Ressourcenpotenzial und Umweltbelastung der Schwermetalle Cadmium, Blei und Quecksilber in Österreich. Available at: http://www.umweltbundesamt.at/fileadmin/site/publikationen/REP0229.pdf.
[141] Ibid.
[142] Wikipedia lists 17 crematoria (https://de.wikipedia.org/wiki/Krematorien_in_%C3%96sterreich), which is more than listed in other sources (http://www.umweltbundesamt.at/fileadmin/site/publikationen/REP0229.pdf, https://www.benu.at/ratgeber/bestattung/krematorium/, https://austria-forum.org/af/AEIOU/Feuerbestattung). All sources note an increase in cremation in Austria, so the highest number is likely most accurate for the current situation.
UBA 2009 notes 10 crematoria fort he year 2005. Source: Umweltbundesamt (2009): RUSCH Ressourcenpotenzial und Umweltbelastung der Schwermetalle Cadmium, Blei und Quecksilber in Österreich. Available at: http://www.umweltbundesamt.at/fileadmin/site/publikationen/REP0229.pdf.

Category	Air emissions from crematoria					
	2005	…	2011	…	2017	2018
Number of cremations per year [143]	N/A	N/A	26,509	N/A	N/A	N/A
Share of crematoria equipped with abatement technologies (%)[144]	30%	N/A	N/A	N/A	N/A	N/A
Average efficiency of the abatement technologies (%)	N/A	N/A	N/A	N/A	N/A	N/A
Cost of mercury capture per cremation (EUR)	N/A	N/A	N/A	N/A	N/A	N/A

The number of crematoria in Austria has increased in recent years from 10 in 2015 to approximately 17 in 2018 (see table above). The share of cremations has also increased steadily from 16.2% in 1995 to 42% in 2015[145].

The number of cremations was 26,509 in 2011 (see table above) and has likely increased since, given the upward trend in the share of cremations noted above.

In 2005, 3 out of 10 crematoria had installed secondary mercury emission abatement technologies: two crematoria used spray absorption with activated carbon and lime, while one used an exhaust gas cleaning system consisting of cyclone, fabric filter and fixed bed adsorber including lime injection (without activated coke)[146]. Data on mercury emission abatement efficiency and cost was not available.

National policies and measures

Table 19 Policies and measures to phase down or phase-out the use of dental amalgam

Category	Type	Ongoing	Under development
Measures to phase down or phase-out dental amalgam	Dental amalgam bans, phasing-out or phasing down	From the 1st of July 2018 dental amalgam can no longer be used for[147]: • Dental restorations in milk teeth and in children under 15 years of age, unless the dentist considers it necessary given the specific conditions of the patient. • Dental restorations in pregnant women, unless considered necessary;	No

[143] Most recent figure available. Source: https://derstandard.at/1373513579973/Am-Ende-des-Lebens-bleibt-nicht-nur-Asche.
[144] Most recent figure available. Source: Umweltbundesamt (2009): RUSCH Ressourcenpotenzial und Umweltbelastung der Schwermetalle Cadmium, Blei und Quecksilber in Österreich. Available at: http://www.umweltbundesamt.at/fileadmin/site/publikationen/REP0229.pdf
[145] https://www.benu.at/ratgeber/bestattung/krematorium/
[146] Umweltbundesamt (2009): RUSCH Ressourcenpotenzial und Umweltbelastung der Schwermetalle Cadmium, Blei und Quecksilber in Österreich. Available at: http://www.umweltbundesamt.at/fileadmin/site/publikationen/REP0229.pdf.
[147] National plan on measures to phase down the use of dental amalgam (Article 10(3) of the Mercury Regulation)

Category	Type	Ongoing	Under development
		• In patients with impaired renal function or progressive degenerative diseases of the peripheral or central nervous system amalgam is not indicated. Dental amalgam must also not be used: • for retrograde root fillings; • as material for stump abutments under crowns or bridges; • as sealing material for cast crowns.	
	National guidelines, promoting the use of mercury-free materials	No	No
	Supporting research and development in respect of mercury-free dental restorations	No	No
	Others :	From 1 Jan 2019 dental amalgam can only be used in readily dosed capsules (no longer in bulk)[148]	No
Measures to manage waste and emissions from dental amalgam	Requirements for the installation and maintenance of separators	"In Austria, dental treatment facilities [that process or remove amalgam according to the German version of this text] must be equipped with separators which recover more than 95% of the amalgam from the wastewater (AEV Medizinischer Bereich – Ordinance on Wastewater Emissions in the Medical Sector)."[149]	No
	Requirements for the collection and treatment of solid waste from separators	Amalgam waste from dental practices are classified as hazardous waste with the code SN 35326 for mercury-containing waste, which can only be disposed of via authorised waste operators in compliance with Article 25 of Waste Management Act ("Abfallwirtschaftsgesetz 2002").[150]	No
	Requirements for mercury	No	No

[148] Source: http://stmk.zahnaerztekammer.at/zahnaerztinnen/newsletter/newsletter-mai-2017/amalgam/
[149] Source: Umweltbundesamt (2009): RUSCH Ressourcenpotenzial und Umweltbelastung der Schwermetalle Cadmium, Blei und Quecksilber in Österreich. Available at: http://www.umweltbundesamt.at/fileadmin/site/publikationen/REP0229.pdf.
[150] Ibid.

Category	Type	Ongoing	Under development
	emissions from crematoria		
	Standards for mercury concentrations in sludge for the use of land spreading	No	No
	Supporting research and development in respect of reducing emission and releases of mercury to the environment	No	No
	Others	No	No

The main identified measures to reduce the potential risks from dental amalgam in Austria are requirements to use only readily dosed capsules of dental amalgam (as opposed to bulk amalgam), to use separators in dental treatment facilities with a minimum removal efficiency of 95%, and to classify their waste as hazardous which requires disposal only via authorised waste operators.

HEALTH SERVICES AND INSURANCE

Data on the average price of dental restoration per type of material was not available. However, in 2017 the Austrian social security insurances paid a total of €1.01 billion for dental treatment and dental restoration[151]. The average cost per case was €97.54 for dental treatment and €456.12 for dental replacement[152].

The share of cost for dental restoration covered by social security insurance for the different materials is summarised in the table below. Dental amalgam is used and paid in full for back teeth, while for front and canine teeth (and for certain other cases) also composite or compomer fillings are also paid in full. Cements are used only as a temporary solution, but are also paid in full. All materials in cases where they are not paid in full are paid up to 80% of the price for a comparable amalgam filling.

Table 20 Quantitative data on dental restorations

Category	Category	Price	Reimbursement by social security %
Restoration	Dental amalgam	N/A	100% for back teeth
	Composite resins	N/A	100% for front and canine teeth (or for

[151] 2017 Jahrbuch der GESUNDHEITSSTATISTIK. Her N/A ausgegeben von STATISTIK AUSTRIA. Wien 2019.
[152] Ibid.

Category	Category	Price	Reimbursement by social security %
			children, pregnant/ breast-feeding women, patients with relevant allergies or renal insufficiency); 80% of the price for a comparable amalgam filling in all other cases
	Glass ionomer cements	N/A	100%
	Compomers	N/A	100% for front and canine teeth (or for children, pregnant/ breast-feeding women, patients with relevant allergies or renal insufficiency); 80% of the price for a comparable amalgam filling in all other cases
	Ceramics	N/A	80% of the price for a comparable amalgam filling in all other cases; 100% for patients with relevant allergies
Material	Dental amalgam	N/A	Included in the above
	Composite resins	N/A	Included in the above
	Glass ionomer cements	N/A	Included in the above
	Compomers	N/A	Included in the above
	Ceramics	N/A	Included in the above

Source: https://www.ooegkk.at/cdscontent/?contentid=10007.705167

GOOD PRACTICES IN THE SELECTED AREAS

The only practices in Austria to reduce the potential risks from dental amalgam identified are requirements to:

- use only readily dosed capsules of dental amalgam;
- use separators in dental treatment facilities with a minimum removal efficiency of 95%; and
- classify their waste as hazardous.

These are summarised below.

Table 21 Good practices template

Category	***Use of readily dosed capsules of dental amalgam***	***Separators in dental treatment facilities***	***Classify waste as hazardous***
Type of enforcement	*Mandatory*	*Mandatory*	*Mandatory*
Target	*Reduction of exposure to mercury in dental practices*	*Reduction of release of mercury from dental practices*	*Improvement of waste treatment*
Achievements	*Unknown*	*Unknown*	*Unknown*
Financial aspects	*Costs borne by dentists and depending on negotiations with social security passed on to the insurance.*	*Costs borne by dentists and depending on negotiations with social security passed on to the insurance.*	*Costs borne by dentists and depending on negotiations with social security passed on to the insurance.*
Challenges	*None identified*	*None identified*	*None identified*
Transferability	*No issues identified*	*No issues identified*	*No issues identified*
Sources	*Dentist association*[153]	*Umweltbundesamt 2009*[154]	*Umweltbundesamt 2009*[155]

[153] http://stmk.zahnaerztekammer.at/zahnaerztinnen/newsletter/newsletter-mai-2017/amalgam/
[154] Umweltbundesamt (2009): RUSCH Ressourcenpotenzial und Umweltbelastung der Schwermetalle Cadmium, Blei und Quecksilber in Österreich. Available at: http://www.umweltbundesamt.at/fileadmin/site/publikationen/REP0229.pdf.
[155] Ibid.

Belgium

INTRODUCTION

Belgium is a country of 11.4 million inhabitants. The capital and largest city is Brussels. The country spent 42,430 million euros (10.0% of its GDP) in healthcare expenditure in 2016.

Table 22 Key socio-economic and health *data (2018)*

General information	
Population (million):	11.4
GDP per capita (PPP, EUR):	0.9; 35,300
GDP per capita (rank in the EU):	10
Unemployment rate (%):	6.0
Minimum monthly wage (EUR):	1,593.81
Number of dentists per hundred thousand inhabitants :	74.82 (2016)
Dental outpatient curative care (PPS per inhabitant):	108.46 (2016)
Dental outpatient curative care (percentual share of total current health expenditure (CHE)):	3.29 (2016)

DENTAL AMALGAM USE, ALTERNATIVES AND TRENDS

Number of restorations per type of material

There is clearly a decreasing trend in the use of non-adhesive techniques (dental amalgam) in Belgium. The fraction of restorations with adhesive materials to the total number of restorations decreased from 100% in 2006 to ca. 20% in 2014[156] and 7% in 2018. Information on the number of restorations with dental amalgam and with adhesive materials is provided in the table and figure below.

Table 23 Number of restorations per type of material (2018)

Material	Number of restorations [1]
Dental amalgam*	400,049

[156] VITO, 2016. Beste Beschikbare Technieken (BBT) voor voorkoming & beperking van amalgaamhoudend afvalwater bij tandartspraktijken. Vijfde Draft.

Material	Number of restorations [1]
Composite resins	N/A
Glass ionomer cements	N/A
Compomers	N/A
Ceramics	N/A
Others : Adhesive techniques/materials	5,162,138

[1] Source: data provided by RIZIV

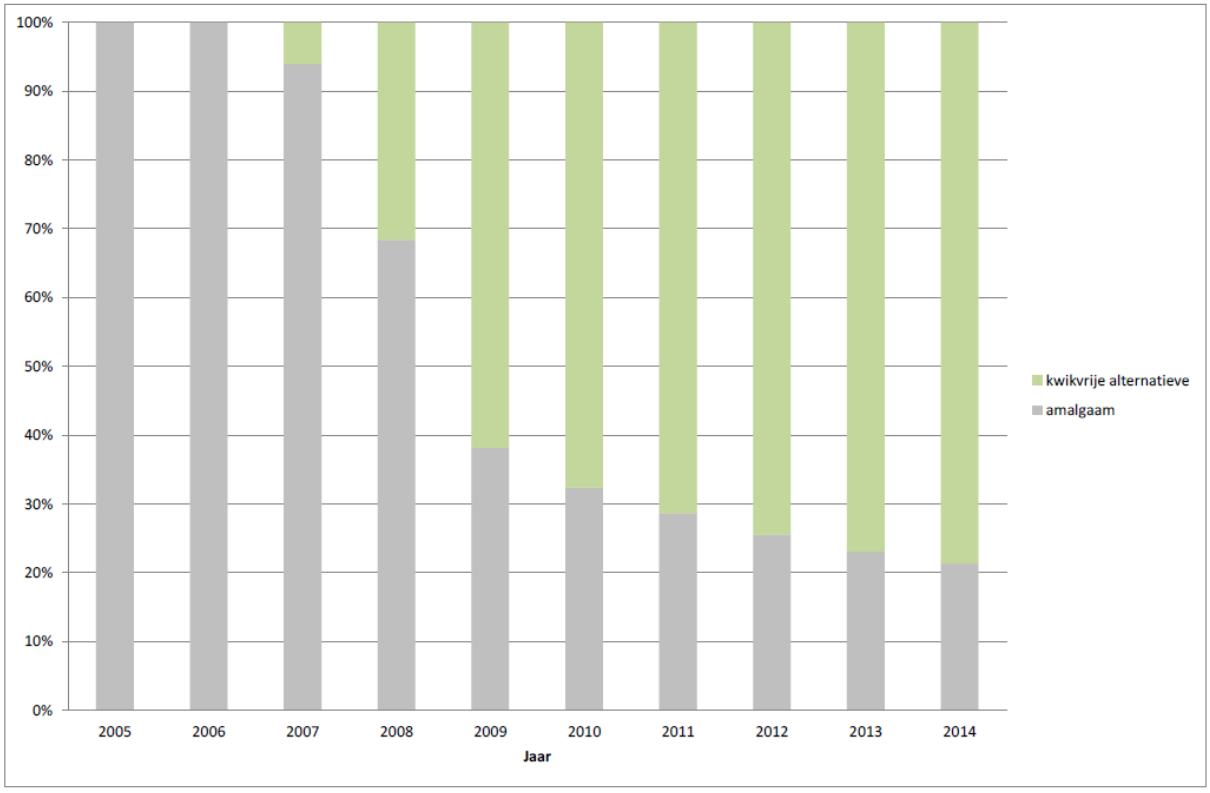


Figure 16 Evolution of the number of restorations with dental amalgam ("amalgaam") and alternative materials ("kwikvrije alternatieven") in Belgium (source: VITO, 2016[156]).

Dental sector

The table below presents information on the number of dentists in Belgium as well as Eurostat data on self-reported unmet needs for dental examination due to urbanisation and for dental care due to financial reasons.

Table 24 Quantitative data on the dental sector

	Number					
	2013	2014	2015	2016	2017	2018
Dentists[157] (number) [1]	N/A	9,015	9,177	9,401	9,617	N/A
Dental clinics[158] (number)	N/A	N/A	N/A	N/A	N/A	N/A
Average turnover per clinic (thousand EUR)	N/A	N/A	N/A	N/A	N/A	N/A
Self-reported unmet needs for dental examination due to urbanisation (%)	3.0	3.9	3.7	3.8	3.7	N/A
Self-reported unmet needs for dental care due to financial reasons (%)	N/A	N/A	N/A	N/A	N/A	N/A

[1] Source: ***https://overlegorganen.gezondheid.belgie.be***

Dentists in Belgium can get a specially recognised or accredited title/position for the following three categories (Articles 3 en 4 of the Royal Order from 25 November 1991):

- general dentist;
- dentist specialised in orthodontics; and
- dentist specialised in periodontology.

The Royal Order of 19 August 2011 relates to the planning of offering dentist services and regulates the accreditation of dentitsts by limiting the number of people getting access to a university degree and finally becoming dentists.

The list of accredited dentists can be accessed via the following link:

http://docs.health.belgium.be/FilesEcad/Dent_Visa_Nl.csv

Companies manufacturing dental amalgam and alternative materials

No data or information has been identified related to companies in Belgium manufacturing dental amalgam and alternative materials.

Table 25 Annual sales per company and material

Company	Material	Amounts
[Name of company]	Dental amalgam*	N/A

[157] The term "dentists" refers to individual professionals

[158] The term "dental clinics" refers to establishments which offer dental treatment, including dental practices

Company	Material	Amounts
	Composite resins	N/A
	Glass ionomer cements	N/A
	Compomers	N/A
	Ceramics	N/A

Extra-EU Imports and exports of dental amalgam and alternative restoration materials

No data or information has been identified related to extra-EU imports and exports of dental amalgam and alternative restoration materials for Belgium.

No data available for extra-EU imports and exports of material.

Waste treatment from amalgam separators and water waste treatment facilities

Table 26 Quantitative data on water and solid waste from dental amalgam

Category	Mercury waste treatment					
	2013	2014	2015	2016	2017	2018
Share of dental chairs equipped with amalgam separators (%)	N/A	N/A	N/A	N/A	N/A	N/A
Share of waste from separators treated in specialised treatment facilities (%) [1]	N/A	N/A	N/A	N/A	N/A	100
Average dental amalgam removal efficiency of separators (%) [2]	N/A	N/A	N/A	N/A	N/A	95
Cost of collection and treatment of waste from separators per kg (thousand EUR)	N/A	N/A	N/A	N/A	N/A	N/A
Concentration of mercury in sewage sludge (µg/L) [3]	N/A	N/A	N/A	N/A	N/A	N/A

[1] Source: OVAM (Openbare Vlaamse Afvalstoffenmaatschappij)

[2] Source: VITO, 2016. Beste Beschikbare Technieken (BBT) voor voorkoming & beperking van amalgaamhoudend afvalwater bij tandartspraktijken. Vijfde Draft.

[3] A value of 500 µg/kg (dry matter) of mercury in sewage sludge in 2018 has been reported in the online questionnaire, with a range of 200-1000 µg/kg.

Amalgam waste from dentistry (inter alia amalgam capsules, production residues, sludge from amalgam separators, old drain pipes containing amalgam-containing sludge) are categorised as hazardous waste (industrial waste). Waste is considered as hazardous waste materials when containing one or more hazardous properties. Amalgam waste is stored in airtight, UN-approved packaging for liquids, in accordance with ADR, i.e. the European treaty on the international transport of dangerous goods by road.

Teeth filled with amalgam are categorised as risk-containing medical waste (industrial waste). Risk-containing medical waste (RMA) is medical waste that entails a special risk. It can cause a microbiological or viral infection, poisoning or injury. Teeth filled with amalgam are stored in cardboard boxes with a plastic inner bag, with the inscription of hazardous medical waste, in accordance with ADR.

Amalgam waste and filled teeth with amalgam are collected by a registered collector, waste dealer or broker. Dental practices (other than dental departments of hospitals) often involve collection rounds where the transporter stops at different customers. In addition to these collection rounds, a central collection point at a hospital can also offer a solution for the smooth collection of waste from dental practices. The hospital must then have a permit for the storage of waste from third parties.

The provisions concerning the management, inter alia, internal collection and storage of waste in Flanders are set out in VLAREMA. For industrial waste materials, including amalgam waste and teeth filled with amalgam, these provisions include[159]:

- Separate collection and storage (e.g. separate collection of hazardous and non-hazardous waste). The producer (dentist) is obliged to separately collect, store and adequately identify the different waste streams if this is required to efficiently remove the waste or to enable their useful application.
- Waste Register. The producer (dentist) must keep a waste register in which (among other things) the nature, origin, composition and quantity of the waste produced, the destination and the method of recovery or disposal are stated.
- A receipt upon delivery. The delivery to a processing plant or to a registered collector, waste dealer or broker takes place upon delivery of a receipt. This receipt contains the following information: date of issue, name and place of residence of the producer or establishment from which the waste is received, name and place of residence of the person who receives the waste, the nature, origin, composition and quantity of the waste delivered.
- Notification obligation. The producer (dentist) must report the data determined by the Flemish Government to the administration every year.

The medical waste ultimately ends up at a processing company. The processing installation must have the necessary permits to process the medical waste.

In Flanders, amalgam waste and RMA are processed together by a specialised processor in Antwerp, in a rotary kiln for medical waste. Hazardous components such as mercury are processed during gasification in the rotary kiln.

Further information is in the waste material sheet "Risk-containing medical waste (RMA)" in the Medical waste management manual (Public Flemish Waste Agency (OVAM), 2014).

[159] OVAM – medical waste: https://www.ovam.be/medisch-afval

Number of Cremations

Table 27 Quantitative data on cremations

Category	Air emissions from crematoria					
	2013	2014	2015	2016	2017	2018
Number of crematoria [1]	N/A	N/A	N/A	N/A	21	N/A
Number of cremations per year [2]	58,904	58,831	63,488	63,469	65,221	N/A
Share of crematoria equipped with abatement technologies (%)	N/A	N/A	N/A	N/A	N/A	N/A
Average efficiency of the abatement technologies (%)	N/A	N/A	N/A	N/A	N/A	N/A
Cost of mercury capture per cremation (EUR)	N/A	N/A	N/A	N/A	N/A	N/A

[1] Source: http://www.crematorium.be/overzicht-crematoria

[2] Source: http://www.crematorium.be/cijfers

The relative number of cremations compared to traditional burials has increased in recent years, from 44% in 2006 to 52% in 2012[160].

National policies and measures

Table 28 Policies and measures to phase down or phase-out the use of dental amalgam

Category	Type	Ongoing	Under development
Measures to phase down or phase-out dental amalgam	Dental amalgam bans, phasing-out or phasing down	"Verordening kwik" Regulation 2017/852 on Mercury	No
	National guidelines, promoting the use of mercury-free materials	No	No
	Supporting research and development in respect of mercury-free dental restorations	No	No
	Others :	No	No

[160] Source: https://uitvaartpro.be/statistieken/

Category	Type	Ongoing	Under development
Measures to manage waste and emissions from dental amalgam	Requirements for the installation and maintenance of separators	VLAREM II, Annex 5.3.2 Installation of separator (with certificate according to quality standards); maximum daily average of total mercury concentration in wastewater from dental clinics: 0.3 mg/l [1]	No
	Requirements for the collection and treatment of solid waste from separators	The conditions of the collection and transport of waste are laid down in Chapter 6 of the Decree of the Flemish Government establishing the Flemish regulation on the sustainable management of material cycles and waste [Flanders].	No
	Requirements for mercury emissions from crematoria	Each incineration plant must comply with the following conditions when operating. The emission limit values relate to a reference oxygen level of 11%: the following emission limit values apply to the discharged waste gases: Parameter: mercury and its compounds, expressed in Mercury Emission limit value: 0.2 mg/Nm³ [2]	No
	Standards for mercury concentrations in sludge for the use of land spreading	The criteria for raw materials intended for use as fertiliser or soil-improving agent are determined in subsection 2.3.1 of the Vlarema [Flanders].	No
	Supporting research and development in respect	No	No

Category	Type	Ongoing	Under development
	of reducing emission and releases of mercury to the environment		
	Others :	No	The Flemish Government commissioned a study to determine the Best Available Techniques for the prevention and reduction of wastewater from dental clinics containing amalgam. The study is currently on hold [3]. Following this BAT study, the emission limit values might be reviewed in order to prevent contamination of surface water (and other compartments). Supplementary legal measures related to the prevention of mercury in water are probably to be undertaken by the Flanders authorities in 2020.

[1] Flanders - VLAREM II. Order of the Flemish Government of 1 June 1995 concerning General and Sectoral provisions relating to Environmental Safety. Part 5. SECTORAL ENVIRONMENTAL CONDITIONS FOR CLASSIFIED ESTABLISHMENTS; Appendix 5.3.2 (Sectoral discharge conditions for industrial wastewater). See Annex B of this report.

[2] Flanders - VLAREM II. Order of the Flemish Government of 1 June 1995 concerning General and Sectoral provisions relating to Environmental Safety. Part 5. SECTORAL ENVIRONMENTAL CONDITIONS FOR CLASSIFIED ESTABLISHMENTS; Chapter 5.58. CREMATORIA Article 5.58.1. - 5.58.3

[3] personal communication, VITO

HEALTH SERVICES AND INSURANCE

Dental care is provided by dentists who are mostly self-employed and publicly financed through compulsory health insurance on a fee-for-service basis. Dentists' fees are decided by the National Commission of Representatives of Dentists and Sickness Funds. Every two years an agreement is made in which the financial and administrative relations between dentists and sickness funds are stipulated[161].

[161] European Commission, 2010. Health systems performance assessment, available at: http://www.euro.who.int/__data/assets/pdf_file/0014/120425/E94245.PDF

It is common for citizens to enrol in health plans that cover restorations. Patients will usually cover part of the costs, however, this part is very low for the more basic treatments.

In principle there is no difference in reimbursement based on the restoration materials used. The price depends on the size of the restoration, i.e. one, two, three or more fillings. Up to a maximum of two restorations per tooth per year are reimbursed.

The information presented in the table below reflects the reimbursement by the 'Christelijke Mutualiteit (CM)', one of the largest health insurance schemes in Belgium.

Table 29 Quantitative data on dental restorations

Category	Category	Price [1]	Reimbursement by social security %
Restoration	One tooth surface	31.50 euro	62-81% (up to 100% with additional insurance)
	Two tooth surfaces	47.50 euro	62-81% (up to 100% with additional insurance)
	Three or more tooth surfaces	63.00 euro	71-86% (up to 100% with additional insurance)
	Additional honorarium for treatment with adhesive techniques (no amalgam) – price per tooth	12 euro	63-75% (up to 100% with additional insurance)
Material	Dental amalgam	N/A	N/A
	Composite resins	N/A	N/A
	Glass ionomer cements	N/A	N/A
	Compomers	N/A	N/A
	Ceramics	N/A	N/A

[1] Source: https://www.cm.be/diensten-en-voordelen/ziekte-en-behandeling/terugbetalingen-behandelingen/tandartsen/bewarende-verzorging

GOOD PRACTICES IN THE SELECTED AREAS

No information has been identified on good practices to complete the table below.

NUMBER OF RESTORATIONS

Table 30 Number of restorations per type material

Material	Number of restorations [1]				
	2014	2015	2016	2017	2018
Dental amalgam*	798,067	720,834	618,435	478,900	400,049
Adhesive techniques/materials	4,922,599	5,132,066	5,212,531	5,127,781	5,162,138

[1] Source: data provided by RIZIV

VLAREM II APPENDIX 5.3.2. SECTORAL DISCHARGE CONDITIONS FOR INDUSTRIAL WASTEWATER
Sector 43 Dentists

The installation must be provided with amalgam separator.

A certificate issued or ratified by an expert institution (such as the Institut für Bautechnik in Berlin (Germany) and the Odontological Institute at the Arhus Universitet in Denmark) must be added to the amalgam separator.

The amalgam separator removes the amalgam from the wastewater before the wastewater is mixed with other wastewater.

The separator is connected to a sampling device so that a sample can easily been taken.

The total mercury content of the discharged water may be used as a daily average not exceed 0.3 mg per liter.

The amalgam separator is placed as follows:

- the connection is made as close as possible to the treatment unit;
- both the spitting bowl and the extraction system are placed on the amalgam separator plugged in;
- water that does not come from the spitting bowl or from the extraction system is not allowed to flow through the amalgam separator; and
- the treatment unit is equipped with a coarse filter.

At the first placement of an amalgam separator in an existing installation, all the amalgam-containing sludge contained in the sewer system will be removed in accordance with the regulatory provisions, in particular with regard to the processing of waste.

Possible techniques are:

- renew the amalgam-containing pipe of the inner sewer, up to the connection to the public sewer system;
- empty the indoor sewer over the same distance; and
- flush the pipes after the sewer system has been closed.

When renewing the indoor sewer system or the pipes, all of the amalgam-containing sludge that is present in the part before the connection to the amalgam separator, must be removed in the same way.

All waste containing mercury, such as production surpluses, amalgam residues captured by the coarse filter, amalgam fillings in extracted teeth, as well as the amalgam-containing sediment in the amalgam separator is regarded as hazardous industrial waste, which cannot be emitted in the wastewater.

The amalgam separator is in good condition, the maintenance is in accordance with the supplier's manual or another code of good practice.

The specified flow rate is not allowed to be exceeded.

The amalgam remaining must be removed as frequently as needed for an optimal functioning of the amalgam separator. The remains must be delivered to an accredited collector or registered transporter of waste materials.

Croatia

INTRODUCTION

Croatia is a country of central Europe with 4.105 million of inhabitants. The capital and largest city is Zagreb. The Republic of Croatia is a parliamentary system. The Ministry of Health is in charge of health care and welfare in Croatia. The country spent 7.18% of its gross domestic product in healthcare in 2016[162]. Croatia has a universal health care system administrated by the Croatian Health Insurance Fund.

Table 31 Key socio-economic and health data

General information	
Population (million):	4.105
GDP per capita (PPP, EUR):	4.0; 11,500
GDP per capita (rank in the EU):	N/A
Unemployment rate (%):	8.5
Monthly minimum wage (EUR) (2019):	505.90
Number of dentists per hundred thousand inhabitants (2016):	80.07
Dental outpatient curative care (PPS per inhabitant) (2016):	95.01
Dental outpatient curative care (Percentual share of total current health expenditure (CHE)) (2016):	7.47

DENTAL AMALGAM USE, ALTERNATIVES AND TRENDS

Number of restorations per type material

Table 32 Number of restorations per type material

Material	Number of restorations
Dental amalgam*	N/A
Composite resins	N/A
Glass ionomer cements	N/A

[162] Eurostat : Health care expenditure by financing scheme [hlth_sha11_hf]

Material	Number of restorations
Compomers	N/A
Ceramics	N/A
Others	N/A

Dental sector and effectiveness

Table 33 Quantitative data on the dental sector

	Number					
	2013	2014	2015	2016	2017	2018
Dentists[163] (number, Eurostat)	3,225	3,327	3,347	3,341	N/A	N/A
Dental clinics[164] (number)	N/A	N/A	N/A	N/A	N/A	N/A
Average turnover per clinic (thousand EUR)	N/A	N/A	N/A	N/A	N/A	N/A
Self-reported unmet needs for dental examination due to urbanisation (%)*	2.5	2.2	1.0	1.2	1.2	N/A
Self-reported unmet needs for dental care due to financial reasons (%)*	N/A	3.8	N/A	N/A	N/A	N/A

**Data collected from Eurostat*

Croatia has a compulsory public health insurance which is administrated by HZZO (Hrvatski zavod za zdravstveno osiguranje). Dentist can either be under contract with HZZO or not, in the latest case, services are not reimbursed.

According to the national health institute (HZJZ), around 16% of dentists are practicing in publicly owned institutions (European Observatory on Health Systems and Policies, 2006).

Manufacturing companies of dental amalgam and alternative materials

No data available for the time being.

[163] The term "dentists" refers to individual professionals
[164] The term "dental clinics" refers to establishments which offer dental treatment, including dental practices

Table 34 Annual sales per company and material

Company	Material	Amounts
[Name of company]	Dental amalgam	N/A
	Composite resins	N/A
	Glass ionomer cements	N/A
	Compomers	N/A
	Ceramics	N/A

Extra-EU Imports and exports of dental amalgam and alternative restoration materials

No data available for the time being for extra-EU imports and exports per material.

Waste treatment from amalgam separators and water waste treatment facilities

According to the Ministry of environment and energy (MZOE), dental amalgam wastes are collected and treated by specialized companies either in Croatia or abroad.

The reader may find information on dental amalgam waste quantities reported by Croatian operators in annex from Croatian environment and nature agency (HAOP) as well as monthly concentration of mercury in sludge (mg/kg of dry matter) in annex.

Number of Cremations

The data and information in this section has been communicated by MZOE.

Crematoria are not equipped with abatement technologies. At least once per year, a list of air pollutants encompassing solid particles, CO, NOX, TVOC, HCl, HF are being monitored. Measurements were performed by The CEM system (Continuous Emission Monitoring System) on the 28th January 2019 and were compliant with limit value set in the regulation on pollutant emissions from stationary sources into the air (OG 87/17) article 157.

Table 35 Quantitative data on cremations

Category	Air emissions from crematoria					
	2013	2014	2015	2016	2017	2018
Number of crematoria	1	1	1	1	1	1

Category	Air emissions from crematoria					
	2013	2014	2015	2016	2017	2018
Number of cremations per year	5,451	5,392	5,975	5,770	6,099	6,440
Share of crematoria equipped with abatement technologies (%)	0	0	0	0	0	0
Average efficiency of the abatement technologies (%)	N/A	N/A	N/A	N/A	N/A	N/A
Cost of mercury capture per cremation (EUR)	0	0	0	0	0	0

NATIONAL POLICIES AND MEASURES

Table 36 Policies and measures to phase down or phase-out the use of dental amalgam

Category	Type	Ongoing	Under development
Measures to phase down or phase-out dental amalgam	Dental amalgam bans, phasing-out or phasing down	No	No
	National guidelines, promoting the use of mercury-free materials	No	No
	Supporting research and development in respect of mercury-free dental restorations	No	No
	Others	No	No
Measures to manage waste and emissions from dental amalgam	Requirements for the installation and maintenance of separators	No	No
	Requirements for the collection and treatment of solid waste from separators	Ordinance on medical waste management (OG No. 50/15) – general requirements	No
	Requirements for mercury emissions from crematoria	Regulation on limit values for pollutant emissions from stationary sources into the air (OG 87/17)	No

Category	Type	Ongoing	Under development
	Standards for mercury concentrations in sludge for the use of land spreading	Article 7. Ordinance on management of wastewater treatment sludge when used in agriculture (OG No. 38/08)	No
	Supporting research and development in respect of reducing emission and releases of mercury to the environment	No	No
	Others	No	No

HEALTH SERVICES AND INSURANCE

Croatia provides a compulsory health insurance named HZZO coming with a variety of public medical services. Moreover, physicians non-affiliated with HZZO may also operate as private medical care workers and people may choose to contract an additional private insurance (European Observatory on Health Systems and Policies, 2006).

HZZO, in accordance with health ministry and the Croatian national institute of public health (HZJZ), has defined a set of fees for medical care provided by HZZO affiliated physicians and reimbursement rate on health care. Indeed, people are asked to bear a share of the cost except for specific categories (mainly low income and vulnerable categories, see health insurance law 2002).

Healthcare expenditures are covered at 78.45 % in 2016 (Eurostat) while dental care represented 184.2 million € (Eurostat). We should expect dental care reimbursed by HZZO to be lower than the coverage rate provided above as people may rely on private services for which we do not know the share of the market. Out-of-the-pocket cost born by households represented 15.36% of the total health care expenditure in 2016 (Eurostat estimation).

No data for prices/reimbursement rates.

GOOD PRACTICES IN THE SELECTED AREAS

No data for the time being.

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Table 37 : Amalgam waste registry

Županija/County	Godina/Year	Tvrtka ili naziv/Company or name	Naziv organizacijske jedinice/ Name of the organizational unit	Proizvedeno u izvještajnoj godini (t)/produced in the reporting year
Osječko-baranjska	2008	GT Litokarton d.d.	GT Litokarton d.d.	0,13
Krapinsko-zagorska	2008	STOMATOLOŠKA ORDINACIJA LJILJANA HORVAT	STOMATOLOŠKA ORDINACIJA LJILJANA HITREC	0,001
Krapinsko-zagorska	2008	STOMATOLOŠKA ORDINACIJA DANICA TOMAŠKOVIĆ	STOMATOLOŠKA ORDINACIJA DANICA TOMAŠKOVIĆ	0,002
Krapinsko-zagorska	2008	STOMATOLOŠKA ORDINACIJA DR HRVOJE MEDIJA	STOMATOLOŠKA ORDINACIJA DR HRVOJE MEDIJA	0,001
Krapinsko-zagorska	2008	STOMATOLOŠKA ORDINACIJA DR BISERKA PERINIĆ	STOMATOLOŠKA ORDINACIJA BISERKA PERINIĆ	0,0005
Krapinsko-zagorska	2008	STOMATOLOŠKA ORDINACIJA DR. BORIS ZUBANOVIĆ	STOMATOLOŠKA ORDINACIJA BORIS ZUBANOVIĆ	0,0001
Krapinsko-zagorska	2008	STOMATOLOŠKA ORDINACIJA DR JOSIP PERINIĆ	STOMATOLOŠKA ORDINACIJA DR JOSIP PERINIĆ	0,0005
Šibensko-kninska	2008	Dom zdravlja Drniš, ugovorna zdr. ustanova	Dom zdravlja Drniš	0,001
Splitsko-dalmatinska	2009	DOM ZDRAVLJA U SPLITU	SINJ	0,0001
Grad Zagreb	2009	Klinički bolnički centar Zagreb	GUNDULIĆEVA	0
Međimurska	2013	ORDINACIJA DENTALNE MEDICINE JURICA VRČEK, DR.DENT.MED.	Ordinacija dentalne medicine Jurica Vrček, dr.dent.med.	0,001
Grad Zagreb	2013	Klinička bolnica Dubrava	Klinička bolnica Dubrava	0,016
Grad Zagreb	2014	Dom zdravlja ZAGREB-CENTAR	RUNJANINOVA	0,0005
Grad Zagreb	2015	Klinički bolnički centar Zagreb	GUNDULIĆEVA	0,000035
Osječko-baranjska	2016	Dom zdravlja Đakovo	DOM ZDRAVLJA ĐAKOVO	0,003
Šibensko-kninska	2017	Dom zdravlja Šibenik	Dom zdravlja Šibenik	0,00054
Bjelovarsko-bilogorska	2017	Dom zdravlja Bjelovarsko-bilogorske županije	Ispostava Čazma	0,001

Soures: E-PRTR database (called Environmental Pollution Register – EPR, Croatian: ROO) from Croatian Environment and Nature Agency (HAOP)

Table 38 : monthly mercury concentration in sludge in Croatia

Izvještaj CUPOV Zagreb												
Godišnji izvještaj												
Monitoring deponiranog mulja												
Godina/ Year: 2013.-2018.												
udio žive (Mercury) u otpadnom mulju	**siječanj (Jan)**	**veljača (Feb)**	**ožujak (Mar)**	**travanj (Apr)**	**svibanj (May)**	**lipanj (Jun)**	**srpanj (Jul)**	**kolovoz (Aug)**	**rujan (Sep)**	**listopad (Oct)**	**studeni (Nov)**	**prosinac (Oct)**
Godina/ Year: 2013.-2018.	*mg/kg s.t.*											
2013.	<1	1,2	<1	<1	1,13	1,97	1,35	1,75	1,34	1,26	<1	0,81
2014.	1,02	<1	1,36	1,3	1,24	1,41	1,16	1,08	1,21	<1	1,35	2,33
2015.	1,69	1,94	1,49	1,66	1,86	1,67	2,22	1,57	1,38	2,13	2,07	<1
2016.	1,17	1,34	1,25	3,91	2,61	1,94	1,58	2,08	1,85	1,9	1,81	1,72
2017.	2,2	1,21	1,65	1,35	1,59	1,59	2,04	1,83	2,37	<1	1,82	1,62
2018.	1,77	1,98	1,38	1,8	1,53	1,34	1,7	2,1	2,3	<1	1,5	1,56
s.t. = suha tvar (dry matter)												
Napomena: Parametri ispitivanja određeni su pravilnikom o zaštiti polj.zemljišta NN15/92 , Pravilnikom o gospodarenju muljem iz UPOV u poljorivredi NN38/08, Studijom utjecaja na okoliš CUPOVZ-a, Pravilnikom o zaštiti polj. zemljišta od onečišćenja NN32/10.												
Rezultati su u tablicu prepisani s Ispitnih izvještaja koje dostavlja Nastavni zavod za javno zdravstvo dr. Andrija Štampar.												

Source : MZOE

Bulgaria

INTRODUCTION

Bulgaria is a country in Southeast Europe with 7.050 million of inhabitants. The capital and largest city is Sofia. The country spends 8.23% of its GDP in health care in 2016.

Table 39 Key socio-economic and health data

General information	
Population (million):	7.050
GDP per capita (PPP, EUR):	3.8 ; 6,550
GDP per capita (rank in the EU):	28
Unemployment rate (%):	5.2
Monthly minimum wage (EUR) (2019):	286.33
Number of dentists per hundred thousand inhabitants (2016):	112.39
Dental outpatient curative care (PPS per inhabitant) (2016):	42.86
Dental outpatient curative care (Percentual share of total current health expenditure (CHE)) (2016):	3.34

HEALTH SERVICES AND INSURANCE

Bulgaria created an autonomous national health insurance fund that has been decentralized to the regional level (28 regional health insurance funds). It is possible for patients as well as firms to contract complementary private health insurances[165]. Prevalence of private complementary coverage is unknown for the time being.

Dental care spending represented 131.71 million euros in 2016 corresponding to 3,3% of total health spending.

Data on the reimbursement rate and prices of dental restoration material is missing. According to Europstat, 48 % of total health spending is funded by households themselves in 2016.

KEY BARRIERS AND DRIVERS TO PHASING OUT DENTAL AMALGAM

[165] European Observatory on Health Systems and Policies. (2007). Bulgaria health system review. Health Systems in Transition, 9(1).

In its National Action Plan, Bulgaria has outlined the lack of data on dental amalgam uses as well as alternative dental restoration materials. Despite the lack of quantitative estimate, the NAP points out the increasing demand for alternative materials such as resin composites for aesthetic purposes as well as health concerns on dental amalgam. The NAP states that awareness on alternative materials for both dentists and patients require future actions. The NAP emphasises the need for data collection, providing information to dentist students as well the need for increased prevention on oral health and provide more information on risks of dental amalgam to the population (Bulgarian Health Authorities, 2019).

GOOD PRACTICES IN THE SELECTED AREAS

No data available.

Cyprus

INTRODUCTION

Cyprus is an island country in the Eastern Mediterranean. The largest city, capital, and seat of government of the island of Cyprus is Nicosia. The country spent 1,255.20 million euro (6.79% of GDP) in healthcare in 2016[166].

Table 40 Key socio-economic and health data

General information	
Population (million):	0.864
GDP per capita (PPP, EUR):	2.7 ; 23,300
GDP per capita (rank in the EU):	15
Unemployment rate (%):	8.4
Minimum wage (EUR):	N/A
Number of dentists per hundred thousand inhabitants:	103.57 (2016)
Dental outpatient curative care (PPS per inhabitant):	88.04 (2016)
Dental outpatient curative care (Percentual share of total current health expenditure (CHE)):	5.29 (2016)

DENTAL AMALGAM USE, ALTERNATIVES AND TRENDS

Number of restorations per type material

There is no official data on the number of restorations per material. Based on an expert opinion it is estimated that approximately 300,000 restorations per year are carried out with the use of dental amalgam. Dentists use mainly mercury-free materials, as it is estimated that on average only 1 restoration per day is carried by each dentists. Young dentists graduating from Universities often are trained only on mercury-free restorations.

The Cypriot government plans to phase-down dental amalgam. By 2025, the use of dental amalgam will be phased-out for all patients under 18 years of old (with certain exceptions). In the same year the country plans to assess the feasibility for a complete phase-out for all patients, again with certain exceptions.

[166] Eurostat (online data codes : hlth_sha11_hf, demo_gind and nama_10_gdp).

Dental sector and effectiveness

Table 41 Quantitative data on the dental sector

	Number					
	2013	**2014**	**2015**	**2016**	**2017**	**2018**
Dentists[167] (number)	N/A	N/A	N/A	N/A	N/A	Approximately 1,000
Dental clinics[168] (number)	N/A	N/A	N/A	N/A	N/A	Approximately 1,000
Average turnover per clinic (thousand EUR)	N/A	N/A	N/A	N/A	N/A	N/A
Self-reported unmet needs for dental examination due to urbanisation (%)*	7.4	8.6	4.1	3.6	3.6	N/A
Self-reported unmet needs for dental care due to financial reasons (%)*	N/A	3.1	N/A	N/A	N/A	N/A

There are no official data on the number of dentists in Cyprus. It is estimated that there are approximately 1,000 dentists. Almost in all cases, the dental offices are operated by a single dentist. The dental sector in Cyprus is predominantly private, as approximately only 40 dentists work in public hospitals and health centres.

According to Eurostat data, the unmet needs of for dental care, either for financial reasons or the demographic distribution range between 3.1% - 3.4%. In recent years, the unmet needs due to urbanisation dropped significantly, from 7.4% in 2014 to 3.6% in 2016. At the EU28 level, Cyprus performs below average both on the urbanisation and financial aspects (i.e. in the EU the average unmet needs correspond to 12.3% both for the reason of urbanisation and financial aspects).

Manufacturing companies of dental amalgam and alternative materials

There is no production of restoration materials in Cyprus.

Extra-EU Imports and exports of dental amalgam and alternative restoration materials

No data exist on the imports of dental filling materials.

[167] The term "dentists" refers to individual professionals
[168] The term "dental clinics" refers to establishments which offer dental treatment, including dental practices

Waste treatment from amalgam separators and water waste treatment facilities

Table 42 Quantitative data on water and solid waste from dental amalgam

Category	Mercury waste treatment					
	2013	2014	2015	2016	2017	2018
Share of dental chairs equipped with amalgam separators (%)	N/A	N/A	N/A	N/A	N/A	N/A
Share of waste from separators treated in specialized treatment facilities (%)	N/A	N/A	N/A	N/A	N/A	N/A
Average dental amalgam removal efficiency of separators (%)	N/A	N/A	N/A	N/A	N/A	N/A
Cost of collection and treatment of waste from separators per kg (thousand EUR)	N/A	N/A	N/A	N/A	N/A	400-500 EUR / year
Concentration of mercury in sewage sludge (µg/L)	N/A	N/A	N/A	N/A	N/A	N/A

In Cyprus, waste from amalgam separators are collected locally and treated in specialised facilities in third European countries. The cost for the collection and treatment of amalgam separators is estimated at 400-500 EUR per year. The purchase of amalgam separators has dropped in recent years from up to 2,500 EUR to 1,200 EUR, mainly to an increase competition.

Number of Cremations

Currently there are no crematoria in Cyprus.

NATIONAL POLICIES AND MEASURES

Table 43 Policies and measures to phase down or phase-out the use of dental amalgam

Category	Type	Ongoing	Under development
Measures to phase down or phase-out dental amalgam	Dental amalgam bans, phasing-out or phasing down	According to the Cypriot NAP, by 2025 the use of dental amalgam will be phased-out for all patients under 18 years of old (with certain exceptions).	According to the NAP, in 2025 the country will assess the feasibility for a complete phase-out for all patients, again with certain exceptions.

Category	Type	Ongoing	Under development
	National guidelines, promoting the use of mercury-free materials	The NAP envisages the development of communication activities to raise awareness on the environmental risks of dental amalgam.	No
	Supporting research and development in respect of mercury-free dental restorations	The NAP envisages R&D activities on mercury - free filling materials.	No
	Others:	No	No
Measures to manage waste and emissions from dental amalgam	Requirements for the installation and maintenance of separators	The Department of Environment has organised meetings with dentists to inform them of their obligations (paragraph 4 art.10 of EU Regulation 2017/852)	The DOE will take into account the provisions of installations and maintenance of separators to better apply the regulations and set these provisions in its national plans.
	Requirements for the collection and treatment of solid waste from separators	Waste management companies are obliged to collect and export waste from amalgam separators, as no treatment method is available in Cyprus currently. The NAP envisages the development of a certification process to ensure that amalgam separators, have a minimum efficiency of 95% and that they are properly installed and maintained.	No
	Requirements for mercury emissions from crematoria	No	No
	Standards for mercury concentrations in sludge for the use of land spreading	No	No

Category	Type	Ongoing	Under development
	Supporting research and development in respect of reducing emission and releases of mercury to the environment	No	No
	Others:	No	No

In relation to measures to phase down the use of dental amalgam, the Cypriot Government is planning to phase-out dental amalgam. The exact timelines and provisions will be included in the National Action Plan.

Cyprus has transposed the relevant EU legislation on the waste collection and treatment of amalgam separators. There are no additional measures, moving beyond these requirements. Nevertheless, the Department of Environment plans to strengthen the measures in relation to the maintenance of separators. The exact provisions will be included in the National Action Plan.

HEALTH SERVICES AND INSURANCE

Dental care is not covered by health care system in Cyprus, with the exception of removable dentures (partial or full) which are provided to low income categories only. This applies only on public hospitals and health centres which in general represent only a small part of the health system in the country. Dental restorations that take place in private dental clinics are not reimbursed, neither partially or fully. Currently the Government is working on a reimbursement scheme to be put in place as of 1st January 2020. This scheme is expected to cover basic treatment only, whereas the restorations will be excluded.

As shown in the table below, the cost of restoration is normally 50 EUR both for dental amalgam restorations and mercury-free materials. In few cases the price can reach 70 EUR. Overall, there is no difference between the costs.

Table 44 Quantitative data on dental restorations

Category	Category	Price	Reimbursement by social security %
Restoration	Dental amalgam	50 -70 EUR	0%
	Composite resins	50 -70 EUR	0%
	Glass ionomer cements	N/A	N/A
	Compomers	N/A	N/A
	Ceramics	N/A	N/A

Category	Category	Price	Reimbursement by social security %
Material	Dental amalgam	N/A	N/A
	Composite resins	N/A	N/A
	Glass ionomer cements	N/A	N/A
	Compomers	N/A	N/A
	Ceramics	N/A	N/A

GOOD PRACTICES IN THE SELECTED AREAS

No data available.

Czech Republic

INTRODUCTION

Czech Republic is a country of Central Europe with 10.610 million of inhabitants. The capital and largest city is Prague. The country spent 12,609.76 million euro (7.15% of GDP) in healthcare in 2016[169].

Table 45 Key socio-economic and health data

General information	
Population (million):	10.610
GDP per capita (PPP, EUR):	2.4 ; 17,606
GDP per capita (rank in the EU):	20
Unemployment rate (%):	2.2
Minimum wage (EUR):	518.97 (2019 S1)
Number of dentists per hundred thousand inhabitants:	75.29 (2016)
Dental outpatient curative care (PPS per inhabitant):	104.28 (2016)
Dental outpatient curative care (Percentual share of total current health expenditure (CHE)):	5.34 (2016)

DENTAL AMALGAM USE, ALTERNATIVES AND TRENDS

Number of restorations per type material

The table below provides the number of restorations covered by the national health system only.

Table 46 Number of restorations per type material

Material	Number of restorations per year					
	2013	2014	2015	2016	2017	2018
Dental amalgam	3,330,157	3,052,782	2,909,897	2,732,974	N/A	N/A

[169] Eurostat (online data codes : hlth_sha11_hf, demo_gind and nama_10_gdp)

Material	Number of restorations per year					
	2013	2014	2015	2016	2017	2018
Composite resins	N/A	N/A	65,297	62,384	N/A	N/A
Glass ionomer cements	N/A	N/A	N/A	N/A	N/A	N/A
Compomers	N/A	N/A	N/A	N/A	N/A	N/A
Ceramics	N/A	N/A	N/A	N/A	N/A	N/A
Others	N/A	N/A	N/A	N/A	N/A	N/A

In Czech Republic, the health system covers costs only for dental amalgam, and composite resins for patients under 18 years old. For adults, the full cost of restorations with the use of mercury-free materials are fully covered by patients. Data on this type of restorations do not exist.

The information in the table refer only to restorations covered by the national health system. By being covered by public health insurance, amalgam fillers have relatively accurate statistics on their use. Dentists report "dental caries treatment with permanent dentition", either by self-curing resin (in the range of incisors and canines) or by previously unrecognized and now cured amalgam from pre-prepared doses. The proportion of self-curing resins is very likely to be small to negligible due to their obsolescence (most patients prefer other materials from their own resources). Therefore, it can be assumed that the vast majority of performances correspond to the number of amalgam fillings.

Based on this data, the use of dental amalgam in Czech Republic between 2013 and 2016 has dropped by approximately 22% (on average 7% per year). According to the Czech Chamber of Dentists new dentists are gradually using more and more alternative and therefore, this trend is expected to increase. It is also important to highlight that the effect of ban of use of dental amalgam to children and pregnant women resulting from the Mercury Regulation and which is effective as of 1rst of July 2018 has not been captured yet in the statistics.

Today, dentistry students work almost exclusively with alternative materials - especially composites and various types of glass ionomer cements. The teaching of ceramic indirect fillings and partial dentures, including CAD-CAM technique, is still marginal. However, there are now over 200 (out of 8400 active dentists) in-office CAD-CAM indirect filling systems (mainly CEREC). Thus, even though the undergraduate teaching is theoretically conceived, they are gradually promoting and gradually gaining market share in postgraduate studies organized by the Czech Dental Chamber (hereinafter the Czech Dental Chamber).

According to the National Action Plan, by 2030 the use of dental amalgam will represent less of 1% of the dental fillings used in the country. A national expert, consulted in the context of this study, indicated that if a phase-out of dental amalgam takes place earlier than 2030, that would have a significant consequences on the national health system. Nevertheless, it was pointed out that the Czech dentistry is ready for phase down.

Dental sector and effectiveness

Table 47 Quantitative data on the dental sector

	Number					
	2013	**2014**	**2015**	**2016**	**2017**	**2018**
Dentists[170] (number)	8,200	8,200	8,300	8,400	8,500	8,500
Dental clinics[171] (number)	5,000	5,000	5,000	5,000	5,000	5,000
Average turnover per clinic (thousand EUR)	N/A	N/A	N/A	N/A	N/A	N/A
Self-reported unmet needs for dental examination due to urbanisation (%)*	1.7	1.6	1.1	1.0	1.0	N/A
Self-reported unmet needs for dental care due to financial reasons (%)*	N/A	0.7	N/A	N/A	N/A	N/A

Between 2013 and 2018, the number of dentists has increased slightly between 8,200 to 8,500 dentists (about 3.5%). During the same period, the number of dental clinics remained stable, meaning that the average size of clinics has increased from 1.6 to 1.7 per clinic. Therefore, the average size of dental clinics remains small.

According to the Czech Dental Chamber, in Czech Republic, the number of cases of dental caries and the number of applied dental fillings are not recorded. There are no studies, estimating these volumes. Neither it is possible to estimate the percentage of amalgam fillings and their alternatives as a percentage.

