Study on the potential for reducing mercury pollution from dental amalgam and batteries

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Executive summary

This report presents the findings of the study on 'Potential for reducing mercury pollution from dental amalgam and batteries' carried out for the European Commission (DG Environment). It mainly consists of two assessments of policy options to reduce environmental impacts from dental amalgam (Part A of the report) and from mercury-containing batteries (Part B of the report).

The health and environmental risks associated with mercury (Hg) are well known and have led the Commission to adopt an EU Mercury Strategy in 2005[1], with the aim to '*reduce mercury levels in the environment and human exposure, especially from methylmercury in fish*'. The review of the Strategy's implementation[2], in 2010, acknowledged the progress made with regard to a number of actions proposed in 2005 such as the adoption of the Mercury Export Ban Regulation[3], the phase-out of mercury use in certain measuring devices under the REACH Regulation[4], the submission of additional mercury use restriction proposals under REACH, and the EU's contribution to the progress of international negotiations on the global mercury treaty. The review also highlighted areas for further improvement, among which the remaining uses of mercury in several applications where mercury-free alternatives exist and are already used to some extent; this concerns in particular dental amalgam and button cell batteries, which are the subject of the present study.

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[1] Communication from the Commission to the Council and the European Parliament – Community Strategy Concerning Mercury – COM (2005) 20 final

[2] Communication from the Commission to the European Parliament and the Council on the review of the Community Strategy Concerning Mercury, COM(2010)723final. The EC's Communication was informed by a report by BIO Intelligence Service prepared for DG ENV in 2010 (http://ec.europa.eu/environment/chemicals/mercury/pdf/review_mercury_strategy2010.pdf)

[3] Regulation (EC) No 1102/2008 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

[4] Commission Regulation (EC) No 552/2009 of 22 June 2009 amending Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII

Assessment of policy options to reduce environmental impacts from dental amalgam use

Dental amalgam is a combination of metals, containing about 50% of mercury in the elemental form, the other metals being silver (about 35%), tin, copper, and other trace metals. Dental amalgam has been used for over 150 years for the treatment of dental cavities and is still used due to its specific mechanical properties and the long-term familiarity of many dental practitioners with amalgam. 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 the dental amalgam 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 and hot beverages (mercury excreted by humans).

Problem definition

Dental amalgam is one of the main remaining uses of mercury in the EU. In 2007, dental amalgam was the second largest mercury use in the EU after chlor-alkali production[27] and it is expected to become the largest mercury use once mercury cell-based chlor-alkali production is phased out in the EU (target date 2020). In the present study, the EU mercury demand for dentistry was estimated to range between 55 and 95 t Hg/year in 2010 (75 t Hg/year on average).

Although dental use of mercury seems to have been declining over the last few years, it remains a significant contributor to overall environmental mercury releases in the EU.

It is roughly estimated that 45 t Hg/year from EU dental practices end up in chairside effluents, with only a part of which being captured and treated as hazardous waste in compliance with EU legislation. Mercury in dental waste represents about 50 t Hg/year. It is roughly estimated that dental amalgam contributes 21-32% to overall EU mercury emissions to air and up to 9-13% to overall EU mercury emissions to surface water. Mercury emitted to the air can be partly deposited into other environmental compartments (soil, surface water, vegetation). Emissions to soil and groundwater are also significant, although their contribution to overall mercury releases to this environmental compartment is more difficult to quantify. It is estimated that about half of the mercury released from current and historical dental amalgam use remains potentially bioavailable, with the potential to contaminate fish in particular, the other half being either sequestered for long-term (stored in hazardous waste landfills) or recycled for new purposes.

The fundamental problem with the current situation is that certain population groups – and especially women of childbearing age and children – are subject to high risk levels of exposure to mercury, principally in the form of methylmercury through diet. This presents a risk of negative impacts on health, in particular affecting the nervous system and diminishing intellectual capacity. There are also environmental risks, for example the disturbance of microbiological activity in soils and harm to wildlife populations. More than 70% of the European ecosystem area is estimated to be at risk today due to mercury, with critical loads for mercury exceeded in large parts of western, central and southern Europe[5].

The problem of mercury pollution from dental amalgam is twofold: in the first place, pollution is caused by the historical use of dental amalgam, while the current use of dental amalgam adds up to mercury releases from historical practice. The drivers of the problems identified can be described as a combination of market and regulatory failures.

Pollution due to historical use of dental amalgam mainly results from non-compliance of dental facilities with EU waste legislation and a lack of anticipation with regard to EU legislation on water quality.

Some of the emissions associated with the historical use of dental amalgam, e.g. emissions from burial and emissions from amalgam deterioration in mouths, are difficult to tackle due to their diffuse nature. However, a significant part of these emissions can be minimised through proper waste and wastewater management in dental facilities and the use of efficient mercury abatement devices in crematoria.

The handling of dental amalgam waste as hazardous waste (which involves the use of efficient amalgam separators, the segregation of amalgam waste from other waste types and its treatment as hazardous waste) is a matter of enforcing EU legislation on waste[6]. Adequate handling of dental amalgam waste is also necessary to achieve certain goals of EU legislation on water quality[7]: mercury is considered as a priority hazardous substance, requiring a cessation of emissions, discharges and losses within 20 years after adoption of measures. The present study estimated that around 25% of EU dental facilities are still not equipped with amalgam separators. Besides, a significant proportion of separators are not adequately maintained, which reduces significantly their mercury capture efficiency. Although it is much easier to capture mercury at dental facilities than once it is mixed with other urban effluents, the installation and maintenance costs of an amalgam separator are borne by dentists, while local authorities (i.e. the taxpayers) bear the cost of removing mercury from urban sewage sludge.

In the absence of further EU policy action, environmental impacts due to the historical use of dental amalgam will continue to occur for several decades since they are due to the removal of old fillings, the loss of teeth, the progressive deterioration of existing fillings and the end of life of amalgams when people decease. Mercury releases from dental practices may decrease progressively along with the modernisation of dental practices, as new dental practices are generally equipped with amalgam separators. It is however highly unlikely that 100% of dental practices become compliant with the relevant requirements of EU waste legislation in the short term without any further enforcement actions from public authorities. With regard to the end of

[5] This concept is mainly based on ecotoxicological effects and human health effects via ecosystems. It is generally defined as a quantitative estimate of an exposure to one or more pollutants below which significant harmful effects on specified sensitive elements of the environment do not occur.

[6] Waste Framework Directive (2008/98/EC)

[7] In particular: Water Framework Directive (2000/60/EC), Decision 2001/2455/EC and Directive 2006/11/EC on dangerous substances and Directive 2008/105/EC on priority substances

life of amalgams, future mercury releases from burial are likely to remain stable and will occur for several decades. Concerning mercury emissions from cremation, a stabilisation seems to have occurred since 2005, but future trends are difficult to predict.

With regard to the current use of dental amalgam, solutions are available to phase out mercury use in most medical conditions

Although Hg-free alternatives to dental amalgam exist and can be used in most medical conditions[8], they are still not widely used in a number of Member States (e.g. FR, PL, UK, CZ, RO, ES, and GR). The main reasons behind this situation are as follows:

- Hg-free dental restorations are more expensive for patients, as compared with dental amalgam restorations, in many Member States. This is both due to the higher actual cost of most Hg-free restorations (the Atraumatic Restorative Treatment or 'ART' being an exception) and the fact that Hg-free restorations are not always reimbursed by the existing national insurance schemes at the same level as dental amalgam.
- Not all dentists are properly trained and skilled in conducting Hg-free restorations and insufficiently trained dentists may be more reluctant to propose Hg-free restorations to patients.
- Many dentists are not aware of the benefits of ART, a cheap Hg-free restoration technique already widely used in developing countries and which may have a significant potential in the EU.
- Some dentists are reluctant to change their current practice and to invest in new equipment required to handle Hg-free fillings. In parallel, they may not be fully aware of the seriousness of the environmental impacts caused by dental amalgam and of the societal benefits of reducing mercury emissions.
- Not all patients are fully aware of the pros and cons associated with the different types of filling materials. In particular, many patients are not aware of the presence of mercury in dental amalgam and the extent of the associated environmental impacts.
- Some dentists consider that, although Hg-free materials have been used in some countries for many years, the absence of long-term environmental and health effects of these materials has not been fully demonstrated.

The fact that Hg-free dental restorations are more expensive than dental amalgam restorations can be seen as a market failure in the sense that negative externalities associated with the use of dental amalgam (management of dental waste and effluents) are not factored in the actual price of dental amalgam restorations.

[8] Currently the most commonly used alternatives to dental amalgam are composites, glass ionomer cement, compomers, giomers, sealants, and dental porcelain.

If no further EU policy action is taken, the current use of dental amalgam will continue to generate environmental impacts that will occur over the whole lifetime of the amalgam fillings; a large part of the associated environmental emissions would occur during a period of 10 to 15 years after the placement of amalgam (this is the average lifetime of an amalgam filling)[9] but the actual environmental impacts (adverse effects to ecosystems) and possible indirect human health effects will occur for several decades.

In the absence of further EU policy action, dental amalgam may continue to be progressively substituted with Hg-free materials, mainly as a result of growing aesthetic concerns, although it is difficult to predict the speed of this decline. Dental amalgam may well continue to be used for many years in some of the less wealthy Member States. In the present study, it is estimated that EU demand for dental mercury will decrease and will stabilise around 27 to 43 t Hg/year in 2025 (2010-2025 being the time horizon for the present assessment). This represents an annual decrease of approximately 5% over a 15-year time horizon.

In the absence of any changes to national health insurance schemes, it is expected that Hg-free dental restorations will continue to be more expensive for patients than amalgam restorations in the future, however the cost difference will tend to decrease due to innovation and increased competition concerning the production of Hg-free filling materials as well as improved dentists' skills in the handling of Hg-free materials.

Possible human health impacts of dental amalgam are still the subject of significant scientific debate.

While there is a common viewpoint among stakeholders that the adverse environmental effects of dental amalgam use need to be addressed, there is not sufficient scientific consensus on the *direct* health effects of dental amalgam to justify further policy action on this sole basis. For this reason, the objectives of future policy action concerning dental amalgam only refer to the *environmental side* of the problem and *indirect* health effects. However, because possible health impacts are relevant to the assessment of some policy options, the present study included a short review of the scientific literature on this issue.

Policy objectives and options

The general objective of any future policies in relation to mercury in dental amalgam will be to reduce the environmental impacts from the use of mercury in dentistry and to reduce the contribution of dental amalgam to the overall mercury problem. In the long-term, this should contribute to achieving reduced mercury levels in the environment, at EU and global level, especially levels of methylmercury in fish. This long-term policy objective can be achieved through specific policy actions aiming to 1) minimise mercury emissions from current and historical use of mercury in dentistry and 2) minimise and, where feasible, eliminate the source of pollution, i.e. phase out dental amalgam use.

[9] Some amalgam restorations will last shorter (many of them last less than 2 years) while others have been reported to last up to 40 to 50 years (WHO (2010) Future use of materials for dental restoration).

Four policy options have been selected for analysis:

- **'No policy change' option** (baseline scenario)
- **Option 1: Improve enforcement of EU waste legislation regarding dental amalgam –** The Commission would ask Member States to report on measures taken to manage dental amalgam waste in compliance with EU waste legislation (i.e. presence of amalgam separators in dental practices) and to provide evidence of the effectiveness of the measures in place (i.e. adequate maintenance of these separators in order to ensure a minimum 95% efficiency and amalgam waste to be collected and treated by companies with the adequate authorisation to handle this type of hazardous waste).
- **Option 2: Encourage Member States to take national measures to reduce the use of dental amalgam while promoting the use of Hg-free filling materials –** The Commission would encourage Member States to take national measures aiming to reduce the use of dental amalgam (for example via a Communication to be adopted in 2013) and Member States would have to report annually to the Commission on the measures taken and their effect. Such measures would include, in particular, measures aiming to: improve dentists' awareness of the environmental impacts of mercury and the need to reduce its use; review dental teaching practices so that Hg-free restorations techniques are given preference over dental amalgam techniques; improve dentists' awareness and skills with regard to the Hg-free and cost-efficient Atraumatic Restorative Treatment (ART); and improve public dental health to reduce the occurrence of cavities.
- **Option 3: Ban the use of mercury in dentistry** – One possibility would be to add the use of mercury in dentistry to Annex XVII of the REACH Regulation[10], with the possibility to define limited exemptions to take into account specific medical conditions where dental amalgam cannot be substituted at present. In the present study, it is assumed that such a legal requirement would be adopted in 2013 and would become applicable 5 years later, i.e. in 2018, in order for all the stakeholders to anticipate the ban.

Analysis of impacts

Information sources include previous studies, recent mercury emission data and information from stakeholders.

The evidence base for the analysis of impacts first includes findings from previous studies on the dental amalgam issue[11]. In order to fill the information gaps highlighted in previous studies and obtain up-to-date data, recent publications and recently published emission data were reviewed

[10] Regulation (EC) No 1907/2006 on Registration, Evaluation, Authorisation and Restriction of Chemicals – Annex XVII of the REACH Regulation contains the list of all restricted substances, specifying which uses are restricted.