According to Eurostat data, the self-reported unmet needs for dental care, remain low (approximately 1% on average). At the same time, according to the Czech Dental Chamber, Czech Republic has an insufficient investment in caries prevention. The number of caries has increased from approximately 201,000 in 2010 to 217,000 in 2016. The prevention measures in the country, according to the Czech Dental Chamber are not sufficient.

Manufacturing companies of dental amalgam and alternative materials

In Czech Republic, there are two manufacturing companies of dental fillings:

- Bome s.r.o.: manufacturing of dental amalgam capsules;
- SAFINA, a.s: manufacturing of dental amalgam fillings and dental alloys for metal-ceramic fillings.

There is no data on the volumes sold by these two companies.

[170] The term "dentists" refers to individual professionals.
[171] The term "dental clinics" refers to establishments which offer dental treatment, including dental practices.

Extra-EU Imports and exports of dental amalgam and alternative restoration materials

According to the Czech Dental Chamber, there is no data on the imports of specific filling materials.

Waste treatment from amalgam separators and water waste treatment facilities

Table 48 Quantitative data on water and solid waste from dental amalgam

Category	**Mercury waste treatment**					
	2013	**2014**	**2015**	**2016**	**2017**	**2018**
Share of dental chairs equipped with amalgam separators (%)	100	100	100	100	100	100
Share of waste from separators treated in specialized treatment facilities (%)	100	100	100	100	100	100
Average dental amalgam removal efficiency of separators (%)	90	90	90	90	90	90
Cost of collection and treatment of waste from separators per kg (thousand EUR)	N/A	N/A	N/A	N/A	N/A	Incineration 40 CZK/kg Metals recycling – positive value – i.e. 500 CZK per solids collector (i.e. 0.5 kg) Collection – price differs by company – free, 50 CZK per solid collector, 390 CZK per kg
Concentration of mercury in sewage sludge (µg/L)	1.20	1.17	1.14	1.19	1.16	data not yet available

In Czech Republic, all dental chairs are equipped with amalgam separators. The average efficiency is estimated at 90%. The average efficiency of ISO certified separators is approximately 98%**172**. This indicates that not all amalgam separators are ISO certified.

In addition, according to the Water Supply and Sewerage Association of the Czech Republic (SOVAK), dental facilities, must ensure the installation of the amalgam separator, with a minimum efficiency of 95%.

There are also limitations of Mercury in wastewater discharged into sewerage, maximum limit 0.010 mg per litter for single sample, 0.005 mg per litter for 24 hours mixed sample.

[172] ISO 11143:2008: requirements and test methods for amalgam separators used in connection with dental equipment in the dental treatment centre, available at: https://www.iso.org/standard/42288.html

According to the Czech Dental Chamber, due to the dropping rates of dental amalgam use, eventually the generated waste of amalgam separators will be approximately 2kg of mercury per year.

All collected waste from amalgam separators are treated in Czech Republic. The cost of collection is approximately 1.5 EUR per separator, plus 15 EUR per kg. In addition, there is a benefit from the collected waste recycling that is estimated at approximately 40 EUR per kg. There is no information on how exactly this benefit is shared between the recycling facilities and waste collectors.

The values on the concertation of Mercury in sewage sludge refer to the amounts of the sludge used directly in agriculture. This represents about 50% of the total sludge production. It must be noted that despite the installation of amalgam separators in Czech Republic, some of the contamination derives from the pipes of old dental workplaces when dental amalgam was accumulated before the separators were installed.

Number of Cremations

Table 49 Quantitative data on cremations

Category	**Air emissions from crematoria**					
	2013	**2014**	**2015**	**2016**	**2017**	**2018**
Number of crematoria	27	27	27	27	27	27
Number of cremations per year	31,040	31,175	31,468	31,469	42,433	N/A
Share of crematoria equipped with abatement technologies (%)	0%	0%	0%	0%	0%	0%
Average efficiency of the abatement technologies (%)	N/A	N/A	N/A	N/A	N/A	N/A
Cost of mercury capture per cremation (EUR)	N/A	N/A	N/A	N/A	N/A	N/A

Crematoria in Czech Republic are not equipped with abatement technologies, specifically targeting the capture of mercury. Nevertheless, all crematoria are equipped with technologies that perform a thermal and oxidative destruction of pollutants. Decree No. 415/2012 all units shall include technologies that maintain a temperature that ensures thermal and oxidative destruction of all exhaust gases (at least 850°C) with a flue gas dwell time of at least 2 seconds. As a secondary abatement technique, dust filters are used in the combustion chamber, which must be dimensioned in such a way that emission limits for particulate matter cannot be exceeded.

NATIONAL POLICIES AND MEASURES

Table 50 Policies and measures to phase down or phase-out the use of dental amalgam

Category	Type	Ongoing	Under development
Measures to phase down or phase-out dental amalgam	Dental amalgam bans, phasing-out or phasing down	The NAP envisages that by 2030, the use of dental amalgam will represent only 1% of the total number of restorations.	No
	National guidelines, promoting the use of mercury-free materials	No	No
	Supporting research and development in respect of mercury-free dental restorations	No	No
	Others:	No	No
Measures to manage waste and emissions from dental amalgam	Requirements for the installation and maintenance of separators	Yes	No
	Requirements for the collection and treatment of solid waste from separators	Same conditions for collection and treatment as other hazardous waste – approved persons (approved operational conditions), electronic evidence of transport, reporting (in case of production 100 kg and more), etc. according to waste framework directive.	No
	Requirements for mercury emissions from crematoria	No requirements for mercury emission.	The NAP envisages the installation of filtration systems in crematoria.
	Standards for mercury concentrations in sludge for the use of land spreading	4 mg/kg – decree no. 437/2016 Coll. – conditions for use of treated sewage sludge in agriculture.	No

Category	Type	Ongoing	Under development
	Supporting research and development in respect of reducing emission and releases of mercury to the environment	No	The NAP envisages the decontamination of the wastewater system in the Czech Republic.
	Others:	No	No

Czech Republic has transposed the relevant EU legislation on the waste collection and treatment of amalgam separators. There are no additional measures, moving beyond these requirements. In addition, there are no specific requirements addressing mercury emissions from crematoria.

HEALTH SERVICES AND INSURANCE

Public dental plans provide preventive treatment, check-ups, standard fillings, simple extractions, and noncomplex endodontic treatments. Public insurance will not cover things that are considered "not standard". Supplemental health plans are not common in the Czech Republic. There are no provisions for vulnerable groups.

Basic materials (dental amalgam, composite resins for children under 18 – frontal location, glass ionomer cements for children under 15 and pregnant or breastfeeding women) and treatment is fully covered in the case of a dental treatment. The list of procedures that are covered is defined in a specific decree. Other materials or treatments are not covered by public health insurance and are paid by out-of-pocket payments. There is no partial coverage or co-payment (either full reimbursement or none).

According to the Czech Dental Chamber, the Czech Republic has some significant advantages in this regard against a number of other countries in terms of long-term teaching of alternative filling materials in undergraduate studies of dentistry. Nevertheless, there is an insufficient investment in caries prevention and, in particular, absolute preference for dental amalgam in reimbursement of health insurance companies, where in most indications it is the only reimbursed materials.

The use of dental amalgam is particularly popular in the older population, who appreciate their own stability and are reliant on the public health system which covers only dental amalgam fillings. Gradually, the percentage of alternative restorative materials used for the oldest generation is increasing, while it is projected that by 2030, at least 2,000 dentists (out of 8,400 will retire. In the youngest generation of doctors, dental amalgam is often rejected fillings, mainly due to high invasiveness but also with regard to environmental aspects.

Table 51 Quantitative data on dental restorations

Category	Category	Price	Reimbursement by social security %
Restoration	Dental amalgam	19.12 EUR	100 %

Category	Category	Price	Reimbursement by social security %
	Composite resins	19.33 EUR	100 % (for children under 15 and pregnant women only)
	Glass ionomer cements	19.12 EUR	100 % (for children under 15 and pregnant women only)
	Compomers	N/A	0 %
	Ceramics	N/A	0 %
Material	Dental amalgam	N/A	N/A
	Composite resins	N/A	N/A
	Glass ionomer cements	N/A	N/A
	Compomers	N/A	N/A
	Ceramics	N/A	N/A

GOOD PRACTICES IN THE SELECTED AREAS

No data available

Denmark

INTRODUCTION

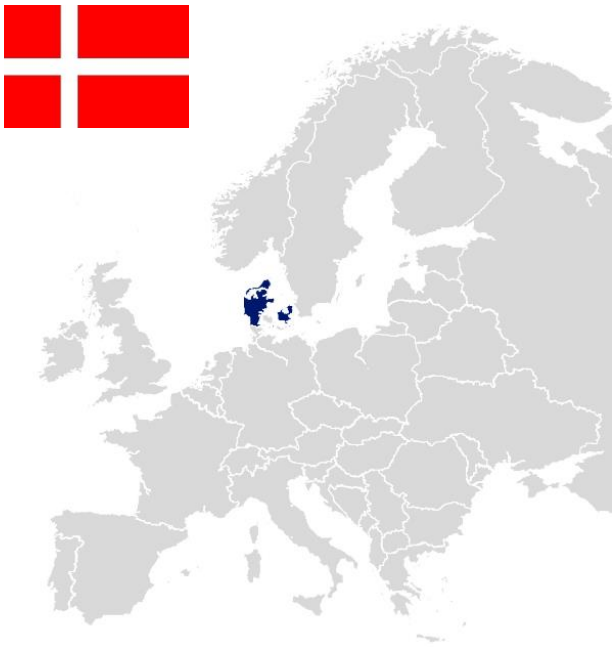
Denmark is a Scandinavian Nordic country with a population of 5.7 million inhabitants. It is a constitutional monarchy with a parliamentary system, ruled in practice by a Prime Minister and the other government ministers.

The country is the 4th one in the EU in terms of gross domestic product (GDP). The country kept its local currency, the Danish Krone (DKK).

The territory is divided in 5 administrative regions and 98 municipalities, the biggest region in terms of population being Hovedstaden including the capital city of Copenhagen.

The regional councils are responsible for National Health Service, which is financed mainly through local income taxes. In 2017, 10.2% of the national GDP was spent on health care[173].

Table 52 Key socio-economic and health data

General information	
	
Population (million):	5,781
GDP per capita (PPP, EUR):	0.9 ; 47,500
GDP per capita (rank in the EU):	4
Unemployment rate (%):	5.7
Minimum wage (EUR):	N/A
Number of dentists per hundred thousand inhabitants:	73.99 (2015)
Dental outpatient curative care (PPS per inhabitant):	158.19 (2016)
Dental outpatient curative care (Percentual share of total current health expenditure (CHE)):	4.44 (2016)

DENTAL AMALGAM USE, ALTERNATIVES AND TRENDS

Number of restorations per type material

In Denmark, dental amalgam use in dental fillings decreased of 92% in 10 years; it decreased from 22% of dental fillings in 2007 to 1.7% in 2017.

Table 53 Number of restorations per type material

[173] OECD, Health expenditure and financing. Available at: https://stats.oecd.org/Index.aspx?DataSetCode=SHA

Material	Number of restorations
Dental amalgam	1.7% of dental fillings (2017)
Composite resins	N/A
Glass ionomer cements	N/A
Compomers	N/A
Ceramics	N/A
Others	N/A

Dental sector and effectiveness

Table 54 Quantitative data on the dental sector

	Number					
	2013	2014	2015	2016	2017	2018
Dentists[174] (number)	1,258	N/A	N/A	N/A	N/A	N/A
Dental clinics[175] (number)	3,331	N/A	N/A	N/A	N/A	N/A
Average turnover per clinic (thousand EUR)	N/A	N/A	N/A	N/A	N/A	N/A
Self-reported unmet needs for dental examination due to urbanisation (%)*	4.0	4.4	4.0	3.7	4.3	N/A
Self-reported unmet needs for dental care due to financial reasons (%)*	N/A	12.9	N/A	N/A	N/A	N/A

**Data collected from Eurostat*

In Denmark, the dental sector is mainly composed of dentists working for the private sector. In 2013, the dental workforce was composed of 73% (3331) dentists working in the private sector, against 27% (1258) working in the public sector.[176]

Tandlægeforeningen is the Danish Dental Association which goal is to carry the interests of public and private dentists in Denmark, to ensure the quality and credibility of the dental services provided.

[174] The term "dentists" refers to individual professionals
[175] The term "dental clinics" refers to establishments which offer dental treatment, including dental practices
[176] Sveriges Tandläkarförbund, Nordic Dentistry in Numbers (2015). Available at: https://tandlakarforbundet.se/app/uploads/2017/02/nordiska-tandlaxxkarsiffror-2015.pdf

Manufacturing companies of dental amalgam and alternative materials

No data available.

Extra-EU Imports and exports of dental amalgam and alternative restoration materials

No data available.

Waste treatment from amalgam separators and water waste treatment facilities

No data available.

Number of Cremations

Today, most of Danish people choose cremation. The number and proportion of cremation increased continuously from 2013 to 2017.

Table 55 Quantitative data on cremations

Category	**Air emissions from crematoria**					
	2013	**2014**	**2015**	**2016**	**2017**	**2018**
Number of crematoria[177]	20	20	20	20	20	N/A
Number of cremations per year	42,349 (81% of deaths)	41,532 (81% of deaths)	42,238 (82% of deaths)	43,792 (83% of deaths)	44,209 (83% of deaths)	N/A
Share of crematoria equipped with abatement technologies (%)	N/A	N/A	N/A	N/A	N/A	N/A
Average efficiency of the abatement technologies (%)	N/A	N/A	N/A	N/A	N/A	N/A
Cost of mercury capture per cremation (EUR)	N/A	N/A	N/A	N/A	N/A	N/A

NATIONAL POLICIES AND MEASURES

Table 56 Policies and measures to phase down or phase-out the use of dental amalgam

[177] The Cremation Society of Great Britain: https://www.cremation.org.uk/statistics

Category	Type	Ongoing	Under development
Measures to phase down or phase-out dental amalgam	Dental amalgam bans, phasing-out or phasing down	Danish Statutory Order on the ban of import, sale and export of mercury and mercury-containing products no. 73 of 25 January 2016 (permanent molars are exempted from this ban under conditions*).	No
	National guidelines, promoting the use of mercury-free materials	The Danish Dentist Association offers guidance to Danish dentists regarding the restrictions on dental amalgam use.	The Danish Dentist Association offers guidance to Danish dentists regarding the restrictions on dental amalgam use.
	Supporting research and development in respect of mercury-free dental restorations	No	No
	Others	No	No
Measures to manage waste and emissions from dental amalgam	Requirements for the installation and maintenance of separators	No	No
	Requirements for the collection and treatment of solid waste from separators	No	No
	Requirements for mercury emissions from crematoria	No	No
	Standards for mercury concentrations in sludge for the use of land spreading	No	No
	Supporting research and development in respect of reducing emission and releases of mercury to the environment	No	No
	Others	No	No

* The Danish Statutory Order on the ban of import, sale and export of mercury and mercury-containing products no. 73 of 25 January 2016 prohibits inter alia the use of mercury in products for dental fillings. Exempt from this ban are products for fillings in permanent molars, where the filling is worn. This restriction on the use of mercury in dental fillings has been in force in Denmark since 1 January 1995.

An assessment commissioned by the Danish Health Agency named "phasing-out of amalgam in dental care - clarifying options and recommendations" concluded and recommended that the ban on the use of dental amalgam containing mercury be narrowed down even further, so that the amalgam should only be used as filling in permanent molars in the following instances:

- lack of possibility of drying
- difficult accessibility of the cavity
- especially large cavity
- large distance to neighbouring tooth

These recommendations have been included in the Danish Ministry of Health guideline on the use of dental fillings no 9552 of 5 July 2018.

HEALTH SERVICES AND INSURANCE

Denmark's Health Law sets the universal and equal access to health care to Danish population and the government's obligation to promote health, to prevent and treat illness, suffering and functional limitations with quality of care, transparency and access to information. Thus, all registered people are automatically concerned by publicly financed health care.

The government is in charge to setting the regulations for health services and oversees the supervision of health care managed and financed by the 5 regions and 98 municipalities:

- Regions: Manage and finance hospitals and most of the services provided my private general practitioners (GPs), office-based specialists, physiotherapists, dentists and pharmacists, and specialized rehabilitation tasks.
- Municipalities: Manage and finance nursing services, some dental services, school health services, general prevention and rehabilitation tasks.

Health is the 2nd biggest public expenditure in Denmark after social protection, representing 15.6% of total public expenditures in 2015[178], and 10.2% of the national GDP in 2017[179]. Public healthcare expenditures were of 23,180 million euros in 2014 (+0.09% since 2010) while private healthcare expenditures were of 4.354 million euros. Public healthcare is financed through a national health tax (8% of taxable income)[180].

Dental treatments are covered on average at 40% by public health care, and up to 65% for some diagnostic procedures. Some other procedures such as dentures and crowns are not reimbursed[181].

Patients have the choice between two coverage options:

- Group 1 (98% of the population) is required to register to a general practitioner (GP) and needs a referral from him/her to consult a specialist. There is no out-of-pocket payment for medical services, which are paid by the regions.

[178] Healthcare Denmark and Ministry of Health, Healthcare in Denmark – An Overview (2016). Available at: https://www.sum.dk/English/~/media/Filer%20-%20Publikationer_i_pdf/2016/Healthcare-in-dk-16-dec/Healthcare-english-V16-dec.ashx

[179] OECD, Health expenditure and financing. Available at: https://stats.oecd.org/Index.aspx?DataSetCode=SHA

[180] The Commonwealth Fund, The Danish Health Care System. Available at: https://international.commonwealthfund.org/countries/denmark/

[181] European Commission, Denmark – Health care. Available at : https://ec.europa.eu/social/main.jsp?catId=1107&langId=en&intPageId=4488

- Group 2 (2% of the population) has a free choice of GP and does not need a referral to consult a specialist. They make a co-payment to supplement the automatic payment for medical services.

Dental services are fully covered for children and teens under 18.

Complementary voluntary insurance can be purchased by individuals and covers statutory co-payments (mainly pharmaceuticals and dental care) and services not fully covered by public healthcare. Such coverage is used by 39% of the population. In addition to this, supplementary insurance can be held to get expanded coverage. This type of insurance is provided mainly through private employers, and covers 26% of Danes.

Category	Category	Price	Reimbursement by social security %
Restoration	Dental amalgam	253-560 DKK	11-22%
	Composite resins	N/A	N/A
	Glass ionomer cements	453 DKK	8-25%
	Compomers	N/A	N/A
	Ceramics	N/A	N/A
Material	Dental amalgam	N/A	N/A
	Composite resins	N/A	N/A
	Glass ionomer cements	N/A	N/A
	Compomers	N/A	N/A
	Ceramics	N/A	N/A

Table 57 Quantitative data on dental restorations

The prices above are fixed prices agreed for adult dental care with the public health insurance. Private specialists can however set their own fees for patients not covered by public funding.

Dental restorations prices depend on the material type.

- Restorations made from dental amalgam go from 253 DKK to 560 DKK depending if the material is not-combined, combined, or double-combined (double

combined being the most expensive)[182]. Combined amalgam is the most reimbursed type of amalgam restoration (22% of the fee).
- Restorations made from glass ionomer are priced at 453 DKK and are reimbursed at 8% for single-faced to 25% for multi-faced restoration.

GOOD PRACTICES IN THE SELECTED AREAS

No information available.

[182] Tandlaegeforeningen (Danish Dental Association), Prices for dental services (fee tables) with grants. Available at: https://www.tandlaegeforeningen.dk/Patienter/Priser_og_tilskudsmuligheder/tilskud_tandpleje_2016/voksne/gruppe_1_gruppe_2

Estonia

INTRODUCTION

Estonia is a country in Northern Europe with a population of 1.3 million. The capital and largest city is Tallinn. The state of Estonia is a democratic unitary parliamentary republic. The share of gross domestic product spend in healthcare is one of the lowest in Europe (6.68% in 2016). Estonian health care system is financed publicly by social taxation. The ministry of Social Affairs is responsible of public health programmes. The state is divided into 15 counties and local municipalities have a small role in financing[183,184].

Table 58 Key socio-economic and health data

General information	
Population (million):	1.319
GDP per capita (PPP, EUR):	3.6 ; 15,100
GDP per capita (rank in the EU):	22
Unemployment rate (%) (2017):	5.8
Monthly minimum wage (EUR) (2019):	540.00
Number of dentists per hundred thousand inhabitants:	131.35
Dental outpatient curative care (PPS per inhabitant) (2016):	95.53
Dental outpatient curative care (Percentual share of total current health expenditure (CHE)) (2016):	N/A

DENTAL AMALGAM USE, ALTERNATIVES AND TRENDS

Number of restorations per type material

Alternatives are preferably used instead of dental amalgam in Estonia.

No data available.

Dental sector and effectiveness

The Ministry of Social Affairs recognized four dental care specialties in Estonia. Each specialty has its own professional association[185]. The **Estonian Dental Association (EHL – Esti Hambaarstide Liit**) gathers more than 970 dentists (70% of Estonian

[183] http://appsso.eurostat.ec.europa.eu/nui/submitViewTableAction.do
[184] http://www.euro.who.int/__data/assets/pdf_file/0011/377417/hit-estonia-eng.pdf?ua=1
[185] http://www.euro.who.int/__data/assets/pdf_file/0011/377417/hit-estonia-eng.pdf?ua=1

dentists). The association aims at protecting the rights of dental professions and improving dental care in Estonia.[186]

Dental care is regulated by the Health Services Organization Act and the Health Insurance Act. There are no public dental clinics in Estonia. Dental health care is mainly provided by private dentists who have a licence to provide these cares. Private fees are not regulated and there are no dental insurance schemes.[187]

Table 59 Quantitative data on the dental sector

	Number					
	2013	**2014**	**2015**	**2016**	**2017**	**2018**
Dentists[188] (number)	N/A	N/A	N/A	N/A	N/A	N/A
Dental clinics[189] (number)	N/A	N/A	N/A	N/A	N/A	N/A
Average turnover per clinic (thousand EUR)	N/A	N/A	N/A	N/A	N/A	N/A
Self-reported unmet needs for dental examination due to urbanisation (%)*	8.3	8.6	11.1	10.0	6.7	N/A
Self-reported unmet needs for dental care due to financial reasons (%)*	N/A	25.0	N/A	N/A	N/A	N/A

**Data collected from Eurostat*

Manufacturing companies of dental amalgam and alternative materials

There are several manufacturing companies of dental materials in Estonia: Iloxia[190], Magnum Medical Oü[191], etc.

No quantitative data available

Extra-EU Imports and exports of dental amalgam and alternative restoration materials

No data available.

Waste treatment from amalgam separators and water waste treatment facilities

The Ministry of Social Affairs established the regulatory framework for dental care provision. Waste collected from amalgam separators is treated as a medical waste (e.g.

[186] https://ehl.ee/hambaarstide-liit/organisatsioon/
[187] EU Manual of dental practice 2015, CED
[188] The term "dentists" refers to individual professionals
[189] The term "dental clinics" refers to establishments which offer dental treatment, including dental practices
[190] http://www.iloxia.com/Dental%20care.html
[191] https://web.magnum.ee/en/companies/

landfilled)[192]. Amalgam separators are advised in Estonia but there are not required by law[193].

No quantitative data available.

Number of Cremations

There are 8 crematoria in Estonia. The Tallina Krematoorium in Tallin is the most important[194].

Table 60 Quantitative data on cremations

Category	Air emissions from crematoria					
	2013	2014	2015	2016	2017	2018
Number of crematoria	6	6	7	8	8	8
Number of cremations per year	N/A	N/A	N/A	N/A	N/A	N/A
Share of crematoria equipped with abatement technologies (%)	N/A	N/A	N/A	N/A	N/A	N/A
Average efficiency of the abatement technologies (%)	N/A	N/A	N/A	N/A	N/A	N/A
Cost of mercury capture per cremation (EUR)	N/A	N/A	N/A	N/A	N/A	N/A

NATIONAL POLICIES AND MEASURES

Table 61 Policies and measures to phase down or phase-out the use of dental amalgam

Category	Type	Ongoing	Under development
Measures to phase down or phase-out dental amalgam	Dental amalgam bans, phasing-out or phasing down	No	A NAP
	National guidelines, promoting the use of mercury-free materials	No	No
	Supporting research and development in respect of mercury-	No	No

[192] Questionnaire from Ministry Environment
[193] https://noharm-europe.org/sites/default/files/documents-files/5269/HCWH_Europe_Mercury_Factsheet_Dec-2017_FINAL_WEB.pdf
[194] http://www.krematoorium.ee/tallinn/en

Category	Type	Ongoing	Under development
	free dental restorations		
	Others :	Dentists use dental amalgam very rarely dental amalgam in Estonia.	No
Measures to manage waste and emissions from dental amalgam	Requirements for the installation and maintenance of separators	No	No
	Requirements for the collection and treatment of solid waste from separators	No	No
	Requirements for mercury emissions from crematoria	No	No
	Standards for mercury concentrations in sludge for the use of land spreading	No	No
	Supporting research and development in respect of reducing emission and releases of mercury to the environment	No	No
	Others :	No	No

HEALTH SERVICES AND INSURANCE

The **Ministry of Social Affairs** is indirectly responsible of the **Health Board** which is responsible of health cares including **dental care services**.

The Estonian healthcare system is financed through general taxation. Contributions are mainly related to social tax (earmarked social payroll taxes) and employment (13% of the employee's gross salary paid by the employer). The **Estonian Health Insurance Fund (EHIF)** helps financing dental care.

For adults, there is 50% of co-insurance and 15% in specific cases (persons over 63 years old, pregnant women, persons with work incapacity, with medical conditions, etc.)[195].

[195] http://www.euro.who.int/__data/assets/pdf_file/0011/377417/hit-estonia-eng.pdf?ua=1

For child dental care, there is no co-payment. The cost is covered by the EHIF. There are annual reimbursement limits of 40€ (adults) and 85€ per year (persons over 63, pregnant women, etc.)[196,197].

No information available about price and reimbursement.

GOOD PRACTICES IN THE SELECTED AREAS

No data available.

[196] http://www.euro.who.int/__data/assets/pdf_file/0011/377417/hit-estonia-eng.pdf?ua=1
[197] EU Manual of dental practice 2015, CED

Finland

INTRODUCTION

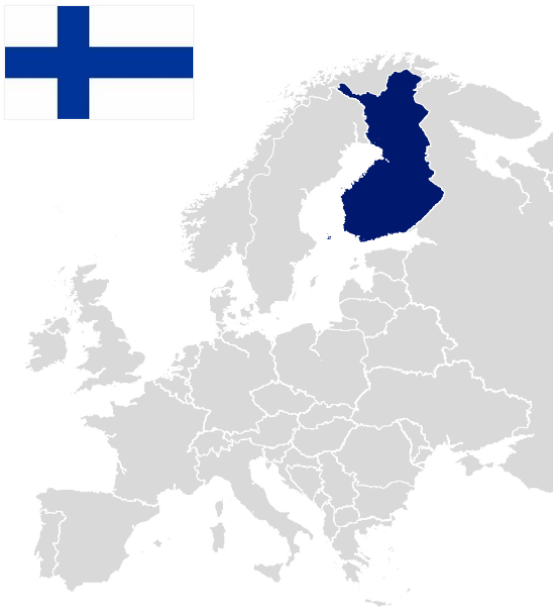
Finland is a Scandinavian Nordic country with a population of 5.5 million inhabitants. The country is a parliamentary republic led by a President and a Prime Minister who owns the executive power, and his government located in the capital city, Helsinki.

The country is organized into 19 regions, 70 sub-regions and 311 municipalities being the fundamental administrative divisions and accounting for half of public spending.

The country is ranked 8th in Europe in terms of gross domestic product (GDP), and it belongs to the euro (€) zone.

The government is responsible for funding, guidance and supervision of healthcare services, while municipalities are responsible for the provision of social welfare and health care services. In 2017, Finland spent 9.2% of its national GDP in health[198].

Table 62 Key socio-economic and health data

General information	
	
Population (million):	5,513
GDP per capita (PPP, EUR):	2.2 ; 37,700
GDP per capita (rank in the EU):	8
Unemployment rate (%):	7.4
Minimum wage (EUR):	N/A
Number of dentists per hundred thousand inhabitants:	73.02 (2014)
Dental outpatient curative care (PPS per inhabitant):	150.55 (2016)
Dental outpatient curative care (Percentual share of total current health expenditure (CHE)):	4.93 (2016)

DENTAL AMALGAM USE, ALTERNATIVES AND TRENDS

Number of restorations per type material

In Finland, roughly 3,000,000 dental restorations were made in 2017. Dental amalgam alternatives seem to be preferred to dental amalgam nowadays, except for the oldest practitioners for whom amalgam is still a preferred material for restoration. Most dentists do not use amalgam anymore.

[198] OECD, Health expenditure and financing. Available at: https://stats.oecd.org/Index.aspx?DataSetCode=SHA

In Helsinki City Clinics (where 5% of the country dentists work), dental amalgam use decreased by 94% in 4 years, going from 1,110 in 2014 to 60g in 2018.

Table 63 Number of restorations per type material

Material	Number of restorations
Dental amalgam*	Around 1% of the fillings made in Finland (estimation of 1,000 to 2,000 g of amalgam per year).
Composite resins	Most of the dental restorations are performed with composite resins.
Glass ionomer cements	N/A
Compomers	N/A
Ceramics	N/A
Others	N/A

Dental sector and effectiveness

The dental sector in Finland is structured by the Finnish dental Association. The Finnish Dental Association is a lobbying and expert organisation for dentists and dentistry founded in 1924.

In Finland, half of the dentists work in public health centres and hospitals, while the other half work in private practices. There are in average 2 dentists per private clinics, while public ones are bigger.

There are 1,000,000 adults visiting clinics every year (both public and private), and children all visit public clinics (800,000/year).

The salary gap between public and private dentistry is small, since the average dentists' salary are:

- Public dentistry: 6,100€/month
- Private dentistry: 7,800€/month

Table 64 Quantitative data on the dental sector

	Number					
	2013	2014	2015	2016	2017	2018
Dentists[199] (number)	N/A	N/A	N/A	N/A	N/A	4,500
Dental clinics[200] (number)	N/A	N/A	N/A	N/A	N/A	1,800 (estimation)
Average turnover per clinic (thousand EUR)	N/A	N/A	N/A	N/A	N/A	N/A
Self-reported unmet needs for dental examination due to urbanisation (%)*	4.6	3.6	5.2	5.4	4.9	N/A
Self-reported unmet needs for dental care due to financial reasons (%)*	N/A	13.1	N/A	N/A	N/A	N/A

**Data collected from Eurostat*

Manufacturing companies of dental amalgam and alternative materials

No data available.

Extra-EU Imports and exports of dental amalgam and alternative restoration materials

No data available.

Waste treatment from amalgam separators and water waste treatment facilities

In Finland, waste from amalgam separators is collected and treated by specialised treatment facilities located in the country. All dental chairs must be equipped with amalgam separator, which have a required efficiency of at least 95% since 1997.

Table 65 Quantitative data on water and solid waste from dental amalgam

Category	Mercury waste treatment					
	2013	2014	2015	2016	2017	2018
Share of dental chairs equipped with amalgam separators (%)	100	100	100	100	100	100

[199] The term "dentists" refers to individual professionals.
[200] The term "dental clinics" refers to establishments which offer dental treatment, including dental practices.

Category	Mercury waste treatment					
	2013	2014	2015	2016	2017	2018
Share of waste from separators treated in specialized treatment facilities (%)	100	100	100	100	100	100
Average dental amalgam removal efficiency of separators (%)	95 or +	95 or +	95 or +	95 or +	95 or +	95 or +
Cost of collection and treatment of waste from separators per kg (thousand EUR)	N/A	N/A	N/A	N/A	N/A	N/A
Concentration of mercury in sewage sludge (µg/L)	N/A	N/A	N/A	N/A	N/A	N/A

Number of Cremations

In 2016 in Finland, more than half of the funerals involved cremations. There has been an increase by 7% of the number of cremations between 2015 and 2016[201]. The number of cremations keeps increasing from 2013 to 2017.

Table 66 Quantitative data on cremations

Category	Air emissions from crematoria					
	2013	2014	2015	2016	2017	2018
Number of crematoria[202]	22	23	23	23	21	N/A
Number of cremations per year	23,702 (46% of deaths)	24,822 (48% of deaths)	25,631 (49% of deaths)	27,483 (51% of deaths)	28,336 (53% of deaths)	N/A
Share of crematoria equipped with abatement technologies (%)	N/A	N/A	N/A	N/A	N/A	N/A
Average efficiency of the abatement technologies (%)	N/A	N/A	N/A	N/A	N/A	N/A
Cost of mercury capture per cremation (EUR)	N/A	N/A	N/A	N/A	N/A	N/A

[201] https://yle.fi/uutiset/osasto/news/rising_cremation_trend_eases_pallbearer_shortage_in_finland/10201454
[202] The Cremation Society of Great Britain https://www.cremation.org.uk/statistics

NATIONAL POLICIES AND MEASURES

Table 67 Policies and measures to phase down or phase-out the use of dental amalgam

Category	Type	Ongoing	Under development
Measures to phase down or phase-out dental amalgam	Dental amalgam bans, phasing-out or phasing down	The use of dental amalgam for children or pregnant/breastfeeding mothers is forbidden.	No
	National guidelines, promoting the use of mercury-free materials	Guideline for restorative dentistry, 2018: recommendation to not use dental amalgam.	The use of dental amalgam will be prohibited in 2030 (at latest).
	Supporting research and development in respect of mercury-free dental restorations	No	No
	Others	No	No
Measures to manage waste and emissions from dental amalgam	Requirements for the installation and maintenance of separators	No	No
	Requirements for the collection and treatment of solid waste from separators	Waste separators must have an efficiency of 95% or more [203]	No
	Requirements for mercury emissions from crematoria	No	No
	Standards for mercury concentrations in sludge for the use of land spreading	No	No
	Supporting research and development in respect of reducing emission and releases of mercury to the environment	No	No
	Others	No	No

[203] Government decision on amalgam-containing wastewater and waste resulting from dental care (1997). Available at: http://www.finlex.fi/en/laki/kaannokset/1997/en19970112.pdf

Health services and insurance

The Finnish healthcare system is based on public healthcare services to which everyone residing in the country is entitled. According to the Constitution of Finland, the public authorities shall guarantee for everyone adequate social, health and medical services. Public healthcare services are funded by tax revenue and client fees charged for services.

Healthcare is steered by legislation, the system of central government transfers to local government, recommendations and guidelines, and supervision. The Ministry of Social Affairs and Health steers healthcare in collaboration with the agencies and institutions under it.

Agencies under the Ministry of Social Affairs and Health include the:

- National Institute for Health and Welfare (THL)
- Finnish Medicines Agency (Fimea)
- Radiation and Nuclear Safety Authority
- Finnish Institute of Occupational Health (TTL)
- National Supervisory Authority for Welfare and Health (Valvira)

Valvira and the Regional State Administrative Agencies are responsible for the supervision of healthcare.

Health services are also provided by private companies, independent professional practitioners and organisations. Kela reimburses a proportion of the costs of healthcare to persons residing in and covered under health insurance in Finland.

The national social security system covers partially the costs of patients' dental restorations. It fully covers dental restorations for children under 18 years old in public clinics. For vulnerable people, social assistance may cover dental restorations depending on his/her income. The reimbursement rate for dental restoration is equal whatever filling material is used. [204]

In public clinics, adult patients pay approximately 35% of the costs, against 85% in private clinics, without any reimbursement differentiation per restoration material.

The fees for dental restorations with amalgam or composite resins are the equal. For ceramics, patients have to pay for the laboratory costs.

In Finland, it is not common to have supplementary health plans covering dental restoration.

Table 68 Quantitative data on dental restorations[205]

Category	Category	Price	Reimbursement by social security %
Restoration	Dental amalgam	50	N/A

[204] EEB, It is now time to phase-out Dental Amalgam Use in the European Union (2016)

[205] More information is available in Finnish here: https://www.kela.fi/documents/10180/0/Hammashoidon+taksan+soveltamisohje+1.1.2018/8d40cc43-928d-40ce-a19b-2a1e3cae0b29

Category	Category	Price	Reimbursement by social security %
	Composite resins	50	N/A
	Glass ionomer cements	50	N/A
	Compomers	50	N/A
	Ceramics	90	N/A
Material	Dental amalgam	0	N/A
	Composite resins	0	N/A
	Glass ionomer cements	0	N/A
	Compomers	0	N/A
	Ceramics	250	N/A

GOOD PRACTICES IN THE SELECTED AREAS

No data available.

France

INTRODUCTION

France is a country of Western Europe with 66.9 million of inhabitants. The capital and largest city is Paris. The French health care system is mainly financed by national health insurance. The country spent 11.54% of its gross domestic product in healthcare in 2016[206].

Table 69 Key socio-economic and health data

General information	
Population (million):	66.926
GDP per capita (PPP, EUR):	1.4; 32,900
GDP per capita (rank in the EU):	11
Unemployment rate (%):	9.1
Monthly minimum wage (EUR) (2019):	1,521.22
Number of dentists per hundred thousand inhabitants:	64.35
Dental outpatient curative care (PPS per inhabitant):	158.37
Dental outpatient curative care (Percentual share of total current health expenditure (CHE)):	4.37

DENTAL AMALGAM USE, ALTERNATIVES AND TRENDS

Number of restorations per type material

Absence of information on the exact number of restorations per material. However, the share of dental amalgam restoration from an ANSM report (National Agency of Drugs Safety, see (ANSM, 2015)) is around **25% in 2011**.

Amalgam restoration seems to concern only **posterior teeth restoration** according to data from Comident (French association of dental material manufacturers). The ANSM report also points out a declining trend in dental amalgam restoration explained by higher use of alternatives.

Those data are not up to date and additional research on the current repartition in dental restoration material are needed to confirm or not the decreasing trend in amalgam use in France.

[206] Eurostat health care expenditure

No data available

Dental sector and effectiveness

Table 70 Quantitative data on the dental sector

	Number					
	2013	**2014**	**2015**	**2016**	**2017**	**2018**
Dentists[207] (number)	40,833	41,223	41,495	41,788	42,197	42,348
Dental clinics[208] (number)	N/A	N/A	N/A	N/A	N/A	N/A
Average turnover per clinic (thousand EUR)	N/A	N/A	N/A	N/A	N/A	N/A
Self-reported unmet needs for dental examination due to urbanisation (%)*	5.5	5.6	3.4	3.4	3.0	N/A
Self-reported unmet needs for dental care due to financial reasons (%)*	N/A	N/A	N/A	N/A	N/A	N/A

**Data collected from Eurostat*

Dentistry is divided between public and private workers.

Three different status (convention with public health care authorities) exist for private sector:

- Sector 1, fees are set and reimbursed by public healthcare insurance at 70%[209].
- Sector 2, dentist may exceed fees set by public healthcare insurance and only a part of them will be reimbursed (70% of the reimbursed base set).
- Sector 3, no convention with public health care and only a small part will be reimbursed.

Dentists are mainly registered as private workers (82% according to (DREES, 2016))

Dentists, like other medical profession, tend to choose to work in a common clinic, especially young practitioners since it allows to share material costs and knowledge. Indeed, the share of private dentists working in a clinic went from 33% to 55% between 2001 and 2015 (DREES, 2016).

Manufacturing companies of dental amalgam and alternative materials

Limited information is available.

[207] The term "dentists" refers to individual professionals
[208] The term "dental clinics" refers to establishments which offer dental treatment, including dental practices
[209] https://www.service-public.fr/particuliers/vosdroits/F1069

One dental material seller reported in an interview that dental amalgam sales dropped and does represent only around 1% of his total turnover (no information with respect to the rest of restoration material).

Table 71 Annual sales per company and material

Company	Material	Amounts
Dentoria SAS	Dental amalgam*	Around 1%
	Composite resins	N/A
	Glass ionomer cements	N/A
	Compomers	N/A
	Ceramics	N/A

Extra-EU Imports and exports of dental amalgam and alternative restoration materials

No information for the time being.

Waste treatment from amalgam separators and water waste treatment facilities

Amalgam separators are mandatory and must follow the norm NF/EN/ISO 11143 for separators in the framework of "arrêté du 30 mars 1998"[210]. Thus, in theory 100% of dental chairs are equipped and 100% of the waste from separators are treated in specialized facilities according to the same regulation.

Table 72 Quantitative data on water and solid waste from dental amalgam

Category	Mercury waste treatment					
	2013	2014	2015	2016	2017	2018
Share of dental chairs equipped with amalgam separators (%)	100%	100%	100%	100%	100%	100%
Share of waste from separators treated in specialized treatment facilities (%)	100%	100%	100%	100%	100%	100%
Average dental amalgam removal efficiency of separators (%)	N/A	N/A	N/A	N/A	N/A	N/A
Cost of collection and treatment of waste from separators per kg (thousand EUR)	N/A	N/A	N/A	N/A	N/A	N/A

[210] https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=LEGITEXT000005625582

Category	Mercury waste treatment					
	2013	2014	2015	2016	2017	2018
Concentration of mercury in sewage sludge (µg/L)	N/A	N/A	N/A	N/A	N/A	N/A

It is up to the dentist to make sure amalgam waste are collected and treated by specialized company. A guideline from ADEME (Environment and Energy Management Agency) on waste from medical dental activities is available*:*

https://www.sfcd.fr/content/files/Guide%20D%C3%A9chets%20ADEME.pdf

Number of Cremations

Regarding the general trends in France, the cremation trend increased since the 80's from 1%, to more than a third in 2018 (37%)[211].

Crematoria must be equipped with abatement technologies according to regulation framework "Arrêté du 28 janvier 2010 relatif à la hauteur de la cheminée des crématoriums et aux quantités maximales de polluants contenus dans les gaz rejetés à l'atmosphère "[212].

Basically, wastes from crematoria are collected and treated by specialised company such as Orthometal (NL) according to French Cremation Association, Or Alliatech-Dental (FR).

CITEPA data on mercury emissions to the atmosphere (https://www.citepa.org/fr/air-et-climat/polluants/metaux-lourds/mercure), depicts sectors contribution such as waste treatment (11% in 2015) but it might include mercury waste other than amalgam waste.

Table 73 Quantitative data on cremations

Category	Air emissions from crematoria					
	2013	2014	2015	2016	2017	2018
Number of crematoria	163	172	177	179	185	N/A
Number of cremations per year	191,503	193,178	209,192	213,195	221,132	N/A
Share of crematoria equipped with abatement technologies (%)	100%	100%	100%	100%	100%	100%
Average efficiency of the abatement technologies (%)	N/A	N/A	N/A	N/A	N/A	N/A
Cost of mercury capture per cremation (EUR)	N/A	N/A	N/A	N/A	N/A	N/A

[211] http://www.association-nationale-crematiste.fr/resources/bulletin+82_p3.pdf
[212]https://www.legifrance.gouv.fr/affichTexte.do;jsessionid=?cidTexte=JORFTEXT000021837100&dateTexte=&oldAction=rechJO&categorieLien=id

Source : http://www.association-nationale-crematiste.fr/resources/bulletin+82_p3.pdf

For further information: http://www.association-nationale-crematiste.fr/

NATIONAL POLICIES AND MEASURES

Table 74 Policies and measures to phase down or phase-out the use of dental amalgam

Category	Type	Ongoing	Under development
Measures to phase down or phase-out dental amalgam	Dental amalgam bans, phasing-out or phasing down	No	No
	National guidelines, promoting the use of mercury-free materials	No	ANSM is planning to update its recommendation and propose the use of dental amalgam only when it is needed.
	Supporting research and development in respect of mercury-free dental restorations	No	No
	Others	No	No
Measures to manage waste and emissions from dental amalgam	Requirements for the installation and maintenance of separators	« Arrêté du 30 mars 1998 relatif à l'élimination des déchets d'amalgame issus des cabinets dentaires »	No
	Requirements for the collection and treatment of solid waste from separators	« Arrêté du 30 mars 1998 relatif à l'élimination des déchets d'amalgame issus des cabinets dentaires »	No
	Requirements for mercury emissions from crematoria	« Arrêté du 28 janvier 2010 relatif à la hauteur de la cheminée des crématoriums et aux quantités maximales de polluants contenus dans les gaz rejetés à l'atmosphère »	No
	Standards for mercury concentrations in sludge for the use of land spreading	No	No
	Supporting research and development in respect of reducing	No	No

Category	Type	Ongoing	Under development
	emission and releases of mercury to the environment		
	Others	No	No

"Arrêté du 30 mars 1998" sets the regulatory framework for dentists regarding dental amalgam waste disposal. It defines amalgam waste management, waste classification inducing mandatory disposal measures as well as requirement for amalgam separators in dentistry clinics.

"Arrêté du 28 janvier 2010" sets the regulatory framework for crematoria pollutants emissions, describing installations required and pollutants thresholds.

HEALTH SERVICES AND INSURANCE

In France, a mandatory national public insurance service exists.

Conventional prices have been determined for a list of health care act and materials, public services do not cover the total amount and will reimburse 70% of the conventional price except for specific condition such as CMU-C beneficiary (addressed to low income people), workplace accidents, etc.

Dental care and consultation fees are set through a convention with dentists unlike materials.

Some acts (see "Dental care" in the table below) are in general carried out before application of the material and could be seen as included in the treatment. They are subject to a conventional price on which the social security reimburses 70%[213].

Material prices are set by the dentist however there exists conventional and maximum prices for a list of materials thus the real price of dental materials might change from one dentist to another in addition to variation due to technical parameters such as the importance of the damage to be treated or the material. According to a 2001 report by the French Senate, despite identical reimbursement schemes for the material, there is a better remuneration of dentists for the work on alternative materials (not the material itself) and therefore an incentive for alternative materials (Sénat, 2001).

In addition to public insurance service, people rely on other organisations such as health mutual (50.8%), insurance (29.3%) or pension funds (19.9%) with either individual contract or collective contract through their company (DREES, 2017). Several types of contract (more or less expensive) are proposed and do cover health care cost to varying degrees.

Dental healthcare expenditures represented €11.3 billion in 2017 (DREES, 2017). Overall, on this total 37% are reimbursed by public services while 40.9% are borne by complementary organisms. The rest is borne by households and does represent around 2,508 K€ corresponding to 17 % of the total healthcare expenditure born by households (or 7.5 % of the total healthcare expenditure).

[213] https://www.ameli.fr/assure/remboursements/rembourse/soins-protheses-dentaires/soins-protheses-dentaires#text_2374

Table 75 Quantitative data on dental restorations

Category	Category	Conventional Price/(Maximum Price)	Reimbursement by social security %
Dental care	Scaling	28.92€	70
	Tooth decay treatment (1 face)	25.06€	70
	Tooth decay treatment (2 faces)	42€	70
	Tooth decay treatment (3 faces or more)	53€	70
	Root canal treatment (incisor or canine)	33.74€	70
	Root canal treatment (premolar)	48.20€	70
	Root canal treatment (molar)	81.94€	70
	Baby tooth extraction	25€	70
	Permanent tooth extraction	33.44€	70
Material	Laying of a monolithic ceramic dental crown other than zirconia on incisors, canines and first premolars	107.50€ (530€)	70
	Laying of a metal-ceramic dental crown on incisors, canines and first premolars	107.50€ (530€)	70
	Laying of a zirconia monolithic ceramic dental crown on incisors, canines and first premolars	107.50€ (480€)	70
	Laying of a non-precious alloy dental crown	107.50€ (320€)	70
	Laying of a bridge with 2 metal-ceramic anchoring pillars and a metal-ceramic intermediate element for incisor replacement	279.5 (1465€)	70
	Laying of a bridge with 2 metallic anchoring pillars	279.5€ (870€)	70

Category	Category	Conventional Price/(Maximum Price)	Reimbursement by social security %
	and a metallic intermediate element		
	Inlay core[214]	90€ (230€)	70

Source: AMELI[215]Good practices in the selected areas

GOOD PRACTICES IN THE SELECTED AREAS

Table 76 Good practices template

Category	Description
Type of enforcement	*Voluntary*
Target	*Decrease of amalgam use*
Achievements	*Decrease of amalgam use.*
Financial aspects	*Do not seem of primary importance*
Challenges	*Still some technical and medical preference for amalgams in some cases among dentists?*
Transferability	
Sources	*See references*

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[214] Reimbursement specific condition see https://www.ameli.fr/assure/remboursements/rembourse/soins-protheses-dentaires/soins-protheses-dentaires#text_2374

[215]https://www.ameli.fr/assure/remboursements/rembourse/soins-protheses-dentaires/soins-protheses-dentaires#text_2374

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Germany

INTRODUCTION

Germany is a country in central and Western Europe with 82.792 million of inhabitants. The capital and largest city is Berlin. The Federal Republic of Germany is a federal parliamentary republic led by a chancellor. The country spent 11.14% of its gross domestic product (GDP) in healthcare in 2016[216].

Table 77 Key socio-economic and health data

General information	
Population (million):	82.792
GDP per capita (PPP, EUR):	1.1; 35,900
GDP per capita (rank in the EU):	9
Unemployment rate (%):	3.4
Monthly minimum wage (EUR) (2019):	1,557
Number of dentists per hundred thousand inhabitants:	85.37
Dental outpatient curative care (PPS per inhabitant):	295.43
Dental outpatient curative care (Percentual share of total current health expenditure (CHE)):	7.16

DENTAL AMALGAM USE, ALTERNATIVES AND TRENDS

Number of restorations per type material

According to the German federal dentist association (BZAEK), only the total number of restorations is recorded statistically, which accounted for 56.110 million in 2016. Despite the lack of statistical evidence, BZAEK reported that the overall trend in dental amalgam has already been decreasing to reach a share of less than 10% (in terms of market share of dental material filling sold) already in 2015. This information is also supported by the German federal government in their national action plan for the phase down of dental amalgam[217].

In 2018, in total, 49.6 million fillings were reimbursed the national health system[218]. The amount 880.000 fillings belonged to the BEMA positions 13 e) to h) (see section

[216] Eurostat : Health care expenditure by financing scheme [hlth_sha11_hf]
[217] German Federal Ministry for the Envirnoment, Nature Conservation and Nuclear Safety. (2019). *the german governement's national action plan for the phase down of dental amalgam*
[218] Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit (BMU) (Ed.) (2019): Nationaler Aktionsplan der Bundesregierung zur schrittweisen Verringerung von Dentalamalgam. Available online at https://www.bmu.de/fileadmin/Daten_BMU/Download_PDF/Chemikaliensicherheit/nationaler_aktionsplan_dentalamalgam_bf.pdf

below on health services and insurance)[219]. Currently, no reliable data are available on the use of dental amalgam or its share in restorations. The National Action Plan suggest that in 2018 there was a 80% decline in caries and 50% decline in the use of fillings. In parallel, the share of dental amalgam restorations reduced to around 5-7%. As a material, amalgam is considerably cheaper than composites so that that the share of fillings made of amalgam is probably higher, but it is not possible to quantify the difference.

Based on the data provided by BZAEK and BEMA and when assumed that the total number of restorations between 2016 and 2018 remained stable, it is estimated that about 12% (6.510 million restorations) of the dental restorations in Germany are not reimbursed by the national health system.

Table 78: Number of fillings in 2018

BEMA Position	Description	Cases in 2018 [Mio.]
13 a)	One surface	13.2252
13 b)	Two surfaces	20.2542
13 c)	Three surfaces	9.3153
13 d)	More than three surfaces or corner construction in the anterior region including the incisal edge	5.9961
13 e)	Composite: one surface	0.3263
13 f)	Composite: two surfaces	0.4193
13 g)	Composite: three surfaces	0.1047
13 h)	Composite: more than three surfaces in posterior teeth	0.0298
	Total	49.6

Based on this estimate, approximately >2.5 million fillings (>5% from 49.6 Mio.) were carried out with the use of dental amalgam in 2018. The amount of amalgam per filling lies in the order of 0.23 to 1.45 g depending on the number of surfaces with am mean between 0.48 and 0.71 g[220]. This would roughly lead to a use of amalgam > 1.2 to 1.7 t per year. With a mercury content of about 50 weight-% in dental amalgam, this would lead to about >0.6 to 0.9 t mercury use per year. These figures do not include surplus amalgam from capsules that was not used in one application or lost during the filling procedure.

[219] Note that Position 13 h) als well as the exception for children up to 15 years, pregnant or breastfeeding women was only introduced in July 2018, so that the number of 800.000 is not comparable to earlier or later years. In 2017, Positions 13 e) to f) covered only 32.800 cases.
[220] Agdembo, A. O.; Watson, P. A.; Rokni, S. (2004): Estimating the weight of dental amalgam restorations. In J. Can. Dental Assoc. 70, 30-30e, checked on 2/11/2020.

In addition, according to an expert option provided in the context of the present study, in 2018 there was an 80% decline in caries and 50% decline in the use of fillings due to preventive measures. This indicates that a reduction on the use of dental amalgam (as well as mercury-free materials) can be expected as a result of such measures.

HEALTH SERVICES AND INSURANCE

In Germany, reimbursable costs for dental services in the public health insurance system are determined by a catalogue called "Uniform valuation scheme for dental services" (BEMA)[221]. The catalogue valuates dental services by means of points that represent the mean total expenses including material and labour costs (Table 79).

BEMA describes the filling of cavities as "preparation of a cavity, filling with plastic filling material including underfilling, application of a matrix or the use of other aids for shaping the filling and polishing". The valuation is subject to how many tooth surfaces are affected by the measure (one to four).

Table 79:Valuation of filling therapies in Germany

BEMA Position (plastic fillings)	Description	Points	Valuation [€]	BEMA Position (composite fillings)	Points	Valuation [€]
13 a)	One surface (F1)	32	34.2	13 e)	52	55.6
13 b)	Two surfaces (F2)	39	41.7	13 f)	64	68.5
13 c)	Three surfaces (F3)	49	52.4	13 g)	84	89.9
13 d)	More than three surfaces or corner construction in the anterior region including the incisal edge (F4)	58	62.1	13 h)	100	107.0

BEMA positions 13 a) to d) do not explicitly address amalgam fillings but covers them as amalgams are one type of plastic filling materials. According to German law, patients are eligible for full reimbursement of costs for an effective but economic filling therapy. Except for cases addressed explicitly in the BEMA catalogue (e.g. children up to 15 years, pregnant or breastfeeding women, amalgam is absolutely contraindicated) fillings are calculated according to 13 a) to d). Only in the mentioned exceptional cases, the costs for using a composite will be fully reimbursed.

The value of points is determined from year to year. In 2018, point values for conservatory services were about 1.07 €[222]. For example, a one surface filling is valuated with 32 points that corresponds to 34.2 €[223].

If a patient chooses to have a more expensive filling material only the costs for an effective and economic filing would be reimbursed. For example, if a cavity must be filled on two surfaces a patient would have the right for a reimbursement according to BEMA 13 b), which would be, in most cases, an amalgam filling (except for those cases

[221] Einheitlicher Bewertungsmaßstab für zahnärztliche Leistungen gemäß § 87 Abs. 2 und 2h SGB V. Anlage A zum BMV-Z. Stand: 1. Juli 2019. https://www.kzbv.de/bema-20190701.download.e93d2503f317c299adec27949fa783c8.pdf
[222] Minor differences exist among German Länder and type of health insurance
[223] The effective value may be slightly different depending on other factors that are considered in reimbursement process.

mentioned in the BEMA catalogue). If the patient chooses to have a composite filling the patient would have to pay for the costs exceeding those costs equivalent to BEMA 13 b). As this additional service is provided outside the public health insurance scheme the total costs are calculated according a catalogue called "fee schedule for dentists" (GOZ)[224]. Calculation of services by GOZ and BEMA differ and are not directly comparable.

GOZ provides a wide range of prices of filligs without specifying the material used. Depending the type of fillings (i.e. 1, 2 or 3 surface fillings) the price of different types of restorations range between 11.98 EUR to 336.41 EUR.

Based on the information provided above, the reimbursable price of dental amalgam restorations range between 34.2 EUR to 62.1 EUR (average price 48.15 EUR). For mercury-free material restorations the price range between 34.2 EUR and 107.0 EUR (average price 107.7 EUR). Given the differences with the prices provided in GOZ, it can be assumed that patients might be required to cover a part of the costs, partially or fully if they are not reimbursed by the national health scheme.

According to a calculation presented by the German Government to the Bundestag, banning dental amalgam would lead to an additional cost burden to the public health system in the order of 1 billion EUR per year[225].

Dental sector and effectiveness

Table 80 Quantitative data on the dental sector

	Number					
	2013	**2014**	**2015**	**2016**	**2017**	**2018**
Dentists[226] (number)	69,886	70,779	75,541	71,926	72,122	N/A
Dental clinics[227] (number)	N/A	N/A	N/A	N/A	N/A	N/A
Average turnover per clinic (thousand EUR)	N/A	N/A	N/A	N/A	N/A	N/A
Self-reported unmet needs for dental examination due to urbanisation (%)*	2.0	2.0	0.6	0.6	0.6	N/A
Self-reported unmet needs for dental care due to financial reasons (%)*	N/A	9.6	N/A	N/A	N/A	N/A

**Data collected from Eurostat*

[224] Bundeszahnärztekammer (2012): Gebührenordnung für Zahnärzte (GOZ). Stand 5. Dezember 2011. Available online at https://www.bzaek.de/fileadmin/PDFs/GOZ/gebuehrenordnung_fuer_zahnaerzte_2012.pdf
[225] Bundesregierung (2018): Antwort der Bundesregierung auf die Kleine Anfrage der Abgeordneten Dr. Bettina Hoffmann, Dr. Kirsten Kappert-Gonther, Kordula Schulz-Asche, weiterer Abgeordneter und der Fraktion BÜNDNIS 90/DIE GRÜNEN – Drucksache 19/3065 –. In Bundestagsdrucksache (19/3065)
[226] The term "dentists" refers to individual professionals
[227] The term "dental clinics" refers to establishments which offer dental treatment, including dental practices

Manufacturing companies of dental amalgam and alternative materials

No data for the time being.

Extra-EU Imports and exports of dental amalgam and alternative restoration materials

No data for the time being.

Waste treatment from amalgam separators and water waste treatment facilities

Table 81 Quantitative data on water and solid waste from dental amalgam

Category	**Mercury waste treatment**					
	2013	**2014**	**2015**	**2016**	**2017**	**2018**
Share of dental chairs equipped with amalgam separators (%)	100	100	100	100	100	100
Share of waste from separators treated in specialized treatment facilities (%)	99	99	99	99	99	99
Average dental amalgam removal efficiency of separators (%)	95	95	95	95	95	95
Cost of collection and treatment of waste from separators per kg (thousand EUR)	0,06	0,06	0,06	0,06	0,06	0,06
Concentration of mercury in sewage sludge (mg/kg) (dry matter)	0,48	0,47	0,39	N/A	N/A	N/A

Source: Enretech Gmbh (recycling and waste management company) (nd= no data), response to questionnaire

In Germany, amalgam separators are mandatory in accordance to EU requirements and amalgam wastes are collected and treated by specialised companies.

The cost of collection is provided based on experience from Enretech Gmbh without revenues from the sale of recycled metals.

Number of Cremations

In Germany, it seems that cremations have been increasing with respect to burials to a point it even exceeds them now. Indeed, it went from 22% in 1992 to 66% in 2017[228].

Table 82 Quantitative data on cremations

[228]https://www.aeternitas.de/inhalt/bestatten_beisetzen/themen/bestattungsformen/feuerbestattung/geschichte_zahlen

Category	Air emissions from crematoria					
	2013	2014	2015	2016	2017	2018
Number of crematoria	159	160	161	162	163	164
Number of cremations per year	581,003	581,798	619,884	628,522	625,590	674,500
Share of crematoria equipped with abatement technologies (%)	≈89%	≈90,5%	≈90,5%	≈90,5%	≈91,5%	≈92%
Average efficiency of the abatement technologies (%)	96.6	96.6	96.6	96.6	96.6	96.6
Cost of mercury capture per cremation (EUR)	2.00	2.00	2.00	2.00	2.00	2.00

Source: RAL Gütegemeinschaft Krematorien (cremtech), answer to questionnaire by German Federation of Crematoria.

NATIONAL POLICIES AND MEASURES

Table 83 Policies and measures to phase down or phase-out the use of dental amalgam

Category	Type	Ongoing	Under development
Measures to phase down or phase-out dental amalgam	Dental amalgam bans, phasing-out or phasing down	German federal government does highlight the role of both oral health prevention measures and dental personnel training, especially information about alternatives materials, in order to phase down dental amalgam use[229]	No
	National guidelines, promoting the use of mercury-free materials	No specific guidance other than older guidance recommending the now legal ban for pregnant and breastfeeding women and children under 15 and individuals with kidney failure or suffering from allergies.	No
	Supporting research and development in respect of mercury-free dental restorations	No	No
	Others	No	No

[229] German Federal Ministry for the Envirnoment, Nature Conservation and Nuclear Safety. (2019). *the german governement's national action plan for the phase down of dental amalgam*

Category	Type	Ongoing	Under development
Measures to manage waste and emissions from dental amalgam	Requirements for the installation and maintenance of separators	No	No
	Requirements for the collection and treatment of solid waste from separators	"erordnung über Anforderungen an das Einleiten von Abwasser in Gewässer (Abwasserverordnung - AbwV) Anhang 50 Zahnbehandlung"	No
	Requirements for mercury emissions from crematoria	"Die Verordnung über Anlagen zur Feuerbestattung (27. BImSchV)"	No
	Standards for mercury concentrations in sludge for the use of land spreading	No	No
	Supporting research and development in respect of reducing emission and releases of mercury to the environment	No	No
	National standards recommending the use of dental amalgam in pre-dosed encapsulated form	DIN EN 1641:2010-02 DIN EN ISO 13897:2018-05	
	Others	No	No

The German NAP[230] draws attention on the "various reports and position papers" issued by the German competent authorities recommending that use of dental amalgam fillings in breastfeeding and pregnant women and children shall be avoided. It also highlights both national standards "DIN EN 1641:2010-022" and "DIN EN ISO 13897:2018-05" regarding the use of pre-dosed encapsulated form for dental amalgam.

"Erordnung über Anforderungen an das Einleiten von Abwasser in Gewässer (Abwasserverordnung - AbwV) Anhang 50 Zahnbehandlung" does provide a regulation framework for dental amalgam waste treatment in water.

"Die Verordnung über Anlagen zur Feuerbestattung (27. BImSchV)" describe the regulation framework surrounding crematoria emissions and required equipment.

GOOD PRACTICES IN THE SELECTED AREAS

No data available.

[230] German Federal Ministry for the Envirnoment, Nature Conservation and Nuclear Safety. (2019). *the german governement's national action plan for the phase down of dental amalgam*

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Greece

INTRODUCTION

Greece (or the Hellenic Republic) is a country of Southeast Europe. The Capital and largest city is Athens. In 2016, the country spent 14,616.36 million euro (8.28% of GDP) in healthcare[231].

Table 84 Key socio-economic and health data

General information	
Population (million):	10.741
GDP per capita (PPP, EUR):	2.2 ; 17,800
GDP per capita (rank in the EU):	19
Unemployment rate (%):	19.3
Minimum wage (EUR):	683.76 (2019 S1)
Number of dentists per hundred thousand inhabitants (2015):	N/A
Dental outpatient curative care (PPS per inhabitant):	74.59 (2016)
Dental outpatient curative care (percentual share of total current health expenditure (CHE)):	4.49 (2016)

DENTAL AMALGAM USE, ALTERNATIVES AND TRENDS

Number of restorations per type material

In Greece, alternative materials are preferred to dental amalgam for dental restorations. Quantitative data on the exact volumes or shares do not exist.

Dental sector and effectiveness

Table 85 Quantitative data on the dental sector

	Number					
	2013	2014	2015	2016	2017	2018
Dentists[232] (number)	9,000	9,000	8,700	8,200	8,700	8,900

[231] Eurostat (online data codes : hlth_sha11_hf, demo_gind and nama_10_gdp)
[232] The term "dentists" refers to individual professionals.

	Number					
	2013	2014	2015	2016	2017	2018
Dental clinics[233] (number)	N/A	N/A	N/A	N/A	N/A	N/A
Average turnover per clinic (thousand EUR)	N/A	N/A	N/A	N/A	N/A	N/A
Self-reported unmet needs for dental examination due to urbanisation (%)*	8.7	12.9	12.5	13.8	10.0	N/A
Self-reported unmet needs for dental care due to financial reasons (%)*	N/A	17.5	N/A	N/A	N/A	N/A

In Greece, there are approximately 8,900 dentists. Overall, the number of dentists has been constant in the last 5 years with a drop in 2016. The reasons of this drop are not known. The dental sector is predominantly private as The National Health Service provides in Health Centre and Hospital Dental Offices only limited number of dental services oriented mainly pain relief cases.

According to Eurostat data, the unmet needs of for dental care, either for financial reasons or the demographic distribution range between 10% - 17.5%, with the highest end referring to financial reasons. At the EU28 level, Greece performs below average on the urbanisation aspect and above average on the financial aspect (i.e. in the EU the average unmet needs correspond to 12.3 % both for the reason of urbanisation and financial aspects).

Manufacturing companies of dental amalgam and alternative materials

In Greece, there is one dental filling manufacturer, DMP Dental Materials Ltd. The company produces both dental amalgam and composite materials. The production volumes are not known.

Extra-EU Imports and exports of dental amalgam and alternative restoration materials

No data exist on the imports and exports of dental filling materials.

Waste treatment from amalgam separators and water waste treatment facilities

Table 86 Quantitative data on water and solid waste from dental amalgam

Category	Mercury waste treatment					
	2013	2014	2015	2016	2017	2018
Share of dental chairs equipped with amalgam separators (%)	N/A	N/A	N/A	N/A	N/A	N/A

[233] The term "dental clinics" refers to establishments which offer dental treatment, including dental practices.

Category	Mercury waste treatment					
	2013	2014	2015	2016	2017	2018
Share of waste from separators treated in specialized treatment facilities (%)	N/A	N/A	N/A	N/A	N/A	N/A
Average dental amalgam removal efficiency of separators (%)	N/A	N/A	N/A	N/A	N/A	N/A
Cost of collection and treatment of waste from separators per kg (thousand EUR)	N/A	N/A	N/A	N/A	N/A	N/A
Concentration of mercury in sewage sludge (µg/L)	1,170	1,070	1,200	1,150	1,020	N/A

In Greece, the waste collected from amalgam separators is collected locally and treated in specialised facilities in third countries. The share of dental chairs equipped with amalgam separators as well as their share in not known.

Overall, the concentration of mercury in sewage sludge has been dropping between 2013 and 2018. Specifically the concentration between 2013 and 2017 dropped by approximately 14.7%.

Number of Cremations

There are no crematoria in Greece.

NATIONAL POLICIES AND MEASURES

Table 87 Policies and measures to phase down or phase-out the use of dental amalgam

Category	Type	Ongoing	Under development
Measures to phase down or phase-out dental amalgam	Dental amalgam bans, phasing-out or phasing down	Academic Institutions, continuous education courses	No
	National guidelines, promoting the use of mercury-free materials	Specialized leaflets providing information on the use of Polymers and Ceramics	No
	Supporting research and development in respect of mercury-free dental restorations	Academic Institutions, scientific societies	No
	Others	No	No

Category	Type	Ongoing	Under development
Measures to manage waste and emissions from dental amalgam	Requirements for the installation and maintenance of separators	No	No
	Requirements for the collection and treatment of solid waste from separators	No	No
	Requirements for mercury emissions from crematoria	No	No
	Standards for mercury concentrations in sludge for the use of land spreading	16-25 mg/kg DS	5 mg/kg DS
	Supporting research and development in respect of reducing emission and releases of mercury to the environment	No	No
	Others	No	No

In relation to measures to phase down the use of dental amalgam, currently there are no concrete measures, other that the promotion of mercury-free materials in universities and institutions, as well as the dissemination of information on the use of composites and dental amalgam.

As regards, the concentration of dental amalgam in sewage sludge form land spreading, the Greek Government is proposing more strict standards. Specifically, the standards are expected to be reduced from 25mg/kg (currently the maximum standard) to 5mg/kg.

HEALTH SERVICES AND INSURANCE

In Greece, the National Health System does not cover the cost of dental treatments. Therefore, patients are 100% responsible of all costs. The National Health Service provides in Health Centre and Hospital Dental Offices limited number of dental services oriented mainly to pain relief cases. In these cases, the material used is predominantly dental amalgam. Some large firms offer to their employees a private insurance which covers restorations with mercury-free materials. The share of the population that is benefited from this type of insurances is not known.

The cost of restorations between dental amalgam and alternative materials can differ significantly. In certain cases restorations with the use of dental amalgam can be cheaper than composite resins.

Table 88 Quantitative data on dental restorations

Category	Category	Price	Reimbursement by social security %
Restoration	Dental amalgam	45-55 EUR	0%
	Composite resins	50-70 EUR	0%
	Glass ionomer cements	35-50 EUR	0%
	Compomers	N/A	N/A
	Ceramics	300-500	0%
Material	Dental amalgam	N/A	N/A
	Composite resins	N/A	N/A
	Glass ionomer cements	N/A	N/A
	Compomers	N/A	N/A
	Ceramics	N/A	N/A

GOOD PRACTICES IN THE SELECTED AREAS

No data available.

Hungary

INTRODUCTION

Hungary is a country in central Europe with 9.778 million of inhabitants. The capital and largest city is Budapest. Hungary has a universal health care financed by the national health insurance. The country spent 7.36% of its gross domestic product in healthcare in 2016[234].

Table 89 Key socio-economic and health data

General information	
Population (million):	9.778
GDP per capita (PPP, EUR):	5.1; 12,500
GDP per capita (rank in the EU):	24
Unemployment rate (%):	3.7
Monthly minimum wage (EUR) (2019):	464.20
Number of dentists per hundred thousand inhabitants:	61.98 (2016)
Dental outpatient curative care (PPS per inhabitant):	84.08
Dental outpatient curative care (percentual share of total current health expenditure (CHE)):	5.46 (2016)

DENTAL AMALGAM USE, ALTERNATIVES AND TRENDS

Number of restorations per type material

Information below has been provided for 2018 by both the Dental Section of the Hungarian Medical Chamber and State Secretariat for Health (EMMI).

The line "others" incorporates the non-amalgam restoration material all together.

Table 90 Number of restorations per type material for 2018

Material	Number of restorations
Dental amalgam	77 147
Composite resins	N/A
Glass ionomer cements	N/A

[234] Eurostat

Material	Number of restorations
Compomers	N/A
Ceramics	N/A
Others	1,867,708

Dental sector and effectiveness

Table 91 Quantitative data on the dental sector

	Number					
	2013	**2014**	**2015**	**2016**	**2017**	**2018**
Dentists[235] (number, Eurostat)	5,963	6,203	5,936	N/A	N/A	N/A
Dentists [236]	6,405	6,628	6,854	7,069	7,321	7,659
Dental clinics[237] (number, Eurostat)	4,632	4,813	4,998	5,177	5,385	5,581
Average turnover per clinic (thousand EUR)	N/A	N/A	N/A	N/A	N/A	N/A
Self-reported unmet needs for dental examination due to urbanisation (%)*	4.5	4.1	4.0	2.2	1.8	1.7
Self-reported unmet needs for dental care due to financial reasons (%)*	N/A	9.4	N/A	N/A	N/A	N/A

**Data collected from Eurostat*

The Hungarian health system is based on a universal public health insurance administrated by its national health insurance fund "Nemzeti Egészségbiztosítási Alapkezelő" (NEAK).

Both private and public dental clinics exist, but only the privete ones are supported by NEAK. No information on the share of private sector prevalence has been identified.

Manufacturing companies of dental amalgam and alternative materials

There is no dental filling manufacturer in Hungary, dentists do work only with imported material (information from EMMI and Hungarian medical chamber).

[235] The term "dentists" refers to individual professionals.
[236] from Hungarian official figures which include suspended, retired and non-active dentist.
[237] The term "dental clinics" refers to establishments which offer dental treatment, including dental practices.

Extra-EU Imports and exports of dental amalgam and alternative restoration materials

Hungarian dental traders sell only EU-imported filling materials (Hungarian medical chamber). No quantitative information available.

Waste treatment from amalgam separators and water waste treatment facilities

Table 92 Quantitative data on water and solid waste from dental amalgam

Category	Mercury waste treatment					
	2013	2014	2015	2016	2017	2018
Share of dental chairs equipped with amalgam separators (%)	N/A	N/A	N/A	N/A	N/A	50%
Share of waste from separators treated in specialized treatment facilities (%)	N/A	N/A	N/A	N/A	N/A	N/A
Average dental amalgam removal efficiency of separators (%)	N/A	N/A	N/A	N/A	N/A	97%
Cost of collection and treatment of waste from separators per kg (thousand EUR)	N/A	N/A	N/A	N/A	N/A	N/A
Concentration of mercury in sewage sludge (µg/L)	N/A	N/A	N/A	N/A	N/A	N/A

Source: EMMI

Amalgam waste is collected and treated by specialized companies within Hungary according to EMMI and the Hungarian medical chamber in accordance with Act 2012 – CLXXXV on waste management and the new set of decrees based on Minamata convention translated regulation framework 2016/CLII.

Hungarian water utility association reported a mercury average concentration in wastewater sludge of 705 µg/kg (dry matter) associated with a range of 200-2000 µg/kg (dry matter) for 2018.

Number of Cremations

Table 93 Quantitative data on cremations

Category	Air emissions from crematoria					
	2013	2014	2015	2016	2017	2018
Number of crematoria	N/A	N/A	N/A	N/A	N/A	24
Number of cremations per year	N/A	N/A	N/A	N/A	N/A	N/A

Category	Air emissions from crematoria					
	2013	2014	2015	2016	2017	2018
Share of crematoria equipped with abatement technologies (%)	N/A	N/A	N/A	N/A	N/A	N/A
Average efficiency of the abatement technologies (%)	N/A	N/A	N/A	N/A	N/A	60%
Cost of mercury capture per cremation (EUR)	N/A	N/A	N/A	N/A	N/A	N/A

Source: EMMI

NATIONAL POLICIES AND MEASURES

Table 94 Policies and measures to phase down or phase-out the use of dental amalgam

Category	Type	Ongoing	Under development
Measures to phase down or phase-out dental amalgam	Dental amalgam bans, phasing-out or phasing down	No amalgam fillings - under 15 and for pregnant woman	No
	National guidelines, promoting the use of mercury-free materials	Publications of research in professional issues of Dental Section of Hungarian Medical Chamber, lectures on professional conferences.	No
	Supporting research and development in respect of mercury-free dental restorations	No	Not specific, but there are scientific projects ongoing especially in University Centres
	Others	No	No
Measures to manage waste and emissions from dental amalgam	Requirements for the installation and maintenance of separators	No	No
	Requirements for the collection and treatment of solid waste from separators	No	No
	Requirements for mercury emissions from crematoria	No	No

Category	Type	Ongoing	Under development
	Standards for mercury concentrations in sludge for the use of land spreading	No	No
	Supporting research and development in respect of reducing emission and releases of mercury to the environment	No	No
	Others	No	No

According to EMMI and Hungarian medical chamber, Hungary official position is to follow EU Policy.

HEALTH SERVICES AND INSURANCE

Hungary has adopted a compulsory public health insurance funded by active workers contribution that does fully cover conservative dental restoration provided by dentists affiliated with NEAK (EMMI and Hungarian medical chamber).

To be more accurate, public sector reimbursement mechanism is point-based:

- 1 point is 2 HUF (≈ 0,00625 Euro)
- Amalgam filling equals 600-850 points,
- "Aesthetic filling" (e.g. Composite, GI, Compomer) equals 700- 950 (depends on the surfaces)

It is covered by NEAK while any potential difference is paid by the dental care providers (EMMI and Hungarian medical chamber).

Hungarians may contract additional private insurances that may cover private dental care with affiliated clinics. Private sectors dental care is not reimbursed by NEAK. No statistic on the actual share of households contracting complementary private insurances is available.

An interview conducted with an expert from the ministry of rural development in a previous study pointed out that a relevant part of the population opts for private dental care over services by the public sector.

Table 95 Quantitative data on dental restorations

Category	Category	Price	Reimbursement by social security %
Restoration	Dental amalgam	450 - 550 HUF 1.4 – 1.7 EUR	100
	Composite resins	381 – 618 HUF 1.2 – 1.95 EUR	100

Category	Category	Price	Reimbursement by social security %
	Glass ionomer cements	N/A	N/A
	Compomers	N/A	N/A
	Ceramics	N/A	N/A
Material	Dental amalgam	220 – 375 HUF/ gr 0,7– 1,18 EUR / gr	N/A
	Composite resins	N/A	N/A
	Glass ionomer cements	N/A	N/A
	Compomers	N/A	N/A
	Ceramics	N/A	N/A

Source: EMMI/Hungarian medical chamber (rest of data is unknown)

GOOD PRACTICES IN THE SELECTED AREAS

None good practice guidance was found for Hungary for the time being.

Ireland

INTRODUCTION

Ireland is an island in the North Atlantic with 4.830 million of inhabitants. The capital and largest city is Dublin. The country spent 20,171.70 million euro (7.38% of GDP) in healthcare in 2016[238].

Table 96 Key socio-economic and health data (2018)

General information	
Population (million):	4.830
GDP per capita (PPP, EUR):	5.4; 59,400
GDP per capita (rank in the EU):	3
Unemployment rate (%):	5.8
Minimum monthly wage (EUR):	1656.20
Number of dentists per hundred thousand inhabitants:	N/A
Dental outpatient curative care (PPS per inhabitant):	N/A
Dental outpatient curative care (Percentual share of total current health expenditure (CHE)):	N/A

DENTAL AMALGAM USE, ALTERNATIVES AND TRENDS

Number of restorations per type material

Table 97 Number of restorations per type material

Material	Number of restorations
Dental amalgam*	222,241
Composite resins	176,278
Glass ionomer cements [1]	14,563

[238] Eurostat (online data codes : hlth_sha11_hf, demo_gind and nama_10_gdp)

Material	Number of restorations
Compomers	N/A
Ceramics	N/A
Others (Copolymers)	483[1]

Source: Irish Dental Association

A study from the Environmental Protection Agency (2017-2019) found that resin composite is most commonly placed as a restorative material (71%), followed by dental amalgam (20%), and a small percentage of glass ionomer and resin-modified glass ionomer cements[239]. This information is not in line with the data in Table 2.1 where dental amalgam appears to have the highest share of the total restorations (2018). The information in Table 2.1 is however restricted to government only schemes for adults and children. The EPA study includes private care.

Based on expert opinion provided by the Department of Communications, Climate Action and Environment, the figures on the table above apply to individuals over 16 years old that are equipped with a medical card. About one-third of the Irish adult population are entitled to a medical card and can avail of free dental care annually, of this one-third, only one-third use their eligibility annually and only one-third of these end up getting dental restorations. Therefore, the statistics provided in the table above relate to only 3% of the Irish population.

The share of the population that is not equipped with a medical card (i.e. 68% of adults) use private dental facilities for their treatment. In general, the evidence indicates that children receive alternatives to amalgam.

More detailed and historical data is provided in Table 103.

A recent publication from the Environmental Protection Agency, published the results of a survey that was carried out in relation to the use of restoration materials by dental practitioners in Ireland[240]. According to the results of the survey, 71% of restorations were performed with composites, 20% with dental amalgam and 9% with other mercury-free materials. In total, 21% of dentists believed that having to place composite in back teeth routinely instead of amalgam could have negative financial implications for their practice while 52% disagreed with this statement. When dentists were asked how long it would take to restore a moderately deep two-surface mesio-occlusal cavity in a lower first molar with amalgam, the average number of minutes estimated was 21. To restore the same sized cavity with a composite would take 30 minutes on average. When dentists were then asked if they felt that routinely placing posterior composites would cause appointment delays in the practice, 38% agreed and 50% disagreed. When dentists were asked if they believed that patients have less postoperative sensitivity following an amalgam filling than following a composite filling, 36% agreed and 36% disagreed, with the remainder being unsure or expressing no difference.

[239] Irish National plan on measures to phase down the use of dental amalgam (Article 10(3) of the Mercury Regulation)
[240] Environmental Protection Agency Research (2020), Study on Usage and Waste Management of Amalgam Dental Fillings and Mercury-free Alternative:
http://www.epa.ie/researchandeducation/research/researchpublications/researchreports/Research_Report_307.pdf

When exploring, why dentists why dentists continue to use amalgam, the study found that 5% reported not being confident in their technical ability to place composites and 33% did not receive clinical training in the placement of posterior composites as part of their dental school training. There was a large difference in the proportion of dentists using amalgam often or all the time between private adult patients requiring a single posterior restoration (17%) and medical card patients (46%).

A large number of the dentists surveyed (58%) received their dental school training during and prior to the 1990s. At this time, many dental students may not have received clinical training in the placement of composites for posterior teeth. Consequently, 31% of dentists surveyed reported not having received clinical training in the placement of posterior composite as part of their dental school training. In addition, 24% reported being more confident in placing amalgam than composite and 5% were not confident in their technical ability to place composites in unretentive cavities. Dentists who participated in the survey cited hands-on training or a combination of hands-on training with online training, seminars and lectures as the most appropriate form of continuing professional development, which gives a good indication of what is required in terms of further training among those who require it.

Dental sector

Table 98 Quantitative data on the dental sector

	Number					
	2013	**2014**	**2015**	**2016**	**2017**	**2018**
Dentists[241] (number)	2,190	2,127	2,147	2,131	1,904	2,500
Dental clinics[242] (number)	N/A	N/A	N/A	N/A	N/A	N/A
Average turnover per clinic (thousand EUR)	50-60K public only from adult services (DTSS)[1]	50-60K public only from adult services (DTSS)	50-60K public only from adult services (DTSS)	50-60K public only from adult services (DTSS)	70-80 K public services only from adult services (DTSS)	N/A
Self-reported unmet needs for dental examination due to urbanisation (%)	5.8	5.9	5.1	3.4	3.2	N/A
Self-reported unmet needs for dental care due to financial reasons (%)	N/A	73.1	N/A	N/A	N/A	N/A

[241] The term "dentists" refers to individual professionals
[242] The term "dental clinics" refers to establishments which offer dental treatment, including dental practices

Source: Irish Dental Association, See Table 104 for detailed data

[1] DTSS: Dental Service and Treatment

The dental profession in Ireland is regulated by the Dental Council of Ireland, a statutory body created under the Dentists Act 1985. The Dental Council presently maintains four registers relating to dentistry:

- Register of Dentists
- Register of Dental Specialists (in respect of Oral Surgery and Orthodontics)
- Register of Dental Hygienists
- Register of Dental Nurses

The vast majority of registered dentists in Ireland work within the private sector, mainly as general dental practitioners. General dental practitioners in private practice are also the main providers of public dental services for adults via the State-run dental treatment schemes (i.e., DTSS). While formal recognition of dental specialisation presently covers only oral surgery and orthodontics, de facto specialisation in other fields also exists as many dentists with postgraduate training and qualifications limit their practices to various specialisations (e.g., endodontics, periodontics, paediatric dentistry). Private sector dental practitioners normally operate on a fee-per-item basis; public sector dentists are salaried government employees and do not receive fees from their public patients. Less than one in five registered dentists (15%) and registered hygienists (16%) are employed by the Health Service Executive (HSE) (based on whole time equivalent (WTE) employment as of April 2008). The Register of Dental Nurses is a voluntary register maintained by the Dental Council of Ireland and does not provide a valid estimate of the dental nurse workforce in Ireland[243].

Manufacturing companies of dental amalgam and alternative materials

According to the Department of Communications, Climate Action & Environment, the manufacturing of dental amalgam and alternative materials does not take place in Ireland.

Extra-EU Imports and exports of dental amalgam and alternative restoration materials

No data or information has been identified related to extra-EU imports and exports of dental amalgam and alternative restoration materials for Ireland.

Waste treatment from amalgam separators and water waste treatment facilities

Table 99 Quantitative data on water and solid waste from dental amalgam

[243] Dental Health Foundation https://www.dentalhealth.ie/dentalhealth/services.html

Category	Mercury waste treatment					
	2013	2014	2015	2016	2017	2018
Share of dental chairs equipped with amalgam separators (%)	N/A	N/A	N/A	N/A	N/A	All of salaried dental services contain amalgam separators. Estimate from EPA research study of chairs in practice with separators is 87%
Share of waste from separators treated in specialized treatment facilities (%)	N/A	N/A	N/A	N/A	N/A	N/A
Average dental amalgam removal efficiency of separators (%)	N/A	N/A	N/A	N/A	N/A	95
Cost of collection and treatment of waste from separators per kg (thousand EUR)	N/A	N/A	N/A	N/A	N/A	N/A
Concentration of mercury in sewage sludge (µg/L)	N/A	N/A	N/A	N/A	0.4 mg/kg	0.6/mg/kg

Source: Irish Dental Association

The national action plan confirms that separators present an average dental amalgam removal efficiency of 95% (National plan on measures to phase down the use of dental amalgam (Article 10(3) of the Mercury Regulation)), specifying that this is true specifically for separators put into service after the 1st of January 2018.

Number of Cremations

Table 100 Quantitative data on cremations

Category	Air emissions from crematoria					
	2013	2014	2015	2016	2017	2018
Number of crematoria	4	4	5	6	7	7
Number of cremations per year	4,041	4,474	4,981	5,498	5,978	N/A
Share of crematoria equipped with abatement technologies (%)	N/A	N/A	N/A	N/A	N/A	N/A

Category	Air emissions from crematoria					
	2013	2014	2015	2016	2017	2018
Average efficiency of the abatement technologies (%)	N/A	N/A	N/A	N/A	N/A	N/A
Cost of mercury capture per cremation (EUR)	N/A	N/A	N/A	N/A	N/A	N/A

Source: https://www.cremation.org.uk/statistics

NATIONAL POLICIES AND MEASURES

Table 101 Policies and measures to phase down or phase-out the use of dental amalgam

Category	Type	Ongoing	Under development
Measures to phase down or phase-out dental amalgam	Dental amalgam bans, phasing-out or phasing down	Ban on dental amalgam in under 15s, pregnant &lactating women. National Oral Health Policy published April 3rd 2019 (Smile agus Sláinte); Oral health promotion programmes, prevention, and expansion of care for young children and adults to focus on prevention. Ireland's phase down plan as per the EU Mercury Regulation will form part of this overall National Oral Health Care Policy.	As part of new government contracts for primary care alternatives to amalgam will be promoted as the preferred restoration.
	National guidelines, promoting the use of mercury-free materials	Dental Council of Ireland have published guidelines in 2018 on the use of Dental Amalgam explaining the EU legislation and the rationale behind it Irish Dental Council and HSE salaried services have also published clinical guidance for dentists.	An evidence synthesis of restorative materials and interventions for different age groups has been recently completed by the Irish Health Research Board. This will inform future guidance on the preferred restorations in different settings.
	Supporting research and development in respect of mercury-free dental restorations	Two related research projects in University College Cork (UCC). Two Environmental Protection Agency funded studies on the usage and waste management	The Irish Health Research Board has completed an evidence review to inform the use of mercury-free dental restorations

Category	Type	Ongoing	Under development
		of dental amalgam and its alternatives are currently being conducted in University College Cork.	
	Others	No	No
Measures to manage waste and emissions from dental amalgam	Requirements for the installation and maintenance of separators	Under the existing EU Waste Directive 2008/98/EC there is a requirement in Ireland to separate & collect hazardous (amalgam) wastes. There is also the PARCOM recommendation 93/2 See Dental Council of Ireland Guidelines.	No
	Requirements for the collection and treatment of solid waste from separators	See Dental Council of Ireland Guidelines.	No
	Requirements for mercury emissions from crematoria	No	No
	Standards for mercury concentrations in sludge for the use of land spreading	Compliance with Council Directive of 12 June 1986 on the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture.	No
	Supporting research and development in respect of reducing emission and releases of mercury to the environment	See sources in table notes.	No
	Others :	No	No

Sources:
Department of Health National Oral Health Policy published April 3rd 2019: https://health.gov.ie/blog/publications/smile-agus-slainte-national-oral-health-policy/EPA Research: https://www.epa.ie/researchandeducation/research/ Assessment of the environment and health impacts arising from mercury-free dental restorative materials: https://www.ucc.ie/en/ohsrc/research/epaproject/ Usage and Waste Management of Amalgam Dental Fillings and Mercury Free Alternatives: https://www.ucc.ie/en/dentalschool/news/amalgam-study-funded-by-the-epa-environmental-protection-agency-.html

HEALTH SERVICES AND INSURANCE

For a dental treatment to qualify for tax relief it must be classified as a specialised treatment. Any treatments that fall under the category of routine care do not qualify for dental tax refunds. Routine dental treatments include things like tooth extractions, scaling and filling, as well as the repair of artificial teeth and dentures. Dental treatments that do qualify as specialised include enhancements like bridges, crowns and veneers, as well as components like gold posts and inlays, or replacement tips. Root canals along with periodontal (gum) and orthodontic (tooth alignment – braces) treatments also qualify, as does the surgical extraction of wisdom teeth at a hospital.

Tax relief is given as a percentage of the expenses patients have incurred; this relief for qualifying dental expenses, like those identified above, is given at the standard rate of 20%. That means citizens can claim back 20% of the costs of qualifying specialised treatments[244].

Table 102 Quantitative data on dental restorations

Category	Category	Price	Reimbursement by social security %
Restoration	Dental amalgam	€50	N/A
	Composite resins	€51.50	N/A
	Glass ionomer cements	N/A	N/A
	Compomers	N/A	N/A
	Ceramics	N/A	N/A
Material	Dental amalgam	In salaried services material is paid for by the government; but for adults the cost of the material is covered by the restoration fee.	None
	Composite resins	In salaried services material is paid for by the government; but for adults the cost of the material is covered by the restoration fee	None
	Glass ionomer cements	In salaried services material is paid for by the government; This is currently not available for adults under	None

[244] https://www.irishtaxrebates.ie/claim-tax-back-dental-expenses/

Category	Category	Price	Reimbursement by social security %
		the government DTSS scheme	
	Compomers	In salaried services material is paid for by the government; This is currently not available for adults under the DTSS scheme	None
	Ceramics	In salaried services material is paid for by the government; This is currently not available for adults under the government adult DTSS scheme	None

The current state funding only supports anterior (front teeth) white or non-amalgam fillings. There is no facility to pay for posterior composites (white fillings) currently. The expectation in Ireland is that the dental profession, as put forward by other countries in EU, will expect to be compensated with additional remuneration if posterior composites are introduced to the State system. If amalgam is not to be funded under a new state system it is expected that the cost to the state may be one third higher than when amalgam was used predominantly

GOOD PRACTICES IN THE SELECTED AREAS

No information has been identified on good practices to complete the table below.

NUMBER OF RESTORATIONS

Table 103 Number of restorations per type material, historical data

Material	Number of restorations per year					
	2013	2014	2015	2016	2017	2018
Dental Amalgam						
Adults	283,797	278,190	260,376	239,187	234,645	218,042
Children	*13,656*	*13,665*	*12,295*	*12,575*	*11,120*	*4,199*
Composite resins						
Adults	143,784	143,129	139,437	132,205	132,671	127,188
Children	*22,579*	*24,041*	*26,760*	*30,629*	*35,465*	*49,090*

Material	Number of restorations per year					
	2013	**2014**	**2015**	**2016**	**2017**	**2018**
Glass ionomer cements						
Children	*9,114*	*90,602*	*10,886*	*12,748*	*13,840*	*14,563*
Copolymers						
Children	*947*	*472*	*285*	*604*	*496*	*483*
Ceramics	N/A	N/A	N/A	N/A	N/A	N/A
Others	N/A	N/A	N/A	N/A	N/A	N/A
Resin Modified Glass ionomer cement	N/A	N/A	N/A	N/A	N/A	N/A

Source: Irish Dental Association

According to the Irish Dental Association, data is restricted to government only schemes for adults and children. An adult Dental Treatment Services Scheme for those over 16 years of which approximately 1.609 million or 34% of the population are eligible. Approximately 1 in 3 of those eligible avail of the government scheme every year (389,482 patients in 2018). Salaried government services provide care for children to two main age groups; 7 and 12 years of age. The children's data was collated in an ad-hoc fashion prior to 2018. In parallel, a country wide research survey funded by the Environmental Protection Agency (EPA, 2017-2019) included private care. Due to a poor response rate it may be subject to response bias. From this study 1,152000 amalgams were estimated to have been provided in the year. Nearly double the amount of composites was provided to 2,016000 in the same year. The study stated that resin composite is most commonly placed as a restorative material (71%), followed by dental amalgam (20%), and a small percentage of glass ionomer and resin-modified glass ionomer cements[245]. Encapsulated amalgam only is used in government salaried dental clinics for children and special care adults. From the EPA research survey conducted on dentists in independent practice, encapsulated amalgam is used for 92% of patients and other forms of amalgam are used for the remainder.

245 Irish National plan on measures to phase down the use of dental amalgam (Article 10(3) of the Mercury Regulation)

Dental sector

Table 104 Quantitative data on the dental sector, detailed data

	Number					
	2013	**2014**	**2015**	**2016**	**2017**	**2018**
Dentists[246] (number)						
Adults	1,790	1,827	1,847	1,831	1,604	Not available
Children	300	300	300	300	300	300
Dental Council	2,649	2,758	,2828	2,949	3,113	3,217
Dental clinics[247] (number)						
	722	722	722	722	722	722
Adults	221	221	221	221	221	221
Children						
Average turnover per clinic (thousand EUR)	50-60K public only from adult services (DTSS)	50-60K public only from adult services (DTSS)	50-60K public only from adult services (DTSS)	50-60K public only from adult services (DTSS)	70-80 K public services only from adult services (DTSS)	N/A

Source: Irish Dental Association

The data regarding dentists and clinics refers only to government and publicly funded care. All private care is excluded. The Dental Council numbers, i.e. total numbers of dentists registered in the country, are included for reference (in the table on page 6). The dental practices and clinics are also confined to those who provide publicly funded care but this was determined from a once off research study.

[246] The term "dentists" refers to individual professionals.
[247] The term "dental clinics" refers to establishments which offer dental treatment, including dental *Irish Dental Association* practices.

Italy

INTRODUCTION

Italy (Italian Republic) is a country of Southern Europe surrounded by the Mediterranean Sea. With 60.5 million, it is the fourth-most populous state of the European Union. The capital and largest city is Rome. The Government of Italy is a democratic republic established by the Italian constitution (1946). Healthcare is a constitutional right for all Italian citizens. Under the constitution, the Italian government controls the taxes to finance health care system and defines the essential levels of care for each region (**Livelli essenziali di assistenza, LEA**). Italy spent 8.94% (2016) of its total gross domestic product (GDP) on health care[248]. The 20 regions of Italy and 5 autonomous provinces (Sicily, Sardinia, etc.) have the responsibility to organize health units and to deliver good health services to Italian citizens[249].

Table 105 Key socio-economic and health data

General information	
Population (million):	60.483
GDP per capita (PPP, EUR):	1.0 ; 26,700
GDP per capita (rank in the EU):	13
Unemployment rate (%):	11.2 (2017)
Average salary (EUR):	N/A
Number of dentists per hundred thousand inhabitants:	80.09
Dental outpatient curative care (PPS per inhabitant):	N/A
Dental outpatient curative care (Percentual share of total current health expenditure (CHE)):	N/A

DENTAL AMALGAM USE, ALTERNATIVES AND TRENDS

Number of restorations per type material

THE USE OF DENTAL AMALGAM IN ITALY IS LIMITED AS ALTERNATIVE MATERIALS ARE PREFERRED.

Table 106 Number of restorations per type material (Source: Unione Nazionale Industrie Dentarie Italiane –UNIDI)

[248] Eurostat : Health care expenditure by financing scheme [hlth_sha11_hf]
[249] https://international.commonwealthfund.org/countries/italy/

Material	Number of restorations* per year					
	2013	2014	2015	2016	2017	2018
Dental amalgam	1,510,000	1,340,000	1,200,000	N/A	N/A	N/A
Composite resins	N/A	N/A	N/A	N/A	N/A	N/A
Ceramics	N/A	N/A	N/A	N/A	N/A	N/A

** Restorations' include both dental fillings and crowns made because of defects on the teeth*

Dental sector and effectiveness

Most dentistry is exercised in liberal (private practice). In 2015, only 4% of dental care was provided within the National Health System. Due to the cost, the use of dental specialists is limited. In many areas, only emergency treatments are provided[250].

In Italy, there are two main dental associations: **AIO (Associazione Italiane Odontoiatri)**[251] and **ANDI (Associazione Nazionale Dentisti Italiani)**[252]. According to these associations, there is an increase of public supply during the last few years.[253]

Table 107 Quantitative data on the dental sector (Source: Federazione Nazionale degli Ordini dei medici e degli odontoiatri-FNOMCeO; Associazione Nazionale Dentisti Italiani-ANDI)

	Number					
	2013	2014	2015	2016	2017	2018
Dentists[254] (number)	59,083	60,067	60,567	61,132	61,807	62,428
Dental clinics[255] (number)	39,947	N/A	40,000	N/A	N/A	N/A
Average turnover per clinic (thousand EUR)	N/A	N/A	N/A	N/A	N/A	N/A
Self-reported unmet needs for dental examination due to urbanisation (%)*	9.8	10.3	9.9	8.5	2.1	N/A
Self-reported unmet needs for dental care due to financial reasons (%)*	N/A	12.9	N/A	N/A	N/A	N/A

[250] EU Manual of Dental Practice 2015, CED
[251] https://www.aio.it/iscriviti-ad-aio/
[252] https://andi.it/andi/chi-siamo/
[253] EU Manual of Dental Practices 2015, CED
[254] The term "dentists" refers to individual professionals
[255] The term "dental clinics" refers to establishments which offer dental treatment, including dental practices

**Data collected from Eurostat*

Manufacturing companies of dental amalgam and alternative materials

The Italian Dental Industry Association **(UNIDI – Unione Nazionale Industrie Dentarie Italiane)** associates the main Italian manufacturers of equipment and materials for dentists and dental technicians. The manufacturers of precious and non-precious alloys in Italy are: 8853, ANTEEA, ITALOR, Ivoclar vivadent, Gruppo MICERIUM, Microtecnor, Orotig and Ruthinium Group.[256]

Table 108 Production levels of dental materials (Source: Associazione Nazionale Commercio Articoli Dentari - ANCAD)

Material	Production levels (unit: l)					
	2013	2014	2015	2016	2017	2018
Encapsulated dental amalgam (mercury component only)	N/A	N/A	10,886 Boxes of pre-dosed encapsulated form (50)	12,057 Boxes of pre-dosed encapsulated form (50)	6,742 Boxes of pre-dosed encapsulated form (50)	7,091 Boxes of pre-dosed encapsulated form (50)

Annual sales per company and material: No data available.

Extra-EU Imports and exports of dental amalgam and alternative restoration materials

According to UNIDI, the Italian production for dental manufacturers is almost 880 million Euro with 58% exportations in 2016[257].

No quantitative data available. Waste treatment from amalgam separators and water waste treatment facilities

Dental clinical waste is stored during the practice and taken over by a special sanitary waste company at the end of every month. Dental amalgam are normally removed once a year. All these operations and the quantities of waste should be recorded in a specific document. In Italy, amalgam separators are not required by law[258].

Number of Cremations:

Cremation in Italy is framed by law: Legge n.130 del 30 marzo 2001 "Disposizioni in materia di cremazione e dispersion delle ceneri"[259].

[256] http://www.unidi.it/en/associati/leghe-preziose-e-non
[257] http://www.unidi.it/en/associati/leghe-preziose-e-non
[258] https://noharm-europe.org/sites/default/files/documents-files/5269/HCWH_Europe_Mercury_Factsheet_Dec-2017_FINAL_WEB.pdf
[259] http://www.parlamento.it/parlam/leggi/01130l.htm

NATIONAL POLICIES AND MEASURES

Table 109 Policies and measures to phase down or phase-out the use of dental amalgam

Category	Type	Ongoing	Under development
Measures to phase down or phase-out dental amalgam	Dental amalgam bans, phasing-out or phasing down	Ministerial decree n°.261 of 10 October 2001 which, among other things, prohibits the use, the import and the placing on the market in Italy of dental amalgam not prepared in the pre-dosed encapsulated form. It also prohibits the laying and removal of amalgam in patients with an allergy to amalgam, pregnant or breastfeeding women, children under six years of age, patients with severe kidney disease[260].	No
	National guidelines, promoting the use of mercury-free materials	No	No
	Supporting research and development in respect of mercury-free dental restorations	No	No
	Others	No	No
Measures to manage waste and emissions from dental amalgam	Requirements for the installation and maintenance of separators	No	No
	Requirements for the collection and treatment of solid waste from separators	No	No
	Requirements for mercury emissions from crematoria	No	No

[260] page 21 of the official gazette http://www.gazzettaufficiale.it/eli/gu/2001/11/09/261/sg/pdf

Category	Type	Ongoing	Under development
	Standards for mercury concentrations in sludge for the use of land spreading	No	No
	Supporting research and development in respect of reducing emission and releases of mercury to the environment	No	No
	Others	No	No

HEALTH SERVICES AND INSURANCE

Italian public healthcare is funded through taxation. The government decides the National Health Plan and national budget and funds are allocated to the regions. The **« essential level of assistance » (LEA-Livelli essenziali di assistenza)** establishes the national health coverage which should be guarantee for all citizens.

Health care is provided through the **Italian national health system (SSN-Servizio Sanitario Nazionale)**. The Italian national health system (SSN) guarantees dental restorations to individuals in developmental age and to vulnerable people (the specific situations are indicated by national regulation). Various exemptions exists for people under specific medical conditions and income levels who can have small co-payments. This is not common for citizens to enrol in supplementary health plans that cover dental restorations.

Each region manages its own health local public enterprises **(Aziende sanitaria locali)** and hospital public enterprises (**Aziende ospedaliere).** So, health services change significantly from one region to another.

Oral healthcare is part of the National Health Service. Patients have only to pay a co-payments for dental care as restorative treatments or implants provided by NHS dentists (public). Dental care is mostly private in Italy (only 4% of dental care is provided within the NHS) so most of the population (almost 95%) pays for dental care out of pocket. In some areas, only emergency treatments are provided.

Private healthcare insurance plans exist. There is a difference between private and public social security in relation to the coverage of dental treatment costs. There are provisions for vulnerable groups[261,262,263].

Table 110 Quantitative data on dental restorations (Source: Questionnaire from the Ministry of Health)

[261] Questionnaire from Italian Ministry of Health
[262] EU Manual of Dental Practice 2015, CED
[263] https://international.commonwealthfund.org/countries/italy/

Category	Category	Price	Reimbursement by social security %
Restoration	Dental amalgam	100-150	0
	Composite resins	150-200	0
	Glass ionomer cements	N/A	N/A
	Compomers	N/A	N/A
	Ceramics	340-400 (onlay-inlay)	N/A
Material	Dental amalgam	N/A	N/A
	Composite resins	N/A	N/A
	Glass ionomer cements	N/A	N/A
	Compomers	N/A	N/A
	Ceramics	N/A	N/A

GOOD PRACTICES IN THE SELECTED AREAS

No data available.

Latvia

INTRODUCTION

Latvia is a country in the Baltic region of Northern Europe. The capital and largest city is Riga. In 2016, the country spent 1,556.09 million euro (6.21% of GDP) in healthcare[264].

Table 111 Key socio-economic and health data (2018)

General information	
Population (million):	1.9
GDP per capita (PPP, EUR):	5.6; 12,300
GDP per capita (rank in the EU):	26
Unemployment rate (%):	7.4
Minimum wage (EUR):	430.00
Number of dentists per hundred thousand inhabitants:	72.01 (2016)
Dental outpatient curative care (PPS per inhabitant):	65.11 (2016)
Dental outpatient curative care (Percentual share of total current health expenditure (CHE)):	5.46 (2016)

DENTAL AMALGAM USE, ALTERNATIVES AND TRENDS

Number of restorations per type material

Table 112 Number of restorations per type material

Material	Number of restorations
Dental amalgam*	2018: 12,359 (children only) 2017: 127,404 (children only) 2015: 163,685 (children only)
Composite resins	N/A
Glass ionomer cements	N/A

[264] Eurostat (online data codes : hlth_sha11_hf, demo_gind and nama_10_gdp)

Material	Number of restorations
Compomers	N/A
Ceramics	N/A
Others	N/A

* Source: Cabinet of Ministers (2019) "National plan on measures to phase down the use of dental amalgam for 2019-2020 (Article 10(3) of the Mercury Regulation)". Order of the Cabinet of Ministers Nr. 329. Riga, 2nd July 2019

According to the National Plan concerning the measures to phase-out the use of dental amalgam[265] its use has decreased by more than a tenfold between 2017 and 2018 (from 127 thousand restorations to 12 thousand restorations per year). However, this information only covers the use of dental amalgam in children (18 years old or younger) who have received state funded dental services. Overall, about 47% of children have used state funded dental services in the recent years. The remaining 53% include children who used services of private dental service providers and those not attending a dentist in a given year. Therefore, data available on the use of dental amalgam in children is partial.

According to the Plan, the decrease has been driven by the requirements and implementation of the Regulation 2017/852 article 10 (2). Since July 2018, the use of dental amalgam was prohibited for children younger than 14 years old (unless justified for clinical reasons) driving the significant reduction. Improved state funding of alternative materials (starting from 2018) has also contributed to the reduction in use.

Data is available from the Latvian Dentist Association[266] on the number of visits to a (state funded) dentist by children per year. In 2015, the number of restorations using dental amalgam accounted for 34% of the total number of children visits (516 thousands). In 2018, it accounted only for about 2% of annual visits (about 520 thousands).

It should be noted, that no information is being collated on the use of dental amalgam in adults in Latvia. The National Plan highlights that there are plans to develop a joint information system covering private dental services providers (2020-2021) that may provide a mechanism for collating such data in the future.

Dental sector and effectiveness

In Latvia, state-funding dental service is only available to:

- children (up to 18 years old) (excluding orthodontics and dentures); and
- Chernobyl nuclear disaster liquidators (recovery personnel) and victims of Chernobyl nuclear power plant accident – 50% state funding of (basic) dental treatments and 100% of plastic dentures costs.

Dental services for adults do not receive any state funding and must be fully covered by the patients (using own resources and/or private medical/dental insurance).

[265] Cabinet of Ministers (2019) "National plan on measures to phase down the use of dental amalgam for 2019-2020 (Article 10(3) of the Mercury Regulation)". Order of the Cabinet of Ministers Nr. 329. Riga, 2nd July 2019 (URL: https://likumi.lv/ta/id/307948-par-zobarstniecibas-amalgamas-lietosanas-pakapeniskas-samazinasanas-planu-2019-2020-gadam; in Latvian)
[266] Latvian Dentist Association (2019). Source: http://www.lza-zobi.lv/lv/par-asociaciju/gada-gramatas

Detailed information on the number of dentists and supporting personnel is available from the annual reports published by the Latvian Dentist Association[267] (2015-2017). The data is disaggregated by qualifications, gender and age and distinguishes between dentists and support personnel including hygienists, nurses and technicians.

Table 113 Quantitative data on the dental sector

	Number					
	2013	**2014**	**2015**	**2016**	**2017**	**2018**
Dentists[268] (number)	N/A	N/A	1,569 dentists plus 1,287 support staff[269]	1,459 dentists plus 1,159 support staff	1,421 dentists plus 1,158 support staff	N/A
Dental clinics[270] (number)	N/A	942[271]	863	814	809	N/A
Average turnover per clinic (thousand EUR)	116[272]	N/A	N/A	N/A	N/A	N/A
Self-reported unmet needs for dental examination due to urbanisation (%)	18.9	18.1	13.9	13.6	13.9	14.2
Self-reported unmet needs for dental care due to financial reasons (%)	N/A	22.6	N/A	N/A	N/A	N/A

The latest data available indicate that there were 1,421 dentists in 2017 in Latvia supported by further 1,158 staff (e.g. nurses)[273].