[11] In particular: SCHER (2008) Opinion on the environmental risks and indirect health effects of mercury in dental amalgam; Summary of Member States responses to 2005 EC survey on management of dental amalgam waste; COWI/Concorde (2008) Options for reducing mercury use in products and applications, and the fate of mercury already circulating in society; EEB/Concorde (2007) Mercury in dental use: environmental implications for the EU

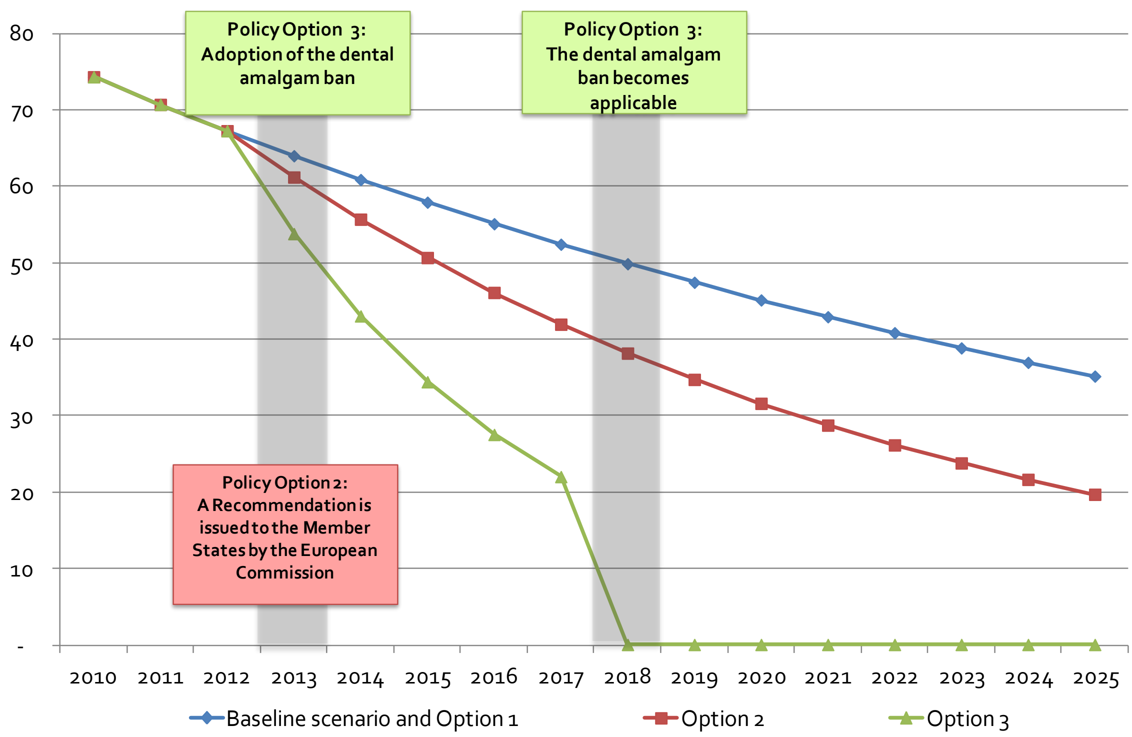
in a second stage[12]. Tailored questionnaires were then sent to about 300 stakeholders including environmental and health authorities within Member States, industry stakeholders (dental associations, dental fillings suppliers, waste treatment industry, crematoria businesses and water treatment industry) as well as NGOs and academic experts. About 40 questionnaire replies were received, with varying levels of detail, including responses from 20 Member States[13]. Finally, follow-up telephone interviews were conducted with several dental fillings manufacturers, national dental associations and researchers.

One major challenge is a lack of reliable and up-to-date data in many Member States on dental amalgam use, related mercury emissions, and dental restoration costs, which required a number of assumptions and extrapolations.

Environmental and socio-economic impacts of the policy options are closely related to the projected trends for dental amalgam use in the EU, over the next 15 years.

A comparison of the different mercury demand projections developed in this study, for the different policy options, is presented in Figure 1 below. The assumptions used to develop these projections are based on the limited information currently available concerning the expected decline of dental amalgam demand in the EU and they carry a large part of uncertainty.

Figure 1: Projected annual demand for dental mercury in the EU (t Hg)



[12] In particular: Emission data from the European Pollutant Release and Transfer Register; OSPAR (2011) Overview assessment of implementation reports on OSPAR Recommendation 2003/4 on controlling the dispersal of mercury from crematoria

[13] AT, BE, BG, CZ, CY, DE, DK, EE, FI, HU, IE, LT, LV, MT, PL, SE, SI, SK, UK. In addition, LU and RO advised that they were not able to provide any valuable information in relation to the study.

While the baseline scenario assumes a gradual decrease in dental amalgam demand over the next 15 years (approximately –5% demand per year) until a threshold of about 35 t Hg/year to be reached in 2025, Option 3 would result in a sharp decrease (approximately 20% annually) of dental amalgam demand from 2013 (when the ban is adopted) to reach zero demand in 2018 once the ban becomes applicable (in fact, very small amounts could still be used after 2018, in accordance with the allowed exemptions, but these are considered to be negligible). Option 2, as an intermediate option between the 'no policy change' and Option 3, would result in a more rapid decline in dental amalgam demand than in the baseline scenario (approximately –9% demand per year) until a threshold of about 19 t Hg/year to be reached in 2025.

- **Environmental impacts**

While the quantities of dental amalgam waste produced are expected to decrease in all options, with a much stronger positive effect under Options 2 and 3, only Option 1 could influence the management of amalgam waste and allow a reduction of mercury releases to air/water/soil associated with this waste stream in the short term. More specifically, Option 1 would avoid the release of approximately 7 t Hg/year to urban wastewater treatment plants in the EU (30% reduction of the mercury load with regard to the baseline situation for 2015).

Mercury releases to air/water/soil due to dental amalgam use are also expected to decrease in all options, due to the progressive substitution of dental amalgam with Hg-free materials; however only Option 2 and – to a greater extent – Option 3 would allow a significant decrease of these emissions in the long term, with an almost complete cessation of mercury releases in the case of Option 3.

Under Option 2, the expected decrease in dental amalgam use would lead to a reduction of mercury releases to the environment (air/water/soil) by at least 3% with regard to the baseline scenario for year 2025.

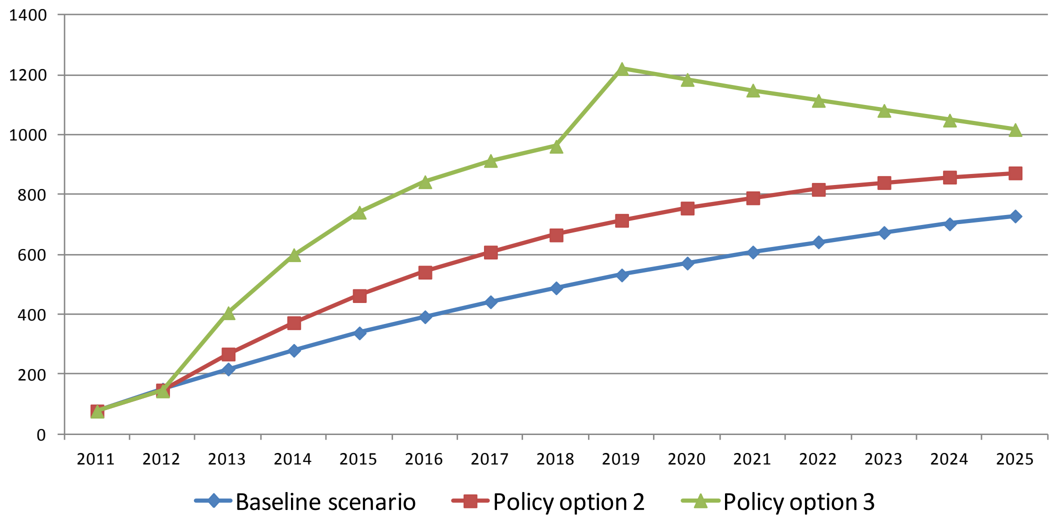
Under Option 3, when the ban starts to apply in 2018, the avoided mercury use is estimated at approximately 50 t Hg/year with regard to the baseline scenario. This option, once implemented, will lead to an immediate decrease in environmental mercury releases. However, because there will still be mercury releases due to old amalgam fillings, it is estimated that, at the time the ban becomes applicable, mercury releases to the environment (air/water/soil) would only be reduced by approximately 15% with regard to the baseline scenario. Mercury releases will progressively decrease over the years in line with the decrease of mercury stocks in people's mouths. Given that the average lifetime of amalgam fillings ranges from 10 to 15 years, it is expected that mercury releases from historical amalgam use would have significantly decreased 15 years after the ban takes effects[14]. The actual environmental impacts (e.g. adverse effects to ecosystems) would however continue to be observed for several decades, given the potential for elemental mercury to be transformed into methylmercury and to accumulate in biota.

[14] Residual mercury releases would be mainly due to amalgam fillings borne by immigrants to the EU and possibly also some specific cremation practices such as the ones reported in Italy (according to the Italian crematoria association Federutility, in Italy approximately 20% of cremations are carried out on human remains and can take place 10 to 20 years after a burial).

Economic impacts

The cost of dental amalgam substitution by Hg-free materials for EU dental patients is an important aspect of the analysis, for Options 2 and 3. The projected evolution of such costs in the baseline scenario and under Options 2 and 3 is shown in Figure 2 below (costs of Option 1 would be similar to the baseline scenario). Projections shown below take into account a progressive decrease in the cost of Hg-free restorations, which was considered as the most realistic scenario. The graph shows that, in all policy options, the annual costs would increase (due to higher numbers of Hg free restorations); however, this increase would progressively slow down in the baseline scenario and Option 2 (due to the decreasing price difference between amalgam and Hg-free restorations). The annual costs tend to converge towards the end of the time period considered (2025).

Figure 2: Annual costs borne by EU dental patients due to the substitution of dental amalgam according to different policy options (million EUR)



While the costs for dental patients are likely to increase under Options 2 and 3, the costs borne by EU taxpayers for the management of mercury pollution (tax contribution to mercury abatement costs in urban wastewater treatment plants and waste management facilities) would be reduced, especially under Option 3, due to reduced mercury releases from dental facilities. For example, a lower mercury content of dental effluents may reduce the need for municipalities to invest in expensive mercury abatement devices in sewage sludge incineration plants[15]. In certain cases, it may also increase the possibilities of using sewage sludge for agricultural purposes, a cheaper management option for sewage sludge.

With regard to economic impacts on crematoria, Option 2 would only have a minimal impact while Option 3 would have a positive economic effect in the long term, by avoiding the need for installing mercury abatement devices in new EU crematoria or for operating the systems already in place.

[15] As an illustration, one large WWTP in Bilbao, Spain, reported that the presence of high mercury levels in sludge required significant a investment in 2010-2011 in order to comply with legislation, in the order of 4.5 million EUR.

An increase in the revenues of the EU dental fillings industry is likely to occur in all options, due to the progressive substitution of dental amalgam with the more sophisticated Hg-free filling materials. This positive effect would be more significant in the case of Options 2 and 3 as the rate of substitution would be increased. Besides, Option 2 and – to greater extent – Option 3 are expected to promote competitiveness and innovation of the EU dental fillings industry.

The administrative burden associated with Options 1 and 3 is expected to remain limited as a legislative framework is already in place in both cases[16]. Option 2 could generate higher administrative burden due to significant communication and awareness raising efforts required to achieve a shift in dental restorations practices.

- **Social impacts**

Options 1, 2 and – to a greater extent - Option 3 would bring health-related benefits by reducing occupational exposure of dental personnel and exposure of the general public to mercury emissions resulting from dental amalgam use. With regard to possible *direct* health risks due to dental amalgam, it is not possible to draw any conclusions given the diverging scientific results obtained to date. The release of small amounts of endocrine disrupting substances (e.g. bisphenol A (BPA)) from certain types of composite resins has not been considered as presenting significant health risks for patients to date, however scientific studies on this issue date back to several years ago (while the issue of endocrine disrupting substances was not yet a high priority topic); it is therefore difficult to draw any conclusions on this aspect.

With regard to EU employment, the impact of the policy options is expected to be negligible. In particular, as the vast majority of EU dental fillings manufacturing companies already produce Hg-free materials[17], a greater substitution of dental amalgam with Hg-free filling materials would not significantly affect employment in this sector.

Conclusions

The most effective way to reach the policy objective, i.e. reducing the environmental impacts of dental amalgam use, would be a combination of Options 1 and 3. While Option 1 tackles environmental impacts from both historical and current dental amalgam use, it focuses on releases from dental practices and is not sufficient in itself to address the whole range of mercury releases from the dental amalgam life cycle (it does not address mercury releases from the natural deterioration of amalgam fillings in people's mouths, from cremation and burial, and residual emissions to urban WWTPs). Option 3 would allow a significant reduction of dental mercury releases within the next 15 years and would virtually eliminate the environmental impacts of dental mercury in the longer term. However, because the cessation of mercury releases, under Option 3, would only be significant after about 15 years, Option 3 needs to be coupled with Option 1 in order to reduce mercury releases from historical use of amalgam in the short term.

[16] EU waste legislation for Option 1 ; REACH Regulation for Option 3

[17] Out of the 57 EU main companies identified, only two companies (in CZ and in IT) produce solely mercury for dental amalgam preparation

Option 2 leaves more flexibility to Member States to implement national measures aimed at reducing dental amalgam use, which would allow them to take into account national specificities (e.g. current level of oral health, cost aspects, specificities of national health insurance schemes); however, the effectiveness of this option is subject to high uncertainty since there would be no binding targets to achieve. In order for this option to be effective in reducing environmental impacts, the administrative costs incurred by public authorities may be higher than in the case of Option 3 (significant awareness raising required in some Member States in order to induce a change in dental restoration practices).

The 'no policy change' option cannot achieve a significant reduction of mercury pollution from dental amalgam. Even if the progressive substitution of dental amalgam with Hg-free materials is expected to continue in the future, a complete phase-out of dental amalgam is very unlikely to happen. In this regard, it is interesting to note that, in Sweden, dentists' organisations and the National Board of Health and Welfare initially claimed that no legislative measures were needed to reduce amalgam use because it would vanish by itself; however, this did not happen after more than a decade, hence the decision of the authorities to introduce a ban. Following implementation of the ban, the use of dental amalgam was rapidly phased out without any problems.

The preferred combination of options is therefore Option 1 + Option 3. It would achieve the highest effectiveness, while the associated costs are considered to be reasonable for the various stakeholders, especially as they are considered to be outweighed by the associated environmental and health benefits. The cost efficiency of Option 3 improves with the active promotion of cheaper Hg-free restoration techniques such as ART, the improvement of dentists' skills in Hg-free restoration techniques (resulting in reduced placement durations and therefore reduced labour costs) and a gradual decrease in the price of Hg-free filling materials thanks to continuous innovation and increased competitiveness within this industry sector. Implementing Option 1 should be relatively feasible from a political point of view as it is about enforcing existing legal requirements (rather than creating new requirements) and it is the logical follow-up of Action 4 of the EU Mercury Strategy[18]. The implementation of Option 3 may be more challenging, not because of the actual costs of the changes required, but mainly due to the changes in professional habits that need to occur among dentists, especially in some Member States, and the time required for all EU dentists to be well skilled at performing mercury-free restorations. The implementation of Option 3 can also be considered as a logical follow-up of Action 8 of the EU Mercury Strategy[19] and seems necessary to achieve mercury-related requirements of EU legislation on water quality.

[18] '*The Commission will review in 2005 Member States' implementation of Community requirements on the treatment of dental amalgam waste, and will take appropriate steps thereafter to ensure correct application*'

[19] '*The Commission will further study in the short term the few remaining products and applications in the EU that use small amounts of mercury. In the medium to longer term, any remaining uses may be subject to authorisation and consideration of substitution under the proposed REACH Regulation, once adopted*'

Assessment of policy options to reduce environmental impacts from mercury-containing batteries

Mercury has already been eliminated from most batteries – button cell batteries being one of the exemptions – as a result of hazardous substance restrictions imposed by the Batteries Directive[20]. The Directive prohibits the placing on the market of all batteries and accumulators containing more than 0.0005% Hg by weight, with the exception of button cells that are allowed up to a Hg content of 2% by weight. Hence, the present study focuses on button cell batteries ('button cells') which are one of the remaining uses of mercury in the EU. Button cell batteries are small, thin energy cells that are commonly used in watches, hearing aids, and other electronic devices.

Problem definition

In 2010, the total button cells market in EU was estimated to be around 1,080 million button cell units. The quantity of mercury contained in these button cell batteries was estimated to range between 2.3 and 14.4 t Hg.

Mercury-containing button-cell batteries are a source of mercury pollution mainly because of inadequate end-of-life waste management.

Although Hg-containing batteries are classified as hazardous waste by Commission Decision 2000/532/EC, only a certain proportion is required to be separately collected for further recycling: the Batteries Directive requires that at least 25% of portable batteries and accumulators, including button cells, be separately collected by September 2012, increasing to 45% by September 2016. Besides, the minimum collection rate set by the Directive is not achieved in all Member States. As a result, a significant proportion of Hg-containing batteries ends up in incineration plants or landfills for non-hazardous waste (if mixed with household waste). It is roughly estimated that, in 2009, approximately 88% of button cells waste escaped separate waste collection schemes and ended up with mixed non-hazardous waste[21]; the amount of mercury contained in these button cells is approximately 5.5 t Hg/year.

Non-hazardous waste treatment methods are not designed for battery waste; in the case of mercury-containing button cell waste, non-hazardous waste treatment methods have the potential to release mercury to air, water and soil. This mercury can then become bioavailable and accumulate in biota, leading to environmental and human health risks.

[20] Directive 2006/66/EC on batteries and accumulators and waste batteries

[21] Based on data provided by the European Battery Recycling Association (EBRA)

Increasing separate collection rates of batteries is a challenging task.

In the absence of further policy actions, the button cells waste collection rate in EU is likely to progressively increase and reach the minimum thresholds set under the Batteries Directive, i.e. 25% by September 2012 and 45% by September 2016. However, it will probably take a long time before high collection and recycling rates are achieved in all Member States. Thus, even a strong enforcement of the Battery Directive would not be sufficient to solve the problem of mercury pollution due to improper management of button cell waste.

In the present study, the collection rate reported for 2009, i.e. 12%[22], has been used as an estimate of the current situation, while the legislative target of 45% has been used as an estimate of the likely situation in 2016.

The problem can be solved by substituting Hg-containing button cells by Hg-free alternatives.

According to the stakeholders consulted in the present study, Hg-free versions are now commercially available for all applications of the four main types of button cells (Lithium, Silver oxide, Alkaline and Zinc-air) in EU. Majority of the stakeholders confirmed that the performance parameters such as self-discharge, leak resistance, capacity and pulse capability of Hg-free button cells are the same for all application areas as compared to traditional Hg-containing button cells. Hg-free alternatives also have a similar shelf-life as compared to the Hg-containing button cells. Costs of Hg-free alternatives are currently slightly higher (approximately 10%) than Hg-containing versions, however with a higher share of Hg-free button cells placed on the market, the extra cost of these button cells will tend to be offset. Also, the adverse environmental and health effects of mercury (negative externalities) are currently not factored in the price of Hg-containing button cell batteries.

The EU button cell market is already experiencing a shift towards Hg-free button cells.

This shift is expected to continue in the coming years, driven by recent developments in the USA[23] and environmental responsibility policies of the manufacturers; however, it is not known how fast a complete phase-out of mercury would occur.

[22] Based on data provided by the European Battery Recycling Association (EBRA)

[23] Three US States (Maine, Connecticut and Rhode Island) have enacted legislations to ban the sale of mercury-containing button cell batteries from mid-2011 (with an exemption for low sales volume silver oxide button cells until 1 January 2015 in the State of Maine, for economic reasons). In addition, all US battery manufacturers have voluntarily committed to eliminating mercury in button cell batteries sold in the USA by 2011.

Policy objectives and options

The general objective of any future policies in relation to mercury in button cell batteries will be to reduce the environmental impacts from the use of mercury in these products and to reduce their contribution to the overall mercury problem. In the long-term, this should contribute to achieving reduced mercury levels in the environment, at EU and global level, especially levels of methylmercury in fish. This general objective may take decades to be achieved, as the present levels of mercury in the environment are representative of past mercury emissions, and even without further emissions it would take some time for these levels to fall.

This long-term policy objective can be achieved through specific policy actions aiming to restrict and, where feasible, eliminate mercury from button cell batteries.

Two policy options have been selected for analysis:

- **Option 1: 'No policy change'** (baseline scenario)
- **Option 2: Ban the placing on the market of mercury-containing button cell batteries in the EU –** This ban would involve deleting the exemption contained in (Article 4 (2)) of the Batteries Directive, concerning the maximum allowable mercury content of button cells. No exemption to this ban is proposed here, based on the feedback received from industry stakeholders consulted as part of this study. It is assumed that the ban would become applicable around 18-24 months after adoption of the legislative change, which corresponds to the time that is likely to be required by the industry for the implementation of this change.

Analysis of impacts

The evidence base for the analysis of impacts included previous studies[24], EU market statistics from Eurostat (PRODCOM) as well as information provided by stakeholders. As information from PRODCOM is not available for button cell batteries specifically, the missing information was collected via questionnaires and telephonic interviews with relevant stakeholders: button cells manufacturers, recyclers, waste compliance organisations and industry associations.

- **Environmental impacts**

In the 'no policy' change scenario, an amount of mercury of approximately 4 to 6.4 t Hg/year contained in button cell batteries would continue to escape separate waste collection schemes and would therefore end up with mixed non-hazardous waste (based on quantities estimated for 2010). A significant proportion of the mercury present in non-hazardous waste cannot be sequestered by non-hazardous waste treatment methods and is therefore emitted to air, water and soil/groundwater depending on the fate of the waste.

Option 2 would bring significant environmental benefits, as it would avoid the introduction of around 8.4 t Hg/year contained in button cells placed on the EU market, when compared to the baseline scenario. The resulting environmental emissions of mercury, due to inadequate end-of-

[24] Previous studies in the context of the Batteries Directive review (see http://ec.europa.eu/environment/waste/batteries/

life management of the button cells, would also be avoided. However, the actual environmental impacts of mercury from button cells, including adverse effects to ecosystems, will probably take several decades to fully disappear given the potential for the emitted mercury to be transformed into methylmercury and to bioaccumulate.

Economic impacts

An overview of the economic impacts associated with the two policy options is presented in Table 1 below. The analysis showed that a ban on mercury in button cell batteries would have very limited economic impacts with regard to the baseline scenario.

Table 1: Overview of economic impacts associated with the two policy options

Policy Option / Impact Indicator	Option 1 'No policy change'	Option 2 'Mercury ban in button cell batteries'
Costs of turnover losses for button cell manufacturers/importers/traders	o	≈ Marginal or neutral cost related to investments in R&D and assembly lines adaptation for the button cell manufacturers in EU
Competitiveness of EU battery industry and innovation	o	+ Would foster innovation and create additional business opportunities for EU button cell companies to play a leading role in the global context
Costs or turnover losses for retailers	o	o Retailers will most likely pass on the increase in cost (of purchase of alternatives to Hg-containing button cells) entirely to consumers
Cost for consumers	o	? An average Hg-free button cell sold in EU will cost 10% more (approximately an increase of around EUR 0.13/unit of button cell) to the consumer than the average Hg-containing button cell. This impact may however be lower given the current and natural evolution of market share of Hg-free button cells in EU (which is expanding)
Costs of turnover losses for waste collectors and recyclers	o	+ Up to 30-40% lower recycling cost for the recycling of all button cell waste collected in EU, compared to Option 1.
Administrative burden for MS authorities	o	≈ Marginal or neutral cost since Hg restrictions in portable batteries (other than button cells) are already implemented in EU under the Battery Directive

++: Strongly positive impact / +: Positive impact / o: No significant effect (similar to the baseline) / -: Negative impact
- -: Strongly negative impact / ≈: Marginal/Negligible impact / ?: Uncertain impact

- **Social impacts**

Under the 'no policy change' option, no significant changes are expected in the future with regard to the number of jobs in the button cell industry or with regard to public health quality.

The phase-out of mercury in button cells (Option 2) may theoretically slightly affect the employment generation in EU, primarily in relation to production and end-of-life management of button cells. However, due to a lack of information concerning the extent of these impacts, their quantification is not possible. Besides, Option 2 will have a positive impact on public health quality in the long term, due to the elimination of exposure to mercury emissions associated with the end of life of button cells.

Conclusions

Based on the analysis conducted in this study, the ban on the placing on the market of mercury-containing button cells in the EU emerges out as a clear winner in terms of environmental benefits, with very limited adverse economic impacts as compared with the 'no policy change' option. A legal ban would be to accelerate the transition to Hg-free alternatives and the reduction of costs for the production of Hg-free button cells.

The phase-out of mercury in button cells placed on the EU market would also create a level playing field for button cell manufacturers/importers/traders around the global market as Hg-containing buttons cells have already been banned in other parts of the world (e.g. US States of Maine, Connecticut and Rhode Island). Such a phase-out in the EU would therefore foster innovation and create business opportunities for EU button cell companies to play a leading role in the global context.

Besides, such a policy option would encourage countries importing large amounts of button cells to the EU market, such as China (where most button cells are manufactured), to switch to the manufacture of Hg-free button cells, which could have a global impact on the use of mercury in this industry sector.

Chapter 1: Introduction

This report presents the findings of the study on 'Potential for reducing mercury pollution from dental amalgam and batteries' carried out for the European Commission (DG Environment). It mainly consists of two assessments of policy options to reduce environmental impacts from dental amalgam and mercury-containing batteries, respectively. This introductory chapter explains the general context underlying the study, the objectives of the study and the overall approach and methodology followed.

1.1 The mercury issue

Mercury (Hg) and most of its compounds are highly toxic to humans, ecosystems and wildlife. High doses can be fatal to humans, but even relatively low doses can have serious adverse impacts on the developing neurological system, and have been linked with possible harmful effects on the cardiovascular, immune, and reproductive systems. Mercury also retards microbiological activity in soil, and is a priority hazardous substance under the Water Framework Directive (2000/60/EC). According to the World Health Organization (WHO), a safe level of mercury – below which no adverse effects occur – has not been established.

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.

Mercury is persistent and can change in the environment into methylmercury, one of its most toxic forms. Methylmercury accumulates in the food chain and humans can be exposed especially through ingestion of contaminated food (e.g. contaminated fish). Methylmercury readily passes both the placental barrier and the blood-brain barrier, inhibiting potential mental development even before birth. Hence exposure of women of child-bearing age and children is of greatest concern.

Although mercury is released by natural sources like volcanoes, additional releases from anthropogenic sources, like coal burning and use in a wide range of products and processes, have led to significant increases in environmental and human exposure. Past releases have also created a 'global pool' of mercury in the environment, part of which is continuously mobilised, deposited and re-mobilised. Further emissions add to this global pool circulating between air, water, sediments, soil and biota. Estimates of current global anthropogenic air emissions are still relatively uncertain and vary between 1,230 and 4,000 tonnes/year[25.] In addition to primary

[25] Selin NE (2009) Global Biogeochemical Cycling of Mercury: A Review, Annual Review of Environment and Resources 34: 43-63; UNEP Chemicals (2008) The global atmospheric mercury assessment: sources, emissions and transport; Pirrone N et al. (2010) Global mercury emissions to the atmosphere from anthropogenic and natural sources. Atmospheric Chemistry and Physics Discussion

emissions, mercury can be re-emitted once deposited. Natural emissions plus re-emissions are estimated to be around 1,800-5,200 tonnes/year globally[2].