General dentists account for the majority of doctors (94% in 2017), while dentists specialised in orthodontics, periodontology, endodontics, children dentistry and surgeons account for the remaining 6%[274].

Dental services in Latvia are provided by public and private practices owned by individuals, groups of dentists or corporate entities. Public hospitals such as Riga Stradiņa University Institute of Stomatology[275] also offer oral and maxillofacial surgery, carry out clinical work and academic research in the field of stomatology. In 2017, there were 809 dental service providers of which 89% were private and 11% were public. In

[267] Latvian Dentist Association (2019). Source: http://www.lza-zobi.lv/lv/par-asociaciju/gada-gramatas
[268] The term "dentists" refers to individual professionals
[269] Support staff includes dental nurses, assistants, technicians and dental hygienists.
[270] The term "dental clinics" refers to establishments which offer dental treatment, including dental practices
[271] Information from State Revenue Service (2014).
[272] Calculated using the State Revenue Service data on annual turnover (50.8 million Euro of 437 taxpayers)
[273] Latvian Dentist Association (2018). Annual report 2017
[274] Latvian Dentist Association (2018). Annual report 2017
[275] Source: https://www.stomatologijasinstituts.lv/en

order to provide state funded services, dental service providers must have a contract with the National Health Service (NHS).

In 2013, the average annual turnover was 116 thousand Euro[276]. Dental service providers with the annual turnover between 10-100 thousand Euro accounted for 60% of reporting companies while companies with the turnover between 100 thousand – 1 million Euro accoutned for further 24%. Dental service providers with a turnover between 10 thousand and 1 million Euro accounted for 84% of reporting companies and 71% of total annual turnover (36.3 million Euro of 50.8 million Euro). It should be noted that this data does not cover all dental service providers in Latvia.

Manufacturing companies of dental amalgam and alternative materials

Table 114 Annual sales per company and material

Company	Material	Amounts
[Name of company]	Dental amalgam*	N/A
	Composite resins	N/A
	Glass ionomer cements	N/A
	Compomers	N/A
	Ceramics	N/A

The National Plan[277] to phase-out amalgam use in dentistry highlights that data on manufacturing and use of dental amalgam and other materials is commercially sensitive and not publically available. The Plan contemplates opportunities to cooperate with distributors of dental materials in data collation and identification of trends in the use of dental amalgam.

Extra-EU Imports and exports of dental amalgam and alternative restoration materials

No data available

No such data is available for Latvia. The National Plan notes, however, that Customs Department of the State Revenue Service may internally hold some information on imports of amalgam from third countries.

Waste treatment from amalgam separators and water waste treatment facilities

Table 115 Quantitative data on water and solid waste from dental amalgam

[276] Calculated using the State Revenue Service data on annual turnover (50.8 million Euro of 437 taxpayers)
[277] Cabinet of Ministers (2019) "National plan on measures to phase down the use of dental amalgam for 2019-2020 (Article 10(3) of the Mercury Regulation)". Order of the Cabinet of Ministers Nr. 329. Riga, 2nd July 2019

Category	Mercury waste treatment					
	2013	2014	2015	2016	2017	2018
Share of dental chairs equipped with amalgam separators (%)	100%	100%	100%	100%	100%	100%
Share of waste from separators treated in specialized treatment facilities (%)	N/A	N/A	N/A	N/A	N/A	N/A
Average dental amalgam removal efficiency of separators (%)	N/A	N/A	N/A	N/A	N/A	N/A
Cost of collection and treatment of waste from separators per kg (thousand EUR)	N/A	N/A	N/A	N/A	N/A	N/A
Concentration of mercury in sewage sludge (µg/L)	N/A	N/A	N/A	N/A	N/A	N/A

Cabinet regulation No.60 "Regulations Regarding Mandatory Requirements for Medical Treatment Institutions and Their Structural Units", (Adopted 20 January 2009) prescribes that the surplus of dental amalgam seals need to be collected and transferred to operators who have the permit for hazardous waste management in accordance with the laws and regulations regarding the procedures for issuing, extension, review and cancellation of waste management permits. In order to prevent mercury discharges to sewage, dental equipment outlets must be equipped with dental amalgam separators.

Data available on annual generation of dental amalgam wastes in Latvia suggests that in 2017 a total of 0.09 tonnes of dental amalgam wastes (180110) was produced[278]. Historically, dental amalgam waste generation ranged from 0.06 tonnes in 2016 up to 0.26 tonnes in 2015:

- 0.06 tonnes in 2016;
- 0.26 tonnes in 2015;
- 0.10 tonnes in 2014; and
- 0.20 tonnes in 2013.

According to Eurostat statistics, 33% of sludge produced from urban wastewater treatment plants was used in agriculture in 2013. The agricultural use of sludge has decreased compared to 2011, when it was 45%[279].

Number of Cremations

Table 116 Quantitative data on cremations

[278] Latvijas Vides, ģeoloģijas un meteoroloģijas centrs (2018). Valsts statistiskā pārskata "Nr.3 – Atkritumi. Pārskats par atkritumiem"kopsavilkums par 2017.g.
[279] http://appsso.eurostat.ec.europa.eu/nui/submitViewTableAction.do

Category	Air emissions from crematoria					
	2013	2014	2015	2016	2017	2018
Number of crematoria	2	2	2	2	2	2
Number of cremations per year	2,150	2,222	2,395	2,909	3,443	3,826
Share of crematoria equipped with abatement technologies (%)	100%	100%	100%	100%	100%	100%
Average efficiency of the abatement technologies (%)	N/A	N/A	N/A	N/A	N/A	N/A
Cost of mercury capture per cremation (EUR)	N/A	N/A	N/A	N/A	N/A	N/A

Cremation is still a relatively unpopular when compared to traditional burial. In the recent years there has been a growth in the number and share of cremations. In particular, it has increased from 7.5% in 2013 to 12% in 2017[280].

The Latvian State Audit Office (2018) highlighted that lack of available burial spaces particularly in the largest cities is one of the drivers of an increased demand for cremation[281].

NATIONAL POLICIES AND MEASURES

Table 117 Policies and measures to phase down or phase-out the use of dental amalgam

Category	Type	Ongoing	Under development
Measures to phase down or phase-out dental amalgam	Dental amalgam bans, phasing-out or phasing down	Regulation 2017/852 on Mercury, Article 10 Implementation of Regulation No 2017/852 article 10 (2)	The national plan in accordance with the requirements laid down in Article 10 of Regulation (EU) 2017/852 concerning the measures to phase down the use of dental amalgam: "Amalgam use in dentistry phasing down plan for 2019-2020" Preparation of national plan according Regulation No 2017/852 article 10 (3)
	National guidelines, promoting the use	Cabinet Regulation No. 555 " Procedures for the	No

[280] Source: Central Statistical Bureau of Latvia (number of annual deaths divided by cremations) https://www.csb.gov.lv/lv/statistika/statistikas-temas/iedzivotaji/mirstiba/galvenie-raditaji/miruso-skaits
[281] Latvian State Audit Office (2018) Cemetery management in Latvia. Riga, 2018

Category	Type	Ongoing	Under development
	of mercury-free materials	Organisation and Payment of Health Care Services" (28 August 2018) ensures access to state-funded dental services (including use of alternatives) for children under 18 years of age	
	Supporting research and development in respect of mercury-free dental restorations	No	No
	Others	No	No
Measures to manage waste and emissions from dental amalgam	Requirements for the installation and maintenance of separators	National legislation include requirements for separators - Cabinet Regulation No. 60 "Regulations Regarding Mandatory Requirements for Medical Treatment Institutions and Their Structural Units" (adopted 20 January 2009)	No
	Requirements for the collection and treatment of solid waste from separators	Cabinet Regulation No. 60 "Regulations Regarding Mandatory Requirements for Medical Treatment Institutions and Their Structural Units" requires collecting and managing amalgam wastes as hazardous wastes. Cabinet Regulation No.302 "On waste classification and hazardous properties" (19 April 2011 classify dental amalgam as 'hazardous waste'.	No
	Requirements for mercury emissions from crematoria	No	No
	Standards for mercury concentrations in sludge for the use of land spreading	Cabinet Regulation No.362 "On the use, monitoring and control of sewage sludge and its compost" (2 May 2006) sets out a concentration limit of 10 mg/kg of Mercury in the	No

Category	Type	Ongoing	Under development
		sewage sludge used in agriculture.	
	Supporting research and development in respect of reducing emission and releases of mercury to the environment	No	No
	Others	No	No

Latvia is implementing provisions of the **Regulation 2017/852 on Mercury** setting out measures to phase down or phase-out dental amalgam (Article 10). In particular:

- Dental amalgam is not recommended for dental treatment of deciduous teeth, of children under 14[282] years and of pregnant or breastfeeding women since July 2018 (except when deemed strictly necessary by the dental practitioner based on the specific medical needs of the patient).
- The "National Plan on measures to phase down the use of dental amalgam for 2019-2020"[283] has been developed in accordance with the Article 10(3) and currently subject to public consultation. The Plan stipulates three strategic measures including:
    - Determination and Analysis of Amalgam Usage Indicators
    - Dental health prevention and oral health promotion
    - Training and further education of students, practitioners, public education on reducing amalgam use
- Article 10(4) requires dental service providers to be equipped with an amalgam separator from 1 January 2019. Requirements for the installation and maintenance of separators. In Latvia, **Cabinet Regulation No. 60 "Regulations Regarding Mandatory Requirements for Medical Treatment Institutions and Their Structural Units"** (adopted 20 January 2009; amended 17 May 2018) sets out requirements for amalgam separators. Waste from amalgam separators must collected and treated by specialised treatment facilities licenced to handle hazardous wastes. Cabinet Regulation No.302 "On waste classification and hazardous properties" (19 April 2011 classify dental amalgam as 'hazardous waste'.

Furthermore, Latvia complies with the requirements of the EC Directive 86/278/EEC, on the protection of the environment, and in particular of the soil. **Cabinet Regulation No.362 "On the use, monitoring and control of sewage sludge and its compost"** (2 May 2006) sets out standards for mercury concentrations in sludge for the use of land spreading (10 mg/kg).

[282] NHS has set an age limit at 14 years as opposed to 15 years old.
[283] Cabinet of Ministers (2019) "National plan on measures to phase down the use of dental amalgam for 2019-2020 (Article 10(3) of the Mercury Regulation)". Order of the Cabinet of Ministers Nr. 329. Riga, 2nd July 2019

HEALTH SERVICES AND INSURANCE

In Latvia, state-funding dental services are only available to children (under 18 years of age) and Chernobyl nuclear disaster victims and liquidators (50% state funding of (basic) dental treatments).

Access to state-funded health services (including dental services) is stipulated in the Cabinet Regulation No. 555 "Procedures for the Organisation and Payment of Health Care Services" (28 August 2018). Each year, NHS approves and publishes a list of medical manipulations and associated tariffs (Order #16-2/191, 31.08.2018) which is maintained in a form of the Service Tariff Database[284].

Dental services in Latvia are provided by public and private practices owned by individuals, groups of dentists or corporate entities. In order to provide state funded services (for children and other stipulated groups), dental service providers must have a contract with the National Health Service (NHS). Providers are then reimbursed for the dental services provided to eligible groups in accordance with the annually approved tariffs (see the table below). In 2017, state-funded dental services amounted to 8.5 million Euro.

Dental services for adults do not receive any state funding and must be fully covered by the patients (using own resources and/or private dental insurance). It should be noted that according to the Law on Personal Income Tax, all tax payers can recover 20% of annual healthcare payments including payments for dental restorations. In the 2018 the limit was set at 600 Euro (i.e. 120 Euro (20% of 600 Euro per year))[285].

A study by the Competition Authority (2007)[286] reported that dental service providers operate in free market conditions and set the price for their services in line with their marketing strategy (including affordability of the targeted market segment), operational costs (e.g. materials, wages etc.) and qualifications. This results in a significant variation in tariffs for the same restoration service e.g. 8 LVL-70 LVL (depending on material and size of the filling).

A number of insurance companies offer private health insurance plans to employers and individuals in Latvia including Balta, Seesam, Ergo, BTA, BAN. In 2010, more than 7% of inhabitants were covered by private medical insurance. Private medical insurance is typically offered by employeers as part of an employment package who receive corporate tax reductions. Insurance companies also offer private medical insurance plans to individuals[287].

Inclusion of dental services and associated limits in the insurance plans differs between and within insurance providers. Often these are part of extended and more expensive insurance plan packages[288].

Prices of state-funded restorations using different materials are presented in the table below. These prices are set annually by the NHS and form the basis for payments reimbursing dental services providers for treating children and victims and liquidators of Chernobyl nuclear disaster.

[284] Source: National Health Service http://www.vmnvd.gov.lv/lv/ligumpartneriem/ligumu-dokumenti/pakalpojumu-tarifi
[285] Tax credit value cannot exceed the annual personal income tax value.
[286] Source: https://www.kp.gov.lv/tirgu-uzraudziba/tirgu-uzraudzibas-zinojumi
[287] SPKC (2013). Veselības sistēmas pārejas periodā: Latvija. Pārskats par veselības sistēmu līdz 2011.gadam
[288] SPKC (2013). Veselības sistēmas pārejas periodā: Latvija. Pārskats par veselības sistēmu līdz 2011.gadam

Table 118 Quantitative data on dental restorations

Category	Category	Price (Euro)	Reimbursement by social security %
Restoration	Dental amalgam	10.47-20.84	100% children (<18 y.o) 50% Chernobyl victims and personnel max 20% of 600 Euro per year (120 Euro) (adults)
	Composite resins	17.72-33.14	100% children (<18 y.o) 50% Chernobyl victims and personnel max 20% of 600 Euro per year (120 Euro) (adults)
	Glass ionomer cements	11.36-20.01 (deciduous teeth) 13.33-15.15 (permanent teeth)	100% children (<18 y.o) 50% Chernobyl victims and personnel max 20% of 600 Euro per year (120 Euro) (adults)
	Compomers	13.45-22.84 (deciduous teeth) 15.66 (permanent teeth)	100% children (<18 y.o) 50% Chernobyl victims and personnel max 20% of 600 Euro per year (120 Euro) (adults)
	Ceramics	N/A	N/A
Material	Dental amalgam	Covered above	
	Composite resins	Covered above	
	Glass ionomer cements	Covered above	
	Compomers	Covered above	
	Ceramics	Covered above	

Note 1: The prices reflect state-funded restorations for children and Chernobyl nucler disaster victims and liquidators only. The ranges reflect the number of surfaces subject to restoration (1 to 4 or more per tooth).
Source: NHS Service Tariff Database (Order #16-2/191, 31.08.2018).

Restoration prices for adults are freely set by service providers and are typically higher than the NHS prices. For example, the Riga Stradiņa University Institute of Stomatology[289] charges between 35 and 60 Euro for one restoration using dental amalgam (depending on the number of treated surfaces). This compares to 10 to 21 Euro under the state-funding.

GOOD PRACTICES IN THE SELECTED AREAS

No information has been identified on good practices to complete the table below.

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[289] Source: https://www.stomatologijasinstituts.lv/lv/cenas

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Lithuania

INTRODUCTION

Lithuania is a country in the Baltic region of Europe. Vilnius is the capital and largest city. The country spent 2,581.36 million euro (6.64% of GDP) in healthcare in 2016290.

Table 119 Key socio-economic and health data (2018)

General information	
Population (million):	2.8
GDP per capita (PPP, EUR):	4.3; 13,300
GDP per capita (rank in the EU):	19
Unemployment rate (%):	6.2
Minimum wage salary (EUR):	555.00
Number of dentists per hundred thousand inhabitants:	97.17 (2016)
Dental outpatient curative care (PPS per inhabitant):	122.29 (2016)
Dental outpatient curative care (Percentual share of total current health expenditure (CHE)):	7.93 (2016)

DENTAL AMALGAM USE, ALTERNATIVES AND TRENDS

Number of restorations per type material

According to the National Public Health Centre (Ministry of Health) no data is available for any material.

Table 120 Number of restorations per type material

Material	Number of restorations
Dental amalgam*	4.6%
Composite resins	-
Glass ionomer cements	-

290 Eurostat (online data codes : hlth_sha11_hf, demo_gind and nama_10_gdp)

Material	Number of restorations
Compomers	-
Ceramics	-
Others	-

Dental sector

Table 121 Quantitative data on the dental sector

	Number					
	2013	2014	2015	2016	2017	2018
Dentists[291] (number)	N/A	3,585	3,666	3,828	3,951	4,023
Dental clinics[292] (number)	N/A	2,237	2,854	2,390	2,461	2,437
Average turnover per clinic (thousand EUR)	N/A	N/A	N/A	N/A	N/A	N/A
Self-reported unmet needs for dental examination due to urbanisation (%)	4.3	4.4	4.2	4.5	3.8	N/A
Self-reported unmet needs for dental care due to financial reasons (%)	N/A	6.8	N/A	N/A	N/A	N/A

Source: Questionnaire response (Ministry of Health)

Manufacturing companies of dental amalgam and alternative materials

No data or information has been identified related to companies in Lithuania manufacturing dental amalgam and alternative materials.

Extra-EU Imports and exports of dental amalgam and alternative restoration materials

No data or information has been identified related to extra-EU imports and exports of dental amalgam and alternative restoration materials for Lithuania.

Waste treatment from amalgam separators and water waste treatment facilities

[291] The term "dentists" refers to individual professionals
[292] The term "dental clinics" refers to establishments which offer dental treatment, including dental practices

According to the Ministry of Environment, no information on waste treatment from amalgam separators and water waste treatment facilities is available.

Number of Cremations

Table 122 Quantitative data on cremations

Category	Air emissions from crematoria					
	2013	2014	2015	2016	2017	2018
Number of crematoria	1	1	1	1	1	1
Number of cremations per year	2,118	2,770	3,502	N/A	N/A	N/A
Share of crematoria equipped with abatement technologies (%)	100	100	100	100	100	100
Average efficiency of the abatement technologies (%)	N/A	N/A	N/A	N/A	N/A	N/A
Cost of mercury capture per cremation (EUR)	N/A	N/A	N/A	N/A	N/A	N/A

Source: Questionnaire response (Ministry of Environment)

NATIONAL POLICIES AND MEASURES

Table 123 Policies and measures to phase down or phase-out the use of dental amalgam

Category	Type	Ongoing	Under development
Measures to phase down or phase-out dental amalgam	Dental amalgam bans, phasing-out or phasing down	No	National plan on measures to implement to phase down the use of dental amalgam
	National guidelines, promoting the use of mercury-free materials	No	The last decade dentist students are no longer trained to work with dental amalgam
	Supporting research and development in respect of mercury-	No	No

Category	Type	Ongoing	Under development
	free dental restorations		
	Others	No	No
Measures to manage waste and emissions from dental amalgam	Requirements for the installation and maintenance of separators	Article 10 (4) of Regulation 2017/852 provides that dental care facilities which use dental amalgams or remove dental amalgam fillings or teeth containing such fillings must have amalgam separators installed to hold and collect the amalgam particles. The same Regulation specifies that the department of environment shall organise and reinforce the requirements for the establishment of amalgam separators in dental care facilities.	No
	Requirements for the collection and treatment of solid waste from separators	No specific requirements for solid waste from separators, but all hazardous waste has to be collected and treated according to Republic of Lithuania Law on Waste management.	No
	Requirements for mercury emissions from crematoria	Crematoria shall install abatement technique that ensure mercury emission do not exceed 0.1 mg/m^3. Mercury emissions shall be measured periodically, at least twice every year (average emission value calculated by taking 3 samples within single cremation).	No
	Standards for mercury concentrations in sludge for the use of land spreading	For use on agricultural land Mercury <1 mg/kg	
	Supporting research and development in respect of reducing emission and releases of mercury to the environment	No	No
	Others	No	No

Source: Questionnaire responses (Ministry of Environment, Ministry of Health)

1. Measures to phase down or phase out dental amalgam:

- Dentistry students in Lithuanian universities are only introduced to the history of tooth filling, listing the materials used, including amalgams, but they have not been trained in dental amalgams since 2008.
- The implemented measures to phase out dental amalgam will be evaluated every calendar year, based on the following criteria: number of legislation acts aimed at monitoring the use of dental amalgam; the amount of amalgam placed on the Lithuanian market during the year; the total amount of amalgam used per year; the total amount of amalgam used per year for milk teeth treatment, teeth of infants up to 15 years of age and teeth of breastfeeding women; the number of hours provided in dental study programs for training in the reduction of dental amalgam use and the use of alternative dental fillings; the number of measures implemented per year to inform the public about the health risks of mercury.
  By the 1st of February each year the authorities and bodies implementing the action plan will submit a report on the implementation of the measures of the previous year to the National Centre of Public Health under the Ministry of Health. By the 1st of March each year the National Centre of Public Health will draw up a report on the implementation of the plan, to be submitted to the Coordinating Authority for the implementation of Regulation 2017/852.

2. Measures to manage waste and emissions from dental amalgam:
   - Optimising the provision of dental care services, to ensure that the use of dental amalgam fillings and removal of teeth sealed with these fillings takes place only in dental institutions belonging to the Lithuanian National Health System, in order to achieve the highest standards of waste management.

HEALTH SERVICES AND INSURANCE

Table 124 Quantitative data on dental restorations

Category	Category	Price (€)	Reimbursement by social security %
Restoration	Dental amalgam	N/A	N/A
	Composite resins	N/A	N/A
	Glass ionomer cements	N/A	N/A
	Compomers	N/A	N/A
	Ceramics	N/A	N/A
Material	Dental amalgam	4.03	0
	Composite resins	6.72	0

Category	Category	Price (€)	Reimbursement by social security %
	Glass ionomer cements	6.72	0
	Compomers	3.36-5.04	0
	Ceramics	N/A	0

Source: Questionnaire response (Ministry of Health)

GOOD PRACTICES IN THE SELECTED AREAS

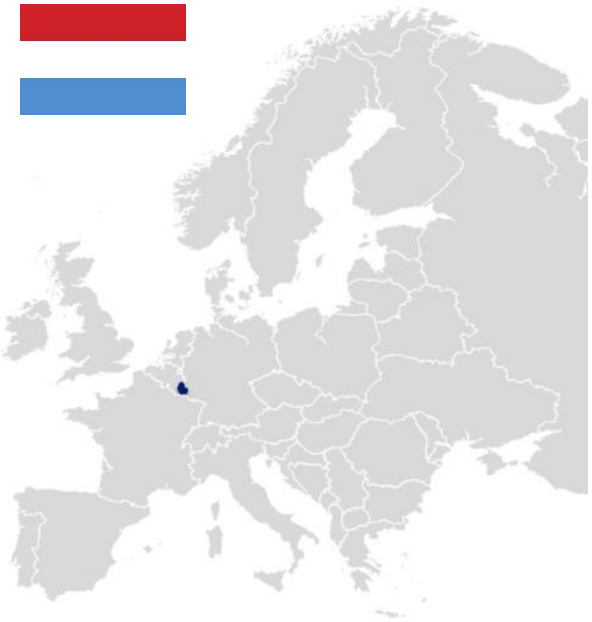
No information has been identified on good practices to complete the table below.

Luxembourg

INTRODUCTION

Luxembourg is a landlocked country in western Europe. The capital and largest city is Luxembourg City. The country spent 2,915.41 million euro (5.47% of GDP) in healthcare[293].

Table 125 Key socio-economic and health data (2018)

General information	
	
Population:	602 005
GDP per capita (PPP, EUR):	0.6; 80,800
GDP per capita (rank in the EU):	1
Unemployment rate (%):	5.4
Minimum wage salary (EUR):	2,071.10
Number of dentists per hundred thousand inhabitants (2015):	N/A
Dental outpatient curative care (PPS per inhabitant):	199.43 (2016)
Dental outpatient curative care (percentual share of total current health expenditure (CHE)):	5.68 (2016)

DENTAL AMALGAM USE, ALTERNATIVES AND TRENDS

Number of restorations per type material

No data on number of restorations per material type was available.

Table 126 Number of restorations per type material

Material	Number of restorations
Dental amalgam*	N/A
Composite resins	N/A
Glass ionomer cements	N/A

[293] Eurostat (online data codes : hlth_sha11_hf, demo_gind and nama_10_gdp)

Material	Number of restorations
Compomers	N/A
Ceramics	N/A
Others	N/A

Dental sector and effectiveness

Table 127 Quantitative data on the dental sector

	Number					
	2013	**2014**	**2015**	**2016**	**2017**	**2018**
Dentists [294] (number) [1]	460	476	506	550	581	N/A
Dental clinics[295] (number)	N/A	N/A	N/A	N/A	N/A	N/A
Average turnover per clinic (thousand EUR)	N/A	N/A	N/A	N/A	N/A	N/A
Self-reported unmet needs for dental examination due to urbanisation (%)	1.6	1.4	1.1	1.1	0.6	N/A
Self-reported unmet needs for dental care due to financial reasons (%)	N/A	10.1	N/A	N/A	N/A	N/A

Note 1: Source: Ministry of Health, Luxembourg

There is a state-funded healthcare system in Luxembourg that provides basic dental care for citizens. Within one calendar year and up to a total amount that, as of July 2018, stands at 60 euros, services included in the dentists' nomenclature are fully covered by health insurance[296].

As every dentist is working individually, there are no public dental clinics in Luxembourg. All dentists are registered with public insurance, however, which enables them to treat

[294] The term "dentists" refers to individual professionals
[295] The term "dental clinics" refers to establishments which offer dental treatment, including dental practices
[296] https://cns.public.lu/en/publications/depliant/remboursement-soins-dentaires.html

patients under the public health care system. Patients pay dentists directly but can later file for reimbursements of up to 80-100% from the public health insurance system.[297]

Manufacturing companies of dental amalgam and alternative materials

According to the Ministry of Health, Luxembourg is not manufacturing any of these materials.

Extra-EU Imports and exports of dental amalgam and alternative restoration materials

No data on extra-EU imports and exports of dental amalgam and alternative restoration materials was available.

Waste treatment from amalgam separators and water waste treatment facilities

Table 128 Quantitative data on water and solid waste from dental amalgam

Category	Mercury waste treatment					
	2013	2014	2015	2016	2017	2018
Share of dental chairs equipped with amalgam separators (%) [1]	100%	100%	100%	100%	100%	100%
Share of waste from separators treated in specialized treatment facilities (%)	N/A	N/A	N/A	N/A	N/A	N/A
Average dental amalgam removal efficiency of separators (%)	N/A	N/A	N/A	N/A	N/A	N/A
Cost of collection and treatment of waste from separators per kg (thousand EUR)	N/A	N/A	N/A	N/A	N/A	N/A
Concentration of mercury in sewage sludge (µg/L)	N/A	N/A	N/A	N/A	N/A	N/A

Note 1: The EU Hazardous Waste Directive is incorporated into law and is actively enforced. Amalgam separators are legally required. Source: https://noharm-europe.org/sites/default/files/documents-files/5269/HCWH_Europe_Mercury_Factsheet_Dec-2017_FINAL_WEB.pdf

According to Eurostat statistics, 34% of sludge produced from urban wastewater treatment plants was used in agriculture in 2015. The agricultural use of sludge has decreased compared to 2012, when it was 47%[298].

[297] https://www.expatica.com/lu/healthcare/specialists/find-a-dentist-in-luxembourg-1291018/
[298] http://appsso.eurostat.ec.europa.eu/nui/submitViewTableAction.do

Number of Cremations

Table 129 Quantitative data on cremations

Category	Air emissions from crematoria					
	2013	2014	2015	2016	2017	2018
Number of crematoria [1]	1	1	1	1	1	N/A
Number of cremations per year [1]	2,276	2,404	2,204	2,187	2,371	N/A
Share of crematoria equipped with abatement technologies (%) [2]	N/A	N/A	N/A	100%	100%	N/A
Average efficiency of the abatement technologies (%)	N/A	N/A	N/A	N/A	N/A	N/A
Cost of mercury capture per cremation (EUR)	N/A	N/A	N/A	N/A	N/A	N/A

Note 1: Source: https://www.cremation.org.uk/statistics
Note 2: According to Luxembourg's implementation report on Recommendation 2003/4 of the OSPAR agreement, the one crematorium in the country is fitted with abatement technology. Source: https://www.ospar.org/documents?d=35427

According to Flamma, a non-profit organisation in Luxembourg promoting cremation, nearly 60% of the population decides to be cremated after death[299].

NATIONAL POLICIES AND MEASURES

Table 130 Policies and measures to phase down or phase-out the use of dental amalgam

Category	Type	Ongoing	Under development
Measures to phase down or phase-out dental amalgam	Dental amalgam bans, phasing-out or phasing down	N/A	National plan under development. Details are currently unavailable
	National guidelines, promoting the use of mercury-free materials	N/A	N/A
	Supporting research and development in respect of mercury-free dental restorations	N/A	N/A
	Others	N/A	N/A

[299] https://today.rtl.lu/news/luxembourg/1261689.html

Category	Type	Ongoing	Under development
Measures to manage waste and emissions from dental amalgam	Requirements for the installation and maintenance of separators	N/A	N/A
	Requirements for the collection and treatment of solid waste from separators	N/A	N/A
	Requirements for mercury emissions from crematoria	The Oslo-Paris Commission (OSPAR) agreement, of which Luxembourg is a signatory	N/A
	Standards for mercury concentrations in sludge for the use of land spreading	The EC Directive 86/278/EEC, on the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture	N/A
	Supporting research and development in respect of reducing emission and releases of mercury to the environment		
	Others	N/A	N/A

1. Measures to phase down or phase-out dental amalgam:
   - Dental amalgam bans, phasing-out or phasing down
     In 2017, the European Commission Regulation (EU) 2017/852 on Mercury was adopted by Member States to ratify and enforce the Minamata Convention on Mercury, which requires participating countries to phase-out their use of dental amalgam. According to a response to the questionnaire, a national plan is currently being developed to phase down the use of dental amalgam, however details of this plan are currently not available.

2. Measures to manage waste and emissions from dental amalgam
   - Requirements for mercury emissions from crematoria
     Luxembourg is a signatory of the Oslo-Paris Commission (OSPAR) agreement on eliminating mercury emissions from crematoria. OSPAR Recommendation 2003/4 recommends Best Available Techniques (BAT) which could be taken at crematoria to prevent and control the dispersal of mercury to the environment. Luxembourg has implemented this recommendation and according to its implementation report, the one crematorium in the country is fitted with the appropriate abatement technologies.[300]

[300] https://www.ospar.org/documents?d=35427

- Standards for mercury concentrations in sludge for the use of land spreading
  The EC Directive 86/278/EEC, on the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture provides guidelines on, for e.g., maximum permissible concentrations of potentially toxic elements in soil after application of sewage sludge and maximum annual rates of addition[301].

HEALTH SERVICES AND INSURANCE

Table 131 Quantitative data on dental restorations

Category	Category	Price	Reimbursement by social security %
Restoration [1]	Dental amalgam	€38.6- €77.4	80%
	Composite resins	N/A	N/A
	Glass ionomer cements	N/A	N/A
	Compomers	N/A	N/A
	Ceramics	N/A	N/A
Material	Dental amalgam	N/A	N/A
	Composite resins	N/A	N/A
	Glass ionomer cements	N/A	N/A
	Compomers	N/A	N/A
	Ceramics	N/A	N/A

Note 1: Source: Ministry of Health, Luxembourg

There is a state-funded healthcare system in Luxembourg that provides basic dental care for citizens. Within one calendar year and up to a total amount that, as of July 2018, stands at 60 euros, services included in the dentists' nomenclature are fully covered by health insurance. Most basic dental treatments are eligible for 80-100% reimbursement. For prescription medicines, the reimbursement is typically around 78%.

100% reimbursement is available for the following treatments:

- Orthodontics
- Surgical extractions
- Dental extractions

[301] http://adlib.everysite.co.uk/resources/000/247/164/sludge-report.pdf

- Gum and dental care

For dental implants, there is a reimbursement of 120 euros per implant.

Private insurance is recommended for patients that require substantial dental treatment as the national health insurance system only covers basic treatment[297].

According the Ministry of Health, amalgam is considered to be the most "useful and necessary" filling material. Social security reimburses 80% of the charge for amalgam fillings, with possible additional costs to be covered by the patient. Other filling materials might lead to additional restoration costs. Good practices in the selected areas.

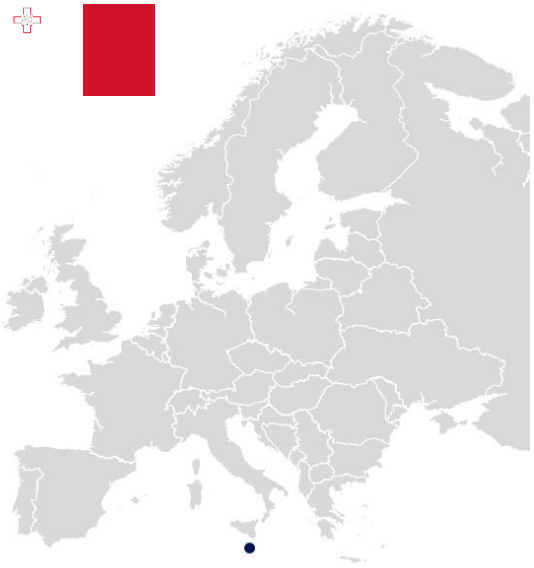
No information has been identified on good practices to complete the table below.

Malta

Introduction

Malta is a Southern European island country in the Mediterranean Sea. It is one of the smallest and densely populated country in the world with a population of 475 701 inhabitants. Valetta is the capital and largest city of Malta. Malta is a republic with a unicameral Parliament. The country spent 9.33% of its gross domestic product in healthcare in 2015[302].

Table 132 Key socio-economic and health data

General information	
	
Population (million):	0.475
GDP per capita (PPP, EUR):	3.6; 21,500
GDP per capita (rank in the EU):	16
Unemployment rate (%):	3.7
Monthly minimum wage (EUR) (2019):	757.64
Number of dentists per hundred thousand inhabitants:	47.00 (2016)
Dental outpatient curative care (PPS per inhabitant):	70.60 (2015)
Dental outpatient curative care (percentual share of total current health expenditure (CHE)):	2.80 (2015)

DENTAL AMALGAM USE, ALTERNATIVES AND TRENDS

Number of restorations per type material

Alternative materials are preferred to dental amalgam in Malta[303]. The information of the numbers of restorations per year are not available in the country[304].

Dental sector and effectiveness

Dentistry is governed by the Maltese Health Care Professions Act of 2003. Dentists are registered with the Medical council of Malta after their graduation. In Malta, oral health services are provided in public or private sectors[305]. There is an increase of the number of dentists and clinics in Malta respectively from 234 in 2013 to 329 in 2018 and 103 in 2013 and 106 in 2018.

[302] Health care expenditure by financing scheme
[303] Questionnaire Health aspects
[304] Questionnaire Health aspects
[305] EU Manual of Dental Practice 2015, CED

Table 133 Quantitative data on the dental sector (Source: Number of dentists from medical council registers; number of clinics from health care standards directorate who take care of licensing)

	Number					
	2013	**2014**	**2015**	**2016**	**2017**	**2018**
Dentists[306] (number)	234	245	258	277	308	329
Dental clinics[307] (number)	103	104	100	103	104	106
Average turnover per clinic (thousand EUR)	N/A	N/A	N/A	N/A	N/A	N/A
Self-reported unmet needs for dental examination due to urbanisation (%)*	1.0	1.2	1.0	1.2	0.4	N/A
Self-reported unmet needs for dental care due to financial reasons (%)*	N/A	3.8	N/A	N/A	N/A	N/A

**Data collected from Eurostat*

Manufacturing companies of dental amalgam and alternative materials

There is no manufacturer of dental materials in Malta.

Extra-EU Imports and exports of dental amalgam and alternative restoration material

The existence of a register of dental material imports is not known and there is no export of dental materials from Malta.

Waste treatment from amalgam separators and water waste treatment facilities

The use of amalgam separators are legally required. The waste from amalgam separators is collected locally and treated by specialised facilities in third countries[308]. The EU Hazardous Waste Directed is incorporated into law and is actively enforced[309].

Table 134 Quantitative data on water and solid waste from dental amalgam

Category	**Mercury waste treatment**					
	2013	**2014**	**2015**	**2016**	**2017**	**2018**
Share of dental chairs equipped with	100	100	100	100	100	100

[306] The term "dentists" refers to individual professionals
[307] The term "dental clinics" refers to establishments which offer dental treatment, including dental practices
[308] Questionnaire health aspects
[309] Dental amal in the EU, heading towards a phase-out ? 2017 Health care without harm.

Category	Mercury waste treatment					
	2013	2014	2015	2016	2017	2018
amalgam separators (%)						
Share of waste from separators treated in specialized treatment facilities (%)	N/A	N/A	N/A	N/A	N/A	N/A
Average dental amalgam removal efficiency of separators (%)	N/A	N/A	N/A	N/A	N/A	N/A
Cost of collection and treatment of waste from separators per kg (thousand EUR)	N/A	N/A	N/A	N/A	N/A	N/A
Concentration of mercury in sewage sludge (µg/L)	N/A	N/A	N/A	N/A	N/A	N/A

Number of Cremations

There is no crematoria in Malta.

NATIONAL POLICIES AND MEASURES

Table 135 Policies and measures to phase down or phase-out the use of dental amalgam

Category	Type	Ongoing	Under development
Measures to phase down or phase-out dental amalgam	Dental amalgam bans, phasing-out or phasing down	Dental associations have been aware of the need to phase down and eventually phase-out dental amalgam	No
	National guidelines, promoting the use of mercury-free materials	No	No
	Supporting research and development in respect of mercury-free dental restorations	No	No

Category	Type	Ongoing	Under development
	Others :	No	No
Measures to manage waste and emissions from dental amalgam	Requirements for the installation and maintenance of separators	Ongoing since 2008	No
	Requirements for the collection and treatment of solid waste from separators	Waste collection of amalgam sludge is carried out by licensed waste collectors and taken to the local environmental authority which disposes of it by sending it abroad	No
	Requirements for mercury emissions from crematoria	No crematoria in Malta	
	Standards for mercury concentrations in sludge for the use of land spreading	No	No
	Supporting research and development in respect of reducing emission and releases of mercury to the environment	No	No
	Others :	No	No

HEALTH SERVICES AND INSURANCE

The Maltese Ministry for Health is responsible for the provision of health services. All persons residing in Malta can participate and be covered by the **Malta social security** and have access to health services for free[310].

The Maltese health system consists of a public sector (free at the point of service) and a private sector. Emergency dental treatment are provided for free in public hospitals or Maltese health centres (public service clinics) for children under the age of 16, all diabetics and people on social security (means tested). However, most dentists have their own private practices[311]. For private practice, the patient has to pay directly the dental treatment received. All restorations done privately are paid for by the patient out of pocket and there is no coverage. Insurance for dental cover is not common.

There is no reimbursement of any type of restoration. Government provides restorations directly and uses all types of materials.

[310] http://www.euro.who.int/__data/assets/pdf_file/0009/332883/Malta-Hit.pdf?ua=1

[311] https://www.welcome-center-malta.com/the-maltese-health-care-system-explained/

Table 136 Quantitative data on dental restorations

Category	Category	Price	Reimbursement by social security %
Restoration	Dental amalgam	70	0
	Composite resins	70	0
	Glass ionomer cements	70	0
	Compomers	70	0
	Ceramics	250	0
Material	Dental amalgam	2	0
	Composite resins	6	0
	Glass ionomer cements	2	0
	Compomers	3	0
	Ceramics	75	0

GOOD PRACTICES IN THE SELECTED AREAS

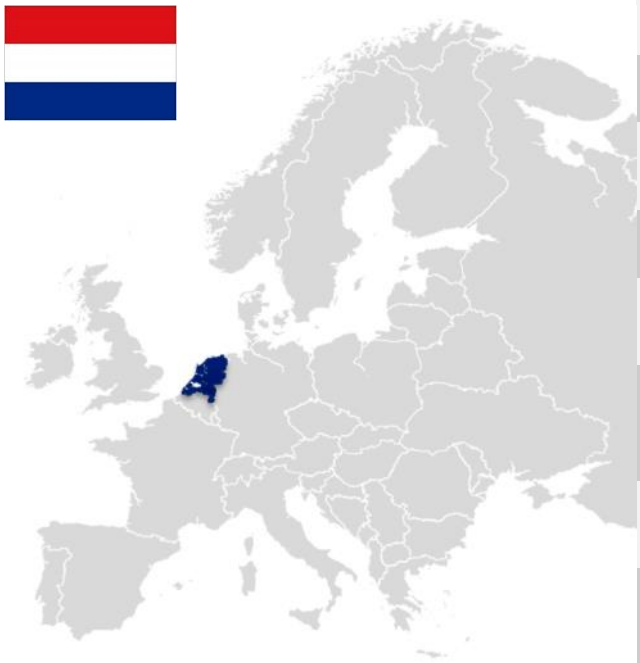
No data available.

The Netherlands

INTRODUCTION

The Netherlands is a country of Northwestern Europe with 17.2 million of inhabitants. The capital and largest city is Amsterdam. The country spent 72,963.30 million euro (10.30% of GDP) in healthcare[312].

Table 137 Key socio-economic and health data (2018)

General information	
	
Population (million):	17.2
GDP per capita (PPP, EUR):	2.1; 41,600
GDP per capita (rank in the EU):	6
Unemployment rate (%):	3.8
Minimum monthly wage (EUR):	1,615.80
Number of dentists per hundred thousand inhabitants:	46.7 (2017)
Dental outpatient curative care (PPS per inhabitant):	131.92 (2016)
Dental outpatient curative care (Percentual share of total current health expenditure (CHE)):	3.48 (2016)

DENTAL AMALGAM USE, ALTERNATIVES AND TRENDS

Number of restorations per type material

In the Dutch national plan on measures to phase down the use of dental amalgam (Article 10(3) of the Mercury Regulation) (2019) it is indicated that there is a decreasing trend in the use of dental amalgam for restorations (in absolute and relative terms). The relative use of dental amalgam in 2018 is reported as 0.55%. The table below presents the number of restorations reported for 2015-2018.

*Table 138 Number of restorations per type material (2015-2018)**

Material	Number of restorations (% of total restorations)
Dental amalgam	2018: 43,699 (0.5%) 2017: 52,569 (0.6%)

[312] Eurostat (online data codes : hlth_sha11_hf, demo_gind and nama_10_gdp)

Material	Number of restorations (% of total restorations)
	2016: 65,968 (0.8%) 2015: 78,915 (1.0%)
Composite resins	2018: 7,541,951 (94.9%) 2017: 7,800,325 (94.6%) 2016: 7,914,310 (94.3%) 2015: 7,702,844 (93.6%)
Glass ionomer cements / compomers	2018: 359,746 (4.5%) 2017: 390,709 (4.7%) 2016: 412,949 (4.9%) 2015: 444,216 (5.4%)

*Data provided by Ministry of Infrastructure and Water Management, Ministry of Health, Welfare and Sport and the Institute for Public Health and the Environment

Dental sector and effectiveness

Table 139 Quantitative data on the dental sector

	Number					
	2013	**2014**	**2015**	**2016**	**2017**	**2018**
Dentists[313] (number) [1]	N/A	7,925	8,220	8,175	7,975	N/A
Dental clinics[314] (number)	N/A	N/A	N/A	N/A	4,600[2]	N/A
Average turnover per clinic (thousand EUR)	N/A	N/A	N/A	N/A	N/A	N/A
Self-reported unmet needs for dental examination due to urbanisation (%)	1.1	1.7	0.4	0.3	0.1	N/A
Self-reported unmet needs for dental care due to financial reasons (%)	N/A	2.9	N/A	N/A	N/A	N/A

[1] Source: CBS StatLine – Medisch geschoolden: https://opendata.cbs.nl/statline/?dl=151A1#/CBS/nl/dataset/81551NED/table

[313] The term "dentists" refers to individual professionals
[314] The term "dental clinics" refers to establishments which offer dental treatment, including dental practices

[2] No exact number on clinics is available for The Netherlands. This is an estimation from the National Association of Dentists (KNMT: https://www.staatvandemondzorg.nl/organisatie-van-tandartspraktijken/)

The organisation of the dental sector in The Netherlands differentiates several types of dentists: dentist, differentiated dentist (specialist), hygienist and technical specialist (dental prosthesis) who produce and repair missing teeth or parts and structures. These are all regulated professions under the "Wet Beroepen in de Individuele Gezondheidszorg (Wet BIG)".

In recent years several changes have taken place in the organisation of the dental sector and especially in the way dentists cooperate. There is a trend towards more collaboration between dentists, but also between prevention assistants and hygienists. This has led to an increase in the size of clinics and number of patients per clinic. Services at dental clinics also seem to be evolving towards providing services throughout the chain. Evolutions in technology (ICT) will support this transition [source: www.staatvandemondzorg.nl].

Manufacturing companies of dental amalgam and alternative materials

No data or information has been identified related to companies in The Netherlands manufacturing dental amalgam and alternative materials.

Extra-EU Imports and exports of dental amalgam and alternative restoration materials

No data or information has been identified related to extra-EU imports and exports of dental amalgam and alternative restoration materials for The Netherlands.

Waste treatment from amalgam separators and water waste treatment facilities

Table 140 Quantitative data on water and solid waste from dental amalgam

Category	**Mercury waste treatment**					
	2013	**2014**	**2015**	**2016**	**2017**	**2018**
Share of dental chairs equipped with amalgam separators (%) [1]	100	100	100	100	100	100
Share of waste from separators treated in specialised treatment facilities (%) [2]	100	100	100	100	100	100
Average dental amalgam removal efficiency of separators (%) [3]	≥95	≥95	≥95	≥95	≥95	≥95
Cost of collection and treatment of waste	N/A	N/A	N/A	N/A	N/A	N/A

Category	Mercury waste treatment					
	2013	2014	2015	2016	2017	2018
from separators per kg (thousand EUR)						
Concentration of mercury in sewage sludge (µg/L) [4]	Effluent: 0.0046	Effluent: 0.0094	Effluent: 0.0102	N/A	N/A	N/A
Sewage sludge transported to waste treatment installation - concentration of mercury (mg/kg dry weight) [5]	0.732	0.685	0.618	0.554	N/A	N/A

[1] Data for clinics; Source:http://www.emissieregistratie.nl/erpubliek/documenten/Water/Factsheets/Nederlands/Lozingen%20vanuit%20tandartspraktijken.pdf

[2] Source: https://www.infomil.nl/onderwerpen/integrale/activiteitenbesluit/activiteiten/tandheelkunde/lozingsvoorschriften/

[3] Source: https://www.infomil.nl/onderwerpen/lucht-water/handboek-water/activiteiten/activiteiten/technische/amalgaamafscheiders/

[4] Effluent data from WATSON database: http://www.emissieregistratie.nl/erpubliek/erpub/default.nl.aspx?submodule=watson

[5] Rijkswaterstaat Ministry of Infrastructure and Water management; personal communication

N/A: not available

Waste from amalgam separators is collected and treated by specialised treatment facilities.

Number of Cremations

Table 141 Quantitative data on cremations

Category	Air emissions from crematoria					
	2013	2014	2015	2016	2017	2018
Number of crematoria [1,2]	N/A	80	85	93	N/A	100
Number of cremations per year [3]	86,018	85,493	93,177	93,907	96,688	100,089
Share of crematoria equipped with abatement technologies (%) [4]	100	100	100	100	100	100

Category	Air emissions from crematoria					
	2013	2014	2015	2016	2017	2018
Average efficiency of the abatement technologies (%) [4]	Max emission : 0.05 mg/Nm^3 (when total volume ≥ 0.25 g/h	Max emission : 0.05 mg/Nm^3 (when total volume ≥ 0.25 g/h	Max emission : 0.05 mg/Nm^3 (when total volume ≥ 0.25 g/h	Max emission : 0.05 mg/Nm^3 (when total volume ≥ 0.25 g/h	Max emission : 0.05 mg/Nm^3 (when total volume ≥ 0.25 g/h	Max emission : 0.05 mg/Nm^3 (when total volume ≥ 0.25 g/h
Cost of mercury capture per cremation (EUR)	N/A	N/A	N/A	N/A	N/A	N/A

[1] Data 2014- 2016 2014-2016: https://uitvaartmedia.com/w/wp-content/uploads/2017/08/UitvaartBranchemonitor_Marktontwikkelingen_en_concurrentieverhoudingen_2017_08.pdf;

[2] Data 2018; source: www.crematorium.nl;

[3] Source:https://www.lvc-online.nl/viewer/file.aspx?FileInfoID=194;

[4] https://www.infomil.nl/onderwerpen/lucht-water/lucht/activiteiten/crematoria/#hbc2a753f-6bac-435a-b15f-e85a94be75ba

NATIONAL POLICIES AND MEASURES

Table 142 Policies and measures to phase down or phase-out the use of dental amalgam

Category	Type	Ongoing	Under development
Measures to phase down or phase-out dental amalgam	Dental amalgam bans, phasing-out or phasing down	Activity Decree[315] (registration of dental practices, the installation of amalgam separators in new and existing practices, the testing methods of dental separators, releases to surface water); Regulation providing a list of collectors, carriers, traders and mediators of waste (intake of mercury waste).	No
	National guidelines, promoting the use of mercury-free materials	See above	No
	Supporting research and development in respect of mercury-free dental restorations	No	No

[315] Activiteitenbesluit: https://www.infomil.nl/onderwerpen/integrale-regels/activiteitenbesluit/

Category	Type	Ongoing	Under development
	Others :	The Dutch dentistry faculties have stopped teaching students to use dental amalgam since 1997[316].	No
Measures to manage waste and emissions from dental amalgam	Requirements for the installation and maintenance of separators	The use and maintenance of an amalgam separator according to norm NEN-EN-ISO 11143 is prescribed in national law ("Activity decree")	No
	Requirements for the collection and treatment of solid waste from separators	The use and maintenance of an amalgam separator according to norm NEN-EN-ISO 11143 is prescribed in national law ("Activity decree")	No
	Requirements for mercury emissions from crematoria	The maximum mercury emissions to air and BAT are prescribed in national law ("Activity decree")	No
	Standards for mercury concentrations in sludge for the use of land spreading	Land spreading of sewage sludge is not performed in the Netherlands	No
	Supporting research and development in respect of reducing emission and releases of mercury to the environment	Under national law ("Activity decree") companies are obliged to minimise their emissions of national substances of very high concern (ZZS), which includes mercury. Part of this obligation is a 5-yearly investigation of feasible measures to further minimise emissions of ZZS.	No
	Others :	No	No

In the 1980s and 1990s dental practices were identified as an important source of mercury in Dutch surface waters.

Activities to phase-out the releases to Dutch surface water date from 1990 when the report "Afvalwaterproblematiek in de tandheelkundige verzorging. Aanbevelingen met betrekking tot de sanering van de lozingen afkomstig van tandartspraktijken,

[316] National Action Plan (Article 10(3), Mercury Regulation), 2019

tandheelkundige faculteiten en tandtechnische laboratoria" (CUWVO, 1990) was published. To solve the problems with mercury two lines of practices were followed:

- To reduce the amount of mercury released to surface water
- To arrange the proper handling of mercury waste

The authors of the above-mentioned report realised that the proposals would not immediately result in regulations. To accelerate measures on mercury releases voluntary agreements with the branch organisation of dental practices were made in 1991. The first legislative texts followed in 1995.

The agreement, which was signed on 23 February 1991 by the Ministry of Transport, Public Works and Water Management (V&W), several local and regional authorities (VNG, IPO and Unie van Waterschappen) and the Dutch Society for the Advancement of Dentistry (NMT) aimed at a 95% reduction of mercury releases.

The legislative texts regulated, among others, the registration of dental practices, the installation of amalgam separators in new and existing practices and the testing methods for dental separators. The latter two came into force in 1998. At present, releases to surface water are regulated by the so called Activity Decree, which covers the previous regulations, whereas the intake of mercury waste is regulated by a regulation providing a list of collectors, carriers, traders and mediators of waste. (Regeling inzamelaars, vervoerders, handelaars en bemiddelaars van afvalstoffen)[317].

As a result of these measures, the use of dental amalgam was reduced to 0.8% in 2011.

HEALTH SERVICES AND INSURANCE

Dental health care in The Netherlands is provided in primary care by private dentists and dental hygienists. Most citizens register with a dentist. Most dentists work in small independent practices (about 70%). Dental hygienists are specialised in preventive care and can be visited directly or upon referral from the dentist. Preventive tasks and relatively simple dental care are increasingly being undertaken by dental hygienists[318].

In secondary care, there are two specialist medical professions: dental surgeons and orthodontists. Most dental surgeons work in hospitals, and most orthodontists work in ambulatory settings outside the hospital.

The majority of dental treatment for children (under the age of 18) is reimbursed by the national insurance (Zorgverzekeringswet). This insurance covers all restorations and total costs of the treatment (Article 2.7 of the Zorgverzekeringswet)[319]. Restorations for people above the age of 18 are not reimbursed or instead are covered by additional health insurance schemes.

Maximum tariffs apply to dental treatment in The Netherlands, regardless of whether citizens are covered by health insurance or not. In general, all dentists use the agreed maximum tariffs (presented in the table below).