The primary source of anthropogenic mercury emissions is coal combustion, accounting for 60%, or even more, of global mercury emissions. Unintentional mercury emissions also occur in other industrial processes (non-ferrous metal production, cement manufacture, etc.). For the EU-27, atmospheric mercury emissions were estimated at approximately 73 t in 2009, having shown a significant decrease since 1990 (-65% between 1990 and 2009)[26]. Emissions have continued to decrease in recent years although at a slower rate than in the 1990s.

Additional mercury emissions are also due to the intentional use of mercury in a wide range of products and processes. At the global level, artisanal and small-scale gold mining (ASGM) remains the largest mercury use sector, other key uses being the production of vinyl chloride monomers (VCM), the production of chlor-alkali and the use of mercury in batteries, dental fillings, lamps and measuring and control devices. At EU level, mercury is used in more than 60 different applications and mercury consumption was estimated to range between 320 and 530 tonnes in 2007[27]. In 2007, the main applications in the EU were: chlor-alkali production (41% of total EU mercury use), dental amalgam (24%), measuring equipment and techniques (16%), production of chemicals (e.g. polyurethane elastomer representing 7%), batteries (4%) and light sources (3%). According to these figures, once the use of mercury is phased out in chlor-alkali production in accordance with EuroChlor's voluntary agreement (target date 2020), dental amalgam will become the largest mercury use in the EU.

The consequence of current mercury uses and associated emissions will be adding up to the 'global mercury pool'. Part of the mercury from this global pool is continuously mobilised, deposited and re-mobilised. It circulates between air, water, sediments, soil and biota, eventually contaminating fish and causing other problems, until it finally reaches a long-term sink. While there is no prospect of an immediate solution to this problem, action can be taken now in order to reduce the amount of new mercury released by human activities to this global pool.

Mercury releases from mercury-containing products and processes contribute significantly to overall mercury releases from anthropogenic activities in the EU.

The largest source of mercury exposure for most people in developed countries is inhalation of mercury vapour from dental amalgam[28]. Exposure to methylmercury mostly occurs via diet.

[26] EEA (2011) European Union emission inventory report 1990–2009 under the UNECE Convention on Long-range Transboundary Air Pollution (LRTAP), Table 2.13 (http://www.eea.europa.eu/publications/eu-emission-inventory-report-1990-2009)

[27] COWI/Concorde (2008) Options for reducing mercury use in products and applications, and the fate of mercury already circulating in society. Report for the European Commission, DG Environment (http://ec.europa.eu/environment/chemicals/mercury/pdf/study_report2008.pdf)

[28] Communication from the Commission to the Council and the European Parliament – Community Strategy Concerning Mercury – COM (2005) 20 final (eurlex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=COMfinal&an_doc=2005&nu_doc=20)

1.2 EU policy context

The health and environmental risks associated with mercury have led the EU to develop a comprehensive strategy addressing mercury pollution both in the EU and globally. The Commission adopted its Community Strategy concerning Mercury in 2005[28], setting out 20 actions with the aim to 'reduce mercury levels in the environment and human exposure, especially from methylmercury in fish'.

In December 2010, the Commission published a Communication on the review of the Community Strategy concerning Mercury[29]. The review of the Strategy's implementation[30] showed that significant progress had been made with regard to a number of actions proposed in 2005 such as e.g. the adoption of the Mercury Export Ban Regulation[31], the phase-out of mercury use in certain measuring devices under the REACH Regulation[32], the submission of additional mercury use restriction proposals under REACH[33], and the EU's contribution to the progress of international negotiations on the mercury treaty. The review also highlighted areas for further improvement, among which the remaining uses of mercury in several applications where mercury-free alternatives exist and are already used to some extent; this concerns in particular dental amalgam and button cell batteries.

1.3 International policy context

Since the early 2000's, various countries of the world have been cooperating within the framework of the United Nations Environment Programme (UNEP) to reach agreement on international measures to reduce mercury levels in the environment. Until now, these measures have been implemented on a voluntary basis.

In February 2009, world environment ministers agreed that negotiations should be opened on a Multilateral Environmental Agreement (MEA) on mercury within the framework of the UNEP. Five meetings of the Intergovernmental Negotiating Committee (INC) to prepare a global,

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[29] Communication from the Commission to the European Parliament and the Council on the review of the Community Strategy Concerning Mercury, COM(2010)723final (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52010DC0723:EN:NOT).

[30] The EC's Communication was informed by a report by BIO Intelligence Service prepared for DG ENV in 2010 (http://ec.europa.eu/environment/chemicals/mercury/pdf/review_mercury_strategy2010.pdf)

[31] Regulation (EC) No 1102/2008 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 (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32008R1102:EN:NOT)

[32] Commission Regulation (EC) No 552/2009 of 22 June 2009 amending Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII

[33] Two REACH Annex XV Restriction Reports submitted by ECHA in 2010, concerning mercury use in additional measuring devices (http://echa.europa.eu/doc/restrictions/annex_xv_restriction_report_mercury_en.pdf) and phenylmercury compounds (http://echa.europa.eu/doc/restrictions/annex_xv_restriction_report_phenylmercury_compounds_en.pdf)

legally-binding instrument on mercury are planned until 2013[34]. The first three meetings took place in June 2010, January 2011, and October 2011.

The MEA on mercury is intended to cover the entire life cycle of mercury, from extraction to permanent storage, as well as all the major sources of emissions. With regard to mercury use in products and processes, the draft convention text currently includes a list of possible mercury uses that have been proposed for prohibition measures[35] (version of 27 June 2011). Dental amalgam and batteries are currently included in this list, among other applications, with the possibility to define allowable use exemptions. In the case of dental amalgam, a global phase-down of this application has been discussed during previous meetings (rather than specific exemptions).

1.4 Objectives of the study

In a context of growing evidence concerning the adverse environmental effects of mercury contained in dental amalgam and button cell batteries on the one hand, and recent policy developments within Member States and at the international levels on these topics on the other hand, this study aims to provide the Commission with an evidence base in order to inform future EU policy actions. Specific objectives are as follows:

- Establish the current situation with regards to the quantities of mercury used in dental amalgam and batteries in the EU and examine the environmental impacts of these products over their life cycle

- Propose and compare relevant policy options in order to reduce the environmental impact of these products and promote the use of mercury-free alternatives, with the objective to minimise and, where feasible, eliminate mercury use, on the basis of their respective economic, social, and environmental impacts.

[34] Further details available on the UNEP mercury webpage: www.unep.org/hazardoussubstances/MercuryNot/MercuryNegotiations/tabid/3320/language/en-US/Default.aspx

[35] UNEP(DTIE)/Hg/INC.3/3. New draft text for a comprehensive and suitable approach to a global legally binding instrument on mercury (www.unep.org/hazardoussubstances/Mercury/Negotiations/INC3/INC3MeetingDocuments/tabid/3487/language/en-US/Default.aspx)

1.5 Overall approach, methodology and timeframe

The study builds upon previous work conducted on the issue of mercury pollution from dental amalgam and batteries at EU level. It aims to complement and update these previous studies, by analysing the most recent data and by looking at the full EU picture in a comprehensive manner.

The methodology included three main tasks as shown in the figure below.

Figure 3: Task structure

Task 1: Scientific/Market review and assessment of environmental impacts

- **Subtask 1.1:** Scientific review on health aspects of using dental amalgam
- **Subtask 1.2:** Assessment of environmental impacts from the use of dental amalgam in EU 27
- **Subtask 1.3:** Market review on dental amalgam and Hg-free alternatives
- **Subtask 1.4:** Market review on Hg-containing batteries and Hg-free alternatives

Task 2: Impact assessment (IA)

- **Subtask 2.1:** IA of policy options to reduce the environmental impact of dental Hg
- **Subtask 2.2:** IA of policy options to reduce the environmental impact of Hg from batteries

Task 3: Recommendations

- **Subtask 3.1:** Workshop
- **Subtask 3.2:** Conclusions and recommendations

Task 1

Task 1 aimed to develop an evidence base to inform the assessment of policy options in Task 2. It consisted in collecting and analysing information and quantitative data to characterise the environmental impacts of dental amalgam and assessing its contribution to the overall mercury problem in the EU. It also included the preparation of a brief overview of the ongoing scientific debate on health aspects of using dental amalgam, focusing on the most recent developments on this topic. Market reviews related to dental amalgam and mercury-containing batteries, as well as their mercury-free alternatives, were also conducted under Task 1.

While Subtask 1.1 relied on a review of scientific literature, the other subtasks relied on desktop research complemented with stakeholder consultation through questionnaires and telephone interviews.

▷ Dental amalgam

With regard to the dental amalgam issue, following the review of publicly available information, tailored questionnaires were sent to various types of stakeholders in order to fill the information gaps related to environmental and socio-economic aspects of the problem:

- Environmental and health authorities within Member States (see the questionnaire in Annex A)
- Industry stakeholders: dental associations, dental fillings suppliers, waste treatment industry, crematoria businesses and water treatment industry
- NGOs and academic experts.

In total, questionnaires were sent to about 300 organisations/institutions. To date, we have received:

- Responses from environmental and/or health authorities from 20 Member States[36], with varying levels of detail (few Member States were able to provide all relevant data)
- 5 responses from national dental associations
- 2 responses from dental fillings suppliers
- 4 responses from cremation organisations
- 5 responses from water treatment organisations
- 4 responses from NGOs and academic experts.

In addition, several dental fillings manufacturers, national dental associations and researchers were contacted by telephone to obtain additional information and a telephone interview was also held with the Council of European Dentists (CED).

One major challenge is a lack of reliable and up-to-date data in many Member States on dental amalgam use, related mercury emissions, and dental restoration costs, which required a number of assumptions and extrapolations. Stakeholders active at the EU level (CED, FIDE[37], ADDE[38]) informed that they do not hold data on dental amalgam use in the EU nor any data on the size of the EU market for dental amalgam.

▷ Batteries

With regard to button cell batteries, a review of previous relevant studies[39] was first carried out and was followed by a review of the latest publicly available EU market statistics from Eurostat (PRODCOM). As information from PRODCOM is not available at the necessary level of detail (in

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[36] AT, BE, BG, CZ, CY, DE, DK, EE, FI, HU, IE, LT, LV, MT, PL, SE, SI, SK, UK. In addition, LU and RO advised that they were not able to provide any valuable information in relation to the study.

[37] Federation of the European Dental Industry

[38] Association of Dental Dealers in Europe

[39] Previous studies in the context of the Batteries Directive review (see http://ec.europa.eu/environment/waste/batteries/

particular, it does not provide specific data for button cell batteries), the information was collected via questionnaires and telephonic interviews with relevant stakeholders: button cells manufacturers, recyclers, waste compliance organisations and industry associations[40]. Main stakeholders consulted include:

- European Portable Battery Association (EPBA[41])
- European Battery Recycling Association (EBRA[42])
- Battery Compliance Organisations in the Member States (e.g. SCRELEC in France, GRS in Germany, BEBAT in Belgium, REBAT in Hungary, STIBAT in The Netherlands)
- Battery recycling companies
- Battery manufacturers (e.g. VARTA, Energizer, JVC, Sony, GP batteries, Panasonic).

Task 2

Task 2 consisted of two assessments of policy options to reduce the environmental impacts of mercury from dental amalgam and batteries. These assessments were based on data collected and analysed during Task 1 of the study. The methodology employed to carry out these assessments follows the Commission's Impact Assessment Guidelines.

Task 3

Task 3 includes a stakeholder consultation workshop (March 2012) during which the preliminary findings of the study will be presented and discussed with the stakeholders.

Timeframe of the study

The study started in June 2011 and will be completed by the end of May 2012. The present report contains the outputs of Tasks 1 and 2. Based on the outcomes of the consultation (Task 3), recommendations will be developed and a final report will be submitted.

1.6 Document structure

This report is divided into two parts addressing the two issues:

- Part A is an assessment of policy options to reduce environmental impacts from dental amalgam use
- Part B is an assessment of policy options to reduce environmental impacts from mercury-containing batteries, with particular focus on button cell batteries.

[40] Five responses (button cells battery manufacturers) were received and phone interviews were carried out with representatives of EPBA (European Portable Battery Association) and EBRA (European Battery Recycling Association).

[41] www.epbaeurope.net

[42] www.ebra-recycling.org/

Each part of the report follows the same structure:

- A definition of the problem to be addressed and the objectives of future policy action (Chapter 2 in Part A and Chapter 6 in Part B)
- A description of policy options to be investigated (Chapter 2 in Part A and Chapter 7 in Part B)
- An analysis of environmental, economic and social impacts of the selected policy options (Chapter 3 in Part A and Chapter 8 in Part B)
- A comparison of policy options to achieve the objectives previously set out, and the conclusions of the assessment (Chapter 5 in Part A and Chapter 9 in Part B).

The annexes of the report provide the evidence base developed as part of this project to support the two assessments, as well as the questionnaires developed to collect information from the stakeholders. The evidence base includes, in particular, an analysis of environmental impacts of the dental amalgam life cycle, a literature review of the health impacts of dental amalgam, a market review of dental amalgam and mercury-free alternatives, and a market review of mercury-containing and mercury-free button cell batteries.

PART A: Assessment of policy options to reduce environmental impacts from dental amalgam use

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Chapter 2: Problem definition and objectives

This chapter describes the problems associated with the use of dental amalgam, the main drivers for these problems and the key actors. It also describes the current policy context, the current situation with regard to environmental and socio-economic aspects of the problem as well as the likely evolution of the impacts in the absence of any further EU policy action. Finally, the objectives of future policy action to address the dental amalgam issue are defined, in line with the problems and drivers identified.

It is important to note that this study focuses on the *environmental* impacts of dental amalgam use and assesses policy options aiming to address these *environmental* concerns (which also lead to indirect human health effects via diet). Current scientific knowledge and uncertainties on possible *direct health effects* of dental amalgam are briefly mentioned in the problem definition and are taken into account in the assessment of policy options, however they are not the main focus of this study.