Table 143 Quantitative data on dental restorations

[317] Source: https://wetten.overheid.nl/jci1.3:c:BWBR0016608&z=2018-01-01&g=2018-01-01

[318] European Commission, 2010. Health systems performance assessment, available at: http://www.euro.who.int/__data/assets/pdf_file/0008/85391/E93667.pdf

[319] https://wetten.overheid.nl/BWBR0018492/2019-03-30/#Hoofdstuk2_Paragraaf1_Artikel2.7

Category	Category	Price	Reimbursement by social security %
Restoration [1]	Dental amalgam	24.07 EUR – single surface 38.40 EUR – two surfaces 49.86 EUR – three surfaces 69.92 EUR – more than three surfaces	N/A
	Composite resins	45.85 EUR – single surface 60.18 EUR – two surfaces 71.64 EUR – three surfaces 91.70 EUR – more than three surfaces	N/A
	Compomers and Glass ionomer cements	35.53 EUR – single surface 49.86 EUR – two surfaces 61.32 EUR – three surfaces 81.38 EUR – more than three surfaces	N/A

[1] Source: https://www.tandarts.nl/tandartstarieven/2019#vullingen

GOOD PRACTICES IN THE SELECTED AREAS

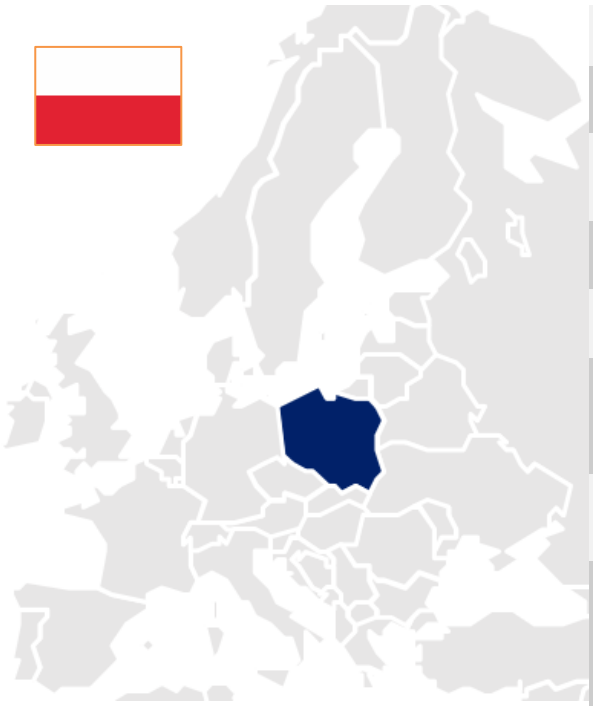
No information has been identified on good practices to complete the table below.

Poland

INTRODUCTION

Poland is a country located in Central Europe with 37.977 million of inhabitants. The capital and largest city is Warsaw. The country spent 27,756.39 million euro (6.52% of GDP) in healthcare[320].

Table 144 Key socio-economic and health data (2018)

General information	
	
Population (million):	37.977
GDP per capita (PPP, EUR):	5.2; 12,400
GDP per capita (rank in the EU):	25
Unemployment rate (%):	3.9
Minimum wage salary (EUR):	523.09
Number of dentists per hundred thousand inhabitants (2015):	33.18 (2015)
Dental outpatient curative care (PPS per inhabitant):	72.42 (2016)
Dental outpatient curative care (Percentual share of total current health expenditure (CHE)) (2016):	5.03 (2016)

DENTAL AMALGAM USE, ALTERNATIVES AND TRENDS

Number of restorations per type material

No data on the number of restorations in Poland has been identified.

Dental sector and effectiveness

Dental health care in Poland can be divided into primary dental care, provided mainly by dental practitioners with no specialization, and secondary dental care, provided by specialists. Tertiary dental care is provided at wards of maxillofacial surgery (located mainly in public hospitals).

General individual practices constituted almost 60% of all practices in 2009. Dental care provision is largely private in Poland. However, the number of dental practices providing services financed from public funds has been growing in recent years[321].

[320] Eurostat (online data codes : hlth_sha11_hf, demo_gind and nama_10_gdp)
[321] Source: European Commission, 2011. European Observatory on Health Systems and Policies. Available at: http://www.euro.who.int/__data/assets/pdf_file/0018/163053/e96443.pdf

Table 145 Quantitative data on the dental sector

	Number					
	2013	**2014**	**2015**	**2016**	**2017**	**2018**
Dentists[322] (number) [1]	12,322	13,088	12,603	13,308	N/A	N/A
Dental clinics[323] (number)	N/A	N/A	N/A	N/A	N/A	N/A
Average turnover per clinic (thousand EUR)	N/A	N/A	N/A	N/A	N/A	N/A
Self-reported unmet needs for dental examination due to urbanisation (%)	5.0	4.8	4.2	3.7	2.1	N/A
Self-reported unmet needs for dental care due to financial reasons (%)	N/A	11.4	N/A	N/A	N/A	N/A

[1] Source: https://www.statista.com/statistics/463526/dentists-employment-in-poland/

Manufacturing companies of dental amalgam and alternative materials

No data or information has been identified related to companies in Poland manufacturing dental amalgam and alternative materials.

Extra-EU Imports and exports of dental amalgam and alternative restoration materials

No data or information has been identified related to extra-EU imports and exports of dental amalgam and alternative restoration materials for Poland.

Waste treatment from amalgam separators and water waste treatment facilities

No data or information has been identified related to waste treatment from amalgam separators and water waste treatment facilities for Poland.

[322] The term "dentists" refers to individual professionals
[323] The term "dental clinics" refers to establishments which offer dental treatment, including dental practices

Number of Cremations

Table 146 Quantitative data on cremations

Category	Air emissions from crematoria					
	2013	2014	2015	2016	2017	2018
Number of crematoria [1]	29	38	46	52	52	N/A
Number of cremations per year	N/A	N/A	N/A	N/A	N/A	N/A
Share of crematoria equipped with abatement technologies (%)	N/A	N/A	N/A	N/A	N/A	N/A
Average efficiency of the abatement technologies (%)	N/A	N/A	N/A	N/A	N/A	N/A
Cost of mercury capture per cremation (EUR)	N/A	N/A	N/A	N/A	N/A	N/A

[1] Source: https://www.cremation.org.uk/statistics

NATIONAL POLICIES AND MEASURES

No information on national policies and measures has been identified.

HEALTH SERVICES AND INSURANCE

Dental services available to the insured population are listed in the 2004 Law on Health Care Services Financed from Public Sources and the 2009 regulation of the Minister of Health delineating guaranteed dental benefits. These services can be accessed free of charge in any dental care institution contracted by the NFZ and include general dental care for children and adults, oral surgery and periodontics, orthodontic care for children under 18, dental prostheses, emergency dental care and preventive dental services for children and youths under 19. Some services, such as check-ups, tooth radiography, removal of dental plaque and dental prostheses are subject to frequency limitations.

Fees for dental services in the private sector are not regulated and are freely set between dentists and their patients. Guaranteed dental services listed in the 2009 Regulation are provided free of charge as long as the provider has a contract with the NFZ. Providers are then reimbursed by the NFZ according to agreed fee schedules. Fees for dental services used by the NFZ for reimbursement are determined every year.

The NFZ finances dental care in the same way as general health care, that is, from insurance contributions. The amount of available financing is set annually in the NFZ financial plan and usually accounts for 3–4% of the total cost of all reimbursed health care benefits. Specialist dental care and dental care programmes may also be financed from the state or local budgets.[324].

No data on the price of restoration and reimbursement has been identified.

[324] Source: European Commission, 2011. European Observatory on Health Systems and Policies. Available at: http://www.euro.who.int/__data/assets/pdf_file/0018/163053/e96443.pdf

GOOD PRACTICES IN THE SELECTED AREAS

No information has been identified on good practices to complete the table below.

Portugal

INTRODUCTION

Portugal, officially the Portuguese Republic, is a country of the Iberian Peninsula in southwestern Europe. The capital and largest city is Lisbon. The Portuguese government is a unitary semi-presidential constitutional republic. The Ministry of Health is responsible of developing healthcare and managing the **National Health Service (Serviço Nacional de Saúde)[325].** In 2016, the government spent 9.08% of the gross domestic product in health care expenditure.[326]

Table 147 Key socio-economic and health data

General information	
Population (million):	10.291
GDP per capita (PPP, EUR):	N/A
GDP per capita (rank in the EU):	18
Unemployment rate (%):	7.0
Monthly minimum wage (EUR) (2019):	700.0
Number of dentists per hundred thousand inhabitants:	N/A
Dental outpatient curative care (PPS per inhabitant):	N/A
Dental outpatient curative care (Percentual share of total current health expenditure (CHE)):	N/A

DENTAL AMALGAM USE, ALTERNATIVES AND TRENDS

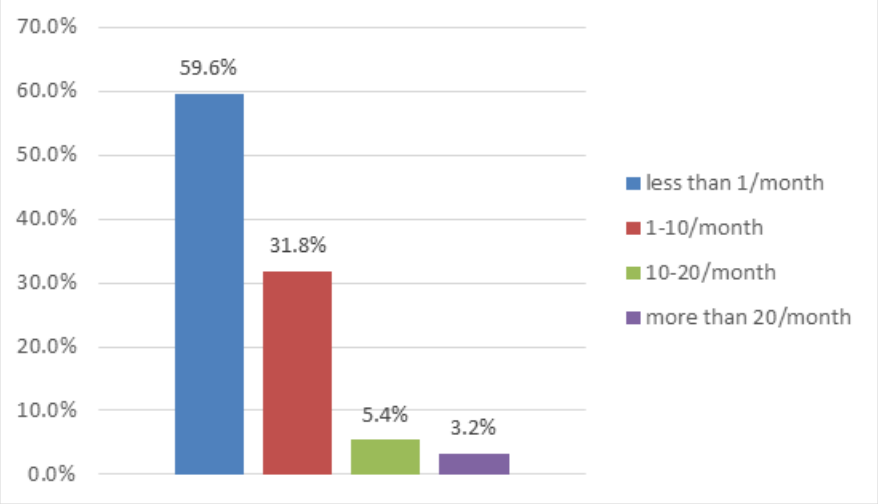
Number of restorations per type material

In October 2019 a questionnaire was sent by Direção-Geral da Saúde[327] to all 5,372 entities registered as dentistry clinics. 17.2% participated in this questionnaire. According to the results of the questionnaire, 30% of the dental clinics still perform restorations with the use of dental amalgam, whereas 70% use only mercury free-materials. From the dental clinics that use dental amalgam, 59.6% perform less one restoration with dental amalgam, 31.8% 1 to 10 restorations per month, 5.4% 10-20 restorations per month and 3.2% more than 20 restorations per month. From these figures, it is not possible to estimate the exact number of dental amalgam fillings as the number of total restorations is not known.

[325] https://www.sns.gov.pt/
[326] Health care expenditure by financing scheme [hlth_sha11_hf] Last update: 05-03-2019
327 Information provided in the context of this study

The results of the questionnaire are presented in the figure below.

Figure 17: Number of dental amalgam restorations performed monthly



In addition, the situation in Primary Health Care was monitored, and it was found that in health centres the percentage of dental restorations with amalgam was 7.6%. Regarding the remaining materials, 86.3% was performed with composite resin and 6.1% of dental restorations were made with glass ionomer cement.

Overall a precise estimate in relation to the use of dental amalgam in both private and public services, is not possible. Based on the information from the questionnaire it can be assumed that the use of dental amalgam in Portuguese dental clinics is very limited with a considerable amount still used in cases covered by the Primary Health Care.

Dental sector and effectiveness

Portuguese dentists work almost exclusively in private practice. The Portuguese Dental association - **Ordem dos Médicos Dentistas**[328] is the national dental association which gathers dentists and regulates dental practice in Portugal.

Table 148 Quantitative data on the dental sector

	Number					
	2013	**2014**	**2015**	**2016**	**2017**	**2018**
Dentists[329] (number)	N/A	N/A	N/A	N/A	N/A	N/A
Dental clinics[330] (number)	N/A	N/A	N/A	N/A	N/A	N/A
Average turnover per clinic (thousand EUR)	N/A	N/A	N/A	N/A	N/A	N/A
Self-reported unmet needs for dental examination due to urbanisation (%)*	14.3	15.7	14.6	14.0	11.6	N/A

[328] https://www.omd.pt/
[329] The term "dentists" refers to individual professionals
[330] The term "dental clinics" refers to establishments which offer dental treatment, including dental practices

	Number					
	2013	2014	2015	2016	2017	2018
Self-reported unmet needs for dental care due to financial reasons (%)*	N/A	26.7	N/A	N/A	N/A	N/A

**Data collected from Eurostat*

Manufacturing companies of dental amalgam and alternative materials

Portuguese dental companies: Ceramed[331], KaVo Dental[332].

No quantitative data available.

Extra-EU Imports and exports of dental amalgam and alternative restoration materials

No quantitative data available.

Waste treatment from amalgam separators and water waste treatment facilities

In Portugal, legislations on hazardous waste exist. Amalgam separators are not compulsory by law but some regulation recommends their use as a complete equipment for dental professionals[333].

According to the survey launched by the Portuguese health authority, the quantities of amalgam waste from dental treatment was 1.09 tons in 2018.

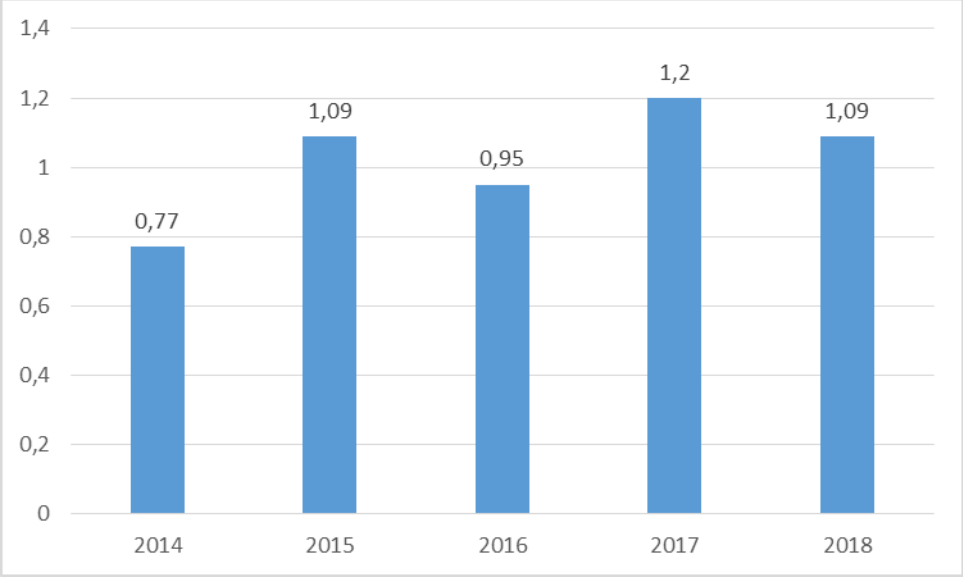


Figure 18: Annual quantities (tons) of amalgam waste from dental treatment

[331] http://www.ceramed.pt/empresa
[332] https://www.kavo.com/widen-language/portuguese-portugal
[333] Dental amalgam in the EU- Heading towards a phase-out ? 2017, Health care without harm.

Number of Cremations

No quantitative data available

NATIONAL POLICIES AND MEASURES
No national policies and measures were identified.

HEALTH SERVICES AND INSURANCE
The Portuguese minister of Health controlled the healthcare and is responsible of the development of health policy and the management of the National Health Service. The **Portuguese National Health Service (SNS – Sistema Nacional de Salude)** is mainly funded through taxations. Additionally to the NHS, for some professions (military, etc.), there is a health subsystems which provides people a contribution to the cost of the healthcare.

Private health insurance and mutual funds are authorized in Portugal and 20% of the population was covered in 2015[334].

Portugal is divided into 5 regions. Regional health administrations are responsible for supervising the health care delivery.

No quantitative data available.

GOOD PRACTICES IN THE SELECTED AREAS

According to Direção-Geral da Saúde[335] the Government of Portugal undertakes to progressively reduce the use of dental amalgam, replacing it with other materials free of mercury. It is proposed to reduce the possibility of performing dental restorations with amalgam in the health units of the National Health Service, being possible only in duly justified situations, people with special needs, not collaborators or in situations where it is concerned to keep the tooth.

[334] EU Manual of dental practice, CED, 2015.
[335] Information provided in the context of this study

Romania

INTRODUCTION

Romania is a country in the Southeast of Europe, bording the Black Sea. With almost 20 million of inhabitants, it is one of the most densely populated country in Europe. The capital and largest city is Bucharest. The Romanian government is a unitary semi-presidential republic. In 2016, the Romanian government spent 5.01% of its gross domestic product in health care expenditure[336].

Table 149 Key socio-economic and health data

General information	
Population (million):	19.530
GDP per capita (PPP, EUR):	4.4 ; 8,700
GDP per capita (rank in the EU):	27
Unemployment rate (%):	4.2
Monthly minimum wages (EUR) (2019):	446.02
Number of dentists per hundred thousand inhabitants:	82.66 (2016)
Dental outpatient curative care (PPS per inhabitant):	29.49
Dental outpatient curative care (Percentual share of total current health expenditure (CHE)):	3.29 (2016)

DENTAL AMALGAM USE, ALTERNATIVES AND TRENDS

Number of restorations per type material

No data available.

Dental sector and effectiveness

Most dental cares are provided by liberal dentists. Almost 90% of dentists are in the private sector and 60% have their own dental office[337].

In Romania, there are two main associations for dentists: the **Romanian Dental Association** and the **Romanian Soc of Stomatology**.

[336] Health care expenditure by financing scheme [hlth_sha11_hf] Last update: 05-03-2019.
[337] EU Manual of dental Practice, 2015 -CED

Table 150 Quantitative data on the dental sector

	Number					
	2013	**2014**	**2015**	**2016**	**2017**	**2018**
Dentists[338] (number)	N/A	N/A	N/A	N/A	N/A	N/A
Dental clinics[339] (number)	N/A	N/A	N/A	N/A	N/A	N/A
Average turnover per clinic (thousand EUR)	N/A	N/A	N/A	N/A	N/A	N/A
Self-reported unmet needs for dental examination due to urbanisation (%)*	10.9	9.9	8.6	6.5	5.4	N/A
Self-reported unmet needs for dental care due to financial reasons (%)*	N/A	9.5	N/A	N/A	N/A	N/A

**Data collected from Eurostat*

Manufacturing companies of dental amalgam and alternative materials

No data available.

Extra-EU Imports and exports of dental amalgam and alternative restoration materials

No quantitative data available.

Waste treatment from amalgam separators and water waste treatment facilities

The Ministry of Health published several orders relative to the disposal of dental waste. Bio-hazard-contaminated dental waste should be collected and incinerated. Amalgam separators are not legally required[340].

No quantitative data available

Number of Cremations

Cremation is allowed in Romania. Crematories are located in Bucharest and Oradea[341].

No quantitative data available.

NATIONAL POLICIES AND MEASURES

[338] The term "dentists" refers to individual professionals
[339] The term "dental clinics" refers to establishments which offer dental treatment, including dental practices
[340] Manual of dental practice, CED 2015.
[341] https://ro.usembassy.gov/u-s-citizen-services/death-of-a-u-s-citizen/disposition-remains-report/
https://www.tandfonline.com/doi/abs/10.1080/13576275.2014.989825?journalCode=cmrt20
http://www.wseas.us/e-library/conferences/2011/Brasov1/LAW/LAW-38.pdf

No national policy and measure was identified

HEALTH SERVICES AND INSURANCE

Healthcare budget is decided by the Ministry of Health and Family and financed through general taxation. The Social Health Insurance System is managed by the **National Social Health Insurance House (NSIH)** at national level and by the **County Social Health Insurance House (CSHIH)** at the local level[342].

According to a national expert, the national health system does not differentiate the reimbursement of dental amalgam and mercury-free fillings.

GOOD PRACTICES IN THE SELECTED AREAS

No data available.

[342] EU Manual of Dental Practice 2015, CED

Slovenia

INTRODUCTION

Slovenia is a European country with 2.067 million of inhabitants. The capital and largest city is Ljubljana. In 2016, the country spent 3,428.78 million euro (8.50% of GDP) in healthcare[343].

Table 151 Key socio-economic and health data (2018)

General information	
Population (million):	2.067
GDP per capita (PPP, EUR):	4.2; 20,200
GDP per capita (rank in the EU):	17
Unemployment rate (%):	5.1
Minimum wage (EUR):	886.63
Number of dentists per hundred thousand inhabitants:	68.81 (2016)
Dental outpatient curative care (PPS per inhabitant):	94.81 (2016)
Dental outpatient curative care (Percentual share of total current health expenditure (CHE)):	4.74 (2016)

DENTAL AMALGAM USE, ALTERNATIVES AND TRENDS

Number of restorations per type material

Table 152 Number of restorations per type material

Material	Number of restorations
Dental amalgam	710,673
Composite resins	302,931
Glass ionomer cements	N/A
Compomers	N/A

[343] Eurostat (online data codes : hlth_sha11_hf, demo_gind and nama_10_gdp)

Material	Number of restorations
Ceramics	N/A
Others	N/A

Source: HIIS: Health Insurance Institute of Slovenia.

Historical data on the number of restorations in Slovenia is presented in Appendix A.

Dental sector and effectiveness

Table 153 Quantitative data on the dental sector

	Number					
	2013	2014	2015	2016	2017	2018
Dentists[344] (number)	N/A	N/A	1,221	1,228	1,229	1,246
Dental clinics[345] (number)	N/A	N/A	N/A	N/A	N/A	N/A
Average turnover per clinic (thousand EUR)	N/A	N/A	N/A	N/A	N/A	N/A
Self-reported unmet needs for dental examination due to urbanisation (%)	0.7	0.7	0.5	0.7	3.8	N/A
Self-reported unmet needs for dental care due to financial reasons (%)	N/A	11.3	N/A	N/A	N/A	N/A

Source: Questionnaire response (Ministry of Health)

Manufacturing companies of dental amalgam and alternative materials

According to the Ministry of Health, there is no manufacturing of dental amalgam in Slovenia. All of the dental amalgam used in Slovenia is imported.

No quantitative data available

Extra-EU Imports and exports of dental amalgam and alternative restoration materials

According to the director of the Chemical Office of the Republic of Slovenia, exact data regarding import of dental amalgam and other materials is not available.

No quantitative data available

[344] The term "dentists" refers to individual professionals.
[345] The term "dental clinics" refers to establishments which offer dental treatment, including dental practices.

Waste treatment from amalgam separators and water waste treatment facilities

According to the Ministry of Health, this data is not available. However, according to Slovenian regulation 100% of dental chairs should be equipped with amalgam separators[346].

The waste collected from amalgam separators is collected locally and treated specialised facilities in third countries.

No quantitative data available

Number of Cremations

Table 154 Quantitative data on cremations

Category	Air emissions from crematoria					
	2013	2014	2015	2016	2017	2018
Number of crematoria	2	2	2	2	2	N/A
Number of cremations per year	15,944	15,671	16,592	N/A	17,001	N/A
Share of crematoria equipped with abatement technologies (%)	N/A	N/A	N/A	N/A	N/A	N/A
Average efficiency of the abatement technologies (%)	N/A	N/A	N/A	N/A	N/A	N/A
Cost of mercury capture per cremation (EUR)	N/A	N/A	N/A	N/A	N/A	N/A

Source: https://www.cremation.org.uk/statistics

NATIONAL POLICIES AND MEASURES

No information on national policies and measures has been identified.

HEALTH SERVICES AND INSURANCE

According to the Ministry of Health, Dental services are partially covered (80%) and it is common for citizens to enrol in supplementary health plans. Dental services for children, adolescents and students are covered 100%. Social security pays 20% more for disabled insured. For children, adolescents and pregnant women there is no additional costs for resin-based composites in transcanine sector. Insured adults must pay out of pocket the difference between dental amalgam and resin-based composite fillings in front teeth.

[346] The Decree regarding the management of amalgam waste generated by health services and related research activities can be found here http://www.pisrs.si/Pis.web/pregledPredpisa?id=URED4839.

Table 155 Quantitative data on dental restorations

Category	Category	Price (€)	Reimbursement by social security %
Restoration	Dental amalgam	26	80%
	Composite resins	48.5	80%
	Glass ionomer cements	N/A	N/A
	Compomers	N/A	N/A
	Ceramics	N/A	N/A
Material	Dental amalgam	N/A	N/A
	Composite resins	N/A	N/A
	Glass ionomer cements	N/A	N/A
	Compomers	N/A	N/A
	Ceramics	N/A	N/A

Source: Ministry of Health

GOOD PRACTICES IN THE SELECTED AREAS

No information has been identified on good practices to complete the table below. Number of restorations

Material	Number of restorations					
	2013	2014	2015	2016	2017	2018
Dental amalgam*	851,365	817,905	798,819	773,980	752,002	710,673
Composite resins	273,936	296,251	297,617	289,631	289,351	302,931

Source: HIIS: Health Insurance Institute of Slovenia.

Slovakia

INTRODUCTION

Slovakia is a central Europe country, with a population of 5.4 million inhabitant, 46% living in rural areas. Slovakia is a parliamentary democratic republic formally led by a president, while the prime minister owns most of the executive power as the head of government. The country is organized into 8 administrative divisions or self-governing regions, and 79 municipalities. Most of the GDP is concentrated the western regions, in particular in Bratislava. In terms of national GDP, Slovakia is ranked 21st in the European Union.

Slovakia provides citizens universal health care. There are currently 3 health insurance companies in Slovakia, publicly and privately owned. In 2016, Slovakia spent 7.10% of its national gross domestic product (GDP) in health care.

Table 156 Key socio-economic and health data

General information	
Population (million):	5,443
GDP per capita (PPP, EUR):	4.0 ; 15,600
GDP per capita (rank in the EU):	21
Unemployment rate (%):	6.5
Minimum wage (EUR):	520.00 (2019 S1)
Number of dentists per hundred thousand inhabitants (2015):	N/A
Dental outpatient curative care (PPS per inhabitant):	73.48 (2016)
Dental outpatient curative care (Percentual share of total current health expenditure (CHE)) (2016):	4.43 (2016)

DENTAL USE, ALTERNATIVES AND TRENDS

Number of restorations per type material

In Slovakia, dental amalgam is still preferred to alternative materials for dental restorations. No quantitative data available.

Dental sector and effectiveness

Dental practices, except for few cases, are privately owned (80%), providing good geographic coverage. nonetheless, provision of oral health care is being threatened by the ageing of dentists in Slovakia.

The main dental association is the Slovak Chamber of Dentists. The mission of the Chamber is to reach an independent, equitable and serious evaluation of the work of dentists, and to create an environment and conditions for a high-quality provision of dental services for patients.

Table 157 Quantitative data on the dental sector

	Number					
	2013	**2014**	**2015**	**2016**	**2017**	**2018**
Dentists[347] (number)	1,616[348]	N/A	N/A	N/A	N/A	N/A
Dental clinics[349] (number)	673	N/A	N/A	N/A	N/A	N/A
Average turnover per clinic (thousand EUR)	N/A	N/A	N/A	N/A	N/A	N/A
Self-reported unmet needs for dental examination due to urbanisation (%)*	2.3	2.4	2.7	2.3	1.9	N/A
Self-reported unmet needs for dental care due to financial reasons (%)*	N/A	4.2	N/A	N/A	N/A	N/A

**Data collected from Eurostat*

Manufacturing companies of dental amalgam and alternative materials

No quantitative data available.

Extra-EU Imports and exports of dental amalgam and alternative restoration materials

No quantitative data available.

Waste treatment from amalgam separators and water waste treatment facilities

Table 158 Quantitative data on water and solid waste from dental amalgam

Category	**Mercury waste treatment**					
	2013	**2014**	**2015**	**2016**	**2017**	**2018**
Share of dental chairs equipped with amalgam separators (%)	100	100	100	100	100	100

[347] The term "dentists" refers to individual professionals
[348] EU Manual of Dental Practice (2015). Available at: http://www.dentistaitaliano.it/documents/CED.EU-Manual2015.pdf
[349] The term "dental clinics" refers to establishments which offer dental treatment, including dental practices.

Category	Mercury waste treatment					
	2013	2014	2015	2016	2017	2018
Share of waste from separators treated in specialized treatment facilities (%)	N/A	N/A	N/A	N/A	N/A	N/A
Average dental amalgam removal efficiency of separators (%)	N/A	N/A	N/A	N/A	N/A	N/A
Cost of collection and treatment of waste from separators per kg (thousand EUR)	N/A	N/A	N/A	N/A	N/A	N/A
Concentration of mercury in sewage sludge (µg/L)	N/A	N/A	N/A	N/A	N/A	N/A

Number of Cremations

Table 159 Quantitative data on cremations

Category	Air emissions from crematoria					
	2013	2014	2015	2016	2017	2018
Number of crematoria	3[350]	3	3	3	3	N/A
Number of cremations per year	N/A	N/A	N/A	N/A	N/A	N/A
Share of crematoria equipped with abatement technologies (%)	N/A	N/A	N/A	N/A	N/A	N/A
Average efficiency of the abatement technologies (%)	N/A	N/A	N/A	N/A	N/A	N/A
Cost of mercury capture per cremation (EUR)	N/A	N/A	N/A	N/A	N/A	N/A

NATIONAL POLICIES AND MEASURES

Table 160 Policies and measures to phase down or phase-out the use of dental amalgam

[350] The Cremation Society of Great Britain : https://www.cremation.org.uk/statistics

Category	Type	Ongoing	Under development
Measures to phase down or phase-out dental amalgam	Dental amalgam bans, phasing-out or phasing down	No	Plans to reduce the reimbursement of amalgam fillings even if they are the cheapest alternative. From 2030 onwards, dental amalgam will be reimbursed only in exceptional cases or when the patient wishes to have a dental amalgam filling.
	National guidelines, promoting the use of mercury-free materials	No	No
	Supporting research and development in respect of mercury-free dental restorations	No	No
	Others	No	No
Measures to manage waste and emissions from dental amalgam	Requirements for the installation and maintenance of separators	The EU Hazardous Waste Directive is incorporated into law and actively enforced. Amalgam separators are legally required.	No
	Requirements for the collection and treatment of solid waste from separators	No	No
	Requirements for mercury emissions from crematoria	No	No
	Standards for mercury concentrations in sludge for the use of land spreading	No	No
	Supporting research and development in respect of reducing emission and releases of mercury to the environment	No	No
	Others	No	No

HEALTH SERVICES AND INSURANCE [351]

The health care system in Slovakia is based on universal coverage, compulsory health insurance, a basic benefit package and a competitive insurance model with selective contracting of health care providers by health insurers, and flexible pricing of health services.

The Health Care Surveillance Authority (HCSA) is responsible for the supervision of health insurance, health care purchasing and health care provision markets.

The Public Health Authority of Slovakia (PHA) is responsible for public health tasks, and is fully financed from the state budget.

In 2005, public health insurance funds were transformed into health insurance companies. Health insurance is divided between 3 companies: one state-owned health insurer (with approximately 65% of the market share), and two privately-owned health insurance companies (Dôvera owning 28% and Union owning 9%). Each health insurance company is allowed to develop its own payment mechanisms and set up its own pricing policy towards contracted providers.

In Slovakia, the social security system covers only partially the cost of dental restorations, the other half is paid by the patients. The Slovakian health care system is characterized by a relatively low level of health care expenditure as a share of GDP; whilst out-of-pocket payments are relatively large.

There is only a small difference in the reimbursement of dental treatment costs between public and private social security. Among private practitioners, 85% have an agreement with insurance companies, 15% of them don't.

Compulsory health insurance contributions are collected by these health insurance companies from employees, employers, public finances and dividends.

The Slovak Government, plans to reduce the reimbursement of amalgam fillings even if they remain the cheapest alternative. From 2030 onwards, dental amalgam will be reimbursed only in exceptional cases or when the patient wishes to have a dental amalgam filling.

Primary care services are provided by general practitioners (GPs) predominantly working in private practices. Patients register with a GP of their choice. Health insurance companies are required by law to contract with each GP and paediatrician licensed by their region. Since 2013 patients need a referral from a GP to see a specialist.

In the June 2014 Eurobarometer study on satisfaction of health systems conducted by the EU Commission, only 50% of Slovak respondents were satisfied with the overall quality of the health care system.

No quantitative data available.

GOOD PRACTICES IN THE SELECTED AREAS

No information is available.

[351] European Observatory on Health Systems and Policies, Slovakia Health System review (2016). Available at: http://www.euro.who.int/__data/assets/pdf_file/0011/325784/HiT-Slovakia.pdf?ua=1

Spain

INTRODUCTION

Spain is a country of Southern Europe with 46.658 inhabitants. Madrid is the capital and largest city of the country. The Kingdom of Spain is a constitutional monarchy with a hereditary monarch and a bicameral parliament. The Spanish National Health System (SNS) is managed by the autonomous communities of Spain and supervised but the National Institute of Health Management (INGESA), which is a part of the Ministry of Health and Social Policy. The country spent 8.97% of its gross domestic product in healthcare in 2016[352].

Table 161 Key socio-economic and health data

General information	
Population (million):	46.658
GDP per capita (PPP, EUR):	2.1; 25,000
GDP per capita (rank in the EU):	14
Unemployment rate (%):	15.3
Monthly minimum wage (EUR) (2019):	1,050
Number of dentists per hundred thousand inhabitants:	N/A
Dental outpatient curative care (PPS per inhabitant) (2016):	170.96
Dental outpatient curative care (percentual share of total current health expenditure (CHE)) (2016):	7.3

DENTAL AMALGAM USE, ALTERNATIVES AND TRENDS

Number of restorations per type material

According to the National Action Plan[353], based on a survey carried out at the national level, dental amalgam is used only in 1% of dental restorations on delicious teeth. The same applies on the total population including children under 16 years of age, the use of amalgam is also residual (around 1%). According to the survey, 83% of Spanish dentists have reduced the use of amalgam in the last 5 years while the rest state that its use has stabilised. In addition, more than 92% of the respondents stated that they have reduced the use of amalgam by more than 50% in the last 5 years. In addition, 90% of the Spanish dentists agree that the total elimination of amalgam is feasible by 2030 while some respondents draw attention to the need to continue using amalgam

[352] Eurostat : Health care expenditure by financing scheme [hlth_sha11_hf]
353 Ministerio de Sanidad, Plan Nacional Para La Reducción Del Uso De Amalgamas Dentales, https://www.mscbs.gob.es/ciudadanos/saludAmbLaboral/docs/Plan_nacional_amalgamas_dental_01_08_03_2020.pdf

for now, in certain clinical circumstances and/or specific patients. Nevertheless, about 75% believe that there are no clinical cases that cannot be met with the use of mercury-free materials.

Dental sector and effectiveness

Spanish health national review from the European health observatory point out that most of dentist are practicing in private sectors[354] (European Observatory on Health Systems and Policies, 2018).

Table 162 Quantitative data on the dental sector

	Number					
	2013	**2014**	**2015**	**2016**	**2017**	**2018**
Dentists[355] (number)	32,445	33,286	34,641	N/A	N/A	N/A
Dental clinics[356] (number)	N/A	N/A	N/A	N/A	N/A	N/A
Average turnover per clinic (thousand EUR)	N/A	N/A	N/A	N/A	N/A	N/A
Self-reported unmet needs for dental examination due to urbanisation (%)*	7.5	7.6	4.9	5.3	4.0	N/A
Self-reported unmet needs for dental care due to financial reasons (%)*	N/A	14.7	N/A	N/A	N/A	N/A

**Data collected from Eurostat*

Manufacturing companies of dental amalgam and alternative materials

No data for the time being.

Extra-EU Imports and exports of dental amalgam and alternative restoration materials

No data for the time being.

Waste treatment from amalgam separators and water waste treatment facilities

[354] European Observatory on Health Systems and Policies, 2018
[355] The term "dentists" refers to individual professionals
[356] The term "dental clinics" refers to establishments which offer dental treatment, including dental practices

Only data for sludge concentration provided by a regional water agency "Consorcio de Aguas Bilbao Bizkaia".

Table 163 Quantitative data on water and solid waste from dental amalgam

Category	Mercury waste treatment					
	2013	2014	2015	2016	2017	2018
Share of dental chairs equipped with amalgam separators (%)	N/A	N/A	N/A	N/A	N/A	N/A
Share of waste from separators treated in specialized treatment facilities (%)	N/A	N/A	N/A	N/A	N/A	N/A
Average dental amalgam removal efficiency of separators (%)	N/A	N/A	N/A	N/A	N/A	N/A
Cost of collection and treatment of waste from separators per kg (thousand EUR)	N/A	N/A	N/A	N/A	N/A	N/A
Concentration of mercury in sewage sludge (µg/Kg of dry matter)	N/A	N/A	1,590	1,590	1,590	1,590

Number of Cremations

No data for the time being.

NATIONAL POLICIES AND MEASURES

The Spanish ministry of health established at national level a plan for a gradual reduction of the use of dental amalgam until the full elimination by 2030.

Table 164 Policies and measures to phase down or phase-out the use of dental amalgam

Category	Type	Ongoing	Under development
Measures to phase down or phase-out dental amalgam	Dental amalgam bans, phasing-out or phasing down	No	According to the National action Plan, the use of dental amalgam will be reduced by limiting its use only to fulfil specific medical needs.
	National guidelines, promoting the use of mercury-free materials	No	Promotion of awareness measures (official campaigns, development of guidance for professionals etc.). Establishment of health centres authorised to implement, remodel or extract dental amalgam fillings.

Category	Type	Ongoing	Under development
	Supporting research and development in respect of mercury-free dental restorations	No	Promotion of research on the development of new materials. Elaboration of surveys and campaigns to control the national market and to collect information on the durability of new restorations.
	Others	No	Sensibilisation of operators involved in the marketing of medical devices the limitations of encapsulated forms of amalgam, as well as health authorities controlling health products market to increase the surveillance and control of these products.
Measures to manage waste and emissions from dental amalgam	**Requirements for the installation and maintenance of separators**	**No**	**No**
	Requirements for the collection and treatment of solid waste from separators	No	No
	Requirements for mercury emissions from crematoria	No	No
	Standards for mercury concentrations in sludge for the use of land spreading	No	No
	Supporting research and development in respect of reducing emission and releases of mercury to the environment	No	No
	Others	No	No

HEALTH SERVICES AND INSURANCE

Spain proposes a universal national health system funded mainly through taxation that has been decentralized to the regional level. Each of the 17 Spanish Autonomous Communities (AC) are responsible for health care provision and management and

participate to the interterritorial Council for the Spanish Health System CISNS) working together with Spanish Health Ministry on overall Spanish Health System coordination (European Observatory on Health Systems and Policies, 2018).

Universal health cover in Spain distinguish 2 types of health services:

- Common package which common to all 17 AC and defined by the CISNS.
    - Core package, primary health care benefits including basic dental health care services not subject to patient cost contribution.
    - Supplementary package, on which pharmaceutical prescriptions and orthoprosthetic devices are subject to out of pocket patient contribution taking into account patient income, final product price as well as monthly payment ceil.
    - Accessory services, "all activities, services or techniques, without character of benefit, that are not considered essential and/or are used as aid-devices for chronic care improvement" (European Observatory on Health Systems and Policies, 2018) involving out of pocket patient contribution.
- Complementary package decided at AC level which might incorporate additional health services given that provide its financing.

In addition, people may choose to contract complementary private insurance concerning around 20% of the Spanish population. Civil servants and specific group of workers are being offered specific health cover system thus it seems that around 80% of civil servant (around 2.2 million of civil servant in 2014) have been contracting a voluntary health insurance (Mutual Funds) which covers part of dental and optical care.

Dental care represented 7,330.9 million EUR in 2016. Most of dentist's work in the private sector and only certain types of treatment is covered under common core package, dental cares are mainly paid by patient through out of pocket contribution. Indeed, it seems that dental care represented 45.9% of household's health spending in 2015 (European Observatory on Health Systems and Policies, 2018).

However, the following treatments are partially covered by the core package (European Observatory on Health Systems and Policies, 2018):

- Teeth extraction;
- Treatment of infections or inflammatory processes, caries prevention (application of topical fluoride, dental fillings, fissure sealing's);
- Preventive measures in pregnant women (as part of the protocol for a healthy pregnancy);
- Caries prevention and counselling on hygiene measures, as part of the services provided by primary health care paediatricians and nurses for children.

Dental fillings are provided by universal public health care as part of the core common package. According to the NAP, oral health care (with the exceptions of certain age groups) is not covered by the national health system, an in general is payed by the patients.

GOOD PRACTICES IN THE SELECTED AREAS

No good practices were identified

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Sweden

INTRODUCTION

Sweden is a Scandinavian Nordic country with a population of 10.1 million. The most densely populated city and Swedish capital is Stockolm. The sovereign state of Sweden is a constitual monarchy with a parliamentary system. The executive power of the country is exercised by the government chaired by the prime minister. Sweden has a Nordic social welfare system that provides universal health care. Sweden spent 10.93 % (2016) of its total gross domestic product (GDP) on health care[357]. Healthcare is mainly delegated to counties and municipalities. The state is divided into 21 counties and 290 municipalities. County councils are in charge of providing good quality health services and medical care to the population.

Table 165 Key socio-economic and health data

General information	
Population (million):	10.120
GDP per capita (PPP, EUR):	1.2 ; 43,300
GDP per capita (rank in the EU):	5
Unemployment rate (%):	6.3
Average salary (EUR):	N/A
Number of dentists per hundred thousand inhabitants (2015):	79.73
Dental outpatient curative care (PPS per inhabitant):	208.56
Dental outpatient curative care (Percentual share of total current health expenditure (CHE)) (2016):	5.48

DENTAL AMALGAM USE, ALTERNATIVES AND TRENDS

Number of restorations per type material

In the 1980, concerns were raised in Sweden about the health and environmental impacts of dental amalgam. Scientific investigations were conducted and brought the National Board of Health and Welfare to evaluate the preconditions to eliminate the use of dental amalgam in 1991. Then, in 1993, dental amalgam used in temporary teeth phased out thanks to an agreement between the government and the county council associations. Another voluntary agreement in 1995 put an **end to amalgam use in dental restorations for children and teenagers**. The objective to phase-out dental amalgam was **expanded to adult dental care in 1997**. In 1999, the Swedish parliament decided to **withdraw financial support for dental amalgam**. The cost of

[357] Eurostat : Health care expenditure by financing scheme [hlth_sha11_hf]

amalgam fillings is no longer reimbursed under the national healthcare system and became comparable with the cost of alternatives. The quantities of mercury sold for amalgam decreased from 980 kg in 1997 to around 100 kg in 2003[358]. Since 2009, a General Ban of mercury has been decided, including dental amalgam, with some exemptions. In 2018, these exemptions were withdrawn (the possibility to apply for onetime/short term dispensation remains). Alternatives are preferred to dental amalgam.

Table 166 Number of restorations per type material (Source: National dental health register, Socialstyrelsen)

Material	Number of restorations* per year					
	2013	**2014**	**2015**	**2016**	**2017**	**2018**
Dental amalgam	NA	4	6	8	1	0
Composite resins	3 200 000	3 100 000	3 050 000	2 900 000	2 850 000	2 750 000
Ceramics	460 000	460 000	470 000	450 000	450 000	430 000

'Restorations' include both dental fillings and crowns made because of defects on the teeth.

Dental sector and effectiveness

In Sweden, **dental care is provided and financed through the counties**. The counties direct the structures hospitals and allow the installation of private practitioners. There are 21 regional Public Dental Service organisations in Sweden today, one in each County Council area. According to the Eurostat data, the number of dentists and dental clinics is decreasing with 7,363 dentists practising in 2008 and 7,813 in 2015. Swedish dentists can practice on their own (Private practice, PP) or be employed within the Public Dental Service (PDS) or dental faculties. The majority of dental care is carried out within the PDS. Specialist treatments, orthodontics and specialist paediatric dental care for example, are provided mainly by specialist employed within the PDS. In some counties, some specialists in PP can also provide care that is financed by the county[359].

The **Swedish Dental Association (SDA) - Sveriges Tandläkarförbund**, established in 1908, gathers 7,500 members (dentists, teachers, students, etc.). Their goal is to promote education, knowledge, quality and expertise among dentist[360].

[358] https://www.kemi.se/global/pm/2011/pm-2-11-phase-out-of-mercury.pdf
[359] https://tandlakarforbundet.se/app/uploads/2017/02/ced-dentistry-in-sweden-2015.pdf
[360] https://tandlakarforbundet.se/in-english/

Table 167 Quantitative data on the dental sector (Source: data from the national dental health register)

	Number					
	2013	**2014**	**2015**	**2016**	**2017**	**2018**
Dentists[361] (number)	10,931	10,960	11,132	11,192	11,238	N/A
Dental clinics[362] (number)	4,500	4,600	4,400	4,200	4,200	4,200
Average turnover per clinic (thousand EUR)	N/A	N/A	N/A	N/A	N/A	N/A
Self-reported unmet needs for dental examination due to urbanisation (%)*	5.7	4.6	3.8	3.6	1.9	N/A
Self-reported unmet needs for dental care due to financial reasons (%)*	N/A	8.1	N/A	N/A	N/A	N/A

**Data collected from Eurostat*

Manufacturing companies of dental amalgam and alternative materials

In 2011, the **Swedish Chemicals Agency** (Kemikalieinspektionen, KEMI) published an **investigation of manufacturers' experiences** on the phasing-out of mercury in dental amalgam put in place in 2009. The assessment of economic impacts (new charges, costs for changed processes, salary costs and investments in new plants and staff) on manufacturing companies for dental amalgam showed that there would not be negative impacts due to the phase-out period and new duties. The ban changed the market shares of filling materials and could potentially allow certain companies to grow and gain market share. The mercury ban induced initial costs for the activities changes and the administrative and practical impacts for companies, but these changes have a long term effect and according to KEMI, could improve competitiveness. The main positive impacts of the phasing-out of dental amalgam for companies drafted by KEMI are: to provide a safer working place for employees, to increase efficiency and productivity and to reduce costs, especially environmental costs[363].

The **Swedish Dental Trade Association** (Föreningen Svenska Dentalhandel, FSD), founded in 1989, gathers the companies established in the Swedish dental market for more than 3 years. Currently, the association has 60 members, including dental manufacturers such as 3M, ARDENT, Doxa, Dentalringen, Swedish dental supplies AB, etc. As example, Ardent is a dental manufacturing company based in Sweden and specialised in the development of dental amalgam alloys with Silver (mercury free)[364].

The **Medical Products Agency** (Läkemedelsverket) is responsible for regulatory control of pharmaceuticals in Sweden, related to medical products and drug information.

Table 168 Annual sales per company and material

[361] The term "dentists" refers to individual professionals
[362] The term "dental clinics" refers to establishments which offer dental treatment, including dental practices
[363] https://www.kemi.se/global/pm/2011/pm-2-11-phase-out-of-mercury.pdf
[364] http://dentalhandel.se/category/medlemmar/

Company	Material	Amounts
[Name of company]	Dental amalgam*	N/A
	Composite resins	N/A
	Glass ionomer cements	N/A
	Compomers	N/A
	Ceramics	N/A

Manufacturing of dental amalgam occurs, but the volumes are very small in relation to the alternative materials. The exact volumes are considered as confidential[365].

Extra-EU Imports and exports of dental amalgam and alternative restoration materials

Since dental amalgam has been banned from Sweden, the country imports and exports very small quantities of dental amalgam. The amounts of dental amalgam and alternatives (composite resins, glass ionomer cements, compomers, ceramics, etc.) imported and exported are considered as confidential.

Waste treatment from amalgam separators and water waste treatment facilities

Best Management Practice should be integrated in the Swedish dental clinics. In 1979, a voluntary agreement was made between authorities and dentists associations, requiring all new dental clinics to be equipped with amalgam separators no later than the 1 January 1980 and all dental clinics no later than the 1 January 1985[366]. Amalgam separators are used to filter amalgam particles out of water, which is discharged to the drains from dental treatments. Separation is achieving either through filtration, settlement, centrifuging or combinations of all three. The amalgam separators must fulfil requirements in the standard Dentistry Amalgam separators (ISO 11143:2008) or alternative standard with equal or better requirements[367]. In order to check that the requirements are complied with, there are supervisory authorities, environmental offices in each county and municipality. All dental clinics are connected to sewage plants and treatment systems.

With amalgam separators, the mercury presents in the sewage plant is coming from historical use of dental amalgam. Wastewater companies made a campaign to clean the historical dental amalgam accumulated in the sewage pipes.

The waste from amalgam separators is collected in containers which are certified and approved by the UN for hazard waste. Then, it is treated by specialised treatment facilities located in Sweden[368]and sent in Germany[369]. Wastewater from dental clinics is

[365] KEMI questionnaire
[366] Naturvardsket
[367] Naturvardsket
[368] Questionnaires Naturvardsver, Socialstylsen.

[369] Interview Petra Hagstrom

treated in municipal wastewater treatment plants and most of the mercury ends up in the sewage sludge which is deposited or spread on farm land[370].

Table 169 Quantitative data on water and solid waste from dental amalgam

Category	Mercury waste treatment					
	2013	2014	2015	2016	2017	2018
Share of dental chairs equipped with amalgam separators (%)	100	100	100	100	100	100
Share of waste from separators treated in specialized treatment facilities (%)	100	100	100	100	100	100
Average dental amalgam removal efficiency of separators (%)	Stated: >99% Minimum required efficiency: 95%	Stated: >99% Minimum required efficiency: 95%	Stated: >99% Minimum required efficiency: 95%	Stated: >99% Minimum required efficiency: 95%	Stated: >99% Minimum required efficiency: 95%	Stated: >99% Minimum required efficiency: 95%
Cost of collection and treatment of waste from separators per kg (thousand EUR)	N/A	N/A	N/A	N/A	N/A	N/A
Medium concentration in sewage sludge from all Swedish sewage treatment plants (mh Mercury per kg dry weight)	N/A	0.5	N/A	0.5	0.5	N/A

The cost differs depending on separator and company. For example, the cost is 0.011 k€/kg for collected and treated waste (118 SEK) and 0.12 k€ for exchange of separator and treatment of waste (1 268 SEK)[371].

Number of Cremations

In Sweden, the total air emissions of Mercury decreased of about 73% between 1990 and 2015, with almost 413 kg of Mercury released in 2015. The main sources of Mercury are electricity, heat generation (combustion) and gasoline use. The reduction of Mercury emissions came from advancements in metal processing and the waste sector such as cremation. Mercury from dental fillings released 5 to 10 grams of mercury, depending on the number and types of dental amalgam[372].

Table 170 Quantitative data on cremations

[370] Questionnaire from Zero Mercury
[371] Waste questionnaire
[372] Swedish environmental protection agency report 2017, Informative inventory report Sweden 2017

Category	Air emissions from crematoria					
	2013	2014	2015	2016	2017	2018
Number of crematoria	63	61	58	58	58	58
Number of cremations per year	72,310	71,280	73,937	73,344	74,744	N/A
Share of crematoria equipped with abatement technologies (%)	100	100	100	100	100	100
Average efficiency of the abatement technologies (%)	95	95	95	95	95	95
Cost of mercury capture per cremation (EUR)	N/A	N/A	N/A	N/A	N/A	2.7€ (28 SEK) per cremation (including the cost of additives and treatment of waste[373]

All large Swedish crematoria have installed mercury control techniques and devices. Mercury emissions can be removed by adding injections of activated carbon to control devices such as bag filters or by using bag filters followed by activated carbon filters[374].The cost of mercury capture per cremation varies with type and size of installation. In 2012, Swedish environmental agencies claimed that the cost was up to 2 000 SEK per captured gram of mercury[375].

NATIONAL POLICIES AND MEASURES

The Swedish legislation established the first regulations to restrict and ban mercury in Sweden in 2009: Ordinance SFS 1998:944; KIFS 2009:2. Articles containing mercury may not be placed on the Swedish market and professionally transferred out of Sweden. The Swedish Chemicals Agency (KemI) may issue regulations concerning exceptions (batteries, etc.). For dental amalgam, certain uses were allowed up to 30th June 2018 on condition that it kept accordance with the Regulations[376,377,378].

According to KIFS 2017:7, healthcare providers could "use dental amalgam under the conditions specified in Annex 3, item 7". Such treatment should "be notified to the National Board of Health and Welfare prior to the first treatment on a patient". Since 30th of June, 2018, Mercury for dental amalgam cannot be place on the Swedish market[379].

Table 171 Policies and measures to phase down or phase-out the use of dental amalgam

[373] Calculated by a crematory with 3,650 cremations in 2018.
[374] EMEP/EEA air pollutant emission inventory guidebook 2016, Marc Deslauriers, David R. Niemi, Mike Woodfield and Katja Hjelgaard ; www.skkf.se/krematorieverksamheten
[375] Questionnaire SE, Kemi
[376] https://www.kemi.se/en/rules-and-regulations/additional-eu-rules/mercury/brief-facts-about-mercury
[377] https://www.government.se/contentassets/12c4d85c2ca64d05827fc131f1a47ab9/sweden-will-ban-the-use-of-mercury
[378] https://www.kemi.se/global/pm/2011/pm-2-11-phase-out-of-mercury.pdf
[379] Swedish Chemicals Agency's Regulations (KIFS 2017:7) on chemical products and biotechnological organisms; adopted on 22 November 2017.

Category	Type	Ongoing
Measures to phase down or phase-out dental amalgam	Dental amalgam bans, phasing-out or phasing down	Ban since 2009; Ordinance SFS 1998:944, KIFS 2009:2
	National guidelines, promoting the use of mercury-free materials	Chemical Products (Handling, Import and Export Prohibitions) Ordinance (1998:944), 8-11 §§. (In Swedish)
	Supporting research and development in respect of mercury-free dental restorations	No
	Others	The Swedish Chemicals Agency's Chemical Products and Biotechnical Organisms Regulations (KIFS 2017:7); Miljöbalk (1998:808)
Measures to manage waste and emissions from dental amalgam	Requirements for the installation and maintenance of separators	The Swedish environmental code applies to dental clinics management of waste. Maintenance of separators is required 1-2 times annually depending on use. There are no requirements with reference to the law as regards the installation of amalgam separators
	Requirements for the collection and treatment of solid waste from separators	Swedish dental clinics are bound to the use of waste management services for waste collection from amalgam separators. KIFS 2009:2 Still handles amalgam when drilling out old fillings. Therefore all chairs must be equipped with amalgam separators requiring regular service. Authorized personnel with permission to transport hazardous waste
	Requirements for mercury emissions from crematoria	No
	Standards for mercury concentrations in sludge for the use of land spreading	No
	Supporting research and development in respect of reducing emission and releases of mercury to the environment	No

Category	Type	Ongoing
	Others	No

HEALTH SERVICES AND INSURANCE

The **Ministry of Health and Social Affairs** establishes principles and guidelines for health care and sets the political agenda for health and medical care. The Ministry operates through several government agencies. The **Swedish National Board of Health and Welfare** (Socialstyrelsen) gives general advices and evaluates legislation and activities conducted by municipalities, county councils and local authorities[380]. The 21 county councils are responsible for financing and providing health care. The Swedish health care system is financed primarily through taxes levied by county councils and municipalities. The **Health and Social Care Inspectorate** (Inspektionen för vård och omsorg, IVO) controls supervision and control over healthcare as well as social services[381].