2.1 Introduction

Dental amalgam is a combination of metals, containing about 50% of mercury in the elemental form, the other metals being silver (about 35%), tin, copper, and other trace metals. Dental amalgam has been used for over 150 years for the treatment of dental cavities and is still used due to its specific mechanical properties and the long-term familiarity of many dental practitioners with amalgam. 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 the dental amalgam 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 and hot beverages (mercury excreted by humans).

2.2 Policy context

2.2.1 EU policy context

In 2008, as part of the implementation of the Community Strategy concerning Mercury (Action 6 of the Strategy), the EC consulted two Scientific Committees on the environmental impact and human safety of dental amalgam, the Committee for Environmental and Health Risks (SCHER) and the Committee for Emerging and Newly Identified Health Risks (SCENIHR). With regard to direct risks for public health, the SCENIHR concluded that – based on the studies reviewed – it was not possible to demonstrate any links between dental amalgam and systemic diseases (e.g. neurological disorders) and that mercury-free alternatives were also safe to use[43]. With regard to environmental impacts, the SCHER concluded that on the basis of the information available, it was not possible to '*comprehensively assess the environmental risks and indirect health effects from use of dental amalgam in the Member States (MS) of the EU 25/27*', and identified a number of knowledge gaps[44]. In order to address these gaps, the SCHER suggested that the following information be obtained:

- More specific information on possible regional-specific differences in the use, release and fate of mercury originating from dental amalgam
- A comprehensive and updated data compilation on the effects to especially (various) environmental species of mercury and methylmercury
- A more comprehensive evaluation of atmospheric emissions and further deposition of mercury from crematoria, taking into account EU-wide practices and possible region-specific local scenarios
- A comprehensive literature review of the bioaccumulation and biomagnification of methylmercury under different EU conditions
- A detailed comparison of the relative contribution of dental mercury to the overall mercury pool - originating from intended and non-intended mercury - in the environment.

Action 4 of the EU Mercury Strategy involved a review by the Commission of '*Member States' implementation of Community requirements on the treatment of dental amalgam waste*', and taking '*appropriate steps thereafter to ensure correct application*'. However, the 2010 review of the Strategy's implementation indicated that there were still significant compliance gaps with regard to the implementation of EU waste legislation in dental practices in several Member States.

Mercury emissions from cremation are not the subject of any specific action of the EU Mercury Strategy and are not covered by any EU legislation, however some policy options to address these emissions were investigated as part of the Extended Impact Assessment (ExIA) of the Strategy in 2005[45]. This ExIA concluded that EU-level action was not appropriate at that stage, mainly because most of the problem with mercury emitted from crematoria was covered by an OSPAR Recommendation and by legislation in some of the remaining Member States which are not parties to the OSPAR Convention[46]. It should be noted, however, that a previous

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[43] SCENIHR (2008) The safety of dental amalgam and alternative dental restoration materials for patients and users (http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_016.pdf)

[44] SCHER (2008) Opinion on the environmental risks and indirect health effects of mercury in dental amalgam (http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_089.pdf)

[45] EC, 2005, Extended Impact assessment of the Community Strategy concerning Mercury (http://ec.europa.eu/environment/chemicals/mercury/pdf/extended_impact_assessment.pdf)

[46] The OSPAR Convention covers twelve Member States: Belgium, Denmark, Finland, France, Germany, Ireland, Luxembourg, Netherlands, Portugal, Spain, Sweden and the United Kingdom.

recommendation from the OSPAR Convention, i.e. the recommendation to phase out mercury use in chlor-alkali plants (PARCOM Decision 90/3), has proven to be poorly implemented and the target date of 2010 has not been met[47]. The ExIA also noted that available data on the extent of emissions from cremation were limited and that future reporting required by the OSPAR Recommendation would provide an initial indication of the extent to which the Recommendation is being applied. No further analysis could be made as part of the Mercury Strategy's review in 2010, due to a lack of recent data.

Given the abovementioned data gaps and the implementation gaps with regard to EU waste legislation applicable to dental amalgam waste, the Commission – in its Communication on the review of the Strategy – expressed its intention to undertake in 2011 a study to assess the use of mercury in dental amalgam with due consideration to all aspects of its lifecycle.

In March 2011, the Environment Council welcomed the Strategy's review and the significant progress achieved in implementing the Strategy by adopting Council Conclusions[48]. In its Conclusions, the Council invited the Commission and Member States to '*consider, where appropriate, the possible need for measures to reduce the environmental impact of mercury in dental amalgam*', on the basis of the investigation planned by the Commission.

Some Member States have put in place legislation that goes beyond EU policy concerning the issue of dental amalgam, in particular:

- Recommendations from health authorities to restrict the use of dental amalgam (e.g. in vulnerable patients) (DE, FR, IT, NL, and Catalonia in ES) or legal provisions to partially or totally prohibit the use of dental amalgam (DK and SE)
- Mandatory installation of amalgam separators in dental facilities (AT, BE, CZ, DE, FR, FI, IT, LV, MT, NL, PT, SE, SI, and the UK)
- Emission Limit Values (ELVs) for mercury and/or requirement for mercury abatement devices at crematoria (BE, CZ, DE, DK, FR, IT, LU, NL, and the UK)
- More stringent mercury limit values in sewage sludge used for agricultural purposes (in many Member States).

Further details on national legislation concerning dental amalgam is provided in Annex B.

[47] There is, however, a voluntary commitment from Euro Chlor to phase out mercury use in EU chlor-alkali production by 2020.

[48] Council of the EU, Council conclusions – Review of the Community Strategy concerning Mercury, Brussels, 14 March 2011 (www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/envir/119867.pdf)

2.2.2 International policy context

In addition to the global mercury treaty under preparation (see Section 1.3), the mercury issue is covered by several existing international agreements. The OSPAR Convention[49] is of particular relevance to this study: Parties to the OSPAR Convention, which include twelve EU Member States, have recommended that Best Available Techniques to reduce mercury air emissions from cremation should be used (OSPAR Recommendation 2003/4, as amended[50]). The HELCOM Recommendation 29/1[51] on the reduction of emissions from crematoria, which applies to three EU Member States (DK, FI, and SE), also 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.

Outside these multilateral agreements, several non-EU countries have taken measures going beyond current EU policy to restrict mercury use in products and processes. For example, Japan, Norway and Switzerland have restricted or almost totally banned the use of dental amalgam, among other mercury uses (through legislation and/or voluntary measures).

Further details on international policies and best practices concerning dental amalgam are presented in Annex B.

2.3 Problem definition

2.3.1 Dental amalgam use

Dental amalgam is one of the main remaining uses of mercury in the EU. In this study, EU consumption of dental amalgam is estimated to represent between 55 and 95 t Hg per year in 2010 with an average value of 75 t Hg per year (further details are provided in Section 2.6.1.1). In 2007, dental amalgam was the second largest mercury use in the EU after chlor-alkali production[27] and it is expected to become the largest mercury use once mercury cell-based chlor-alkali production is phased out in accordance with EuroChlor's voluntary agreement (target date 2020).

2.3.2 Environmental aspects of dental amalgam use

The mercury problem has been briefly described in the introduction to this report (Section 1.1) and further are available in the EU Mercury Strategy[28] or in the UNEP Global Mercury Assessment[52].

The fundamental problem with the current situation is that certain population groups – and especially women of childbearing age and children – are subject to high risk levels of exposure to

[49] OSPAR Convention for the Protection of the Marine Environment of the North-East Atlantic (www.ospar.org)

[50] www.ospar.org/v_measures/browse.asp

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

[52] UNEP (2002) Global Mercury Assessment Report

mercury, principally in the form of methylmercury through diet. This presents a risk of negative impacts on health, in particular affecting the nervous system and diminishing intellectual capacity. There are also environmental risks, for example the disturbance of microbiological activity in soils and harm to wildlife populations. According to calculations based on the critical load concept[53], more than 70% of the European ecosystem area is estimated to be at risk today due to mercury, with critical loads for mercury exceeded in large parts of western, central and southern Europe[54].

Although dental use of mercury seems to have been declining over the last few years, it remains a significant contributor to overall environmental mercury releases in the EU. In the environmental assessment presented in Annex C of this report, it was roughly estimated that 46 t Hg/year from EU dental practices end up in chairside effluents, with only a part of which being captured and treated as hazardous waste in compliance with EU legislation. Mercury in dental waste represents about 52 t/year. It was roughly estimated that dental amalgam contributes 21-32% to overall EU mercury emissions to air and up to 9-13% to overall EU mercury emissions to surface water. Mercury emitted to the air can be partly deposited into other environmental compartments (soil, surface water, vegetation). Emissions to soil and groundwater are also significant, although their contribution to overall mercury releases to this environmental compartment is more difficult to quantify. It is estimated that about half of the mercury released from current and historical dental amalgam use remains potentially bioavailable, with the potential to contaminate fish in particular, the other half being either sequestered for long-term (stored in hazardous waste landfills) or recycled for new purposes.

The problem of mercury pollution from dental amalgam is twofold: in the first place, pollution is caused by the historical use of dental amalgam, while the current use of dental amalgam adds up to mercury releases from historical practice. The drivers of the problems identified can be described as a combination of market and regulatory failures.

2.3.2.1 *Pollution caused by historical use of dental amalgam*

Some of the emissions associated with the historical use of dental amalgam, e.g. emissions from burial and emissions from amalgam deterioration in mouths, are difficult to tackle due to their diffuse nature. However, a significant part of these emissions can be minimised through proper waste and wastewater management in dental facilities and the use of efficient mercury abatement devices in crematoria.

The handling of dental amalgam waste as hazardous waste (which involves the use of efficient amalgam separators, the segregation of amalgam waste from other waste types and its

[53] This concept is mainly based on ecotoxicological effects and human health effects via ecosystems. It is generally defined as a quantitative estimate of an exposure to one or more pollutants below which significant harmful effects on specified sensitive elements of the environment do not occur.

[54] Hettelingh, J.P., J. Sliggers (eds.), M. van het Bolcher, H. Denier van der Gon, B.J.Groenenberg, I. Ilyin, G.J. Reinds, J. Slootweg, O. Travnikov, A. Visschedijk, and W. de Vries (2006). Heavy Metal Emissions, Depositions, Critical Loads and Exceedances in Europe. VROM-DGM report, www.mnp.nl/cce, 93 pp.; CEE Status Reports 2008 (Chapter 7, http://www.rivm.nl/thema/images/CCE08_Chapter_7_tcm61-41910.pdf) and 2010 (Chapter 8, http://www.rivm.nl/thema/images/SR2010_Ch8_tcm61-49679.pdf)

treatment as hazardous waste) is a matter of enforcing EU legislation on waste[55]. Adequate handling of dental amalgam waste is also necessary to achieve certain goals of EU legislation on water quality[56]: mercury is considered as a priority hazardous substance, requiring a cessation of emissions, discharges and losses within 20 years after adoption of measures. Only in 14 MEMBER STATES, national legislation has been adopted to specifically oblige dental facilities to be equipped with efficient amalgam separators. In most other MEMBER STATES, in the absence of specific national legislation or guidance from national authorities, many dental practices are still not equipped with amalgam separators. The present study estimated that around 25% of EU dental facilities are still not equipped with amalgam separators at present. The situation differs widely across Member States, as shown in Table 37 (of Annex H). Besides, previous studies have shown that a significant proportion of separators are not adequately maintained, which can significantly reduce their mercury capture efficiency; in the present study, it is roughly assumed that currently functioning separators have an average efficiency of 70%, while they are normally designed to achieve a minimum 95% efficiency when maintained in good condition. Although it is much easier to capture mercury at dental facilities than once it is mixed with other urban effluents, the installation and maintenance costs of an amalgam separator are borne by dentists, while local authorities bear the cost of removing mercury from urban sewage sludge.

In the absence of further policy action, the share of dental practices equipped with amalgam separators is likely to increase slowly in line with the replacement rate of old dental chairs (as new chairs are generally equipped with amalgam separators). However, in the absence of a stronger enforcement of EU waste legislation, it may take a long time to have all dental facilities equipped with separators and properly maintained so that at least 95% of amalgam particles are captured.

With regard to mercury emissions from crematoria, which are not addressed by EU legislation, EU mercury emissions seem to have remained stable since 2005 due to an increased number of crematoria equipped with mercury abatement devices. Based on the latest estimates, crematoria are responsible for approximately 4% of overall EU mercury releases to the atmosphere[57]; however, there is significant uncertainty on reported emission data (see Annex C for details). This stabilisation of emissions may be partly attributed to the implementation of the OSPAR Recommendation in twelve Member States[58]. In addition, large emitters such as the UK and France have recently implemented more stringent legislation aiming to limit mercury emissions from crematoria. However, it is difficult to predict how EU emissions will evolve in future in the absence of further policy actions, as emission reduction efforts can be partly offset by the increasing cremation rate and the increasing proportion of deceased people having amalgam fillings.

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[55] Waste Framework Directive (2008/98/EC)

[56] In particular: Water Framework Directive (2000/60/EC), Decision 2001/2455/EC and Directive 2006/11/EC on dangerous substances and Directive 2008/105/EC on priority substances

[57] EU mercury releases to the atmosphere estimated at 73 t in 2009 according to LRTAP data

[58] BE, DE, DK, ES, FI, FR, IE, LU, NL, PT, SE, UK. Czech Republic seems to be the only Member State, despite not being party to the OSPAR Convention that has legislation to address mercury emissions from crematoria in place.

2.3.2.2 Pollution caused by current use of dental amalgam

With regard to the current use of dental amalgam, solutions are available to minimise mercury emissions from amalgam waste and to phase out mercury use in most medical conditions.