Sweden has a national social insurance system that provides universal health care. The social insurance are administered by the **Swedish Social Insurance Agency** (Försäkringskassan)[382]. Every Swedish resident at the age of 16 is registered by the social insurance office. The Swedish Dental Care Benefits comprise of a general dental care grant, a specific dental care grant (for certain groups of patients) and a high-cost protection scheme. Until the year they turn 24 years old, children insured in Sweden can receive free dental care[383].

There is no limit of pricing for dental care so dental fees vary. The protection for dental care depends of the high-price of the restauration. For example, if the price of the restoration is 0-2 999SEK, the patient has to pay 100%. If the restoration costs more than 15 001 SEK, the patient has to pay 15% of the price. The price upon which the high-price protection is based is the reference price. All restorations are reimbursed equally, no matter what kind of material is used (ceramics, etc.).

In 1999, the Swedish parliament decided to withdraw financial support for dental amalgam. The cost of amalgam fillings is no longer reimbursed under the national healthcare system. The cost of dental amalgam restorations became comparable with the cost of alternatives.

Patients are required to cover a part of the cost before the high-cost protection scheme is activated (up to 300€). The compensation is directly pay by the Swedish Social Insurance Agency to the dentist for the share that patients do not pay.

In certain cases (long-term illness, disabilities, etc.), the healthcare system's high-price protection also applies to dental care. The specific dental care grant is intended to provide additional support to patients having a higher risk of developing dental problems, due to certain diseases or disabilities. There are also special provisions for vulnerable citizens dependant on the health-care system (e.g. unemployed, disabled, elderly etc.). If patients have a special need of dental care, they can apply for dental care subsidy from there county council or region (county council's dental care subsidy).

Citizens can enrol in supplementary health plans that cover dental restorations. There is no difference between private and public social security in relation to the coverage of

[380] http://www.socialstyrelsen.se/
[381] https://www.ivo.se/
[382] https://www.forsakringskassan.se/
[383] https://www.forsakringskassan.se/privatpers/tandvard/tandvardsstod/!ut/p/z0/04_Sj9CPykssy0xPLMnMz0vMAfIjo8ziTTxcnA3dnQ283b3DDAwcXZ1cQ70cTQx8nYz1g1Pz9AuyHRUB3w3rJQ!!/

dental treatment costs. Moreover, patients can take out a private insurance with their county council dentist and pay a fee every month. Then, this private insurance can cover the fee required for normal dental treatment[384].

Table 172 Quantitative data on dental restorations costs

Category	Material	Cost (€)	Reimbursement by social security %
Restoration per filling	Dental amalgam	N/A	N/A
	Composite resins	60-150	50% up to 1 500€ 85% above 1 500€
	Glass ionomer cements	60-150	50% up to 1 500€ 85% above 1 500€
	Compomers	60-150	50% up to 1 500€ 85% above 1 500€
	Ceramics	570	50% up to 1 500€ 85% above 1 500€
Material	Dental amalgam	N/A	N/A
	Composite resins	Included	
	Glass ionomer cements	Included	
	Compomers	Included	
	Ceramics	Included	

GOOD PRACTICES IN THE SELECTED AREAS

Table 173 Good practices template

Category	Description
Type of enforcement	- Voluntary: increase of environmental awareness - Mandatory: setting rules and regulations
Target	- Reduction of mercury levels in the environment
Achievements	- Reduction of mercury emissions from point sources (Use of amalgam separators)

[384] https://ec.europa.eu/social/main.jsp?catId=1130&langId=en

Category	Description
	- phasing-out the use of mercury in dental alloys and processes and enhancement of alternatives' uses - Improvements of waste management (Collect and treat of mercury already in use) - Final disposal of mercury waste - No recycling of mercury
Financial aspects	- Stop financial support from social insurance for dental amalgam - Stop the production of dental amalgam by Swedish companies - Stop the import and export of mercury and mercury compounds
Challenges	Enhance an international cooperation in phasing-out dental amalgam
Transferability	-
Sources	http://www.naturvardsverket.se/Documents/publikationer6400/978-91-620-8691-6.pdf

United Kingdom

INTRODUCTION

The United-Kingdom of Great Britain and Northern Island is located off the northwestern coast of the European mainland. The capital and largest city is London. The country spent 233,104.67 million euro (9.70% of GDP) in healthcare in 2016[385].

Table 174 Key socio-economic and health data (2018)

General information	
Population (million):	**66.3**
GDP per capita (PPP, EUR):	0.7; 32,400
GDP per capita (rank in the EU):	12
Unemployment rate (%):	4.0
Average salary (EUR):	N/A
Number of dentists per hundred thousand inhabitants	53.15 (2016)
Dental outpatient curative care (PPS per inhabitant):	N/A
Dental outpatient curative care (Percentual share of total current health expenditure (CHE)):	5.48 (2016)

DENTAL AMALGAM USE, ALTERNATIVES AND TRENDS

Number of restorations per type material

Information received from The University of Liverpool Department of Dental Sciences and from the University of Birmingham, relating to the restorations carried out at the university, indicate that dental amalgam is preferred to alternatives, but recent years has seen a shift towards the use of composite resins.

No data on restorations at a national level have been identified.

Dental sector and effectiveness

Table 175 Quantitative data on the dental sector

[385] Eurostat (online data codes : hlth_sha11_hf, demo_gind and nama_10_gdp)

	Number					
	2013	**2014**	**2015**	**2016**	**2017**	**2018**
Dentists[386] (number) [1]	40,423	41,038	41,095	41,483	41,705	42,123
Dental clinics[387] (number) [1]						10,778 (England)
Average turnover per clinic (thousand EUR)						
Self-reported unmet needs for dental examination due to urbanisation (%)	2.9	2.9	3.0	1.8	2.9	-
Self-reported unmet needs for dental care due to financial reasons (%)		4.4	-	-	-	-

Note 1: Source: British Dental Association (BDA). The dentist registration figures are based on the General Dental Council's Annual Reports. The 2018 figure is not yet published but has been obtained on request by the BDA. The registration figures do not constitute the number of dentists actively practising in the UK, and do also not represent the number of dentists practising in the National Health Service (NHS), where amalgam fillings would mainly be placed. Dental practice numbers have been found for England in March 2019. The figure does not include practice numbers in Wales, Scotland and Northern Ireland, so the total of practices will be higher. Not all practices will be placing amalgam fillings. That number is not known and cannot be extrapolated from these figures.

Dental services in the UK are predominantly provided by dental clinics owned by either individual dentists, groups of dentists or corporate entities. Leading corporate entities providing dental services in the UK are IDH (Mydentist), Oasis and Roderick. The primary dentistry services consist of both National Health Services (NHS) and private services.

Public hospitals also provide NHS services along with more acute stomatological treatments, for which patients are referred to by clinics.

NHS services provide only basic treatments to maintain oral health and do not provide services such as cosmetic dentistry, dental implants and majority of orthodontic services.

Due to NHS funding shortages and challenges in recruiting and retaining associate dentists, the past five years have seen a shift towards private dental care, despite it tending to be more expensive. Private dental care usually offers shorter waiting times, attracting a growing number of patients as disposable incomes rise. This rise in household disposable income has also led to an increase in the demand for cosmetic

[386] The term "dentists" refers to individual professionals
[387] The term "dental clinics" refers to establishments which offer dental treatment, including dental practices

dental services. As the NHS steadily increase its charges, the shift towards private dental care is expected to increase[388].

The shortage in supply of quality dental practices is reflected in the prices. Moreover, the growth in the number of small dental companies has increased the demand for large practices, where greater economies of scale can be achieved[389].

As of 2015, the dental services market was valued at £6.5 billion, of which £4.4 billion was due to NHS dentistry and £2.1 billion from private services[388].

Manufacturing companies of dental amalgam and alternative materials

No data on manufacturing companies of dental amalgam and alternative materials was available.

Table 176 Annual sales per company and material

Company	Material	Amounts
[Name of company]	Dental amalgam*	
	Composite resins	
	Glass ionomer cements	
	Compomers	
	Ceramics	

Extra-EU Imports and exports of dental amalgam and alternative restoration materials

No data on extra-EU imports and exports of dental amalgam and alternative restoration materials was available.

Waste treatment from amalgam separators and water waste treatment facilities

Table 177 Quantitative data on water and solid waste from dental amalgam

[388] https://healthcareuk.blog.gov.uk/wp-content/uploads/sites/96/2016/10/Identification-of-FDI-Opportunities-in-the-Dental-Care-Market-in-the-UK.pdf
[389] https://www.christie.com/christieMediaLibraries/christie/PDFs-Publications/Dental/Dental_Business-Outlook-2019.pdf?ext=.pdf

Category	Mercury waste treatment					
	2013	2014	2015	2016	2017	2018
Share of dental chairs equipped with amalgam separators (%) [1]	100%	100%	100%	100%	100%	100%
Share of waste from separators treated in specialized treatment facilities (%)						
Average dental amalgam removal efficiency of separators (%)						
Cost of collection and treatment of waste from separators per kg (thousand EUR)						
Concentration of mercury in sewage sludge (µg/L)						

Note 1: Source: University of Birmingham

The Hazardous Waste Regulations 2005 (England and Wales) classified all dental amalgam as 'hazardous waste', with similar regulations in Scotland and Northern Ireland. Practices that use or remove amalgam are required by law to have amalgam separators fitted in dental chairs, and that the amalgam separators should be of the ISO standards 11143:2008. Furthermore, it is the British Dental Association (BDA)'s position that if suction units are fitted with amalgam separators and if correct waste handling controls are followed, then amalgam separators are not necessary on manual cleaning sinks[390].

According to Eurostat statistics, 74% of sludge produced from urban wastewater treatment plants in 2012 in the UK was used in agriculture[391].

Number of Cremations

Table 178 Quantitative data on cremations

Category	Air emissions from crematoria					
	2013	2014	2015	2016	2017	2018
Number of crematoria [1]	270	273	277	281	291	
Number of cremations per year [1]	436,280	429,254	462,916	459,693	467,748	

[390] https://bda.org/news-centre/latest-news-articles/update-amalgam-separators-on-dirty-sinks-and-washer-disinfectors
[391] http://appsso.eurostat.ec.europa.eu/nui/submitViewTableAction.do

Category	Air emissions from crematoria					
	2013	2014	2015	2016	2017	2018
Share of crematoria equipped with abatement technologies (%) [2]	>50%					
Average efficiency of the abatement technologies (%)						
Cost of mercury capture per cremation (EUR)						

Note 1: Source: https://www.cremation.org.uk/statistics

Note 2: Source: https://www.ospar.org/documents?d=35427. According to UK's implementation report on Recommendation 2003/4 of the OSPAR agreement, more than 135 crematoria were fitted with mercury abatement technologies in 2013

The cremation rate in the UK has increased from 35% in 1960 to 77%in 2017[392].

NATIONAL POLICIES AND MEASURES

Table 179 Policies and measures to phase down or phase-out the use of dental amalgam

Category	Type	Ongoing	Under development
Measures to phase down or phase-out dental amalgam	Dental amalgam bans, phasing-out or phasing down	Control of Mercury (Enforcement) Regulations 2017, which enforces European Commission Regulation (EU) 2017/852 on Mercury	Article 10(3) of the European Commission Regulation (EU) 2017/852 on Mercury which requires a national plan, by 1 July 2019, on measures to phase down the use of amalgam
	National guidelines, promoting the use of mercury-free materials	The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012 The Scottish Dental Clinical Effectiveness Programme (SDCEP) developed implementation guidance on Article 10(2) of the European Commission Regulation (EU) 2017/852 on Mercury and patient information leaflets	

[392] https://www.urnsforashes.co.uk/cremation-statistics/

Category	Type	Ongoing	Under development
	Supporting research and development in respect of mercury-free dental restorations		
	Others :		A reformed dental contract in England and Wales is being tested, which has an increased focus on prevention. The British Dental Association is also pressing for further public health measures
Measures to manage waste and emissions from dental amalgam	Requirements for the installation and maintenance of separators	Article 10(4) of the European Commission Regulation (EU) 2017/852 on Mercury. Hazardous Waste Regulations 2005 Regulation 15: Premises and Equipment	
	Requirements for the collection and treatment of solid waste from separators	See above.	
	Requirements for mercury emissions from crematoria	The Oslo-Paris Commission (OSPAR) agreement, of which the UK is a signatory	
	Standards for mercury concentrations in sludge for the use of land spreading	The Sludge (Use in Agriculture) Regulations of 1989 enforce the EC Directive 86/278/EEC, on the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture.	
	Supporting research and development in respect of reducing emission and releases of mercury to the environment		
	Others :		

1. Measures to phase down or phase-out dental amalgam:

- Dental amalgam bans, phasing-out or phasing down
  In 2017, the European Commission Regulation (EU) 2017/852 on Mercury was adopted by Member States to ratify and enforce the Minamata Convention on Mercury, which requires participating countries to phase-out their use of dental amalgam. The EU Regulation on Mercury is fully supported and implemented through the Control of Mercury (Enforcement) Regulations 2017, which came into force on 1 January 2018. The following provisions related to dental amalgam are contained within the Regulation:
  (i) Article 10(1): From 1 January 2019, dental amalgam shall only be used in pre-dosed encapsulated form
  (ii) Article 10(2): from 1 July 2018, dental amalgam shall not be used for dental treatment of deciduous teeth, of children under 15 years and of pregnant or breastfeeding women, except when deemed strictly necessary by the dental practitioner based on the specific medical needs of the patient
  (iii) Article 10(3): a requirement for a national plan, by 1 July 2019, on measures to phase down the use of amalgam
  (iv) Article 10(4): from 1 January 2019 a requirement for dental facilities to be equipped with an amalgam separator[393].

- National guidelines, promoting the use of mercury-free materials
  The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012, which came into force on 2nd January 2013 restrict the amount of hazardous substances, such as mercury, that can be used in electrical and electronic equipment. This restriction has been extended to a wider range of products and devices including medical devices, in vitro medical devices etc.[394]
  The Scottish Dental Clinical Effectiveness Programme (SDCEP) developed implementation guidance on Article 10(2) of the European Commission Regulation (EU) 2017/852 on Mercury. Patients were also provided with information leaflets to inform them about the restrictions on dental amalgam use and how this could affect the dental treatment offered[395].

- Others
  A reformed dental contract in England and Wales is being tested, which has an increased focus on prevention. The British Dental Association is also pressing for further prevention and public health measures[396].

  In 2016, Public Health England established a Children's Oral Health Improvement Programme Board (COHIPB) with a substantial programme of work to improve children's oral health. In 2019, PHE has established an Adult's Oral Health Oversight Group (AOHOG), which brings together a wide range of departments and agencies that have policies or areas of interest to improve the oral health of adults. PHE has published a best practice guide on preventative dentistry for dentists, 'Delivering Better Oral Health'. This guide brings together existing best practice advice and interventions to improve oral health and sets out clear expectations. A Green Paper on prevention is also planned for the end of 2019 (National

[393] http://www.sdcep.org.uk/wp-content/uploads/2018/06/SDCEP-Dental-Amalgam-Implementation-Advice.pdf
[394] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/679655/rohs-directive-guidance.pdf
[395] http://www.sdcep.org.uk/published-guidance/dental-amalgam/
[396] According to a consultation response

plan on measures to phase down the use of dental amalgam (Article 10(3) of the Mercury Regulation)).

The Welsh Government has established a National Strategic Advisory Forum in Paediatric Dentistry to agree and communicate a national plan for expectations for the provision of dental care and treatment for children. Wales is also finalising a dental amalgam information leaflet for dental patients to be made available in all dental practices in Wales. Among the steps the Welsh government has created various programmes to prevent dental decay. They are: Designed to Smile – the national programme to improve children's dental health; the programme to improve oral health of older people living in care homes in Wales; promotion of the evidence-based toolkit – Delivering Better Oral Health; CDO advice to dental teams on care of children age 0-3 years. This preventive approach will likely contain dental decay, leading to fewer and less invasive techniques (Minimally Invasive Dentistry technique), which are typically performed with composites/ionomers rather than dental amalgam (National plan on measures to phase down the use of dental amalgam (Article 10(3) of the Mercury Regulation)).

Partnerships with dental schools and universities will be further developed to ensure that the future workforce is educated and trained in the use of alternative filings.

2. Measures to manage waste and emissions from dental amalgam:

- Requirements for the installation and maintenance of separators
  Article 10(4) of the European Commission Regulation (EU) 2017/852 on Mercury requires dental facilities to be equipped with an amalgam separator by 1 January 2019[393]. Moreover, the Hazardous Waste Regulations which came into force in 2005 in England and Wales classified all dental amalgam as 'hazardous waste'. Similar regulations also exist in Scotland and Northern Ireland. To comply with the Hazardous Waste Regulations and Regulation 15 (premises and equipment) of the fundamental standards, all dental practices must have an amalgam separator which meet the British Standard Dental equipment – amalgam separators (BS ISO EN 11143:2000). They must also ensure that amalgam is collected and disposed of in accordance with the Hazardous Waste Regulations[397].

- Requirements for mercury emissions from crematoria
  The UK is a signatory of the Oslo-Paris Commission (OSPAR) agreement on eliminating mercury emissions from crematoria. As such, the UK agreed to reduce 50% mercury emissions from crematoria by 2012 and by 2020 all crematoria in the UK will need to have a zero emissions rate[398].

- Standards for mercury concentrations in sludge for the use of land spreading
  The Sludge (Use in Agriculture) Regulations of 1989 enforce the EC Directive 86/278/EEC, on the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture. These

[397] https://dpmmagonline.co.uk/contents/item/151579-dental-waste-disposal-mercury-waste-mercury-waste-disposal
[398] https://www.vitruviusms.co.uk/news/construction/mercury-abatement-in-crematoria-are-you-ready-for-the-2020-deadline.php

regulations provide guidelines on, for e.g., maximum permissible concentrations of potentially toxic elements in soil after application of sewage sludge and maximum annual rates of addition[399].

HEALTH SERVICES AND INSURANCE

Table 180 Quantitative data on dental restorations [1] [2]

Category	Category	Price	Reimbursement by social security %
Restoration per filling- England	Dental amalgam	£62.10 (band 2)	Approx. 20.4%
	Composite resins	£62.10 (band 2)	Approx. 20.4%
	Glass ionomer cements	£62.10 (band 2)	Approx. 20.4%
	Compomers	£62.10 (band 2)	Approx. 20.4%
	Ceramics	£269.30 (band 3)	Approx. 13.8%
Restoration per filling- Wales	Dental amalgam	£46 (band 2)	Approx. 39.5%
	Composite resins	£46 (band 2)	Approx. 39.5%
	Glass ionomer cements	£46 (band 2)	Approx. 39.5%
	Compomers	£46 (band 2)	Approx. 39.5%
	Ceramics	£199.10 (band 3)	Approx. 36.2%
Restoration per filling- Northern Ireland	Dental amalgam	£7.31- £18.81	20%
	Composite resins	£13.87- £21.52	100%
	Glass ionomer cements	£12.57- £17.17	100%
	Compomers	£13.87- £21.52	20%
	Ceramics	£65.26- £108.68	20%
Restoration per filling- Scotland	Dental amalgam	£7.76- £19.92	20%
	Composite resins	£14.64- £22.76	20%

[399] http://adlib.everysite.co.uk/resources/000/247/164/sludge-report.pdf

	Glass ionomer cements	£13.28- £18.16	20%
	Compomers	£14.64- £22.76	20%
	Ceramics	£46.20- £114.96	20%
Material per filling	Dental amalgam	Around £1	-
	Composite resins	£4.51	-
	Glass ionomer cements		-
	Compomers		-
	Ceramics	Varies significantly	-

Note 1: Source: British Dental Association (BDA)
Note 2: For the purposes of the above table, the cost for restorations per filling refers to the NHS patient charge and the reimbursement figure refers to the proportion of the fee paid by the NHS to the dentist that is covered by the NHS, net of the patient charge. Note that some patients are exempt from charges and therefore 100 per cent of the costs is covered by the NHS. The material per filling cost refers to an average indicative cost to the dentist of each material. The system in England and Wales does not operate based on a payment per treatment basis. Patients pay and dentists are paid on the basis of three bands. Restorations are a band 2 treatment and there is a flat payment for this covering any treatment in this band or in band 1, regardless of the number of treatments. The NHS payment to the dentist is 3 Units of Dental Activity (on average worth a gross £78 in England and £75 in Wales) and the England patient charge is £62.10, meaning the net NHS contribution is on average 20.4 per cent, and in Wales the patient charge is £42, meaning the net NHS contribution is on average 38.7 per cent.

The National Health Service (NHS) provides dental services, including restorations, across the UK. Unlike most other NHS provision, dentistry is subject to patient charges. These represent a contribution towards the costs of providing the treatment. However, in England and Wales, patient charges are not based on a percentage of the costs to the NHS to provide a given treatment. In Northern Ireland and Scotland, the patient must pay 80 per cent of the fee paid to the dentist by the NHS, up to a cap of £384. There is also significant private provision of dentistry including restorations and these may involve some form of health payment plan.

NHS dental treatment, including restorations, is provided free of charge to those aged under 18, those aged 18 who are in full-time education, those who are pregnant or who have given birth in the last 12 months, and those in receipt of a specified set of social security benefits, such as for those on low incomes, pensioners on low incomes, disabled people and unemployed people. There is also a Low Income Scheme that provides some subsidy to those who are on low incomes but are not eligible for free treatment.

The NHS dental patient charges are not based on a system of reimbursement. The patient charge is collected by the dentist on behalf of the NHS and dentists are able to claim a fee from the NHS for the treatment they have performed. In England and Wales, there is no differentiation in either the NHS fee to dentists or the NHS charge to patients on the basis of the restoration material for fillings. As a result, the additional costs of composite resin restorations in both time and material costs over amalgam must be covered by the dentist and therefore their net income for restorations using composite resins is significantly lower. Ceramic restorations such as crowns, bridgework or onlays, would attract a higher fee. In Northern Ireland and Scotland, the NHS fee to the dentist

and the patient charge is different depending on the number of surfaces filled and the material used. The increased cost is therefore shared by the patient, the NHS and the dentist. In Northern Ireland and Scotland, restorations would normally use amalgam, with the NHS permitting the use of other materials for under 15s and pregnant and breastfeeding women[400].

http://www.association-nationale-crematiste.fr/resources/bulletin+82_p3.pdf
http://www.association-nationale-crematiste.fr/resources/bulletin+82_p3.pdf
http://www.association-nationale-crematiste.fr/resources/bulletin+82_p3.pdf
http://www.association-nationale-crematiste.fr/resources/bulletin+82_p3.pdf

[400] Source: British Dental Association (BDA)

Appendix C Environmental pressures and health aspects of dental amalgam

Starting from the most recent updates of the SCHER and SCENIHR reports, updated respectively in 2014 and 2015, this section provides a concise review of recent scientific literature on the impact of dental amalgam on the environment (section 0) and human health. It summarises the relevant available information on the dental amalgam life cycle and the environmental pressures of the use of dental amalgam in the EU and the potential association between amalgam and adverse health effects. This review aims at identifying the latest findings, including outstanding disputed issues as well as areas where consensus has been reached.

ENVIRONMENTAL PRESSURES OF THE USE OF DENTAL AMALGAM IN THE EU

Mercury used in dental amalgam can be released into the environment at different stages of its life cycle and can contaminate all environmental compartments (atmosphere, surface water and groundwater, soil and vegetation). This section provides an estimate of the dental waste used in and released from dental clinics. It then summarises mercury emissions to all environmental media: air, soil and water and discusses potential impacts of mercury free-materials. The latter is not in the scope of the study, but any environmental or health concerns will need to be considered in the feasibility assessment to be carried out at a later stage of the study.

Mercury used in dental clinics: quantities used and dental waste treatment

This section provides an estimate of the amounts of dental amalgam used in EU dental clinics as well as the amount of mercury that is released through the removal or placements of amalgam fillings. The latest available published estimate is from 2010. The figures have been updated based on the findings of the online survey conducted in the context of the present study.

Treatment of dental amalgam waste from dental clinics

Dental amalgam is listed as "hazardous" in the European Waste catalogue[401] due to its intrinsic proprieties (bioaccumulation, etc.) and health and environmental toxicity of mercury (which comprises 50% of the amalgam). A dedicated management system is necessary for dental amalgam effluents, which represent a risk for the environment and public health[402]. Dental amalgam as a hazardous waste must be treated and managed considering **Directive 2008/98/EC[403]**, under which dentists are responsible for properly managing amalgam waste[404]. Proper mercury waste management implies minimisation, segregation, reuse and recycling of dental amalgam[405]. Minimisation involves not only the reduction of the use of hazardous material such as dental amalgam, but also the separation of non-hazardous waste from hazardous waste. To that end, in the EU, dental surgeries must be equipped with amalgam separators to

[401] Commission decision of 3 May 2000 on replacing Decision 94/3/EC establishing a list of wastes pursuant to Article 1(a) of Council Directive 75/442/EEC on waste and Council Decision 94/904/EC establishing a list of hazardous waste pursuant to Article 1(4) of Council Directive 91/689/EEC on hazardous waste. Available at: https://eur-lex.europa.eu/eli/dec/2000/532/2015-06-01

[402] Carraro et al. (2016), Hospital effluents management: Chemical, physical, microbiological risks and legislation in different countries. Journal of environmental management.

[403] Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32008L0098)

[404] World Health Organization (WHO) (2011), Future use of Materials for Dental Restoration.

[405] Daou et al. (2015), Current status of dental waste management in Lebanon.

retain and collect amalgam particles to avoid the discharge of dental amalgam into wastewater treatment plants[11].

Amalgam separators are devices installed on a vacuum line at dental surgeries. They filter out and collect solid mercury and other particles from wastewater (using different technologies such as centrifugation, filtration, sedimentation, etc.)[406], to reduce the amount of amalgam released to the sewage system.

According to the EU Manual of Dental Practice[407] published by the Council of European Dentists, 22 out of the 28 EU Member States already have binding legislation requiring the use of amalgam separators (except Bulgaria, Estonia, Ireland, Italy, Lithuania, Portugal and Romania). However, in 2012, around 25% of EU dental facilities were still not equipped with amalgam separators[21]. Moreover, the functioning separators had an average efficiency of 70%, and a significant proportion of separators are not adequately maintained[21], resulting in even lower performance. The most efficient amalgam separators are certified under an International Organization for Standardization (ISO) classification that guarantees 95% removal of solid weight[408].

According to the Mercury Regulation, all new amalgam separators put into service as of 1 January 2018 must provide a retention level of at least 95% of amalgam particles (Article 10 (4a)). A survey has been carried out in the context of the present study in order to determine the current use of dental amalgam and their alternatives, as well as on the implications of the organisation of health services in the different EU Member States and the existing or planned measures to phase down dental amalgam. The results of the survey show that the majority of Member States already achieve this performance with the amalgam separators already installed with a 100% coverage and an efficiency that is equal to or exceeding 95%. Exceptions are the Czech Republic, where amalgam separators seem to have an average efficiency of about 90%; and Ireland where 87% of dental chairs in practice are equipped with amalgam separators. It must be noted, however, that according to Article 10 of the Mercury Regulation, for separators installed after 2018, a retention level of 95% is required. For older separators, retention levels might be (much) lower but need to be upgraded by 1 January 2021. This will also affect the amounts of mercury from dental amalgam that are currently captured in amalgam separators.

Quantities used in dental clinics

According to the latest available estimate prior to the present study, the EU dental amalgam consumption was estimated to range between 55 and 95 t Mercury per year (75 t Mercury /year on average) in 2010[21]. This estimate is based on an average mercury consumption (including wastes) per filling of around 0.8 g[409]. In terms of in-use stock, the total quantity of mercury stored in European citizens' teeth in 2010 was estimated to be about 1,000 t Mercury for the EU27 (EU28 minus Croatia)[410].

The use of mercury for dentistry has been declining in the EU, mainly due to aesthetic aspects but also due to certain legislative developments. Such legislative developments include the ban of dental amalgam use in certain categories of the population and a full ban in Sweden. Nevertheless, mercury from dental amalgam remains a significant contributor to overall European releases from human activities.

[406] Center for Scientific Information, ADA Science Institute (2017), Amalgam separators and waste best management (ada.org).
[407] Council of European dentists (2015), EU Manual of dental practice (http://cedentists.eu/library/eu-manual.html).
[408] ISO 11143:2008 Dentistry – amalgam separators. (https://www.iso.org/standard/42288.html)
[409] Maag et al., 1996, and Skarup et al., 2003 in : UN Environment (2017), Global mercury supply, trade and demand. United Nations Environment Programme, Chemicals and Health Branch. Geneva, Switzerland
[410] BIO Intelligence Service (2012), Study on the potential for reducing mercury pollution from dental amalgam and batteries (http://ec.europa.eu/environment/chemicals/mercury/pdf/review_mercury_strategy2010.pdf).

Quantities released from dental clinics
Mercury can be released at different stages of the dental amalgam life cycle. In dental clinics leakages occur mainly during the preparation and placement phases and then during repairs or removal of dental amalgam fillings.

In 2010 with an estimated average amount of 75 t of mercury use per year by dentists in the EU27, 19 t of mercury were directly released, with 11 t of surplus of mixed amalgam ending up in solid waste and 8 t of surplus ending up in wastewater[21]. Moreover, it is estimated that approximately 38 t Mercury/year from dental amalgam ends up in wastewater because of old amalgam fillings removal so almost 46 t Mercury/year were discharged into wastewater[21]. To date, no updated estimate of the life cycle mercury emissions from dental amalgam has been made. The data on amalgam use are partial or incomplete (see chapter 0). A study conducted by COWI and ICF in 2017 projected the use of dental amalgam use for 2021[411]. According to the study, the projected use of dental amalgam ranges between 20 and 60 tonnes. This indicates a decline compared to the 2010 estimate. However, the wide range of the projection indicates a significant level of uncertainty.

When all sources of releases are considered it has been estimated that in 2010, mercury coming from current and historical dental amalgam use represented 42 t Mercury /year (between 34 to 50 t Mercury /year) released to the environment (air, surface water, soil and groundwater), and which is still bioavailable[21]. Additionally, 38.5 t Mercury /year (31 to 46 t Mercury /year) are sequestered for the long-term or recycled (and hence are no longer bioavailable)[21]. To this end, dental amalgam is a significant source of mercury pollution in the environment.

Mercury released into the environment: air, soil, surface water and groundwater

Mercury from dental amalgam is released into the environment in different ways including: amalgam deterioration in the mouth, burial or cremation, amalgam in dental practices (surplus of amalgam or tooth extraction) and waste management. Releases from waste treatment activities to air, soil, surface water and groundwater depend on the type of water treatment applied, and on whether or not dental amalgam waste is mixed with non-hazardous waste or managed as medical waste with specific collection and treatment of the waste from the amalgam separators. Different mass balances of mercury emissions and concentrations in air, soil and water have been proposed by AMAP/UNEP, E-PRTR (European Pollutant Release and Transfer Register)[412], and BIO intelligence service. They are reported in the updated SCHER report and summarised below.

Mercury concentrations in air
Mercury remains stable in the atmosphere with a relatively long residence time (several months to a year). It can be transported across long distances and redistributed by deposition to soil, air and water[413]. Mercury's physicochemical form and its distribution in the atmosphere depend on the meteorological conditions (temperature, pH, solar irradiation, etc.) and on the oceans and seas, which are sources and sinks of mercury. Atmospheric concentrations of mercury measured in 2010 range from 1.3 to 1.7 $ng.m^{-3}$

[411] COWI and ICF (2017) Support to assessing the impacts of certain amendments to the Proposal of the Commission for a Regulation on Mercury
[412] https://prtr.eea.europa.eu/#/home
[413] F. Sprovieri, N. Pirrone, R. Ebinghaus, H. Kock, A. Dommergue (2010), A review of worldwide atmospheric mercury measurements. Atmos. Chem. Phys.

in the Northern hemisphere, where the majority of emissions occur, and from 1.1 to 1.3 ng.m^{-3} in the Southern hemisphere[414].

Anthropogenic activities are a significant source of mercury pollution of the atmosphere. According to the Global Mercury Assessment, stationary combustion of coal and artisanal gold mining are estimated to be responsible for almost 60% of mercury emissions to air in 2015[415].

In 2010, in the EU27, the mercury emissions to air were about 19 t. Those emissions occur through losses all along the life cycle of dental amalgam: losses during application and separation (3.5 t Mercury /year), losses from sewage sludge (6 t Mercury /year), losses from solid wastes (4.5 t Mercury /year), cremation (3 t Mercury /year) and losses from fillings in use (2 t Mercury /year)[21].

Some mercury emissions also arise during cremations and during incineration of dental amalgam solid waste. A stabilisation of those types of emissions seems to have occurred since 2005[416]. The cremation rate of deceased people in the EU has increased in the last decade mainly due to cultural changes. Nowadays, more crematoria are equipped with mercury abatement technology. In addition, EU citizens now keep their teeth for a longer period due to improvements in dental treatment. Therefore, the amount of historical dental amalgam that is cremated has a tendency to increase. Due to these different parameters, it was estimated that EU mercury emissions from cremation will remain at a similar level to those in 2010 over the following 15 years (i.e. 3 t Mercury /year)[21]. Then gradually, due to an increased preference for mercury-free materials, it is expected that gradually the amounts of mercury emissions from crematoria will drop. The trends in the installation of abatement technologies at crematoria are uncertain. Nevertheless, it can be assumed that an increasing number of crematoria, at least for Parties to the OSPAR Convention will be equipped with such technologies.

Currently, there is no specific legislation at EU level that requires Member States to install mercury abatement technologies in crematoria. The requirements at the EU level are set only through the Oslo-Paris (OSPAR) Recommendation 2003/4, which recommends the use of Best Available Techniques (BAT) and could be applied to crematoria to prevent and control the dispersal of mercury to the environment[417]. Only 11 Member States are signatories to this convention[418]. The survey that was carried out in the context of this study, reveals that at least Croatia, the Czech Republic and Lithuania have not installed such technologies in their crematoria.

Mercury concentrations in surface water and groundwater

Mercury released into the environment can reach the water compartment directly, either through sewage and wastewater; or indirectly through atmospheric mercury deposition (carried by snow, rain, etc.) into the water cycle, from surface water (oceans, lakes, rivers) to groundwater.

In 2010, global releases of mercury from anthropogenic sources to water were 185 t (42.6-582 t Mercury /year)[419]. The total EU27 releases of mercury from dental surgeries was estimated at approximately 2 t Mercury /year. In 2016, the European Federation of

414 D. Kocman, M. Horvat (2011), Non-point source mercury emission from the Idrija Mercury -mine region: GIS mercury emission model, J. Environ. Manag. 92.

415 UN (2018), Global Mercury assessment.

416 BIO Intelligence Service (2010), Review of the Community Strategy concerning Mercury (http://ec.europa.eu/environment/chemicals/mercury/pdf/review_mercury_strategy2010.pdf).

417 https://www.ospar.org/documents?d=35427

418 The OSPAR signatories are Belgium, Denmark, the European Union, Finland, France, Germany, Iceland, Ireland, the Netherlands, Norway, Portugal, Spain, Sweden and the United Kingdom of Great Britain and Northern Ireland

419 UNEP (2013), Global Mercury Assessment 2013: Sources, Emissions, Releases and Environmental Transport. UNEP Chemicals Branch.

National Associations of Water Services for the public and private sectors (Eureau) advocated a ban on dental amalgam. It declared that mercury from dental amalgam is now the major source of mercury in wastewater treatment plants in the EU (especially due to daily erosion of restored teeth)[420].

Before entering wastewater treatment plants, liquid effluents are filtered through the amalgam separator at the dental clinic. There is a minimum set of legislative requirements for the discharge of hazardous wastewater into municipal sewage systems, to ensure low quantities of toxic chemicals releases such as mercury[421]. Different technologies (such as adsorption and synthetic adsorbent, biosorbents, precipitation, coagulation/flocculation, ion exchange, membrane filtration, reverse osmosis and nanofiltration) have the capacity to remove mercury to give concentrations below 0.05 µg/l (UK standard) and 0.77 µg/l (USA standard). Chemical techniques (such as precipitation) are considered the most efficient in removing mercury from water[422]. This pre-treatment is important, as it remains easier to capture mercury at dental facilities than when it is mixed with other urban effluents.

The SCHER report estimated the concentration of mercury in surface water under three different possible scenarios (worst, average and best case). Predicated Environmental Concentrations were calculated for each scenario and compared with the Water Framework Directive[423] Environmental Quality Standards[424,425]. For the best case SCHER scenario (low discharges, 95% of dental chairs equipped with highly efficient amalgam separators, a low number of dentists per inhabitant and low effluent concentration), the Predicted Environmental Concentrations (PEC) are negligible compared to Environmental Quality Standards, whereas for the worst scenario (high amount of discharges, no separators (which occurs in some countries), and high number of dentists per inhabitant), the PEC is above the annual average (AA) and the maximum allowable concentration (MAC) EQS. In the worst-case scenario, there is a potential risk of secondary poisoning due to methylation. SCHER concluded that a risk cannot be excluded but the assessment of methylmercury in water remains uncertain.

However, in particular conditions (worst-case scenarios), SCHER highlights that the WFD EQS can be exceeded and there is therefore a potential risk for water and aquatic ecosystems. Indeed, in water or soil, under anaerobic conditions, metallic mercury can be converted by bacteria into methylmercury, a highly toxic form of mercury and a potent neurotoxin which can be incorporated in the food chain via fish and can bioaccumulate in the food chain[426,427]. In the worst-case scenario, the acceptable level of mercury in fish is exceeded: the methylation rates is higher than 0.1% and the WFD threshold for secondary poisoning exceeded at methylation rates is higher than 0.005%[18].

In the EU, once collected by dental amalgam separators, mercury can be recycled thanks to a retorting process, which involves distilling off the mercury from the amalgam under

[420] EurEau (2016), Dental amalgam and the mercury regulation. (http://www.eureau.org/resources/position-papers/120-dental-amalgam-june-2016/file)
[421] Carraro, E. et al. (2016), Hospital effluents management: chemical, physical, microbiological risks and legislation in different countries. Journal of environmental management, 168.
[422] Hargreaves et al. (2016), Mercury and antimony in wastewater: fate and treatment. Water, air and soil pollution, 227:89.
[423] Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy : https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32000L0060
[424] Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council (http://data.europa.eu/eli/dir/2008/105/oj)
[425]Annual Average (AA) of Environmental Quality Standard (EQS) and Maximum Allowable Concentration (MAC) that have been set for mercury
[426] Trip et al. (2001), Canada-wide standards : a pollution prevention program for dental amalgam waste (http://www.cda-adc.ca/JCDA/vol-67/issue-5/270.pdf)
[427] Parks et al. (2013), The genetic basis for bacterial mercury methylation. Science, Vol. 339, Issue 6125.

reduced pressure[428]. However, the demand for recycled mercury has dropped significantly due to the EU legislation that bans many uses of mercury. Consequently, mercury waste has a negative value and the mercury-recycling sector in the EU is shrinking. In 2015, in the EU the mercury use as a secondary material from recycling amounted to between 30 and 40 t.

Exposures to mercury from dental amalgam

Individuals can be exposed to mercury both directly and indirectly. Direct exposure occurs mainly in patients or dental professionals during the placement or removal of dental amalgam. Indirect exposure refers to mercury that has been released to the environment. The paragraphs below describe the risks and their specificities for both direct and indirect exposure routes.

Indirect exposure to mercury from dental amalgam
Mercury emissions from dental amalgam or other sources are distributed in the environment and can affect individuals via food or water intake and air inhalation. The main source of inorganic mercury (or elemental mercury) are human activities including the use of dental amalgam[429]. Specifically, individuals can be exposed to mercury via the ingestion of drinking water and food contaminated with inorganic mercury and methylmercury.

Dental amalgam accounts for a limited contribution (around 1%) to the overall human inhalation exposure to mercury from anthropogenic sources (22%)[18]. The SCHER report concluded that that mercury from dental amalgam represents a very minor contribution to total human mercury exposure from soil.

Dietary intake of mercury is the most important source of non-occupational exposure to methylmercury[430,431]. The European Food Safety Authority (EFSA) evaluated inorganic mercury and methylmercury in food and established a tolerable weekly intake (TWI) limit for methylmercury of 1.6 µg/kg body weight and of 4 µg/kg body weight for inorganic mercury[432]. The highly toxic form of mercury, methylmercury, is the most common form of mercury found in food, especially in fish and seafood products. Methylmercury in aquatic ecosystems comes from the transformation of the inorganic form of mercury through the action of bacteria present in water and sediments[433]. Nevertheless, the contribution of amalgam use to the concentration of methylmercury found in fish and formed from mercury oxide (II) (Mercury $^{2+}$) dissolved in the oceans from non-anthropogenic sources is unclear. According to EFSA, dietary inorganic mercury exposure in Europe does not exceed the TWI. However, inhalation exposure of elemental mercury from amalgam fillings can increase the internal inorganic exposure to above the TWI.

Pregnant women and young babies (unborn and newborn children) are a group with a higher health risk than the general population. Indeed, during pregnancy, methylmercury can penetrate the placental barrier and harm the unborn child. Moreover, available studies provide evidence of a strong link between amalgam fillings and mercury concentration in breast milk[19].

Direct exposure of mercury coming from dental amalgam

[428] Lee et al. (1981), Recovery of silver and mercury from dental amalgam waste. Resource Recovery and Conservation.
[429] Clarkson TW, Magos L. (2006), The toxicology of mercury and its chemical compounds. Crit Rev Toxicol.
[430] World Health Organization (1990), Methylmercury. Environmental Health Criteria 101. International Program on Chemical Safety.
[431] World Health Organization (1991), Inorganic mercury. Environmental Health Criteria 118. International Programme on Chemical Safety.
[432] EFSA (2018), Scientific Opinion on the risk for public health related to the presence of mercury and methylmercury in food (https://www.efsa.europa.eu/en/efsajournal/pub/2985).
[433] Parks JM, Johs A, Podar M, et al. (2013), The genetic basis for bacterial mercury methylation. Science.

The SCENIHR report concluded that inorganic mercury releases to the environment (triggering a direct release of methylmercury in the environment) have a low risk for serious health effects. Overall, the side effects of a high mercury concentration in the human body (brain, kidney, hair, urine and blood) and the gravity of direct health effects of dental amalgam remain a controversial issue.

The paragraphs below describe the assessment of health risks that relate to dental amalgam. First, some key findings in relation to mercury intake estimates and the identification of the source are discussed (i.e. direct or indirect). The potential direct impacts of dental amalgam fillings on patients during their whole life cycle as well as health personnel during their placement are then considered.

Intake estimates for mercury from dental amalgam
As mercury is mainly eliminated via urine, urinary excretion of mercury is a reliable biomarker to follow systemic exposures to mercury (elemental and inorganic and possibly organic mercury that was demethylated). Scientific data assessed by SCENIHR on the total urinary excretion and the use of dental amalgam, indicates that dental amalgam restorations are currently considered to be the main source of inorganic mercury exposure for humans[19]. The concentration of mercury in the urine of individuals with dental amalgam fillings and particularly in dental personnel is estimated to be significantly higher. It must be noted that many cohort studies are undertaken using non-fish-consuming groups of people because high consumption of fish can interfere with the results of studies[434].

Exposure during the lifetime of the filling
Mercury vapour can be released into the oral cavity and inhaled by patients equipped with amalgam fillings. Releases of mercury occur via erosion of the amalgam or dissolution in saliva and can be increased by e.g. mastication. They depend on different parameters including: number of fillings, filling size and free surface area but also chewing, tooth brushing and other parafunctional activities such as bruxism (an excessive teeth grinding) for example[19,435]. Mercury is then quickly absorbed by human metabolism[436,437,438]. The World Health Organization (WHO) reported a consensus average intake of dental amalgam-derived mercury estimate of 10 µg/day[19].

The immune system, and especially the central nervous system, are linked to significant risks from long-term exposure to mercury[439,440]. Mercury concentration in the adult brain is associated with the number of amalgam fillings. Because the estimated elimination half-life for inorganic mercury in the brain exceeds 10 years, mercury is likely to accumulate in the central nervous system. The accumulated concentrations in brain tissue (as measured in post-mortem specimens) may reach values similar to those inducing neurochemical changes in experimental models in vitro. Such effects have not been convincingly demonstrated in humans as being caused by dental amalgam[19].

As with any other medical or pharmaceutical intervention, attention should be directed towards the placement of any dental restorative material on children and pregnant women. In the foetus, mercury concentration in the kidney (but not in the foetal brain) tends to be associated with the mother's number of amalgam fillings. In this context,

[434] Knezovic, Z., et al. (2016), Monitoring mercury environment pollution through bioaccumulation in meconium. Process safety and environmental protection.
[435] Meesat, R., et al. (2017), Micro-PIXE study of metal loss from dental amalgam. Nuclear instruments and methods in physic research B.
[436] Palkovicova et al. (2008), Maternal amalgam dental fillings as the source of mercury exposure in developing fetus and newborn. Journal of Exposure Science and Environmental Epidemiology, 18 (3).
[437] Díez, S. et al. (2009), Prenatal and early childhood exposure to mercury and methylmercury in Spain, a high-fish-consumer country. Arch Environ Contam Toxicol.
[438] Homme KG, et al. (2014), New science challenges old notion that mercury dental amalgam is safe. Biometals.
[439] Berlin, M., Zalups, R.K., Fowler, B.A. (2015), Mercury. In: Nordberg, G., Fowler, B., Nordberg, M. (Eds.), 4th ed. Handbook on the Toxicology of Metals Volume II.
[440] Nagpal et al. (2017), A review of mercury exposure and health of dental personnel. Safety and health at work.

dental amalgam imposes a significant risk for these vulnerable groups of the population. For this reason, Regulation 2017/852 banned the use of dental amalgam in children under 15 years old[19].

Placement and removal of dental amalgam fillings can expose patients to transient short-term mercury exposure compared to leaving the filling intact. It can result in a transient increase in plasma mercury levels. There is no general justification for banning clinically satisfactory amalgam restorations except if the patient is diagnosed as having allergic reactions to one of the amalgam constituents. The SCENIHR concluded that dental amalgam already in place is not considered a health risk for the general population and does not need to be removed as a preventive measure.

Exposure to mercury in dental personnel
Dental personnel working with amalgam have a higher risk of exposure to mercury than the average population[19]. Studies have noticed the presence of high levels of mercury in the urine and correlations have been found amongst dentists between urinary mercury levels and the number of hours worked in the surgery[19,441].

In any case, exposure of both patients and dental personnel could be minimised by the use of appropriate clinical techniques such as wearing gloves and using proper ventilation and the use of dental amalgam in encapsulated form[19].

Adverse effects in individuals

Mercury exposure can cause different adverse health effects which can be local, systemic or psychological including neurological and kidney diseases, neuropsychological deficits or chronic fatigue, memory impairment and depression[19]. The paragraphs below discuss whether dental amalgam can induce these adverse health effects.

Localised mucosal reactions
Due to allergies or hypersensitivity, dental amalgam in direct contact with the oral mucosa can be responsible for mucosal lesions. Two relevant reaction patterns of allergies can be observed in dental surgeries: the delayed reaction (Type IV) and the immediate reaction (Type I). Allergic reactions can induce an inflammation and cause tissue damage (contact mucositis etc.). The reaction can be local or distant to the amalgam such as urticarial reactions, asthmatic seizures and anaphylaxis for example. In some cases, a strong allergy can occasionally be linked to a Burning Mouth Syndrome.

Chronic inflammatory response of the gingival tissue around restorations may appear as chronic gingivitis, recurrent necrotic gingivitis and periodontal pockets. Moreover, "amalgam tattoos", can occasionally be observed. These are associated with the iatrogenic introduction of small particles of dental amalgam into mucosal tissues. According to SCENIHR, there is no consequence to the presence of these "tattoos", except the blue coloured tissues[442]. Pigmented lesions represent an uncommon diagnosis in oral pathology routines. The most frequent entities are "amalgam tattoo", melanotic macule, and nevus. Patients are usually middle-aged women presenting a small, long-lasting, macular lesion on the cheek mucosa[443]. Metals, including mercury, when they are in close contact with skin or mucosa, can cause contact dermatitis.

[441] Aaseth et al. (2018), Mercury exposure and health impacts in dental personnel. Environmental Research.
[442] Lau et al. (2001) in SCENIHR (2015 updated)
[443] Thalita (2018), Pigmented lesions of the oral mucosa: A cross-sectional study of 458 histopathological specimens. Oral diseases

Local adverse effects such as allergic reactions and other clinical feature characteristics can be induced by dental amalgam fillings but the incidence is low (<0.3% for all dental material in general) and can usually be readily managed[19].

Systemic adverse effects
Epidemiological studies presented in the SCENIHR report highlight the possible health effects of dental amalgam mercury on the organism: nervous, renal, immune, respiratory, cardiovascular, gastro intestinal, haematological and reproductive systems. Different studies have been analysed by the SCENIHR report and only few of them were identified as relevant. Many studies are based on an imprecise exposure assessment, an incomplete adjustment for covariates or do not take into account genetic polymorphism. These insufficient results meant that the SCENIHR could not draw clear conclusions.

When looking at potential systemic effects, elemental mercury is a well-known neurotoxin. In some scientific reports, the presence of dental amalgam has been suggested to be associated with a variety of systemic adverse effects, particularly developmental neurotoxicity as well as neurodegenerative diseases (Alzheimer's disease, Parkinson disease, etc.) and psychological or psychiatric diseases. Mercury accumulates in the human brain and the number of amalgam fillings is associated with the mercury concentration in the adult brain. SCENIHR concluded that dental amalgam may have a negative effect on the nervous system but there is no clear evidence. Moreover, according to SCENIHR, mercury from amalgam fillings may influence visual and auditory systems.

Inorganic mercury also constitutes a hazard to kidney function (clinically decreased function). Several studies presented by SCENIHR show that kidney function parameters can be influenced by mercury from amalgam but there is limited evidence that mercury from dental amalgam fillings affects clinical kidney function in patients. Long-term risk of kidney disease in humans needs to be studied further. Furthermore, as mercury is eliminated via urine, if the kidney function is decreasing, the ability to eliminate mercury and other substances is decreasing too.

Concerning the impact of mercury on the immune system, inorganic mercury exposure can cause adverse effects such as the modification of pro-inflammatory cytokine levels (allergy). However, there is no evidence that autoimmune disease can be provoked in humans by mercury from dental amalgam fillings but it seems that the level of Th1 type cytokines may increase. Mercury is classified as category 1B (reproductive toxin) but the conclusions of the SCENIHR report indicate that there is no reliable evidence on this topic.

More research is required to either confirm or refute the different findings. However, according to the SCENIHR report, epidemiological and clinical evidence concerning adverse effects of dental amalgam, especially in dental personnel, is difficult to identify. Indeed, in clinical studies, it is impossible to measure long-term retention in the brain and kidneys. Moreover, in relation to cumulative past mercury exposures from various origins (e.g. fish consumption), it is difficult to identify the exact source of mercury concentrations in urine and blood.

Adverse health effects in dental personnel
In some studies, dental personnel reported more health conditions, often involving the central nervous system but also respiratory disorders and other symptoms of intoxication, than control groups. Clinical symptoms reported by dental professionals

may be associated with low-level, long-term exposure to occupational mercury, but they may also occur because of ageing and stress[51,444].

Other epidemiological studies reported by the SCENIHR report show on the contrary that the incidence of reported adverse effects seems to be in the same order of magnitude amongst dentists and non-dentists. Dentists seem to be subject to more kidney disorders than control groups but this observation does not seem be correlated with mercury levels. Moreover, they do not show more cognitive symptoms than the control groups. Recent studies do not indicate that dental personnel (which in general, are subject to higher exposures than patients are), suffer from adverse effects that could be attributed to mercury exposure due to dental amalgam. Indeed, dentists can also be exposed to other substances including chloroform, ethanol or benzene which could influence the results of the studies[19].

Genetic predisposition of individuals and subpopulations

Based on mercury toxicokinetics and toxicity studies, it has been shown that genetic factors can contribute to individual susceptibility to mercury exposure and mercury toxicity in adults and children. For example, GSH (Glutathione) is an enzyme that plays a role in mercury tokicokinetics as GSH related genes have specificities to this substrate. Mercury metabolism is also linked to certain ligands, such as selenoproteins or metallothioneins. The genes of these proteins may influence the metobolisation and elimination of mercury in the human body[19].

Single nucleotide polymorphism in a series of genes appears to explain inter-individual differences in exposure biomarker concentrations[445]. In addition, polymorphisms in environmental-responsive genes can influence the levels of mercury biomarkers. These findings on the genotype can improve the ability to assess health risks relative to mercury and to identify vulnerable groups more precisely.

Potential health impacts of alternative materials

Different kinds of mercury-free restorative materials are now used in dentistry for direct or indirect restorations. Alternative materials are adhesive and are aesthetically superior to dental amalgam. Concerning clinical performance, it is scientifically known that composite restorations, glass ionomer have lower durability than dental amalgam in the long-term. The durability is the power to resist stress or force while longevity is the quality of being long-lasting. A study on several millions of restorations presented in the British Dental Journal showed that the survival percentage of restorations after 15 years is 41% for dental amalgam and 34% for composite resin, 28% for glass ionomer. However, crowns have a better survival percentage (53%)[446]. For restorations in posterior teeth, a scientific review in 2015 concluded that composite resin restorations have less longevity and more development of secondary caries compared to amalgam restorations. Concerning fractures, the study did not demonstrate significant statistical differences between the two types of restorations in the same time period[447].