As in the case of historical amalgam use (see the previous sub-section), emissions related to waste and wastewater management are first a matter of effective enforcement of EU waste legislation in Member States and a necessity to comply with long-term requirements of EU legislation on water quality.

The current use of dental amalgam will also generate environmental pollution at later stages of the dental amalgam life cycle (deterioration of amalgams in people's mouths, emissions from cremation and burial, etc.), leading to problems similar to those described in the previous sub-section.

Although Hg-free alternatives to dental amalgam exist and can be used in most medical conditions, they are still not widely used in a number of Member States (e.g. FR, PL, UK, CZ, RO, ES, and GR). The main reasons behind this situation are as follows:

- Hg-free dental restorations are more expensive for patients, as compared with dental amalgam restorations, in many MEMBER STATES. This is both due to the higher actual cost of most Hg-free restorations (the Atraumatic Restorative Treatment or 'ART' being an exception) and the fact that Hg-free restorations are not always reimbursed by the existing national insurance schemes at the same level as dental amalgam.
- Not all dentists are properly trained and skilled in conducting Hg-free restorations and insufficiently trained dentists may be more reluctant to propose Hg-free restorations to patients. This may be partly due to a lack of initial training in Hg-free techniques in dental schools, although the situation is improving in some MEMBER STATES. The lack of skill can also reduce the longevity of the Hg-free fillings (the longevity of Hg-free fillings is very sensitive to the quality of the intervention).
- Many dentists are not aware of the benefits of ART, a cheap Hg-free restoration technique already widely used in developing countries and which may have a significant potential in the EU.
- Some dentists are reluctant to change their current practice and to invest in new equipment required to handle Hg-free fillings. In parallel, they may not be fully aware of the seriousness of the environmental impacts caused by dental amalgam and of the societal benefits of reducing mercury emissions.
- Not all patients are fully aware of the pros and cons associated with the different types of filling materials. In particular, many patients are not aware of the presence of mercury in dental amalgam and the extent of the associated environmental impacts.

- Some dentists consider that, although Hg-free materials have been used in some countries for many years, the absence of long-term environmental and health effects of these materials has not been fully demonstrated.

The fact that Hg-free dental restorations are more expensive than dental amalgam restorations can be seen as a market failure in the sense that negative externalities associated with the use of dental amalgam (management of dental waste and effluents) are not factored in the actual cost of dental amalgam restorations. It also results from a lack of information available to some dentists and citizens about the environmental consequences of using dental amalgam.

2.3.3 Health aspects of dental amalgam use

Possible human health impacts of dental amalgam are still the subject of significant scientific debate. While there is a common viewpoint among stakeholders that the adverse environmental effects of dental amalgam use need to be addressed, there is not sufficient scientific consensus on the *direct* health effects of dental amalgam to justify further policy action on this sole basis. For this reason, the objectives of future policy action concerning dental amalgam defined in Section 2.7 below only refer to the *environmental side* of the problem. However, because possible health impacts are relevant to the assessment of some policy options, this study included a short review of the scientific literature on this issue.

A summary of the current status of the scientific debate is presented here, highlighting the few areas of consensus and the main disputed issues. This summary is based on a detailed literature review that can be found in Annex D.

The health effects of dental amalgam have been controversial ever since this material was introduced, early in the nineteenth century, because of its mercury content. Recent evidence that small amounts of mercury are continuously released from amalgam fillings has fuelled the controversy. The release rate of mercury vapour from amalgams is dependent on several parameters: filling size, tooth characteristics, texture and temperature of ingested food, as well as the surface area, composition, and age of the amalgam. Mercury from amalgam may be transformed into more toxic organic mercury compounds (e.g. methylmercury) by microorganisms present in the oral cavity, in the gastrointestinal tract, and in the natural environment. It has also been shown that dental amalgam is by far the main contributor to mercury body burden. Although there is some consensus on the fact that people with amalgam fillings are exposed to some mercury released from the amalgam, the magnitude of this exposure is subject to controversy. The SCENIHR report (2008) highlighted that the mercury exposure of individuals having mercury fillings is 5 to 30 times lower than limit values for occupational exposure. However, the method used to determine this exposure – which is generally the concentration of mercury in urine and blood – has often been criticised. A number of experiments with animals and humans showed that despite normal or low mercury levels in blood, hair, and urine, high mercury levels were found in critical organs such as brain and kidney. Indirect exposure can also occur once the mercury contained in amalgams is released into the environment (e.g. the aquatic environment). The exposure to environmental methylmercury most frequently occurs through ingestion of fish and seafood consumption.

Exposure to mercury contained in amalgams can cause allergies and may increase the risk of neurological diseases, kidney diseases, autism, autoimmune diseases, and birth defects. While the allergic and other hypersensitivity disorders due to mercury or the other alloy metals contained in dental amalgam are widely accepted, there is no scientific consensus on the other health impacts and, for some scientists, existing studies show little evidence of specific dental amalgam related effects. Pregnant women and children have been the subject of several studies and were found to be more susceptible to lower exposure levels when compared with the rest of the population. Mercury from maternal amalgam fillings is associated with an increase in mercury concentration in the tissues and the hair of foetuses and newborn children. Evidence of neurotoxicity from prenatal methyl-mercury exposure is now considered sufficient for high exposure levels, but again there is no consensus on the health effects related to specific mercury exposure from dental amalgam.

No link has been observed between mercury exposure and negative health effects with respect to dentist mortality, although the mercury blood level is higher in dentists than in a reference population. Adverse health effects on dental nurses' reproductive health were observed in nurses who handled amalgam without adequate measures to protect them from exposure to mercury vapours. Appropriate handling can significantly reduce exposure to mercury, however amalgam is still handled without sufficient protection from mercury exposure in many dental clinics. In terms of neurological or renal diseases, no consistent result was found in a study in Denmark while in other studies signs of stress for renal dysfunction and changes in the brain electrical activity were observed following mercury exposure in dental workers. When considering self-reported symptoms, studies on dental staff workers show increased neuropsychological complaints.

There is also some debate on further research needs on this issue. Some scientists recommend additional studies particularly for investigation of neurodegenerative diseases and immune effects on infants and children, sex-related differences, and susceptibility to mercury toxicity, while others consider that enough research has already been carried out on the subject.

2.4 Who is affected?

As a significant contributor to overall mercury pollution, dental amalgam use affects the entire EU population. All individuals are exposed to mercury pollution to some degree. However, some groups are particularly vulnerable to the health effects of mercury pollution:

- High-level fish consumers; for example, EU populations living in coastal areas are more likely to be exposed to higher levels of methylmercury;
- Children (in particular, due to the increased vulnerability of their developing nervous system);
- Women who are pregnant, breastfeeding or thinking of becoming pregnant (due to the increased vulnerability of the foetus).

Mercury pollution may also negatively affect some activity sectors such as the fishing industry, if levels of methylmercury affect the marketability of fish or consumer confidence.

Other key actors likely to be affected include:

- Dentists, due to possible health effects of exposure to mercury vapours in dental practices and due to the costs for complying with EU waste legislation and the change in habits and equipment required when using alternative methods to dental amalgam restoration. A change in patients' dental care habits may also impact their revenues
- Dental assistants, which may be exposed to mercury vapours in dental practices and associated health hazards
- Dental patients, which have to bear possible cost differences between dental amalgam and Hg-free restoration techniques (possible direct health effects of dental amalgam are not considered here given the current lack of scientific consensus on several aspects of the problem)
- Companies involved in the manufacture and supply of dental fillings and of bulk mercury for dental use, through the revenue they get from their activities, as well as the associated jobs
- Operators of urban WWTPs, local authorities and EU taxpayers, because of the possible extra costs in sewage sludge management caused by the presence of mercury
- Companies providing solutions to manage dental amalgam waste, through the revenue they get from their activities, and the associated jobs
- Operators of crematoria, which may have to bear costs for capturing mercury in flue gases
- Public authorities, due to the administrative burden associated with the enforcement of policy measures required to address pollution from dental mercury
- Private health insurance companies, through the revenues they get from the coverage of dental restoration costs.

2.5 Justification for an EU action

First of all, the mercury pollution issue is a transboundary issue, as airborne mercury can be transported over long distances (i.e. across continents). An EU action would therefore be more effective than uncoordinated actions by the Member States to address this issue.

Because mercury pollution is a global issue, international cooperation is essential. Environmental impacts from dental amalgam use are one of the key issues discussed as part of the international negotiations to prepare a multilateral environmental agreement on mercury by 2013. A global 'phase-down' of dental amalgam use is being considered as one of the commitments that may be included in the future agreement. Complying with this potential commitment will require coordinated action from the EU.

In addition, some of the problems identified are due to poor enforcement of EU legislation on waste and lack of anticipation of measures required to comply with EU legislation on water quality, at Member State level. Only action at EU level is relevant to address these failures.

Finally, with regard to the substitution of dental amalgam by Hg-free materials, some of the key obstacles identified are the unequal levels of dentists' environmental awareness concerning the mercury issue and the unequal skills of dentists in Hg-free techniques, from one Member State to another. It turns out that some Member States would benefit from the experience gained in Nordic Member States where Hg-free fillings have been used for a longer period of time. Action at EU level would foster the sharing of best practices related to Hg-free dentistry and would make the diffusion of such best practices quicker and more effective than uncoordinated action by the Member States.

2.6 Baseline scenario

This section provides a description of the current environmental and socio-economic aspects of dental amalgam use as well as their likely evolution under a 'business as usual' scenario. Before describing these environmental and socio-economic aspects, an analysis of the current and future demand for dental amalgam in the EU is presented, as dental amalgam demand is a key parameter in the present study.

In this study, the time horizon chosen for the description of the baseline scenario and the impacts' analysis is a 15-year horizon running from 2010 to 2025.

Due to the limited quantity of data provided by the stakeholders consulted during the study, the significant uncertainties associated with some of the data and the extrapolations that had to be made in order to obtain the EU27 picture, it must be stressed that the quantitative information presented in this baseline scenario should be considered as rough estimates. However, it is considered that these rough estimates still provide a good basis to compare the relative impacts of the different policy options.

2.6.1 Demand for dental amalgam and other filling materials

2.6.1.1 Current situation

- **Dental amalgam**

Estimates of mercury use associated with dental amalgam were provided by dental associations and national health authorities in 10 Member States . For the other Member States, data was either obtained from previous studies (FR, PL) or roughly estimated according to the methodology detailed in Annex E (15 Member States) which establishes correlations between population counts and dental amalgam use for three different groups of countries. In most

Member States, the data provided corresponds to 2010[59]. The detailed methodology and results are provided in Annex E.

The estimated annual demand for dental mercury per Member State, using this approach, is shown in

[59] In Slovenia the reference year is 2001. In Czech Republic, the data corresponds to an annual average for the period 2006-2011. In France, data derives from 2003 estimates on dental restorations. Polish estimates rely on dental treatment statistics from 2006.

Figure 4 below. At EU27 level, it amounts to 55 t Hg/year in 2010.

Estimates provided by Member States are often based on calculations based on the number of restorations covered by the respective national health insurance schemes. As amalgam may also be used in the private dental sector (although probably to a lesser extent than in the public sector), the estimates provided by Member States are considered to represent the lower end of the possible range of values concerning dental mercury use. In addition, environmental NGOs have argued that dental amalgam use data reported by national health authorities and dental associations is likely to be lower than actual values, considering the strong opposition of certain dentists to a possible restriction of dental amalgam as well as previous occurrences of under-reported mercury use or emissions in other industry sectors[60].

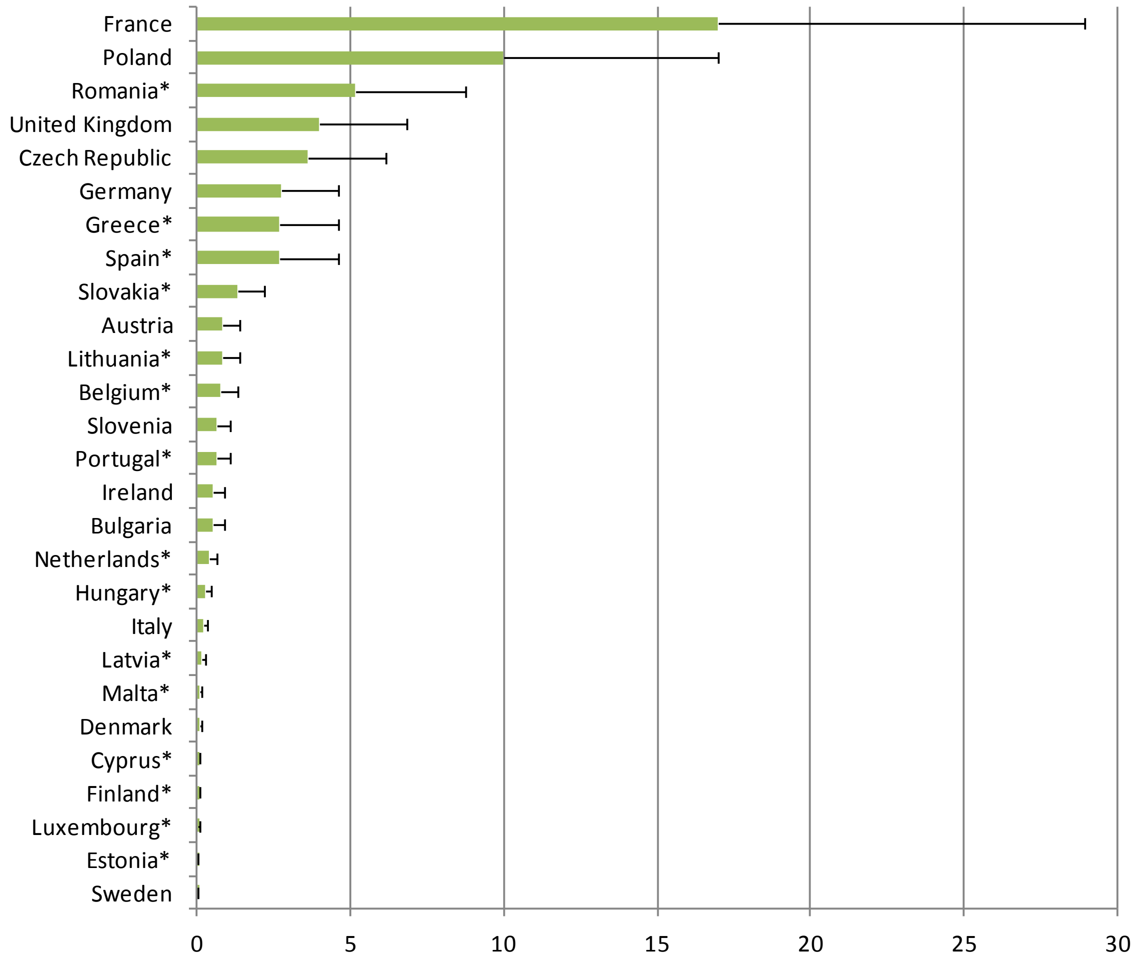
Given the downward trend in the use of dental amalgam in the EU (see the next section), the maximum possible value for dental mercury use is taken as the average value estimated by a previous study for the Commission, corresponding to year 2007, which amounts to 95 t Hg/year[61].