Alternative materials are comprised of different mixtures of chemicals with various toxicological profiles, which interact in different ways with human tissues. The toxicity of some released chemicals (presence of organic compounds, formaldehyde, monomers

[444] Kuras et al. (2018), Biomarkers of selenium status and antioxidant effect in workers occupationally exposed to mercury. Journal of Trace Elements in Medicine and Biology 49.
[445] Parajuli et al. (2016), Genetic polymorphisms are associated with hair, blood, and urine mercury levels in the American Dental Association (ADA) study participants. Environmental research, 247-258.
[446] British dental journal (June 22, 2018), volume 224 n°12.
[447] Moraschini et al. (2015), Amalgam and resin composite longevity of posterior restorations: a systematic review and meta-analysis. Journal of dentistry, 43, 1043-1050.

derived from bisphenol A) are known whereas for others, like nanoparticles (particles with a size from 1 to 100 nm), toxicity remains uncertain[448].

Dental composites contain up to 60% of nano-sized filler particles[449]. Resin-based inorganic filler contains different nanoparticles such as pyrogenic silica (SiO_2) or Zirconium dioxide ((ZrO_2)-SiO_2). Cements such as zinc phosphate cements or hydraulic calcium silicate cements contain respectively zinc oxide (ZnO) or magnesium oxide (MgO) nanoparticles, and calcium silicates (Ca_2SiO_4) and aluminates ($CaAl_2O_4$). Pigments used can also be nanoparticles.

Nanoparticles are mainly produced as dust during intra-oral grinding/polishing and removal of materials. Dental personnel and patients may inhale nanoparticles that damage the lungs. Exposure measurements in dust of dental surgeries showed high concentration of airborne nanoparticles (between 38 and 70 nm) in dust during treatments, however more research is warranted. For the patient, nanoparticles can be released from restorations by wear or swallowing. A general loss of up to 50µm per year can be observed for all dental-restorative materials. Nanoparticles may end up in the intestine by ingestion, especially during removal of restorations. The quantities of nanoparticle uptake seems to be relatively low (0.2-0.4 µg daily with 20 restorations of 480 mm²) and comparable to the total normal daily uptake of nanoparticles (400µg per day). Nanoparticles of silver (AgNP) may also induce an increase of the toxicity of alternative materials[450].

If composite materials are not properly polymerised (mainly light curing or pre-heating composite materials), components can be eluted (removed with a solvent). The amount of released monomers depends on the restorative material composition, the treated teeth surface area and the type of filler particle treatment process[451]. One study demonstrated that composite materials placed in a liquid like ethanol over a long period of time can release small quantities of monomers. In the short-term, the risk related to monomer elution is relatively low but the risk related to long-term exposure is unknown and subsequent chronic exposure needs to be assessed[452].

According to the SCHENIR report, monomers involved in intra-oral placement and polymerisation are "highly cytotoxic to pulp and gingival cells in vitro and there is also evidence that some of them are mutagenic". In addition, several epidemiological cases reported allergic reactions caused by tooth-coloured restorative materials[19].

Composite dust particles can also release hazardous molecules such as the endocrine disruptor Bisphenol A (BPA)[453]. The health risks of the release of BPA are negligible according to the SCEHNIR. The safety of the release of BPA from dental materials is discussed in "The safety of the use of bisphenol A in medical devices" (2015)[454].

Dental personnel are the most exposed to these particles and should take preventive measures. Very limited scientific data is available concerning exposure of patients and dental personnel to these substances and thus more research is required[18].

[448] Priyadarsini et al. (2018), Nanoparticles used in dentistry: A review. Journal of Oral Biology and Craniofacial Research, Volume 8, Issue 1.
[449] Van Landuyt et al. (2013), Nanoparticle release from dental composites. Acta biomaterialia 10 365-374.
[450] Schmalz et al., 2018. Scientific update on nanoparticles in dentistry. International dental journal, 68, 299-305.
[451] Knezevic, Alena et al. (2018), Toxicology of Pre-heated Composites Polymerized Directly and Through CAD/CAM Overlay. Acta stomatologica Croatica vol. 52,3.
[452] Putzeys et al., 2018. Long-term elution of monomers from resin-based dental composites, Dental material 2018.
[453] Cokic et al. (2017), Release of monomers from composite dust. Journal of dentistry 60.
454 SCENIHR (2015) The safety of the use of bisphenol A in medical devices (https://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_040.pdf)

CONCLUSIONS

Mercury from dental amalgam is released to the environment (air, water and soil) mainly through leakages from dental surgeries, cremations and burials. According to the SCHER report, there are certain limitations imposed by the available scientific information to assess the environmental risks and indirect health effects from the use of dental amalgam in the EU. For this reason, the risks were assessed through different scenarios. In the worst-case scenario and in specific local conditions, the PEC can be above the annual average and Maximum Allowable Concentration (MAC) EQS for mercury in water, resulting in a risk of secondary poisoning due to methylation.

Dental amalgam is recognised by dentists and by the SCENIHR report to be an effective restorative material in terms of strength and longevity. It is a material of choice for certain types of restorations, especially in posterior teeth. However, the environmental risks cannot be ignored even if a precise measurement is not possible. These risks are present in all stages of the dental amalgam life cycle, from the placement of dental amalgam to the removal and disposal.

In relation to the potential health effects, the exposure of the general population to mercury occurs mainly due to mercury accumulated in fish and through inhalation (organic mercury, methylmercury) as well as due to direct exposure to dental amalgam (elemental mercury, inorganic mercury). In addition, mercury is released from natural deterioration of amalgam fillings (chewing, brushing, etc.). Dental personnel and patients with amalgam fillings are two groups with higher exposure levels; they are directly exposed to mercury, especially during placement and removal.

Exposure assessments are subject to significant variations due to differences in systemic availability of mercury after inhalation and ingestion. Individual factors influence mercury-release from dental amalgam fillings (such as gum chewing, tooth brushing, etc.). All exposure measurements are also subject to uncertainty (due to fish consumption, etc.) and may not reflect the true mercury concentrations in the target organs. In addition, there is evidence that there is risks of adverse effects (allergies, neurological diseases, etc.) caused by dental amalgam restorations but according to the SCENIHR, the risk of adverse health effects is low. Except for patients with allergic reactions, there is no general justification to clinically remove dental amalgam fillings from restored teeth. However, the assessment of the risks of dental amalgam and the risks of alternative materials requires additional scientific evidence (few data are available for alternatives and the composition is not always known). The choice of materials, dental amalgam or alternatives, should be adapted to the patient (children, pregnant women, etc.) and their use should take into account protection of health and the environment.

Appendix D Methodology and assumptions

The following section provides some key methodological elements that relate to the objectives of the collection of data at Member State and EU levels. In addition, it provides a description of the key assumptions applied on the quantification of the following aspects:

- Use of dental amalgam and alternative materials
- Market for dental amalgam and alternative materials
- Turnover of the manufacturing industry and dentists
- The life cycle of mercury deriving from the use of dental amalgam

For each of these areas the description of assumptions includes the sources of information and the rationale for their development and application.

Key methodological elements

The data and information used in the present study was collected from three different sources: literature reviews, an online survey and targeted interviews. The literature review included reports on different environmental and socio-economic aspects of mercury carried for the European Commission, reports published by UNEP, national reports and scientific papers. Especially for the scientific papers, the focus of the literature review was on the scientific papers published from 2015 onwards as the key objective of this exercise was to provide an update of the SCHER and SCENIHR reports[455]. Information on the National Action Plans were also used, mainly to assess the future trends on the use of dental amalgam as derived by the Member States plans to phase out or phase-down the use of dental amalgam by 2030[456].

In total, the survey was sent to 356 stakeholders from the dental sector as well as manufacturers of dental materials, Member State authorities and environmental agencies, solid waste and waste treatment facilities, crematoria, academia and NGOs. Responses were provided in written form (either through the online questionnaire or in word format) by 58 stakeholders from different fields. Thus, the overall response rate of the online survey was 16%. As shown in the figure below, responses were provided mainly by the water treatment sector (14) followed by environmental authorities (13), dental associations (12) and health authorities (10). A few responses were also provided by the water and wastewater sector, individual experts, a funeral facility and a manufacturer of dental amalgam separators. The questionnaire of survey is provided in Appendix F.

[455] Both the SCHER and SCHENIR reports were published in 2008 and updated in 2015

[456] To date only 14 out of the 28 Member States had submitted their NAPs (AT, BG, CY, CZ, DE, DK, FI, IE, LV, LT, NL, SE, SK, UK)

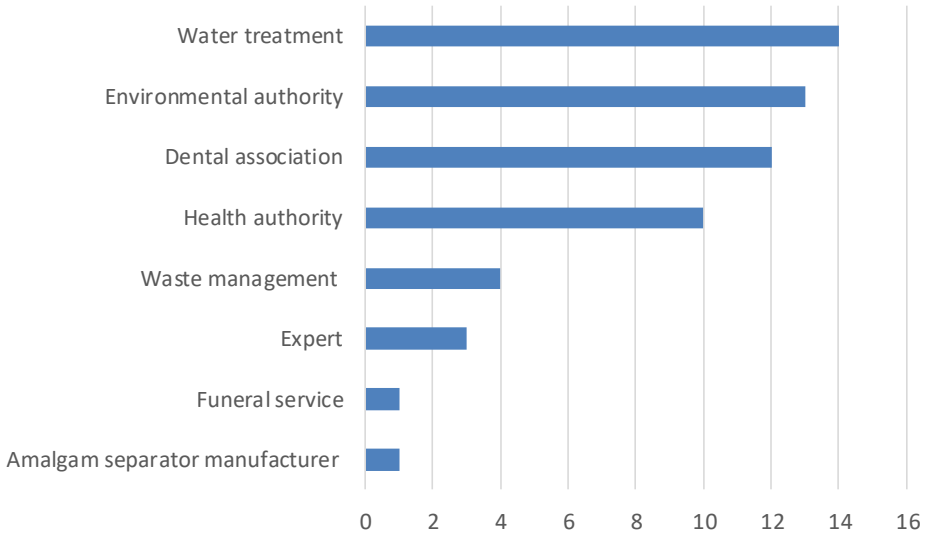


Figure 19: Number of responses per stakeholder category

The number of responses per country varied and, for some countries, no responses were received at all. Specifically, the countries that did not provide information through the survey were: AT, BG, FR, IT and RO. The amount of information received also varied significantly, as certain Member States had very limited information to provide. The project team collected additional information through interviews and literature searches. In total 56 different organisations were contacted with a request for interview. Eventually 23 interviews were carried out in total.

The information in this report has been updated based on the National Action Plans (NAPs) submitted by Member States[457]. Further expert opinions and information was collected during and after a stakeholder consultation that was carried out in Brussels on January 30 2020. In total 20 stakeholders provided comments in written.

Use of dental amalgam and alternative materials

This section provides an overview of the methodology for estimating the current dental amalgam use. The data on the use of dental amalgam and alternative materials is available, fully or partially, only for certain Member States. The data on the use of dental amalgam and alternative materials is available fully or partially, only for 14 Member States. Specifically estimates on the use of dental amalgam was provided only by BE, CY, CZ, DE, ES, FI, FR, HU, IE, IT, LV, NL, PT, SE and SI. Data is available either on the share of dental amalgam and the number of restorations performed with the use of dental amalgam (BE, CZ, CY, HU, IE, IT), or the share of dental amalgam restorations only (DE, ES, FI, FR, LV, NL, PT and SI). Only in IT and NL information on the total number of restorations and the use of dental amalgam is provided. In all other Member States, data exists only on the number of restorations that are reimbursed partially or fully by the national health systems. Further details on the data collected or reported by Member State authorities are provided in Appendix B.

In countries where no information was available, general assumptions were applied based on Member States for which data exists. For each Member State for which data does not exist, a specific reference country was selected based on similar geographical and socioeconomic characteristics including any existing measures to restrict the use of dental amalgam. The amount of amalgam usage was calculated based on the population

[457] To date (March 13 2020), the following NAPs have been submitted by AT, CY, BG, CZ, DE, DK, ES, FI, IE, LT, LV, NL, SI, SK and the UK

ratio with the reference countries. For example, it was assumed that if the population in one country is twice the population of the reference country, the use of dental amalgam is also twice the amount of the reference country. Only in CY, the amount of dental amalgam was estimated based on an expert opinion.

In addition, with the exception of DE, IT and NL, the existing data on the use of dental amalgam corresponds only to the restorations that are covered by the national reimbursement schemes, thus this estimate is conservative. According to the National Action Plan of the Czech Republic, for example, most patients prefer mercury-free materials when a restoration is not reimbursed by the health system. It therefore appears that even patients that do not have access to a national health system prefer mercury-free materials. The National Action Plan assumes that the vast majority of the dental amalgam fillings that are reimbursed by the national reimbursement schemes, correspond to the total amount of these fillings. Nevertheless, evidence shows that in other countries (DE and IE), dental amalgam restorations are done in private facilities and payed out of pocket. For this reason, with the exception of DE and IT the dental amalgam restorations refers to the treatments covered by the reimbursement schemes is considered as the minimum share. Nevertheless, it is also assumed that dental amalgam restorations are also selected over mercury-free restorations when the cost of restorations are covered by the patients. As there is no data on the number of non-reimbursable dental amalgam restorations (that correspond to the maximum usage), these are estimated based on assumptions that are applied in Member States.

The estimates are based on data transferred from one country to another with similar socio-economic characteristics by also taking into account any restrictions on the use of dental amalgam. Specifically, the countries have been grouped based on the following criteria:

- Possible restrictions in place concerning the use of dental amalgam (legal restrictions or recommendations by national authorities)
- Overall trends on the use of the dental amalgam
- Economic wealth

These criteria are applied in Member States where estimates on the use and demand of dental amalgam do not exist. Specifically, where data is not available, the average demand was calculated based on countries with available estimates that belong to the same group. The calculation is further based on the population correlation. For example, if in country A with a population of 10 million, evidence exists indicating that the demand is 2 t, in another country with a population of 5 million and with country A as reference, the demand is 1t.

The table below provides the reference countries used in the estimation for each of the Member States.

It must be noted that as the available information refer to restorations reimbursed by the national schemes only (except DE and IT), for the rest of Member States it was assumed that the total number of restorations covered is equal to the estimates of the BIO Intelligence Service study (2012). In this context, the total number of restorations performed with the use of dental amalgam and alternative-free materials is similar to the total number of restorations of the BIO Intelligence study (approximately 375 million restorations). Specifically, the present study estimates that the total number of restorations is equal to the 373 million restorations due to the update of the estimates in IT and DE as well as the introduction of HR (which was not included in the BIO study). The total number of restorations in HR was estimated based on the population correlation with SI.

The available data, assumptions and estimates are provided in the table below.

Table 181: Reported and estimated data on the number and share of restorations per type of material

Country	Use (kg) in 2018 (min)	Use (kg) in 2018 (max)	Comments on the estimated share	Number of restorations with dental amalgam (covered by the national health systems)	Number of restorations with alternative materials (covered by the national health systems)	Comments
AT	207	289	Assumed the same as in BE	Number of restorations with dental amalgam (covered by the national schemes)	Number of restorations with alternative materials (covered by the national schemes)	n.a
BE	229	321	Dental amalgam is used in 7% of restorations that are covered by the national reimbursement scheme. It is assumed that the share is smaller in restorations where the expenses are fully covered by the patients.	n.a	n.a	n.a
BG	640	2245	Assumed the same as in SI	400,049	5,162,138	Reported - Restorations covered by the national health system
CY	34	34	Based on expert opinion and under the assumption of the use of 850 mg per restoration	n.a	n.a	n.a
CZ	1492	1944	The maximum value represents the share of restorations covered by the national action plan	n.a	n.a	n.a

Country	Use (kg) in 2018 (min)	Use (kg) in 2018 (max)	Comments on the estimated share	Number of restorations with dental amalgam (covered by the national health systems)	Number of restorations with alternative materials (covered by the national health systems)	Comments
DE	2,591	3,628	According to the National Action Plan, the share of dental amalgam restorations reduced to around 5-7%.	2,287,499	n.a	Reported - Restorations covered by the national health system
DK	33	33	Assumed the same as in FI	n.a	n.a	n.a
EE	5	5	Assumed the same as in FI	n.a	n.a	n.a
ES	195	195	According the National Action Plan, dental amalgam is used only in 1% of the restorations	n.a	n.a	n.a
FI	29	29	Around 1% of the fillings in FI are performed with Dental amalgam	n.a	n.a	n.a
FR	3,251	16,256	According to ANSM the share of dental amalgam was around 25% in 2011. Given the current trends, it is assumed that the current trends are similar to the ones of Belgium that range between 5% and 7%.	n.a	n.a	n.a

Country	Use (kg) in 2018 (min)	Use (kg) in 2018 (max)	Comments on the estimated share	Number of restorations with dental amalgam (covered by the national health systems)	Number of restorations with alternative materials (covered by the national health systems)	Comments
GR	908	908	Assumed the same as in CY	n.a	n.a	n.a
HR	714	2,504	Assumed the same as in SI	n.a	n.a	n.a
HU	60	119		n.a	n.a	n.a
IE	421	534	Reported - The maximum refers to the restorations covered by the national health system. It is assumed that in private dentistry the share of dental amalgam restorations is lower	77,147	1,867,708	Reported
IT	811	811	Reported	222,241	176,278	Reported - only for the restorations covered by that national health system.
LT	535	697	Assumed the same as in CZ	n.a	n.a	n.a
LU	1	1	Assumed the same as in NL	n.a	n.a	n.a
LV	190	248	Assumed the same as in CZ	n.a	n.a	n.a
MT	33	33	Assumed the same as in CY	12,358	0	Reported -children only

Country	Use (kg) in 2018 (min)	Use (kg) in 2018 (max)	Comments on the estimated share	Number of restorations with dental amalgam (covered by the national health systems)	Number of restorations with alternative materials (covered by the national health systems)	Comments
NL	37	37	Reported in the Dutch National Action Plan	n.a	n.a	The total number of dental amalgam restorations (both covered by the national reimbursement schemes and covered at the expense of patients) in 2018 is estimated at 43,699 and those with mercury-free materials at 7,901,697.
PL	6,727	8,767	Assumed the same as in CZ. According to a rough estimate, currently According to a rough estimate, currently about 20% of restorations are carried out with the use of dental amalgam.	n.a	n.a	n.a
PT	45	342	Share of the use of dental amalgam covered by the national scheme only. The minimum is assumed the same as in ES (1%).	n.a	n.a	n.a
RO	3,447	12,084	Assumed the same as in SI	n.a	n.a	n.a
SE	0	0	Reported- dental amalgam is banned in SE	n.a	n.a	n.a
SI	360	1261	Reported on restorations covered by the national schemes only. The	n.a	n.a	n.a

Country	Use (kg) in 2018 (min)	Use (kg) in 2018 (max)	Comments on the estimated share	Number of restorations with dental amalgam (covered by the national health systems)	Number of restorations with alternative materials (covered by the national health systems)	Comments
			minimum is assumed the same as in CZ			
SK	871	1136	Assumed the same as in CZ	710,673	302,931	Reported - only for the restorations covered by the national health system.
UK	3,020	3,825	Assumed the same as in IE	n.a	n.a	n.a
EU28 (total)	**26,887**	**58,287**	-	-	-	-

It must be noted that as the available information refer to restorations reimbursed by the national schemes only. Therefore, it was assumed the number of restorations covered by the own expenses of the patients is equal to the difference between the number of restorations covered by the national reimbursement schemes and the estimates of the BIO Intelligence Service study. In this context, the total number of restorations per Member State, performed with the use of dental amalgam and alternative-free materials is equal to the number of restorations of the BIO Intelligence study (approximately 375 million restorations). Nevertheless, the estimates integrate the total number of restorations in DE, IT and NL as reported by the Member State authorities.

While data on the weight of mercury in used dental amalgam does not exist, the volume of mercury is calculated based on the assumption that on average, for each restoration **850 mg** of mercury is used[458].

Broadly, the Member States are grouped in three categories, based on the share of the dental amalgam restoration (absolute share or average share of the range):

- Group 1: high share of dental amalgam use (above 30%):
- Group 2: medium share of dental amalgam use (between 10% and 30%)
- Group 3: low use of dental amalgam (below 10%)

For the Member States with a low use, the share is in practice always below 7% and in certain countries, the use is equal to only 1 kg a year.

For Most Member States a range is of the dental amalgam use is assumed due to uncertainties on the estimates. For Member States with a low use of dental amalgam (i.e. below 3%) an absolute figure is applied as in general in these countries (or their reference countries) specific estimates are provided.

Table 182: Estimated use of dental amalgam in 2018 and number of restorations with dental amalgam and alternative materials

Country	Use (kg)	Share of dental amalgam (%)	Number of restorations with dental amalgam	Number of restorations with alternative materials
BG	640.3 – 2,244.8	20% - 70%	753,321 – 2,640,897	1,125,707 – 3,013,283
HR	714.4 – 2,504.5	20% - 70%	840,482 – 2,946,456	1,255,954 – 3,361,927
RO	3,447.1 – 12,084.3	20% - 70%	4,055,366 – 14,216,790	6,060,039 – 16,221,463
SI	359.7 – 1,260.9	20% - 70%	423,134 – 1,483,371	632,301 – 1,692,538

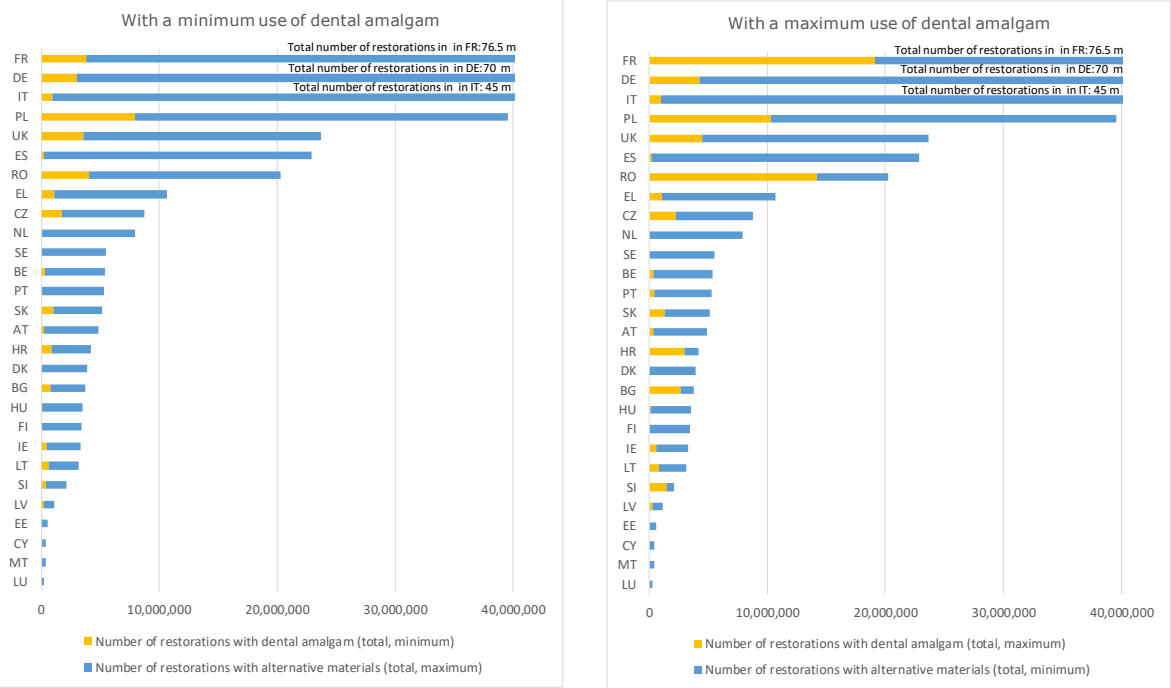
[458] This amount was assumed in the BIO Intelligence Service (2012) Study on the potential for reducing mercury pollution from dental amalgam and batteries that assumed that the amount of 600mg of mercury is used per restoration. In addition, according to Agdembo, A. O.; Watson, P. A.; Rokni, S. (2004): Estimating the weight of dental amalgam restorations, the use of mercury ranges between 480 and 710 mg, thus also corresponding to approximately 600 mg. However, these estimates do not include the amount of mercury that is wasted. According to an expert opinion provided in the context of this study it is estimated that approximately 30% of mercury is wasted during the restoration process. This increases the average amount of mercury per filling at 850 mg with approximately 250 mg being wasted.

Country	Use (kg)	Share of dental amalgam (%)	Number of restorations with dental amalgam	Number of restorations with alternative materials
CZ	1,491.9 – 1,944.4	20% - 26%	1,755,146 – 2,287,499	6,488,232 – 7,020,585
LT	534.7 – 696.9	20% - 26%	629,035 – 819,828	2,325,348 – 2,516,141
LV	190.3 – 248.1	20% - 26%	223,931 – 291,851	827,802 – 895,722
PL	6727 – 8,767.4	20% - 26%	7,914,175 – 10,314,622	29,256,254 – 31,656,701
SK	871.3 – 1,135.6	20% - 26%	1,025,061 – 1,335,972	3,789,334 – 4,100,245
IE	421.3 – 533.6	15% - 19%	495,643 – 627,814	2,676,472 – 2,808,643
UK	3,019.7 – 3,825	15% - 19%	3,552,632 – 4,500,000	19,184,211 – 20,131,579
FR	3,251.3 – 16,256.3	5% - 25%	3,825,000 – 19,125,000	57,375,000 – 72,675,000
CY	34	10%	39,995	359,959
EL	907.9	10%	1,068,074	9,612,662
MT	33.3	10%	39,149	352,337
AT	206.8 – 289.5	5% - 7%	243,243 – 340,541	4,524,325 – 4,621,629
BE	229.4 – 321.2	5% - 7%	269,905 – 377,867	5,020,229 – 5,128,191
DE	2,591.4 – 3,628	5% - 7%	3,048,750 – 4,268,250	5,6706,750 – 5,7926,250
PT	45 – 342.2	1% - 8%	52,974.1 – 402,603	4,894,804 – 5,244,433
HU	59.8 – 118.5	2% - 4%	70,313 – 139,455	3,376,170 – 344,5313
IT	810.6 – 810.6	2.2%	953,662	4,4046,338
DK	33.3	1%	39,150	3,875,850
EE	4.9	1%	5,739	568,174
ES	194.7	1%	22,9018	2,2672,762
FI	29.2	1%	34,374	3,402,987

Country	Use (kg)	Share of dental amalgam (%)	Number of restorations with dental amalgam	Number of restorations with alternative materials
LU	1.1	0.5%	1,250	248,771
NL	37.1	0.5%	43,699	7,901,697
SE	0	0%	0	5,508,000

Based on these estimates and assuming that each dental amalgam restoration uses on average 850 mg of mercury, the following figures provide an estimate with respectively a minimum and a maximum use of dental amalgam.

Figure 20: Number of restorations per filling material per Member State with an average use of dental amalgam (million, 2018)



Trends

As regards trends in the use of dental amalgam, available information exists for 21 Member States (from the study survey and NAPs). As shown on the table below, overall there is a declining trend in all countries.

Table 183: Trend on the use of dental amalgam as indicated by the study survey

Country	Trends
AT	The NAP sets measures for a phasing-down of dental amalgam. Outside the scope of the Mercury Regulation, certain uses are not recommended (i.e.in patients with impaired renal function or progressive degenerative diseases of the peripheral or central nervous system).

Country	Trends
BE	The proportion of restorations with dental amalgam to the total number of restorations decreased from 100% in 2006 to 20% in 2014 and 7% in 2018.
BG	The NAP is setting measures for a phasing-down of dental amalgam, including an amendment of the dentistry curriculum to educate students, dentists and public about the use of alternatives and environmental and human health impacts of dental amalgam use.
CY	There is a declining trend of dental amalgam use in the country. In addition, the NAP is setting measures for a phasing-down of dental amalgam.
CZ	The use of dental amalgam in Czech Republic between 2013 and 2016 has dropped by approximately 22% (on average 7% per year). According to the Czech Chamber of Dentists new dentists are gradually using more and more alternatives and therefore, this trend is expected to increase.
DE	The use of dental amalgam is declining. In 2013, it was reported that it represented 10% of total restorations and 5% in 2018.
DK	The use of dental amalgam decreased from 22% of dental fillings in 2007 to 1.7% in 2017.
EE	Dentists use dental amalgam rarely.
EL	There is declining trend in the use of dental amalgam in the country.
ES	Currently dental amalgam is used only on 1% of the dental restorations. According to the National action Plan, the use of dental amalgam will be reduced by limiting its use only to fulfil specific medical needs.
FI	In Helsinki City Clinics (where 5% of the country's dentists work), dental amalgam use decreased by 94% in 4 years, going from 1,110g in 2014 to 60g in 2018.
FR	Overall there is a declining trend in dental amalgam restoration explained by greater use of alternatives.
HR	N/A
HU	N/A
IE	The use of dental amalgam has been dropping by 5% per year between 2013 and 2017 for the restorations that are covered by the national health system
IT	The use of dental amalgam is dropping by approximately 12% per year

Country	Trends
LT	The use of dental amalgam is dropping. Over the last decade dentistry students are no longer trained to work with dental amalgam. This indicates that the use of dental amalgam will eventually cease as the retired dentists will be replaced by new ones.
LU	N/A
LV	N/A
MT	N/A
NL	The Dutch dentistry faculties have stopped teaching students to use dental amalgam since 1997. As a result of the policy measures, the use of dental amalgam was reduced in The Netherlands to 0.5% in 2018. More recent data has not been identified.
PL	According to a rough estimate, currently about 20% of restorations are carried out with the use of dental amalgam.
PT	N/A
RO	N/A
SE	The use of dental amalgam has been banned since 2009.
SI	Between 2013 and 2018, the use of dental amalgam has dropped by approximately 20%.
SK	Dental amalgam is still preferred to alternative materials for dental restorations.
UK	Dental amalgam is preferred to alternatives, but recent years have seen a shift towards the use of composite resins.

Quantitative data on the trends in dental amalgam use is available for certain Member States. These estimates are provided in the following table. It must be noted that the trend increases in 2018 due to the implementation of Article 10(2) of the Mercury Regulation which bans the use of dental amalgam for dental treatment of deciduous teeth, for children under 15 years and for pregnant or breastfeeding women except in some specific cases.

Table 184: Trends on the use of dental amalgam

Country	Average change per year until 2017	Change between 2017 and 2018	Annual average change

BE	-15.5%	-22.6%	-19.0%
CZ	-7.0%	-10.0%	-8.5%
NL	-18.4%	-20.3%	-19.4%
IE	-4.6%	-9.6%	-7.1%
SI	-3.1%	-5.5%	-4.3%

Based on these trends, the evolution of the use of dental amalgam and alternative materials until 2030 was estimated assuming that no further policy intervention will take place but that current policies continue to be implemented (i.e. the requirements of the Mercury Regulation and phasing down measures that are put forward in the adopted NAPs). These estimates assume that the trends will follow a decrease by a certain annual percentage, based on the available trends in BE, CZ, NL, IE and SI.

The reference countries for the correlation of the annual trends of countries with no available estimates with those where quantitative estimates exist are provided in the table below.

Table 185: Reference countries for the estimation of the evolution on the number of restorations with the use of dental amalgam and alternative materials

Country	Reference country
AT	BE
BE	N/A
BG	SI
CY	SI
CZ	N/A
DE	BE
DK	NL
EE	BE
ES	NL
FI	BE
FR	BE
EL	CZ
HR	SI
HU	SI
IE	N/A
IT	NL
LT	BE
LU	BE
LV	BE
MT	BE
NL	N/A
PL	CZ
PT	BE
RO	SI

SE	NL
SI	N/A
SK	CZ
UK	IE

Market of dental amalgam and alternative materials

The study survey included questions on the market aspects as well as imports and exports. Nevertheless, data on sales of restoration materials was identified for Italy only and, in that case, the information does not cover the entire Italian market. Due to the lack of data on the EU market of restoration materials, the project team explored different databases and sources of information, including the following:

- Eurostat: NACE code 32505010 - Dental cements and other dental fillings; bone reconstruction cements
- ORBIS: NAICS code 2017 339114 – Dental equipment and dental materials
- Market reports from Euromonitor and Gartner
- The study conducted by BIO in 2012[459]
- The study conducted by COWI and ICF in 2017[460]
- The study conducted by ICF, COWI and BIBRO in 2015[461]

The classification codes available in Eurostat and ORBIS are highly aggregated and do not allow an estimation of the market for each restoration material. In addition, neither Euromonitor nor Gartner provide any data on the dental market. The reports conducted by BIO, ICF, COWI and BIBRO do not provide market data specifically on dental amalgam but only on the total amounts of mercury regardless their application.

Given these data gaps, the project team applied the following assumptions:

- The sales of the materials in the EU28 corresponds to the respective number of restorations per material
- A general assumption is applied on the imports and exports (see paragraphs below)

The table below provides an estimation of the prices of restoration materials in three countries. The prices in LT and MT were provided by the health authorities in the study survey and the ones in the UK are estimates of the project team, based on online search. The average of the prices in these countries are assumed as the EU average.

Table 186: Average prices of restoration materials in the EU

Material	Prices in Lithuania (EUR)	Prices in Malta (EUR)	Prices in the UK (EUR)	Average (EUR)
Dental amalgam	**4.0**	**2.0**	**1.2**	**2.4**
Composite resins	6.7	6.0	3.1	**5.3**
Glass ionomer cements	6.7	2.0	4.0	**4.2**
Compomers	4.2	3.0	4.0	**3.7**

[459] BIO Intelligence Service (2012), Study on the potential for reducing mercury pollution from dental amalgam and batteries (http://ec.europa.eu/environment/chemicals/mercury/pdf/review_mercury_strategy2010.pdf)
[460] COWI and ICF (2017) Support to assessing the impacts of certain amendments to the Proposal of the Commission for a Regulation on Mercury
[461] COWI, ICF and BIBRO (2015), Study on EU Implementation of the Minamata Convention on Mercury

Average of alternative materials	**5.9**	**3.7**	**3.7**	**4.4**

Turnover of dentists

The table below provides an estimate of the prices per restoration, both for dental amalgam and alternative materials. The abbreviation N/A indicates that an estimate for the respective Member State has been provided through the study survey. For the rest of the countries the estimate is based on a specific country with similar health price indices provided by Eurostat[462]. Then the correlation of these indices is used to estimate the price in a given country[463].

Table 187: Prices per restoration and type of material in dental clinics (EUR, 2018)

Country	Price per restoration (dental amalgam) (EUR)	Price per restoration (alternatives) (EUR)	Reference country
AT	97.5	97.5	N/A
BE	52.5	52.5	N/A
BG	13.0	13.1	CZ
CY	60.0	60.0	N/A
CZ	19.2	19.3	N/A
DE	48.2	75.0	FR
DK	54.2	60.6	N/A
EE	28.3	28.5	CZ
ES	46.1	46.1	FR
FI	50.0	50.0	N/A
FR	40.0	40.0	N/A
EL	50.0	60.0	N/A
HR	23.0	23.2	CZ
HU	20.4	20.6	CZ
IE	50.0	51.5	N/A
IT	125.0	175.0	N/A
LT	19.9	20.0	CZ
LU	58.0	71.0	DK
LV	15.0	25.0	N/A
MT	70.0	70.0	N/A
NL	45.0	67.3	N/A
PL	19.0	19.1	CZ

[462] Eurostat, Purchasing power parities (PPPs), price level indices and real expenditures for ESA 2010 aggregates [prc_ppp_ind], Health price level indices 2018 (EU28=100)

[463] For example, in BG the health price index is equal to 30.1 and in CZ is equal to 44.3 (EU28=100). Therefore, to estimate the prices in BG, the prices of CZ are multiplied by 0.68.

Country	Price per restoration (dental amalgam) (EUR)	Price per restoration (alternatives) (EUR)	Reference country
PT	33.7	33.7	FR
RO	13.9	14.0	CZ
SE	N/A	105.0	N/A
SI	26.0	48.5	N/A
SK	22.7	22.9	CZ
UK	42.7	45.8	N/A
EU 28	40.8	50.5	

It is assumed that the prices listed above will also remain stable. Nevertheless, as the experience from Sweden showed, the skills of dentists in handling mercury-free filling materials are improving, and this reduces the restoration times for mercury-free materials. A potential reduction of prices is not considered in the estimates of the turnover of dentists until 2030 (under the BaU scenario of the policy options) due to uncertainties on the evolution of prices in general.

It must be highlighted that in most cases the prices indicated refer to the reimbursable costs (i.e. caps), and not to the actual prices charged to the patients. In IT where in general the price of restorations is not reimbursed, the difference between dental amalgam restorations and mercury-free materials is significant. In addition, according to expert opinion, in DE the additional price of composite restorations ranges between 20 to 80 EUR. However, in CY where there is also no reimbursement for dental fillings, the prices are the same, regardless of the restoration material. In addition, the prices of mercury-free materials refer primarily to composite and glass-ionomers. The cost with the use of ceramics can reach up to 570 EUR per filling.

Overall it is noted that costs and prices take into account many other factors (e.g. labour), not just the cost of materials.

Cost for patients and the national reimbursement schemes

The present study collected information on the reimbursement schemes that apply in all Member States. Information was provided for 16 out of the 28 EU Member States. As shown in the table below, from the available information, it appears that the reimbursement schemes differ significantly between Member States. Certain countries do not provide any reimbursements (i.e. GR, EE, IT and MT) whereas others reimburse the full cost of restorations. As regards the difference between Member States, there does not appear to be a significant difference between the reimbursements of materials except for CZ where only dental amalgam restorations are reimbursed. The table also provides some key information in relation to the coverage provided by the national reimbursement schemes, as well as the share of the population that is covered by these schemes. Further details and sources are provided in Appendix B.

Table 188: Share of reimbursement for dental amalgam and mercury-free restorations (2018)

Country	Cost per restoration (EUR, dental amalgam)	Cost per restoration (EUR, alternatives)	Share of reimbursement per restoration (dental amalgam)	Share of reimbursement per restoration (alternatives)	Comments
AT	97.5	97.5	100%	100%	According to System of Health Accounts data, almost half (46%) of the total expenditure to dental practices is financed by social health insurance schemes. Almost all of the rest (50%) is recorded as household out-of-pocket payment. Full reimbursement on alternatives is provided only for front and canine teeth (or for children, pregnant/ breast-feeding women, patients with relevant allergies or renal insufficiency. For all other cases, 80% of the price is covered for a comparable amalgam filling.
BE	52.5	52.5	72%	71.50%	There is no difference in reimbursement based on the restoration materials used. The price depends on the size of the restoration, i.e. one, two, three or more fillings. Up to a maximum of two restorations per tooth per year are reimbursed. The figures in the table represent averages of types of restorations (e.g. one, two or three tooth surfaces)
BG	13.0	13.1	No data	No data	No data
CY	60.0	60.0	No data	No data	Dental care is not covered by health care system in Cyprus, with the exception of removable dentures (partial or full) which are provided to low income categories only. This applies only on public hospitals and health centres which in general represent only a small part of the health system in the country. Dental restorations that take place in private dental clinics are not reimbursed, neither partially or fully.

Country	Cost per restoration (EUR, dental amalgam)	Cost per restoration (EUR, alternatives)	Share of reimbursement per restoration (dental amalgam)	Share of reimbursement per restoration (alternatives)	Comments
CZ	19.2	19.3	100%	0%	The health system covers costs only for dental amalgam, and composite resins for patients under 18 years old. For adults, the full cost of restorations with the use of mercury-free materials are fully covered by patients.
DE	47.6	75	100%	100%	The prices are averages of reimbursable costs for dental services in the public health insurance system. IT is estimated that about 12% (6.510 million restorations) of the dental restorations in Germany are not reimbursed by the national health system. The costs for using a composite is fully reimbursed only in exceptional cases.
DK	54.2	60.6	16%	16.50%	Dental treatments are covered on average at 40% by public health care, and up to 65% for some diagnostic procedures. Dental services are fully covered for children and teens under 18.
EE	28.3	28.5	0%	0%	Dental health care is mainly provided by private dentists. Restoration fees are not regulated and there are no dental insurance schemes.
ES	46.1	46.1	No data	No data	According to the NAP, oral health care (with the exceptions of certain age groups) is not covered by the national health system, an in general is payed by the patients.
FI	50.0	50.0	60%	60%	The national social security system covers partially the costs of patients' dental restorations. It fully covers dental restorations for children under 18 years old in public clinics. For vulnerable people, social assistance may cover dental restorations depending on his/her

Country	Cost per restoration (EUR, dental amalgam)	Cost per restoration (EUR, alternatives)	Share of reimbursement per restoration (dental amalgam)	Share of reimbursement per restoration (alternatives)	Comments
					income. In public clinics, adult patients pay approximately 35% of the costs, against 85% in private clinics, without any reimbursement differentiation per restoration material.
FR	40.0	40.0	70%	70%	In most cases, the ffs of restorations are reimbursed by public healthcare insurance at a 70% rate. There is no differentiation between filling materials. Despite identical reimbursement schemes for the material, there is a higher reimbursement of dentists for mercury-free materials.
EL	50.0	60.0	0%	0%	
HR	23.0	23.2	No data	No data	Patients bear a share of the cost except for specific categories
HU	20.4	20.6	100%	100%	The cost of restorations are covered only in public dental facilities.
IE	50.0	51.5	No data	No data	The share of the population that is not equipped with a medical card (i.e. 68% of adults) use private dental facilities for their treatment. The prices in the table refer to restorations performed by the national health system. In salaried services material is paid for by the government; but for adults the cost of the material is covered by the restoration fee.
IT	125.0	175.0	0%	0%	In 2015, only 4% of dental care was provided within the National Health System.
LT	19.9	20.0	No data	No data	
LU	58.0	71.0	80%	80%	There is a state-funded healthcare system in Luxembourg that provides basic dental care for citizens. Within one calendar year and up to a total amount that, as of July 2018, stands at 60 euros, services included in the dentists' nomenclature are fully covered by

Country	Cost per restoration (EUR, dental amalgam)	Cost per restoration (EUR, alternatives)	Share of reimbursement per restoration (dental amalgam)	Share of reimbursement per restoration (alternatives)	Comments
					health insurance. Most basic dental treatments are eligible for 80-100% reimbursement.
LV	15.0	25.0	20%	20%	Dental services in Latvia are provided by public and private practices owned by individuals, groups of dentists or corporate entities. In order to provide state funded services (for children and other stipulated groups), dental service providers must have a contract with the National Health Service (NHS). Providers are then reimbursed for the dental services provided to eligible groups in accordance with the annually approved tariffs.
MT	70.0	70.0	0%	0%	Emergency dental treatment are provided for free in public hospitals or Maltese health centres (public service clinics) for children under the age of 16, all diabetics and people on social security (means tested). For private practice, the patient has to pay directly the dental treatment received. All restorations done privately are paid for by the patient out of pocket and there is no coverage.
NL	45.0	67.3	50%	50%	The majority of dental treatment for children (under the age of 18) is reimbursed by the national insurance. This insurance covers all restorations and total costs of the treatment (Article 2.7 of the Zorgverzekeringswet) 464. Restorations for people above the age of 18 are not reimbursed or instead are covered by additional health insurance schemes. The prices in this table, refer

[464] https://wetten.overheid.nl/BWBR0018492/2019-03-30/#Hoofdstuk2_Paragraaf1_Artikel2.7

Country	Cost per restoration (EUR, dental amalgam)	Cost per restoration (EUR, alternatives)	Share of reimbursement per restoration (dental amalgam)	Share of reimbursement per restoration (alternatives)	Comments
					to maximum tariffs that applies to dental treatment in The Netherlands, regardless of whether citizens are covered by health insurance or not.
PL	19.0	19.1	No data	No data	The national health system, finances dental care in the same way as general health care, that is, from insurance contributions. Even though dental coverage is comprehensive, access to care may be compromised given the low number of contracted dental practices
PT	33.7	33.7	No data	No data	No Information is available.
RO	13.9	14.0	No data	No data	According to a national expert, the national health system does not differentiate the reimbursement of dental amalgam and mercury-free fillings.
SE	0.0	105.0	N/A	67.50%	
SI	26.0	48.5	80%	80%	Dental services are partially covered (80%) and it is common for citizens to enrol in supplementary health plans. Dental services for children, adolescents and students are covered 100%. Social security pays 20% more for disabled insured. For children, adolescents and pregnant women there is no additional costs for resin-based composites in transcanine sector. Insured adults must pay out of pocket the difference between dental amalgam and resin-based composite fillings in front teeth.
SK	22.7	22.9	No data	No data	In Slovakia, the social security system covers only partially the cost of dental restorations, the other half is paid by the patients.

Country	Cost per restoration (EUR, dental amalgam)	Cost per restoration (EUR, alternatives)	Share of reimbursement per restoration (dental amalgam)	Share of reimbursement per restoration (alternatives)	Comments
UK	42.7	45.8	20%	20%	Unlike most other NHS provision, dentistry is subject to patient charges. NHS dental treatment, including restorations, is provided free of charge to those aged under 18, those aged 18 who are in full-time education, those who are pregnant or who have given birth in the last 12 months, and those in receipt of a specified set of social security benefits, such as for those on low incomes, pensioners on low incomes, disabled people and unemployed people.
EU 28	40.8	49.4	**48%**	**43%**	

The reimbursement schemes, together with the prices of dental restorations greatly affect dental patients. In the baseline scenario, it is assumed that any changes in the selected dental filling materials will affect the costs incurred by dentists for performing the restorations and it is assumed that any changes in such costs will be passed on to dental patients or the reimbursement schemes (i.e. depending on the respective coverage provided). However, the difference in the cost of materials is small; therefore, the main factor affecting the price differences are the differences in the labour costs.

The longevity of a filling can affect the cost difference between amalgam and mercury-free restorations over the long term. A shorter average lifetime of a dental filling requires more frequent restorations. There is a multitude of factors that affect the longevity including the type of filling material and the quality of the placement when composites are concerned. The BIO Intelligence Service Study referred to previous studies indicating diverging views on the differences on their lifetime. According the World Health Organisation (WHO), amalgam fillings used to have a longer average lifetime than composite fillings[465]. However according to the organisation, 'recent data suggest that RBCs (resin-based composites) perform equally well as amalgam' and 'composite resins have been reported to last 12-15 years'.

Revenue of manufacturers

The revenue of manufacturers was based on the number of restorations per year until 2030 and the prices of restoration materials (see Table 186). Note that this relates to revenue linked to dental amalgam and alternative fillings, not to total turnover of the businesses concerned.

Information available suggests that there are 63 dental fillings manufacturers in the EU of which three companies manufacture dental amalgam only (see table below). These companies are located in the CZ, IT and the NL (see table below). No information is available on the SME status of these companies.

[465] According to WHO, Future Use of Materials for Dental Restoration, the average lifetime for amalgam fillings was 10-15 years for dental amalgam fillings and 5-8 years for composites

Table 189 : Manufacturers of dental amalgam only

Company	Country
Bome s.r.o.	CZ
WORLD WORK SRL	IT
M&R Claushuis B.V	NL

Overall, there are more than 65,000 companies operating in the "Manufacture of medical and dental instruments and supplies" sector of which 219 are large companies (equating to about 0.3%)[466]. At the same time, large companies accounted for 56% of total turnover in the EU in 2016.

In the EU, SMEs accounted for 99.7% of companies in the sector and 44% of its turnover. Information is available on Eurostat for the CZ, IT and the NL suggesting a similar pattern except for the Netherlands, where large companies in this sector account for 13% of total turnover[467].

The table below provides a complete list of manufacturers of dental amalgam and mercury-free materials in the EU.

Table 190: List of manufacturers of dental amalgam and mercury-free materials in the EU

Company	Country	Dental amalgam	Mercury-free filling materials	Website	Types of materials
Edelweiss Dentistry Products GmbH	AT		X	www.edelweiss-dentistry.com	Composites
GC EUROPE N.V.	BE		X	www.gceurope.com	Composites, glass ionomers
SpofaDental a.s.	CZ		X	www.spofadental.com	Composites, glass ionomers
Bome s.r.o.	CZ	X		www.bome.cz	
SAFINA, a.s	CZ	X	X	www.safina.cz	Gold alloys
3M ESPE AG	DE		X	www.3mespe.de	Composites, glass ionomers
ACTEON Germany GmbH	DE		X	www.de.acteongroup.com	Composites
Bisico Bielefelder Dentalsilicone GmbH & Co. KG	DE	X	X	www.bisico.de	Composites
Coltène Whaledent GmbH + Co. KG	DE	X	X	www.coltenewhaledent.com	Composites
Creamed GmbH & Co. Produktions- und Handels KG	DE		X	www.creamed.de	Composites
Cumdente GmbH	DE		X	www.cumdente.de	Composites
DC Dental Central Großhandelsges. mbH	DE	X	X	www.dental-central.de	Composites, glass ionomers, ceramics
DENTSPLY DeTrey GmbH	DE	X	X	www.dentsply.de	Composites, glass ionomers, ceramics compomers
DMG Chemisch-Pharmazeutische Fabrik GmbH	DE	X	X	www.dmg-dental.com	Composites

[466] Source: Eurostat: Industry by employment size class (NACE Rev. 2, B-E) [sbs_sc_ind_r2]
[467] Source: Eurostat: Industry by employment size class (NACE Rev. 2, B-E) [sbs_sc_ind_r2]

Company	Country	Dental amalgam	Mercury-free filling materials	Website	Types of materials
Gesellschaft für Dentale Forschung und Innovationen mbH	DE		X	www.gdfmbh.com	Composites
Hager & Werken GmbH & Co. KG	DE		X	www.hagerwerken.de	Composites
Harvard Dental International GmbH	DE		X	www.harvard-dental-international.de	Glass ionomers
Heraeus Kulzer GmbH	DE		X	www.heraeus-dental.com	Composites
Dr. Ihde Dental GmbH	DE		X	www.implant.com	Composites, glass ionomers, ceramics compomers
Indigodental GmbH & Co. KG	DE	X	X	www.indigodental.com	Composites, compomers
Ivoclar Vivadent GmbH	DE	X	X	www.ivoclarvivadent.de	Composites, compomers
Jeneric/Pentron GmbH	DE		X	www.jeneric-pentron.de	Composites
KANIEDENTA GmbH & Co. KG	DE		X	www.kaniedenta.de	Composites, compomers
Kuraray Europe GmbH	DE		X	www.kuraray-dental.eu	Composites
M+W Dental Müller & Weygandt GmbH	DE	X	X	www.mwdental.de	Composites
Kaniedenta Dentalmedizinische Erzeugnisse GmbH & Co. KG	DE		X	www.kaniedenta.de	Composites, compomers
Merz Dental GmbH	DE		X	www.merz-dental.de	
S&C Polymer GmbH	DE		X	http://www.sc-polymer.com/	Composites
Voco GmbH	DE	X	X	www.voco.de	Composites, glass ionomers, compomers
R-dental Dentalerzeugnisse GmbH	DE		X	www.r-dental.com	Composites
SCHOTT Electronic Packaging GmbH	DE		X	www.schott.com/epackaging	Composites, compomers, glass ionomers
Shofu Dental GmbH	DE	X	X	http://www.shofu.de	Composites, compomers, glass ionomers
SPEIKO-Dr. Speier GmbH	DE		X	www.speiko.de	Composites
Tokuyama Dental Deutschland GmbH	DE		X	www.tokuyama-dental.de	Composites, compomers, glass ionomers
UP Dental GmbH	DE		X	www.updental.de	Composites
Willmann & Pein GmbH	DE		X	www.wp-dental.de	Composites, compomers, glass ionomers
Madespa S.A	ES	X	X	www.madespa.com	Composites
Laboratorios Normon	ES		X		Composites
Stick Tech Ltd.	FR		X	www.sticktech.com	Composites
ATO Zizine	FR	X	X	www.zizine.com	Composites, glass ionomers, adhesives
FAST SPLINT	FR		X	www.fast-splint.com	Composites
Générique International	FR		X	www.generiqueinternational.com	Composites
ITENA	FR		X	www.itena-clinical.co	Composites
Septodont Holding	FR	X	X	www.septodont.com	Composites
Dentoria SAS	FR		X	www.dentoria.com	Composites

Company	Country	Dental amalgam	Mercury-free filling materials	Website	Types of materials
DMP Dental Materials Ltd	GR	X	X	www.dmpdental.com	Composites
Kerr	IT	X	X	www.kerrhawe.com	Composites
OGNA SPA	IT		X	www.ogna.it	Composites
WORLD WORK SRL	IT	X		www.worldwork.it	
UAB "MEDICINOS LINIJA"	LT		X	www.i-dental.lt	Composites, glass ionomers
Cavex Holland BV	NL	X	X	www.cavex.nl	Composites, glass ionomers
GCP DENTAL B.V.	NL		X	www.gcp-dental.com	Glass ionomers
M&R Claushuis B.V	NL	X		http://www.mrclaushuis.com	
Nordiska Dental AB	SE	X	X	www.dental-im.com	Composites, compomers
Ardent AB	SE	X	X	www.ardent.se	Composites, compomers
ADVANCED HEALTHCARE LTD.	UK		X	www.ahl.uk.com	Composites, glass ionomers
MEDICEPT UK LTD	UK		X	www.mediceptdental.co.uk	Composites
Perfection Plus Ltd.	UK		X	www.perfectionplus.com	Composites
PSP Dental Co. Ltd.	UK		X	www.pspdentalco.com	Composites, glass ionomers
TECHNICAL & GENERAL Ltd.	UK		X	www.tgdent.com	Composites, glass ionomers
Uno Dent	UK	X	X	http://www.unodent.com	Composites, glass ionomers
Cookson Precious Metals Ltd	UK	Only amalgam alloy powders		www.cooksondental.com	Amalgam alloy powders (silver/copper/tin) (in bulk form and in capsules) and precious metal alloys for crown and bridge work

Imports and exports

No data was provided through the stakeholder survey on the imports and exports of dental amalgam and mercury-free materials. PRODCOM provides estimates of imports and exports as well as production for the NACE 2 code: 32505010 - Dental cements and other dental fillings; bone reconstruction cements. As highlighted above, this code is highly aggregated, as it does not only include dental filling materials. The PRODCOM statistics are presented in the table below.