The range of values used in the rest of this study is therefore **55 to 95 t Hg/year** for the year 2010, with an average value of **75 t Hg/year**.

[60] As an example of under-reported mercury use, Swedish authorities reported an annual use of 24 kg Hg in batteries in 2003, while the actual figure was at least six times larger (KemI (2004) Report 4/04. Mercury – investigation of a general ban, Report by the Swedish Chemicals Inspectorate in response to a commission from the Swedish Government; Hylander, L.D. (2005) Based on trade statistics on batteries from Statistics Sweden and analyses of mercury content of various batteries). Another example of publicly under-reported mercury figures relates to mercury emissions from global waste incineration which are grossly underestimated in official reporting and need to be multiplied by a factor up to five (Pacyna, E.G., and Pacyna, J.M. (2002) Global emission of mercury from anthropogenic sources in 1995, Water Air Soil Pollut. 137, 149, 2002)

[61] COWI/Concorde (2008) Options for reducing mercury use in products and applications, and the fate of mercury already circulating in society. Report for the European Commission, DG Environment

Figure 4: Demand for dental mercury in EU Member States (t Hg/year)



Source: Data provided by national dental associations and/or health authorities via the study questionnaire, taken from previous studies or estimated by BIO using available data.
*Estimated by BIO

This estimate is lower than the estimate published in a previous study carried out in 2008[62]. A previous study estimated the use of dental mercury consumption at approximately 110 t in 1990 for EU15 and 70 t in 2000[63]. A gradual decrease in amalgam use in the EU is consistent with the results of a survey carried out by the Council of European Dentists (CED) in 2010, according to which the use of dental amalgam was decreasing in 27 of the 31 countries that responded. The greatest decreases were observed in countries that have restricted or phased out the use of dental amalgam.

While the gradual decrease in the use of dental amalgam by dentists over the last few years is probably the main reason why dental amalgam demand estimated in this study is lower than previous estimates, it should be noted that these estimates are based on different sources of

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[62] COWI and Concorde E/W (2008): 80-110 t Hg in 2007

[63] RPA (2002) Risks to health and the environment related to the use of mercury products, Report for European Commission - DG Enterprise(http://ec.europa.eu/enterprise/sectors/chemicals/files/studies/rpa-mercury_en.pdf)

information. For example, the 2008 estimates by COWI/Concorde appear to be based on information provided by some dental fillings manufacturers, while in the present study the information mainly comes from national health authorities and dental associations (more than 20 dental fillings manufacturers/suppliers were contacted but only one reply was received; additionally, the FIDE and ADDE industry federations and the CED claimed that they did not have any EU-wide data on dental amalgam production or consumption figures).

As shown in

Figure 4, France appears to have the highest consumption, at some 30% of the total EU demand. Together with Poland, these two countries seem to account for almost 50% of dental amalgam demand in the EU 27. However, it should be noted that the French value relies on dental treatment statistics from 2003[64] while the Polish value relies on dental treatment statistics from 2006[65]; these values may therefore have reduced over the last few years as it was observed in other Member States.

- Encapsulated vs. bulk mercury

In 2007, the share of bulk mercury in dentistry was estimated at approximately 30%[27]. According to a survey carried out by the CED in 2010 covering 29 European countries, in 12 countries the use of encapsulated dental amalgam was required by law and overall in 23 countries the use of bulk mercury was reducing (as the survey was anonymous, the concerned Member States cannot be identified). As part of the present study, little additional information was obtained on this aspect. Ireland, Latvia, Austria, Italy and France replied that the use of bulk mercury is limited or nonexistent in their countries. In Germany, 22% of total dental mercury consumed is reportedly in bulk form.

- Imports and exports

Previous estimates on production of dental amalgam in the EU27 corresponded to 130 t Hg for 2007 and the demand was approximately 95 t Hg; in addition, approximately 25 t of dental Hg were imported and 60 t exported[27]. These values were based on the assumption that 40% to 50% of dental amalgam produced in the EU was exported whereas 20% to 30% of the EU25 demand was imported. By applying these shares to the estimates of dental amalgam use in the present study, it can be estimated that currently approximately 100 t of dental Hg is produced in EU27 companies from which 47 t are exported while an additional 20 t are imported in the EU.

[64] AFSSAPS (2005) Le mercure des amalgames dentaires (http://www.bastamag.net/IMG/pdf/rapport_afssaps_2005_mercure_dentaire.pdf)

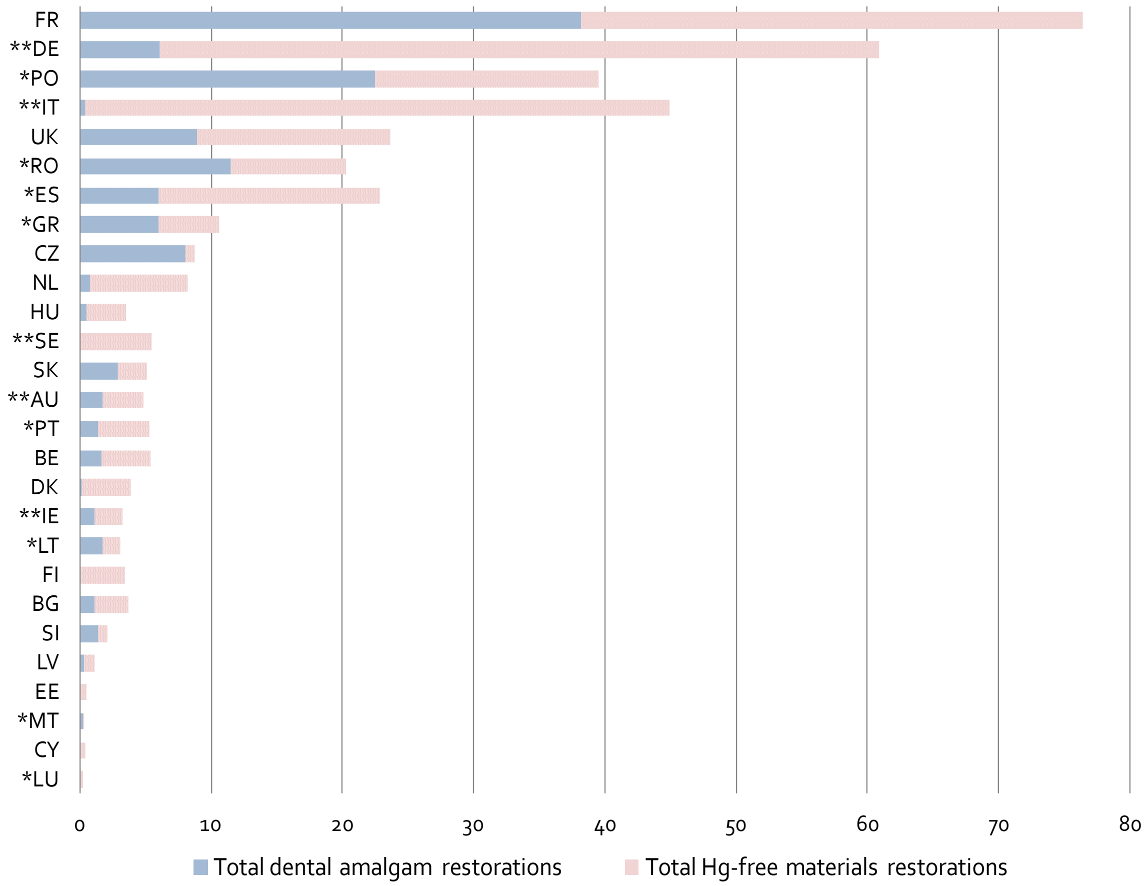
[65] NILU Polska (2009) Cost-benefit analysis of impact on human health and environment of mercury emission reduction in Poland – Stage 1 (http://www.gios.gov.pl/zalaczniki/artykuly/etap1_20101022.pdf)

Alternative materials

Currently the most commonly used alternatives to dental amalgam are composites, glass ionomer cement, compomers, giomers, sealants, and dental porcelain. Composite resin fillings, the most common alternative , are made of an acrylic resin reinforced with powdered glass and they are tooth coloured. Like composite resins, glass ionomer cements are made of an acrylic resin and are tooth-coloured.

Most Member States do not collect data on the amounts of Hg-free materials used in dental practices; however, some information could be obtained in terms of number of restorations per filling material in several Member States and this was extrapolated for other Member States (see Figure 5 below). The approach and detailed results concerning the estimation of the number of restorations per material type are presented in Annex E.

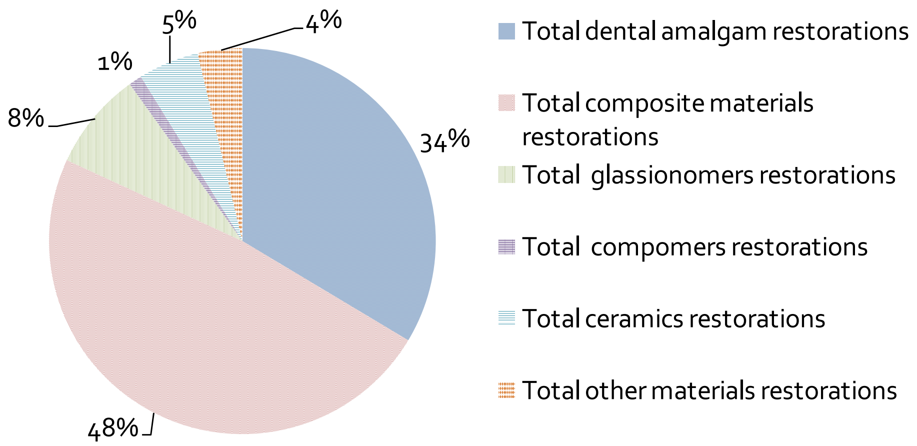
Figure 5: Number of restorations per filling material per Member State (millions per year)



*Estimated (see Annex E)
**Countries that provided a detailed breakdown of Hg free restorations by specific type of material

Based on this data, it can be estimated that in the EU27 approximately 370 million dental restorations are carried out annually, of which 125 million with dental amalgam and 245 million with Hg-free materials[66]. Overall, this indicates that Hg-free materials are used more often than dental amalgam (in approximately 66% of restorations). Approximate shares of dental filling materials used in the EU are illustrated in Figure 6. Regarding shares of each main type of Hg-free material currently used in restorations, it is roughly estimated that the composites, glass ionomers, ceramics, and compomers are used respectively in 48%, 8%, 5% and 1% of dental restorations. This estimate is based on detailed information provided by or identified in 5 Member States (DE, IT, SE, AT, and IE).

Figure 6: Share of dental filling materials used in EU (in number of restorations)



Besides alternative restoration materials used in conventional restoration techniques, another promising alternative to amalgam-based restorations is the Atraumatic Restorative Treatment (ART)[67], a low cost and relatively simple technique (compared with conventional restoration techniques) which uses hand instruments and high-viscosity glass ionomers. In spite of its lower cost, the present use of ART in EU countries is very limited[68] and many dental practitioners are not yet aware of it[69]. Further details on ART are provided in Box 1 below.

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[66] The estimation is based on the average estimated dental amalgam demand (75 t Hg/year in 2010). The values are calculated are based on a value of 600 mg of Hg per restoration and on the breakdown of dental restorations by type of material which was provided by certain Member States (see Annex E for details).

[67] World Health Organization, ART-Atraumatic Restorative Treatment, http://toxicteeth.org/CAPP-ART.pdf; Jo E. Frencken, Evolution of the ART approach: highlights and achievements, J APPL ORAL SCI. 17 (sp issue): 78-83 (2009), http://www.globaloralhealth-nijmegen.nl/ProceedingsTandheelkundeBiWe.pdf

[68] See e.g. Honkala S, Honkala E. (2002) Atraumatic dental treatment among Finnish elderly persons. J Oral Rehabil;29(5):435-440

[69] See e.g. F. J. T Burke, S. McHugh, L. Shaw, M-T. Hosey, L. Macpherson, S. Delargy and B. Dopheide (2005) UK dentists' attitudes and behaviour towards Atraumatic Restorative Treatment for primary teeth, BRITISH DENTAL JOURNAL 199, 365 - 369 (http://www.nature.com/bdj/journal/v199/n6/pdf/4812696a.pdf)

Box 1: The Atraumatic Restorative Treatment (ART)

ART involves removing soft, demineralised tooth tissue using only hand instruments followed by restoration with an adhesive dental restorative material. The advantages of this treatment, compared with conventional restorative techniques , include: provision of restorative dental treatment outside the dental surgery setting, a biologically friendly approach, minimal cavity preparations, low costs, reduced risk for subsequent endodontics and tooth extraction and lower dental anxiety in children and adults (more patient-friendly technique) [70]. Additionally, since ART is not painful, both the time and cost of administering anaesthetics is eliminated[71].