Table 191: PRODCOM statistics on the imports, exports and production (EUR, code 32505010, 2017)

Country	Value of exports (EUR)	Value of imports (EUR)	Value of production (EUR)
Austria	34 848 050	47 049 860	:
Belgium	107 408 370	82 289 930	0
Bulgaria	619 870	3 916 620	0
Croatia	2 219 230	7 732 260	0
Cyprus	0	385 710	0
Czech Republic	6 380 140	12 843 390	Not available
Denmark	2 819 090	11 112 670	0
Estonia	443 030	1 917 950	0

Country	Value of exports (EUR)	Value of imports (EUR)	Value of production (EUR)
Finland	7 115 610	18 507 120	0
France	49 118 840	88 598 680	46 130 792
Germany	486 307 990	175 829 880	432 622 557
Greece	1 484 750	6 493 780	Not available
Hungary	576 510	4 572 070	556 730
Ireland	56 809 900	2 710 610	0
Italy	55 884 760	61 138 140	90 920 000
Latvia	76 130	2 276 730	0
Lithuania	3 677 750	5 466 760	1 106 755
Luxemburg	211 830	1 204 200	0
Malta	0	451 810	0
Netherlands	75 723 290	80 543 940	Not available
Poland	4 602 970	31 585 710	794 302
Portugal	339 210	9 527 840	Not available
Romania	1 804 410	16 375 880	Not available
Slovakia	829 890	5 051 860	0
Slovenia	5 363 080	7 977 260	0
Spain	12 064 790	65 514 070	2 043 933
Sweden	26 195 480	26 204 690	0
United Kingdom	62 053 350	75 793 330	4 982 428
EU28 total	**1 004 978 320**	**853 072 750**	**606 671 172**

The life cycle of mercury deriving from the use of dental amalgam

The following paragraphs provide an estimate of the annual mercury emissions to water, air and soil in 2018 together with the assumptions. Unless otherwise indicated, the assumptions derive from the BIO Intelligence study, as the review of the scientific articles did not identify any recent data. The average annual flows of mercury are also illustrated in Figure 21.

Out of the total amount of mercury used by dentists in the EU28 (estimated at 26.8 t – 58.3 t/year on average), it is assumed that approximately 70% of mercury from dental amalgam remains in patients' teeth while 30% does not remain in the teeth[468]. Specifically, the dental amalgam remaining in patients' teeth during the restorations ranges between 18.8 t - 40.8 t while the amount of 8.1 t – 17.5 t correspond to either the surplus amalgam that remains after the mixing process (4.5 t – 9.8 t) and the carved mercury that remains after the mixing process (3.3 t – 7.2 t). During the carving process an estimated amount of 0.2 t - 0.5 t is released to the air, mainly through drilling. Eventually the removed amalgam together with the surplus of dental amalgam is directed to chairside traps and amalgam separators. The removed amounts represent historical use of dental amalgam (i.e. fillings placed before 2018).

[468] The BIO study assumed that the amount of mercury remaining in patient's teeth corresponds to 75% of the total amount and the rest (25%) is wasted. These figures have been updated based on new evidence provided by an expert in the context of the present study

It is also estimated that approximately 13.2 t - 28.6 t of mercury was used in 2018 to replace old fillings. It can therefore be estimated that the removal of old fillings releases almost the same amount of mercury as is discharged in the wastewater during placement of new dental amalgam fillings. In total, the mercury content discharged to chairside traps and amalgam separators comprises some 3.3 t – 7.2 of carved amalgam plus some 13.2 - 28.6 t of removed amalgam, totalling about 16.5 t - 35.8 t/year of mercury. It must be noted that due to a significantly higher use of dental amalgam in the past, the current amount of mercury from failed fillings applied several years ago might be higher.

From the amount of dental amalgam that is directed to chairside filters and dental amalgam separators, 12.7 t – 27.4 t are assumed to be trapped in amalgam separators and 1.4 t - 3.0 t are released to the wastewater system. It is assumed that approximately 90% of dental clinics are equipped with amalgam separators with an average efficiency of 90%. During this process, it estimated that 0.9 t – 1.9 t are released to the air.

The mercury in solid waste in the present study is estimated at 20.5 t - 44.5 t. An amount of 4.5 t – 9.8 t derives from surplus amalgam from preparation in dental clinics; 12.7 t – 27.4 t is captured in amalgam separators; and 3.4 t – 7.3 t of mercury derives from lost and extracted teeth. The solid waste collected from amalgam separators is treated either as hazardous waste (71%), biomedical waste (5%) or non-hazardous waste (24%)[469]. The vast majority of the hazardous waste is sequestered or recycled (99%) and for biomedical waste, the treated amount corresponds to approximately 50%. The rest of the solid waste (including when treated as non-hazardous waste) is emitted to the air or discharged to water, soil and/or groundwater. An additional amount of 2.1 t is placed in the soil and groundwater through burial.

A significant amount of mercury emissions to the air arise during cremations and during incineration of dental amalgam solid waste. If on average, the content of mercury in each deceased person is 1g and about half of the crematoria are equipped with abatement technologies, it is estimated that the emissions of mercury are approximately 1.6 t. Other sources of atmospheric emissions include releases from dental facilities during the dental restoration processes including drilling (0.2 t - 0.5 t) and releases from existing restorations (0.6 t – 1.3).

For the estimates of the prospective environmental impacts associated with the dental amalgam use under the different policy scenarios between 2018 and 2030 the following assumptions are applied:

- The removed amounts of dental amalgam (i.e. from dental amalgam restorations placed before 2018), will remain the same as in the BaU scenario.
- These estimates assume significant improvements in the efficiency of the amalgam separators as well as an increased number of installations of abatement technologies in crematoria. Specifically, it is assumed that as of 2025, the average efficiency of amalgam separators will increase from 90% to 95% while the amount of mercury that is captured in crematoria, will increase from 50% to 60%.
- Improvements are assumed in treatment methods of mercury collected from dental amalgam separators. While in 2018, it is assumed that 20% of the

[469] According to the BIO study, "In practice, even if the situation is improving, previous surveys have shown that not all dental clinics manage the waste in compliance with the legislation, i.e. it is sometimes mixed with municipal waste and/or with medical waste". However an improvement on the waste management treatment is assumed

collected waste is treated as non-hazardous waste, from 2019 onwards it is estimated that only 10% will be treated as a non-hazardous waste.

- A study in 2018, investigated the longevity of primary teeth restorations and the reasons for failure based on a review of a number of studies[470]. The review covered "the clinical performance of Class 1, Class II, and/or crown restorations due to caries with seven different materials: amalgam (6 studies), compomers (9 studies), composite resin (6 studies), conventional glass-ionomer cement (5 studies), modified resin glass-ionomer cement (4 studies) resin-modified glass-ionomer cement (10 studies) and steel crowns (3 studies)". According to the results of the review, the failure rate of dental amalgam restorations was estimated at 1–28% over three years. To this end, for the estimation of the environmental impacts in the present study it is generally assumed that approximately 14% of the amalgam restorations will fail after 3 years of their placement. This failure rate is considered in the BaU scenario and the policy scenarios. It is further assumed that all failed fillings will be restored with the use of dental amalgam.
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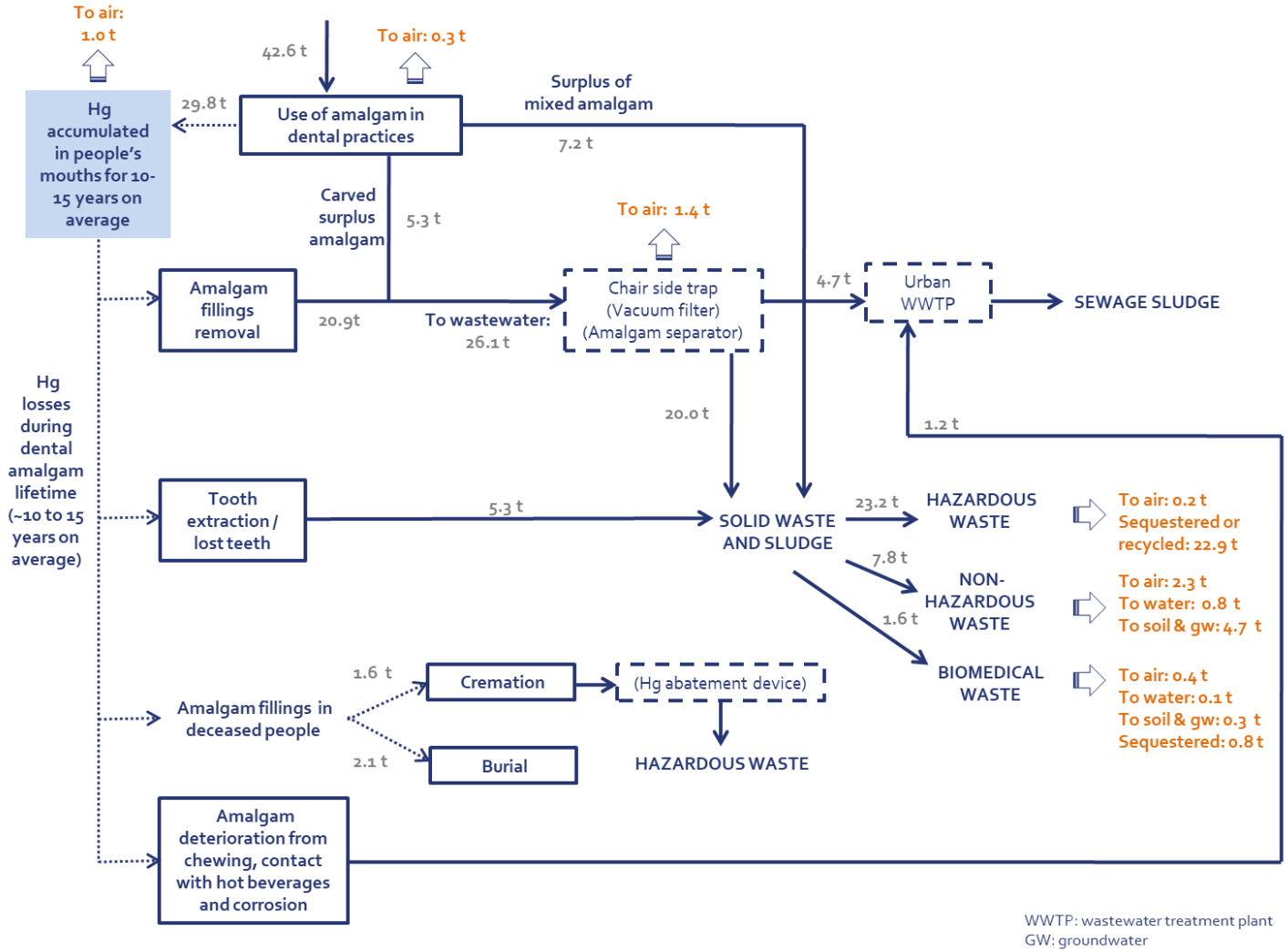
Figure 21: Flows of mercury from dental amalgam in 2018



Appendix E National measures to restrict the use of dental amalgam

This appendix provides a summary of the key findings of the Member State survey in relation to the following aspects:

- National measures that affect the use of dental amalgam and treatment of dental amalgam waste in each Member State
- Cases of current and prospective dental amalgam bans
- Summaries of the key characteristics of the national health systems, particularly in relation to costs and reimbursements

Each of the three aspects above are considered as vital for the performance of the feasibility assessment. Specifically, the national measures that affect the use of dental amalgam and particularly those that have banned or plan to completely phase-out dental amalgam will provide the basis for the estimate of the environmental and socio-economic impacts of a dental amalgam phase-out at EU level. Similarly, the structure of the national health systems and especially the coverage of the reimbursement schemes per type of restoration material will allow the calculation of any additional costs to be imposed by a prospective phase-out as well as the identification of how the coverage of these costs will be distributed within the Member State societies.

The sections below provide a synthesis of the findings on the three aspects above. The draft Member State reports are provided in Appendix B.

NATIONAL MEASURES

The table below provides an overview of existing and planned measures of Member States to address the use of dental amalgam and the treatment of waste from dental amalgam. The table includes only measures that exceed the requirements of the existing EU legislation particularly in relation to the following:

- EC Directive 86/278/EEC, on the protection of the environment, and in particular of the soil (i.e. concerning the concentration of mercury in sludge from wastewater treatment facilities)
- Directive 91/689/EEC of 12 December 1991 on hazardous waste (i.e. concerning the collection and treatment of dental amalgam waste from dental amalgam separators)
- Requirements that are already stipulated in the Mercury Regulation, in relation to the required efficiency of dental amalgam separators that are put on the market as of 1 January 2018
- Implementation of Recommendation 2003/4 on the air emissions from crematoria (concerning the OSPAR signatories only)

Table 192: National and regulatory measures exceeding EU requirements

Country	Measures on the use of dental amalgam	Measures on the treatment of waste from dental amalgam
AT	From the 1st of July 2018 dental amalgam can no longer be used for: • In patients with impaired renal function or progressive degenerative diseases of the peripheral or central nervous system amalgam is not indicated. Dental amalgam must also not be used: • for retrograde root fillings; • as material for stump abutments under crowns or bridges; • as sealing material for cast crowns.	In Austria, dental treatment facilities must be equipped with separators which recover more than 95%.
BE	n.a	Installation of separator (with certificate according to quality standards); maximum daily average of total mercury concentration in wastewater from dental clinics: 0.3 mg/l.
BG	The Bulgarian NAP emphasises the need for data collection, providing information to dentist students as well the need for increased prevention on oral health and provide more information on risks of dental amalgam to the population.	n.a
CY	The Cypriot government plans to phase-down dental amalgam. By 2025, the use of dental amalgam will be phased-out for all patients under 18 years of old (with certain exemptions). In the same year the country plans to assess the feasibility for a complete phase-out for all patients, again with certain exemptions.	Waste management companies are obliged to collect and export waste from amalgam separators, as no treatment method is available in Cyprus currently. The NAP envisages the development of a certification process to ensure that amalgam separators, have a minimum efficiency of 95% and that they are properly installed and maintained.

CZ	The NAP envisages that by 2030, the use of dental amalgam will represent only 1% of the total number of restorations.	The NAP envisages the installation of filtration systems in crematoria and the decontamination of the wastewater system.
DE	The German NAP calls for a phase-down of dental amalgam by 2030.	In Germany, the emmissions of mercury from crematoria and the discharges to water are regulated.
DK	The Danish Statutory Order on the ban of import, sale and export of mercury and mercury-containing products no. 73 of 25 January 2016 prohibits inter alia the use of mercury in products for dental fillings. Exempt from this ban are products for fillings in permanent molars, where the filling is worn. This restriction on the use of mercury in dental fillings has been in force in Denmark since 1 January 1995.	n.a
EE	Guideline for restorative dentistry, 2018: recommendation to avoid using dental amalgam. The country is examining a ban on the use of dental amalgam by 2030 at the latest.	n.a
EL	Promotion of mercury-free materials in universities and institutions, as well as the dissemination of information on the use of composites and dental amalgam.	n.a
ES	According to the National action Plan, the use of dental amalgam will be reduced by limiting its use only to fulfil specific medical needs.	n.a
FI	The use of dental amalgam will be prohibited in 2030 (at the latest)	n.a
FR	The National Agency of Drugs Safety is planning to update its recommendation and propose the use of dental amalgam only when it is needed.	Order of 28 January 2010 on the height of the chimney of crematoria and the maximum quantities of pollutants contained in the gases released into the atmosphere.
HR	Publications of research in professional issues of Dental Section of Hungarian Medical Chamber and lectures on	Ordinance on medical waste management (OG No. 50/15) – general requirements.

	professional conferences, promoting the use of mercury-free materials.	
HU	n.a	Amalgam waste is collected and treated by specialized companies within Hungary.
IE	As part of new government contracts for primary care alternatives to amalgam will be promoted as the preferred restoration. An evidence synthesis of restorative materials and interventions for different age groups has been recently completed by the Irish Health Research Board. This will inform future guidance on the preferred restorations in different settings.	Under the existing EU Waste Directive 2008/98/EC there is a requirement in Ireland to separate & collect hazardous (amalgam) wastes.
IT	n.a	n.a
LT	n.a	Crematoria shall install abatement technique that ensure mercury emissions do not exceed 0.1 mg/m^3. Mercury emissions must be measured periodically, at least twice every year (average emission value calculated by taking 3 samples within single cremation).
LU	n.a	Requirements for mercury emissions from crematoria (Luxembourg is signatory of the Oslo-Paris Commission (OSPAR) agreement).
LV	The "National Plan on measures to phase down the use of dental amalgam for 2019-2020" has been developed in accordance with the Article 10(3) and currently subject to public consultation. The Plan stipulates three strategic measures including, the determination and Analysis of Amalgam Usage Indicators and training and further education of students, practitioners, public education on reducing amalgam use	Requirements are set for amalgam separators. Waste from amalgam separators must collected and treated by specialised treatment facilities licenced to handle hazardous wastes.
MT	n.a	Waste collection of amalgam sludge is carried out by licensed waste collectors and taken to the local environmental authority which disposes of it by sending it abroad.

NL	n.a	Activity Decree (registration of dental practices, the installation of amalgam separators in new and existing practices, the testing methods of dental separators, releases to surface water); Regulation providing a list of collectors, carriers, traders and mediators of waste (intake of mercury waste).
PL	n.a	n.a
PT	n.a	n.a
RO	n.a	n.a
SE	Dental amalgam ban since 2009	The Swedish environmental code applies to dental surgery management of waste. Maintenance of separators is required 1-2 times annually depending on use. Swedish dental surgeries are bound to the use of waste management services for waste collection from amalgam separators.
SI	n.a	n.a
SK	Plans to reduce the reimbursement of amalgam fillings even if they are the cheapest alternative. From 2030 onwards, dental amalgam will be reimbursed only in exceptional cases or when the patient wishes to have dental amalgam fillings.	The EU Hazardous Waste Directive is incorporated into law and actively enforced. Amalgam separators are legally required.
UK	The Scottish Dental Clinical Effectiveness Programme (SDCEP) developed implementation guidance on Article 10(2) of the European Commission Regulation (EU) 2017/852 on Mercury and patient information leaflets.	The Oslo-Paris Commission (OSPAR) agreement, of which the UK is a signatory.

The measures that address the use of dental amalgam, range from existing or planned bans (i.e. respectively SI and CY) to the provision of information or guidance that promote the use of mercury-free restoration materials over dental amalgam. FI, SK and DK have set in place (or in the case of Slovakia, plan to set) strict prerequisites that need to apply to allow the use of dental amalgam.

In relation to requirements on the management of dental amalgam waste, only a few measures have been identified so far that put forward specific requirements in relation to the collection and treatment of waste collected from dental amalgam separators, and which go beyond existing EU law (SE and NL). It must be noted that in certain cases (e.g. the Netherlands) the Member State authorities indicated that they are developing

specific measures for a dental amalgam phase down to be included in the National Action Plans. However, the details of these plans were not shared with the project team as they were still at a draft stage.

France has set specific requirements on crematoria that exceed the recommendations of OSPAR. Latvia, a non-OSPAR country, has also adopted these requirements.

Cases of dental amalgam restrictions

This section provides an overview of Member States where dental amalgam has been banned (or where a phase-out is planned) or restricted to specific cases. To allow a comparison between these countries and a country with a high use of dental amalgam, the case of the Czech Republic is also presented.

It must be noted that before the launch of the online survey at the EU level, the first draft of the template for the data collection was tested through three pilot cases to assess the following aspects:

- Required time for drafting
- Types of information that are particularly difficult to collect
- Identification of significant aspects not included in the draft template

Regarding the selection of the pilot cases, the following Member States were selected, each representing different situations with regards to the use of dental amalgam:

- Sweden where dental amalgam has been phased out
- The Netherlands where dental amalgam has been phasing down due to national measures and/or public awareness
- The Czech Republic where there has historically been a high use of dental amalgam, without national measures on phasing down

DENTAL AMALGAM BAN IN SWEDEN

Currently, the only country that has completely banned the use of dental amalgam in restorations (with only very specific exceptions), is Sweden. Table 193, below provides an overview of this ban.

Table 193: Overview of the dental amalgam ban in Sweden

Category	Description
Type of enforcement	- Voluntary: increase of environmental awareness - Mandatory: setting rules and regulations
Target	- Reduction of mercury levels in the environment
Achievements	- Reduction of mercury emissions from point sources (use of amalgam separators) - Phasing-out the use of mercury in dental alloys and processes and enhancement of alternatives' uses - Improvements of waste management (collect and treat mercury already in use) - Final disposal of mercury waste - No recycling of mercury

Category	Description
	- Ceasing of the production of dental amalgam by Swedish companies - Ceasing of the import and export of mercury and mercury compounds
Financial aspects	- Cease financial support from social insurance for dental amalgam
Challenges	Enhance international cooperation in phasing-out dental amalgam
Sources	http://www.naturvardsverket.se/Documents/publikationer6400/978-91-620-8691-6.pdf

In the 1980, concerns were raised in Sweden about the health and environmental impacts of dental amalgam. Scientific assessments were conducted and led the National Board of Health and Welfare to evaluate the preconditions to eliminate the use of dental amalgam in 1991. Then, in 1993, dental amalgam used in temporary teeth was phased out due to an agreement between the government and the county council associations. Another voluntary agreement in 1995 put an end to amalgam use in dental restorations for children and teenagers. The objective to phase-out dental amalgam was expanded to adult dental care in 1997. In 1999, the Swedish parliament decided to withdraw financial support for dental amalgam. The cost of amalgam fillings was no longer reimbursed under the national healthcare system and became comparable with the cost of alternatives. The quantities of mercury sold for amalgam decreased from 980 kg in 1997 to around 100 kg in 2003[471]. Since 2009, a general ban of mercury has been put in place, including dental amalgam, with some exemptions (e.g. individuals suffering from mental disorders). In 2018, these exemptions were withdrawn (the possibility to apply for onetime/short term dispensation remains).

Economic impacts of the ban
In 2011, the Swedish Chemicals Agency (Kemikalieinspektionen, KEMI) published an investigation of manufacturers' experiences on the phasing-out of mercury in dental amalgam put in place in 2009. The assessment of economic impacts (new charges, costs for changed processes, salary costs and investments in new plants and staff) on manufacturing companies for dental amalgam showed that there would not be negative impacts due to the phase-out period and new duties. The ban changed the market shares of filling materials and could potentially allow certain companies to grow and gain market share. The mercury ban induced initial costs for the activity changes and also administrative and practical impacts for companies, but these changes have a long term effect and according to KEMI, could improve competitiveness. The main positive impacts of the phasing-out of dental amalgam for companies identified by KEMI are: to provide a safer working place for employees, to increase efficiency and productivity and to reduce costs, especially environmental externalities[472].

RESTRICTION OF THE USE OF DENTAL AMALGAM IN DENMARK
The Danish Statutory Order on the ban of import, sale and export of mercury and mercury-containing products no. 73 of 25 January 2016 prohibits inter alia the use of mercury in products for dental fillings. Exempt from this ban are products for fillings in

[471] https://www.kemi.se/global/pm/2011/pm-2-11-phase-out-of-mercury.pdf
[472] https://www.kemi.se/global/pm/2011/pm-2-11-phase-out-of-mercury.pdf

permanent molars, where the filling is worn. This restriction on the use of mercury in dental fillings has been in force in Denmark since 1 January 1995.

An assessment commissioned by the Danish Health Agency named "phasing-out of amalgam in dental care - clarifying options and recommendations" concluded and recommended that the ban on the use of dental amalgam containing mercury be narrowed down even further, so that the amalgam should only be used as a filling in permanent molars in the following instances:

- Lack of possibility of drying
- Difficult accessibility of the cavity (especially large cavity)
- Large distance to neighbouring tooth

These recommendations have been included in the Danish Ministry of Health guideline on the use of dental fillings no 9552 of 5 July 2018.

High use of dental amalgam: The case of Czech Republic

In the Czech Republic, the health system covers costs only for dental amalgam, and composite resins for patients under 18 years of age. For adults, the full cost of restorations with the use of mercury-free materials is fully covered by patients. This is the main reason why the use of dental amalgam remains at high levels.

Nevertheless, the use of dental amalgam in the Czech Republic between 2013 and 2016 has dropped by approximately 22% (on average 7% per year). According to the Czech Chamber of Dentists, new dentists are gradually using more and more alternative materials and therefore this trend is expected to increase. The ban of use of dental amalgam for children and pregnant women resulting from the Mercury Regulation, which is effective as of 1 July 2018 is expected to further decrease the use of dental amalgam. The Czech Dental Chamber expects that, gradually, the use of dental amalgam will represent less than 1% of the dental fillings used in the country.

SPECIFICITIES OF THE NATIONAL HEALTH SERVICES

Table 194 below provides an overview of the cost of restoration per type of material as well as some key provisions of the Member State national health systems with a focus on the reimbursement schemes. Information has been received by or identified in almost all Member States, except of Croatia, Latvia and Romania. Nevertheless, the level of detail varies significantly from one country to another.

Table 194: Cost of restorations and coverage by the national health systems

Country	Cost of restoration	Coverage by the national health system
AT	N/A	Dental amalgam: 100% for back teeth Composite resins and compomers: 100% for front and canine teeth (or for children, pregnant/ breast-feeding women, patients with relevant allergies or renal insufficiency); 80% of the price for a comparable amalgam filling in all other cases Glass ionomer cements: 100% Ceramics: 80% of the price for a comparable amalgam filling in all other cases; 100% for patients with relevant allergies

Country	Cost of restoration	Coverage by the national health system
BE	All materials: 12 EUR – 63 EUR	In principle, there is no difference in reimbursement based on the restoration materials used. The price depends on the size of the restoration, i.e. one, two, three or more fillings. Up to a maximum of two restorations per tooth, per year are reimbursed.
BG	N/A	Approximately 48% of total health spending is funded by households themselves (2016). No data has been identified specifically on the dental sector.
CY	All materials: 50 - 70 EUR	Dental care is covered by the health care system in Cyprus, with the exception of removable dentures (partial or full) which are provided to low income categories only. This applies only to public hospitals and health centres which, in general represent only a small part of the health system in the country. Dental restorations that take place in private dental surgeries are not reimbursed, neither partially or fully. Overall, the price of the restorations are not affected by the type of material used.
CZ	Dental amalgam: 19.12 EUR Composites: 19.33 EUR	Dental restoration with dental amalgam is reimbursed 100%. Restorations with composites also receive a 100% reimbursement but only for children under 15 and pregnant women.
DE	Dental amalgam: 33-60 EUR	Statutory health insurances reimburse the costs of composite resin restorations for persons who suffer from an allergy to amalgam or a have renal insufficiency, for dental treatment of deciduous teeth of children under 15 years and of pregnant or breastfeeding women. Dental amalgam restorations are reimbursed at 100% of the total costs.
DK	Dental amalgam: 34 – 75 EUR Glass ionomer: 60 EUR	Dental treatments are covered on average at 40% by public health care, and up to 65% for some diagnostic procedures. Some other procedures such as dentures and crowns are not reimbursed. Restorations with the use of dental amalgam and glass ionomers receive a reimbursement that ranges, respectively, between 11% and 22% and between 8% and 25%. The exact amount of reimbursement depends on whether the material is not-combined, combined, or double-combined.
EE	N/A	For adults, there is 50% coverage and 85% in specific cases (persons over 63 years old, pregnant

Country	Cost of restoration	Coverage by the national health system
		women, persons with work incapacity, with medical conditions, etc.)
EL	Dental amalgam: 45-55 EUR Composite resins: 50-70 EUR Glass ionomer cements: 35-50 EUR Ceramics: 300-500 EUR	In Greece, the National Health System does not cover the cost of dental treatments. Therefore, patients are 100% responsible for all costs. The National Health Service provides (in Health Centres and Hospital Dental surgeries) limited numbers of dental services oriented mainly to pain relief cases. In these cases, the material used is predominantly dental amalgam.
ES	N/A	Spain has a universal national health system that has been decentralised to the regional level funded through taxation. In addition, people may choose to contract complementary private insurance.
FI	Dental amalgam: 50 EUR Composite resins, glass ionomer cements, compomers: 50 EUR Ceramics: 90 EUR	The national social security system covers partially the costs of patients' dental restorations. It fully covers dental restorations for children under 18 years old in public clinics. For vulnerable people, social assistance may cover dental restorations depending on their income. The reimbursement rate for dental restoration is equal whatever filling material is used. Patients pay approximately 35% of the costs in public clinics against 85% in private clinics, without any reimbursement differentiation per restoration material.
FR	All materials: 25 – 53 EUR	Conventional prices have been determined for a list of health care act and materials. Public services do not cover the total amount and will reimburse 70% of the conventional price except for specific condition such as CMU-C beneficiary (addressed to low income people), workplace accidents, etc. In addition to public insurance, people rely on grouped private insurance provided by the employers (50.8%), private insurance (29.3%) or pension funds (19.9%) with either individual contracts or collective contracts through their company.
HR	N/A	N/A
HU	N/A	Hungary has adopted a compulsory public health insurance scheme funded by active workers' contributions that fully covers conservative dental restoration provided by dentists affiliated with NEAK (EMMI and Hungarian medical chamber).

Country	Cost of restoration	Coverage by the national health system
		Hungarians may purchase additional private insurance that may cover private dental care with affiliated clinics. Private sector dental care is not reimbursed by NEAK. No statistics on the actual share of households contracting complementary private insurance is available.
IE	Dental amalgam: 50 EUR Composite resins: 51.50 EUR	For a dental treatment to qualify for tax relief it must be classified as a specialised treatment. Any treatments that fall under the category of routine care do not qualify for dental tax refunds. Routine dental treatments include things like tooth extractions, scaling and filling, as well as the repair of artificial teeth and dentures. In salaried services material is paid for by the government; but for adults the cost of the material is covered by the restoration fee.
IT	Dental amalgam: 100-150 EUR Composite resins: 150-200 EUR Ceramics: 340-400 EUR (onlay-inlay)	Health care is provided through the Italian national health system (SSN-Servizio Sanitario Nazionale). The SSN guarantees dental restorations to individuals of developmental age and to vulnerable people (the specific situations are indicated by national regulation). Various exemptions exist for people under specific medical conditions and income levels who can have small co-payments. It is not common for citizens to enrol in supplementary health plans that cover dental restorations. Dental care is mostly private in Italy (only 4% of dental care is provided within the National health system) so most of the population (more than 95%) pays for dental care out of pocket.
LT	N/A	N/A
LU	Dental amalgam: 38.6- 77.4 EUR	There is a state-funded healthcare system in Luxembourg that provides basic dental care for citizens. Within one calendar year and up to a total amount that, as of July 2018, stands at 60 euros, services included in the dentists' nomenclature are fully covered by health insurance. Most basic dental treatments are eligible for 80-100% reimbursement.
LV	Dental amalgam: 10.47-20.84 EUR Composite resins: 17.72-33.14 EUR Glass ionomer cements:11.36-20.01 EUR (deciduous teeth)	Dental services in Latvia are provided by public and private practices owned by individuals, groups of dentists or corporate entities. In order to provide state funded services (for children and other stipulated groups), dental service providers must have a contract with the National Health Service (NHS). Providers are then reimbursed for the

Country	Cost of restoration	Coverage by the national health system
	13.33-15.15 EUR(permanent teeth) Compomers:13.45-22.84 EUR (deciduous teeth) 15.66 EUR (permanent teeth)	dental services provided to eligible groups in accordance with annually approved tariffs: • 100% children (<18 y.o) • 50% Chernobyl victims and personnel • max 20% of 600 Euro per year (120 Euro) (adults) Dental services for adults do not receive any state funding and must be fully covered by the patients (using their own resources and/or private dental insurance). Nevertheless, all tax payers can recover 20% of annual healthcare payments including payments for dental restorations with a limit set at 120 EUR.
MT	Dental amalgam: 70 EUR Composite resins:70 EUR Glass ionomer cements: 70 EUR Compomers:70 EUR Ceramics : 250 EUR	Emergency dental treatment is provided for free in public hospitals or Maltese health centres (public service clinics) for children under the age of 16, all diabetics and people on social security (means tested). However, most dentists have their own private practices. For private practice, the patient has to pay directly for the dental treatment received. All restorations done privately are paid for by the patient out of pocket and there is no coverage.
NL	Dental amalgam: 24.07 EUR (single surface), 38.40 EUR (two surfaces), 49.86 EUR (three surfaces), 69.92 EUR (more than three surfaces) Composite resins: 45.85 EUR (single surface), 60.18 EUR (two surfaces), 71.64 EUR (three surfaces), 91.70 EUR (more than three surfaces) Compomers and Glass ionomer cements:35.53 EUR (single surface), 49.86 EUR (two surfaces), 61.32 EUR (three surfaces), 81.38	The majority of dental treatment for children (under the age of 18) is reimbursed by the national insurance. This insurance covers all restorations and total costs of the treatment. Restorations for people above the age of 18 are not reimbursed or instead are covered by additional health insurance schemes.

Country	Cost of restoration	Coverage by the national health system
	EUR (more than three surfaces)	
PL	N/A	Dental services available to the insured population are listed in the 2004 Law on Health Care Services Financed from Public Sources and the 2009 regulation of the Minister of Health delineating guaranteed dental benefits. These services can be accessed free of charge in any dental care institution contracted by the NFZ and include general dental care for children and adults, oral surgery and periodontics, orthodontic care for children under 18, dental prostheses, emergency dental care and preventive dental services for children and youths under 19.
PT	N/A	Currently almost all dental surgeries are private. The public services are just beginning to get established. A reimbursement is provided by surface, starting from a minimum amount and then it increases based on the amount and size of restorations. The exact coverage depends on the specific scheme.
RO	N/A	N/A
SE	Composite resins:60-150 EUR Glass ionomer cements:60-150 EUR Compomers: 60-150 EUR Ceramics: 570 EUR	There is no limit of pricing for dental care so dental fees vary. The reimbursement for dental care depends on the price of the restauration: • 50% up to 1 500 EUR • 85% above 1 500 EUR In 1999, the Swedish parliament decided to withdraw financial support for dental amalgam. The cost of amalgam fillings is no longer reimbursed under the national healthcare system. The cost of dental amalgam restorations became comparable with the cost of alternatives. Patients are required to cover a part of the cost before the high-cost protection scheme is activated (up to 300 EUR).
SI	Dental amalgam: 26 EUR Composite resins: 48.5 EUR	According to the Ministry of Health, Dental services are partially covered (80%) and it is common for citizens to enrol in supplementary health plans. Dental services for children, adolescents and students are covered 100%. Social security pays 20% more for disabled insured people. For children, adolescents and pregnant women there are no additional costs for resin-based composites in the transcanine sector. Insured adults must pay out of pocket the difference between silver

Country	Cost of restoration	Coverage by the national health system
		amalgam and resin-based composite fillings in the transcanine sector.
SK	N/A	In Slovakia, the social security system only partially covers the cost of dental restorations. The other half is paid for by the patients. There is only a small difference in the reimbursement of dental treatment costs between public and private social security. Among private practitioners, 85% have an agreement with insurance companies, 15% of them do not.
UK	Dental amalgam : 70 EUR Composite resins: 70 EUR Glass ionomer cements: 70 EUR Compomers: 70 EUR Ceramics: 304 EUR	The National Health Service (NHS) provides dental services, including restorations, across the UK. Unlike most other NHS provision, dentistry is subject to patient charges. These represent a contribution towards the costs of providing the treatment. However, in England and Wales, patient charges are not based on a percentage of the costs to the NHS to provide a given treatment. In Northern Ireland and Scotland, the patient must pay 80% of the fee paid to the dentist by the NHS, up to a cap of 430 EUR (384 GBP). It must be noted however that approximately 50% of adults in the UK can cover their dental treatment through the NHS. The rest of the population use private dental surgeries.

Appendix F Questionnaire to Member States

Context and objective of the study

Mercury (Hg), a highly toxic and persistent heavy metal, **makes up approximately 50% of dental amalgam**. The health and environmental risks associated with mercury are well known. In this context, dental amalgam has been controversial ever since it was introduced, early in the nineteenth century, because of potential risks due to its mercury content.

Mercury releases from the use of dental amalgam occur at **different stages of its life cycle**, in particular during the placement of new fillings or the removal of old ones at dental practices, at the end of life of persons with amalgam fillings (via cremation or burial), and during the progressive deterioration of amalgam fillings in people's mouths due to chewing, ingestion of hot beverages and corrosion (mercury excreted by humans). Dental amalgam is one of the main **remaining uses of mercury** in the EU.

As response to the environmental and health risks, the Commission has adopted its *Mercury Strategy* in 2005 setting out 20 actions with the aim to reduce mercury levels to the environment and human exposure. A review of the Strategy in 2010 considered phasing out the use of dental amalgam as one of the potential measures to be taken in order to reduce demand for mercury.

At the international level, the "**Minamata Convention on Mercury**" was adopted at a Diplomatic Conference in Japan in October 2013. Dental amalgam is among the products listed in Annex A of the Convention as a mercury-added product to be regulated under the Convention.

In February 2016, the European Commission tabled a proposal for a Regulation on Mercury in order to align the EU to the Minamata Convention and enable the EU to ratify it. Dental amalgam has been a major issue addressed in the legislative process. The resulting **Regulation 2017/852 on Mercury, which** covers the full life cycle of mercury, addresses the use of dental amalgam by setting specific restrictions. The box below, lists the restrictions set by Article 10.

- As from **1 July 2018,** the use of dental amalgam is prohibited for dental treatment of (i) deciduous teeth, (ii) of children under 15 years and (iii) of pregnant or breastfeeding women, unless deemed strictly necessary by the dental practitioner on the ground of specific medical needs of the patient.
- By **1 July 2019**, each Member State must set out and publish on the Internet a national plan on measures to phase down the use of dental amalgam.
- As from **1 January 2019**, dental practitioners are no longer allowed to use dental amalgam in bulk, but only in pre-dosed encapsulated form to prevent exposure of the patient and practitioner.
- As from **1 January 2019**, all dental facilities dealing with dental amalgam (use of amalgam and/or removing dental amalgam fillings) must be equipped with amalgam separators ensuring the retention and collection of amalgam particles with a view to preventing their release into wastewater systems.

Separators will have to maintain a minimum retention level of 95%; immediately in case of new separators, by 1 January 2021 in case of existing separators.
- Dental practitioners must ensure that their amalgam waste (e.g. amalgam residues, particles, fillings and teeth, or parts thereof, contaminated by dental amalgam) are handled and collected by authorised waste management establishments or undertakings (no direct or indirect release into the environment).

Furthermore, Article 19(1)(b) of the Regulation tasks the Commission to report to the European Parliament and to the Council on the outcome of its assessment regarding:

"the feasibility of a phase-out of the use of dental amalgam in the long term, and preferably by 2030, taking into account the national plans referred to in Article 10(3) and whilst fully respecting Member States' competence for the organisation and delivery of health services and medical care"

The **objective of the study is to assist the Commission in assessing the feasibility of a phase-out of dental amalgam** preferably by 2030, as required by Article 19(1)(b).

Currently, there is limited information on the current use of dental amalgam and their alternatives, as well as on the implications of the organisation of health services in the different EU Member States and the existing or planned measures to phase down dental amalgam. The aim of this questionnaire is **to close this knowledge gap** in order to assess the feasibility of a phase-out at the EU level.

The questions are divided into **five sections** covering respectively the use of dental amalgam and alternative materials, the mercury leakages from amalgam fillings; the existing and planned policies and measures, the organisation of health services and insurance; key barriers and drivers to a phase-out.

The study "Assessment of the feasibility of phasing out dental amalgam[473]" started in August 2018 and is expected to finish in February 2020. As part of the consultation process, a stakeholder workshop will be organised in Brussels in autumn 2019. The study is carried out by Deloitte Sustainability (FR), Wood (UK), INERIS (FR) and REC (HU).

[473] Dental practitioners use mercury either in an encapsulated or bulk form. As the use of bulk mercury is prohibited since 1 January 2019, in this study dental amalgam refers only to the pre-dosed encapsulated form

Personal information	
Name, first name:	
Organisation:	
(name, main activity/sector):	
Job title:	
E-mail:	
Phone number:	
Country of location:	
Country concerned by the answers (if different from country of location):	

Dental amalgam use, alternatives and trends

1. Is dental amalgam still widely in use in your country?
    a) Yes, dental amalgam is preferred to alternatives ☐
    b) No, alternatives are preferred to dental amalgam ☐
    c) Don't know ☐

2. Number of restorations per type of material:

Material	**Number of restorations per year**					
	2013	**2014**	**2015**	**2016**	**2017**	**2018**
Dental amalgam						
Composite resins						
Glass ionomer cements						
Compomers						
Ceramics						

Material	Number of restorations per year					
	2013	2014	2015	2016	2017	2018
Others (please specify and add lines as needed):						

Sources, clarifications and other remarks: Click or tap here to enter text.
Provide any relevant contact points or sources of information you may be aware of: Click or tap here to enter text.
Tick the following box, if according to your knowledge this information is not available in your country ☐

3. Information on the dental sector:
   Please tick the following box, if according to your knowledge this information is not available in your country ☐

	Number					
	2013	2014	2015	2016	2017	2018
Dentists[474] (number)						
Dental clinics[475] (number)						
Average turnover per clinic (thousand EUR)						

Sources, clarifications and other remarks: Click or tap here to enter text.
Provide any relevant contact points or sources of information you may be aware of: Click or tap here to enter text.
Tick the following box, if according to your knowledge this information is not available in your country ☐

4. Manufacturing of dental amalgam and alternative materials:

[474] The term "dentists" refers to individual professionals

[475] The term "dental clinics" refers to establishments which offer dental treatment, including dental practices

Material	Unit	Production levels					
		2013	2014	2015	2016	2017	2018
Encapsulated dental amalgam (mercury component only)	kg						
	l						
Bottles of mercury for dental use	kg						
	l						
Pillows of mercury for dental use	kg						
	l						
Composite resins	kg						
	l						
Glass ionomer cements	kg						
	l						
Compomers	kg						
	l						
Ceramics	kg						
	l						
Others (please specify and add lines as needed):	kg						
	l						

Sources, clarifications and other remarks: Click or tap here to enter text.

Provide any relevant contact points or sources of information you may be aware of: Click or tap here to enter text.

Tick the following box, if according to your knowledge this information is not available in your country ☐

5. Extra-EU imports and exports of dental amalgam (encapsulated)and alternative restoration materials:

Please tick the following box, if according to your knowledge this information is not available in your country ☐

Category	Material	Unit	Imports/ exports					
			2013	2014	2015	2016	2017	2018
Imports	Dental amalgam (encapsulated only)	kg						
		EUR						
	Composite resins	kg						
		EUR						
	Glass ionomer cements	kg						
		EUR						
	Compomers	kg						
		EUR						
	Ceramics	kg						
		EUR						
	Others (please specify and add lines as needed):	kg						
		EUR						
Exports	Dental amalgam	kg						
		EUR						
	Composite resins	kg						
		EUR						
	Glass ionomer cements	kg						
		EUR						
	Compomers	kg						

Category	Material	Unit	Imports/ exports					
			2013	2014	2015	2016	2017	2018
		EUR						
	Ceramics	kg						
		EUR						
	Others (please specify and add lines as needed):	kg						
		EUR						

Sources, clarifications and other remarks: Click or tap here to enter text.

Provide any relevant contact points or sources of information you may be aware of: Click or tap here to enter text.

Tick the following box, if according to your knowledge this information is not available in your country ☐

Leakage of mercury from dental fillings

6. Waste treatment from amalgam separators and water waste treatment facilities:
   Please tick the following box, if according to your knowledge this information is not available in your country ☐

Category	Mercury waste treatment					
	2013	2014	2015	2016	2017	2018
Share of dental chairs equipped with amalgam separators (%)						
Share of waste from separators treated in specialized treatment facilities (%)						
Average dental amalgam removal efficiency of separators (%)						
Cost of collection and treatment of waste from separators per kg (thousand EUR)						

Category	Mercury waste treatment					
	2013	2014	2015	2016	2017	2018
Concentration of mercury in sewage sludge (µg/L)						

Sources, clarifications and other remarks: Click or tap here to enter text.
Provide any relevant contact points or sources of information you may be aware of: Click or tap here to enter text.
Tick the following box, if according to your knowledge this information is not available in your country ☐

7. Do you know how the waste collected from amalgam separators is treated?
   a) Collected and treated by specialised treatment facilities located in your country ☐
   b) Collected locally and treated specialised facilities in third countries ☐
   c) Collected and treated by specialised facilities in third countries ☐
   d) Treatment as medical waste (e.g. landfilled) ☐
   e) Don't know ☐

   Sources, clarifications and other remarks: Click or tap here to enter text.

8. Number of cremations and use of abatement technologies:
   Please tick the following box, if according to your knowledge this information is not available in your country ☐

Category	Air emissions from crematoria					
	2013	2014	2015	2016	2017	2018
Number of crematoria						
Number of cremations per year						
Share of crematoria equipped with abatement technologies (%)						
Average efficiency of the abatement technologies (%)						
Cost of mercury capture per cremation (EUR)						

Sources, clarifications and other remarks: Click or tap here to enter text.
Provide any relevant contact points or sources of information you may be aware of: Click or tap here to enter text.
Tick the following box, if according to your knowledge this information is not available in your country ☐

National policies and measures

9. Are you aware of any policies and/or measures in your country to phase-down or phase-out the use of dental amalgam? Are there any measures to manage the waste and emissions from dental amalgam?
   Please tick the following box, if according to your knowledge this information is not available in your country ☐

Category	Type	Ongoing (please describe)	Under development (please describe)
Measures to phase down or phase out dental amalgam	Dental amalgam bans, phasing-out or phasing-down		
	National guidelines, promoting the use of mercury-free materials		
	Supporting research and development in respect of mercury-free dental restorations		
	Others (please specify and add lines as needed):		
Measures to manage waste and emissions from dental amalgam	Requirements for the installation and maintenance of separators		
	Requirements for the collection and treatment of solid waste from separators		
	Requirements for mercury emissions from crematoria		
	Standards for mercury concentrations in sludge for the use of land spreading		
	Supporting research and development in respect of reducing emission and releases of mercury to the environment		
	Others (please specify and add lines as needed):		

Sources, clarifications and other remarks: Click or tap here to enter text.

Health services and insurance

10. How does the social security system work? Are the costs of dental restorations covered partially or fully? Is it common for citizens enrol in supplementary health plans that cover dental restorations?
    Click or tap here to enter text.

11. Is there a difference between private and public social security in relation to the coverage of dental treatment costs? Are there any provisions for vulnerable groups (e.g. unemployed, disabled, elderly etc.)?
    Click or tap here to enter text.

12. What is reimbursed and is this differentiated per restoration material? Are patients required to cover part of the restoration costs? Who pays a possible increase in cost (e.g. insurance, dentist, patient)?
    Click or tap here to enter text.

13. Price per filling and reimbursement by social security:
    Please tick the following box, if according to your knowledge, this data is not available in your country ☐

Category	Material	Cost (EUR)	Reimbursement by social security (%)
Restoration per filling	Dental amalgam		
	Composite resins		
	Glass ionomer cements		
	Compomers		
	Ceramics		
Material per filling	Dental amalgam		
	Composite resins		
	Glass ionomer cements		
	Compomers		
	Ceramics		

Sources, clarifications and other remarks: Click or tap here to enter text.

Key barriers and drivers

Key barriers

A. From the following list, what are the **three most important barriers** of phasing out dental amalgam? Please rank from 1) most important to 5) least important.

a) Dentists are not experienced in restorations with alternative materials Choose
b) Dentists perceive dental restorations with dental amalgam as more durable Choose
c) Dental restorations with alternative materials, require significantly more time compared to restorations with dental amalgam Choose
d) Patients perceive dental restorations with dental amalgam as more durable Choose
e) Lack of dental clinics with the required equipment for restorations with alternative materials Choose
f) The cost of dental amalgam restorations is relatively low as compared to the price of alternatives Choose
g) The reimbursement of social security is higher for dental amalgam restorations compared to alternatives Choose
h) The reimbursement of private insurance is higher for dental amalgam restorations compared to alternatives Choose
i) Other barriers Choose
Please specify if other barriers apply: Click or tap here to enter text.

Key drivers

B. According to you, from the following list, what are the **three most important drivers** of phasing out dental amalgam (please rank from 1) most important to 5) least important)?

a) Increasing consumer awareness on the environmental and associated indirect health effects of dental amalgam Choose
b) Increasing dentist awareness on the environmental and associated indirect health effects of dental amalgam Choose
c) Development of guidelines for dentists promoting alternative materials as a preferable material Choose
d) Fiscal measures to promote the use of alternative materials (e.g. lower VAT compared to alternative materials) Choose
e) Setting a same share of reimbursement in restorations with alternative materials and dental amalgam Choose
f) Training of dentists on restorations with alternative materials Choose
g) Improvements on the durability of restorations with alternative materials Choose
h) Other drivers Choose

Please specify if other drivers apply: Click or tap here to enter text.

Appendix G Regulatory status under REACH

Table 195: Regulatory status under REACH and hazard according to REACH data and the CLP classification of major methacrylate monomers in resin composites (list of chemicals from Giraud T.et al. and Dursun E. et al. ; data from ECHA Substance information database)

Chemical	BPA derivative	CAS Number	Hazards from CLP classification or reported by REACH registrants	REACH Restriction List (A. XVII)	REACH SVHC	Comment
4-MET (4-methacryloxyethyl trimellitic acid)		70293-55-9 (anhydrid)	According to the classification provided by companies to ECHA in REACH registrations this substance is skin sensitizer (anhydrid form)			
Aromatic monomers						
AUDMA (aromatic urethane dimethacrylate) Familly of chemicals						
BHT (butylated hydroxytoluene)		128-37-0	According to the classification provided by companies to ECHA in REACH registrations this substance is very toxic to aquatic life with long lasting effects			Watch list of the Water Framework Directive ; Under Evaluation under REACH for potential concern regarding endocrine disrupting properties
Bis-DMA, Bis MPEPP or BPEDMA (Bisphenol A polyethoxy dimethacrylate or 2,2-bis(4-methacryloxy poly-ethoxyphenyl)propane)	x	3253-39-2	According to the classification provided by companies to ECHA in REACH registrations this substance is skin sensitizer			
Bis-EMA (or EBPADMA or EBPDMA) (Ethoxylated bisphenol-A glycol dimethacrylate)	x	41637-38-1	According to the classification provided by companies to ECHA in REACH registrations this substance may cause long lasting effects to aquatic life			Suspected PBT/vPvB under evaluation under REACH
Bis-GMA (2,2-bis[4-(3-methacryloxy-2-hydroxypropoxy)phenyl]propane)	x	1565-94-2	According to the classification provided by companies to ECHA in REACH			

Chemical	BPA derivative	CAS Number	Hazards from CLP classification or reported by REACH registrants	REACH Restriction List (A. XVII)	REACH SVHC	Comment
			registrations this substance is skin sensitizer			
BPA (Bisphenol A)	x	80-05-7	CLP classification : H317 : Skin Sens. 1 ; H318: Eye Dam. ; H335 : STOT SE 3 ; Flam. Liq. 2 ; H360F : Repr. 1B	Restricted in thermal papers	Included for : reprotoxicity, endocrine disrupter (human health and the environment)	
Butenediol dimethacrylate		2082-81-7	According to the classification provided by companies to ECHA in REACH registrations this substance is skin sensitizer			
DDCDMA (Dimer Dicarbamate Dimethacrylates, a class of chemicals)						
DDDMA (1,10-decandioldimethacrylate, or 1,10-decamethyleneglycoldimethacrylate)		6701-13-9	A majority of C&L data submitters agree this substance is Skin sensitising According to the classification provided by companies to ECHA in REACH registrations this substance is very toxic to aquatic life with long lasting effects			
HDDMA (or 1,6 Hexanediol Dimethacrylate)		6606-59-3	According to the classification provided by companies to ECHA in REACH registrations this substance is harmful to aquatic life with long lasting effects			
HEMA or HEDMA (Hexane diol dimethacrylate or 2-hydroxyethyl dimethacrylate)		868-77-9	According to the classification provided by companies to ECHA in REACH registrations this substance is Skin sensitizing			Evaluation process ongoing (CoRAP) (concern for potential sensitizer and possible CMR)
MMA (Methyl methacrylate)		80-62-6	CLP classification : causes skin irritation, may cause an allergic skin reaction and may cause respiratory irritation.			

Chemical	BPA derivative	CAS Number	Hazards from CLP classification or reported by REACH registrants	REACH Restriction List (A. XVII)	REACH SVHC	Comment
PEGDMA (polyethylene glycol dimethylacrylate)		25852-47-4	According to the classification provided by companies to ECHA in CLP notifications this substance is toxic to aquatic life with long lasting effects.			
TEGDMA (Triethylene glycol dimethacrylate)		109-16-0	According to the classification provided by companies to ECHA in REACH registrations this substance may cause an allergic skin reaction.			
Tricyclodecanedimethanoldimethacrylate (DCP)		43048-08-4	According to the classification provided by companies to ECHA in REACH registrations this substance is toxic to aquatic life with long lasting effects			
UDMA (or 1,6-di(methacryloyloxyethylcarbamoyl)-3,3,5-trimethylhexan)		72869-86-4	According to the classification provided by companies to ECHA in REACH registrations this substance is toxic to aquatic life with long lasting effects			