The cost of ART is much lower than that of dental amalgam restorations (According to the Pan American Health Organization, ART restorations only cost half as much as amalgam restorations[72].) ART uses only inexpensive materials and hand instruments that do not require electricity. This type of treatment can make the control of dental caries available to all people irrespective of their economic and living conditions[73,74].

Because of its low cost and its simplicity as a minimal intervention technique, ART was initially developed for use in the developing countries where population has a limited access to dental treatment. However, in the past year, it has been included as part of the 'minimum intervention' philosophy in developed countries[75]. This philosophy is also supported by the World Dental Federation (FDI)[76], which states that 'operative intervention should focus on the preservation of natural tooth structure and be limited to the removal of friable enamel and infected dentine'. ART and other Minimally Invasive Techniques tend to prolong the life of the tooth before extraction and possibly before expensive implants will be required.

A survey published in the Journal of the American Dental Association revealed that, in the USA, 44% of respondents used ART 'very often/often' and another 23% used it 'sometimes'; furthermore, 40% of respondents reported that continuing education about ART would be 'very desirable or desirable'[77]. According to a specialist of ART, this technique is currently used 'in the most exclusive dental practices' in particular in the USA, the UK and the Netherlands".[78]

[70] Dorri M, Sheiham A, Marinho VCC (2009) Atraumatic restorative treatment versus conventional restorative treatment for the management of dental caries. (Protocol).

[71] F. J. T Burke, S. McHugh, L. Shaw, M-T. Hosey, L. Macpherson, S. Delargy and B. Dopheide (2005) UK dentists' attitudes and behaviour towards Atraumatic Restorative Treatment for primary teeth, BRITISH DENTAL JOURNAL 199, 365 - 369 (http://www.nature.com/bdj/journal/v199/n6/pdf/4812696a.pdf)

[72] Pan American Health Organization, Oral Health of Low Income Children: Procedures for Atraumatic Restorative Treatment (PRAT) (2006), http://new.paho.org/hq/dmdocuments/2009/OH_top_PT_low06.pdf

[73] Phantumvanit P, Songpaisan Y, Pilot T, et al. (1996) Atraumatic restorative treatment (ART): a three-year community field trial in Thailand—survival of one-surface restorations in the permanent dentition. J Public Health Dent 56:141–5

[74] Pan American Health Organization, Oral Health of Low Income Children: Procedures for Atraumatic Restorative Treatment (PRAT) (2006), http://new.paho.org/hq/dmdocuments/2009/OH_top_PT_low06.pdf

[75] See e,g Frencken J. (2009) Evolution of the ART approach: highlights and achievements, J APPL ORAL SCI. 17 (sp issue): 78-83 (2009), http://www.globaloralhealth-nijmegen.nl/ProceedingsTandheelkundeBiWe.pdf

[76] FDI (2002) Minimal Intervention in the Management of Dental Caries, FDI Policy Statement

[77] Seale NS, Casamassimo PS (2003) Access to dental care for children in the United States: a survey of general practitioners. J Am Dent Assoc. 2003;134:1630-40

[78] Jo E. Frencken (2009) Evolution of the ART approach: Highlights and Achievements, JOURNAL OF APPLIED ORAL SCIENCE, V17, Special Issue 2009, http://www.globaloralhealth-nijmegen.nl/Proceedings-Symposium-ART-2009.pdf

2.6.1.2 *Future trends*

In 10 Member States that provided estimates, there is a consensus that the use of dental amalgam is expected to decrease in future years, except in the UK for which two different opinions were received: the British Dental Association (BDA) expects a stabilisation whereas the Department of Environment, Food, and Rural Affairs (DEFRA) expects a decrease. Further details on the responses provided by the Member States are presented in Annex E. The overall downward trend was also suggested by the 2010 CED survey, in which national dental associations from 23 European countries reported that the use of dental amalgam was decreasing, while it was restricted or banned in a further 4 countries[79]. The only manufacturer of dental fillings which replied to the present study's questionnaire (producing both amalgam and Hg-free materials) reported that the use of dental amalgam is decreasing rapidly in the EU.

In future years, the use of dental amalgam may continue to decline in the EU, mainly as a result of growing aesthetic concerns, although it is difficult to predict the speed of this decline. Some estimates of dental amalgam use for previous years (i.e. before 2010) are available, however they are not based on the same information sources as the present study; hence it does not seem relevant to estimate an annual decrease rate based on these values.

This study assumes that, in the absence of further EU action, a decrease in dental amalgam demand in future years will be observed in all Member States, but it will occur at different speeds and the demand will stabilise at different levels depending on the Member States. Following main factors will influence this trend:

- As long as environmental externalities are not included in the price of amalgam fillings, specific groups of the society might not be able or willing to bear the presently higher price for most Hg-free restorations; many of the current health insurance schemes reimburse a similar fixed amount whatever the material chosen and there is no evidence that they will increase the reimbursement of Hg-free restorations in the future
- A lack of skills in the handling of Hg-free filling materials (due to insufficient training and/or experience) and a reluctance to change traditional practices might remain an important factor that might keep dental amalgam more attractive for the majority of dentists in some Member States
- Environmental awareness might not be sufficient to induce a change in dental practices as long as there are no policy incentives or legal measures discouraging or banning mercury use.

The trends could be observed in three groups of Member States, with some common characteristics (see further details in Annex E). The assumptions for each group of countries are summarised in Table 2 below.

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[79] The survey was anonymous, hence it is not possible to identify which Member States responded what.

Table 2: Assumptions on future dental amalgam demand in the baseline scenario

Group	Share of dental amalgam in 2010 (in % restorations)	Expected share of dental amalgam in 2025 (in % restorations)	Dental Hg use in 2010 (t)	Projected dental Hg use in 2025 (t)	Comments
Group 1 **DK, EE, SE, IT**	0-5%	0%	0.3-0.4	0	This group includes countries where amalgam use is very limited and is expected to cease in the mid-term due to policy measures in place (e.g. SE) or other factors
Group 2 **BG, BE, CY, DE, HU, IE, LU, NL, PT, ES, LV**	6-35%	5 to 15%	9 – 12	3– 8	Countries in this group use both types of filling materials. Demand for dental amalgam is expected to continue to decrease until it reaches a relatively low share of restorations.
Group 3 **AU, CZ, FR, GR, LT, MT, PO, RO, SK, SI, UK**	>35%	20-30%	46 - 78	23-35	This group includes countries where dental amalgam is still widely used as well as less wealthy countries where a large proportion of the population might not be able to bear the additional cost of Hg-free restorations. In addition, due to the high current use of dental amalgam, proportionally there would be a higher number of dentists unwilling to change their current practices.
		All 27 MS	55 - 95	27-43	

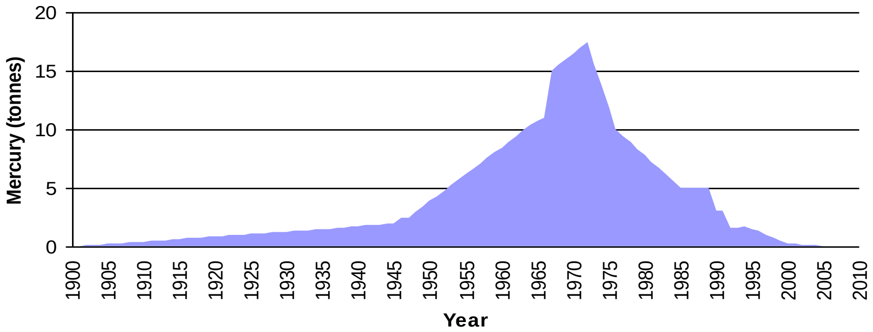
Based on these trends, it can be expected that, in 2025, the use of dental mercury would have decreased by 31 to 47 t Hg in EU27 compared to the 2010 levels and would stabilise at approximately 27 to 43 t Hg/year. A reduction of this size entails that the use of dental amalgam would decrease by approximately 5% annually over a 15-year long period of time.

An average annual reduction of dental amalgam use by 5% seems realistic given information that has been published in previous studies. For example, according to a study carried out for the European Commission in 2002[80], in Finland the use of dental amalgam was reduced by 5.5% annually between 1990 and 2002, in the Netherlands by 5.4% between 1989 and 1990 and in the UK by 5.6% annually between 1992 and 1997. The case of Sweden, where the reduction in dental amalgam demand has been achieved in several steps, can also be mentioned as an example (see Box 2 below).

[80] RPA (2002), Risks to health and the environment related to the use of mercury products, Report for the European Commission - DG Enterprise (http://ec.europa.eu/enterprise/sectors/chemicals/files/studies/rpa-mercury_en.pdf)

Box 2: Evolution of dental amalgam demand in Sweden

In Sweden, the use of dental amalgam started to grow markedly when the Public Dental Health Service in 1938 started to offer free dental care with amalgam to pregnant women and later on to schoolchildren. The amalgam consumption grew rapidly, peaking at more than 17.5 t Hg in 1972. A large part of this mercury was used as an amalgam die, a model of a tooth or several teeth made of amalgam to serve as a basis for further dental treatment of the patient. Based on the precautionary principle with regard to possible health effects to the foetus, in 1970 it was recommended that dental amalgam should no longer be used in pregnant women. After 1972, mercury use in Swedish dentistry decreased also for several other reasons such as environmental considerations and preventive dental care resulting in improved dental health with less need for restorative measures. The decline was 10% per year on average in 1973-79 and only 5% per year in 1980-89. A revitalized debate on the environmental and health aspects of mercury led to a declaration by the Swedish Parliament (Riksdagen) to phase out the use of mercury in dentistry, after which the use of dental amalgam declined by 19% per year on average in the 1990's. Still, the decline based on voluntary measures did not fulfill the objective to phase out all uses of dental amalgam until 1997. Therefore, a decision was taken in the beginning of the 21st century to ban all uses of dental amalgam from June 2009, after which the rate of decline increased at 45% per year from 2000. Until 2012, there was an exception making it possible to use dental amalgam in hospital dentistry in exceptional cases. This possibility was used for less than 10 patients the first year after the general ban had entered into force in 2009. This evolution is illustrated in the graph below[81].



Mercury used annually in dentistry in Sweden

[81] Data sources:

Ferm, R., Larsson J. E. 1973. Kvicksilver : användning, kontroll och miljöeffekter. (Mercury: usage, control, and environmental effects.) SNV PM 421. Solna : Statens naturvårdsverk. (85 pp.) (In Swedish).

Halldin, A., Pettersson, O. 1978. Turnover of mercury in Sweden. Naturvårdsverket rapport SNV PM 928, Solna. 120 pp. (In Swedish; English summary.) ISSN 0346-7309

Hylander, L. D. & Meili, M. 2005. The rise and fall of mercury: converting a resource to refuse after 500 years of mining and pollution. Crit. Rev. Environ. Sci. Technol. 35:1-36

KemI 2004. Report 4/04. Mercury – investigation of a general ban. KemI, October 2004. Report by the Swedish Chemicals Inspectorate in response to a commission from the Swedish Government. http://www.kemi.se/upload/Trycksaker/Pdf/Rapporter/Rapport4_04.pdf

Levander, T. 1991. Kvicksilver i Sverige. Problem och åtgärder. *National Swedish Environmental Protection Agency. (Statens Naturvårdsverk).*(36p.)

The baseline scenario does not take into account any possible technological breakthroughs. In recent years, the benefits in new restoration treatment methods or materials (e.g. the ART technique) have been discussed at the global level, but currently there is no evidence that these may become widely used in the mid-term in the EU in the absence of further policy measures. In this baseline scenario, it is also assumed that the total number of dental restorations will remain stable in the mid-term. This assumption takes into account several aspects which are likely to have diverging effects in future years:

- In most Member States, oral health prevention policies may gradually decrease the needs for dental restorations (both amalgam and Hg-free)
- In some of the less wealthy Member States, there are large unmet needs for dental restorations and while the access to dental health care is gradually increasing, possibly leading to an increasing number of dental restorations
- Simultaneously, the overall improvement of dental health care in all Member States will increase the longevity of natural teeth in elderly people and consequently a larger proportion of the population may need dental treatment.

At present there are no quantitative estimates linking the quality of dental health care systems and the need for restorations in the future. In this context, it is assumed that the overall number of restorations will remain stable in the mid-term.

2.6.2 Environmental aspects

Current situation

Environmental impacts of dental amalgam use in the current situation have been briefly described in Section 2.3.2 above, on the basis of evidence presented in Annex C of this report (Assessment of environmental emissions from dental amalgam use).

Future trends

In the absence of further EU policy action, environmental impacts due to the historical use of dental amalgam will continue to occur for several decades since they are due to the removal of old fillings, the loss of teeth, the progressive deterioration of existing fillings and the end of life of amalgams when people decease. The total quantity of mercury currently stored in people's mouths is estimated to be about 1,000 t Hg for the EU27 (see Annex C for further details). Mercury releases from dental practices may decrease progressively along with the modernisation of dental practices, as new dental practices are generally equipped with amalgam separators. Among the consulted stakeholders , two Member States (UK and HU) stated that modern dental equipment tends to include dental amalgam separators. It is however highly unlikely that 100% of dental practices become compliant with the relevant requirements of EU waste legislation in the short term without any further enforcement actions from public authorities. With regard to the end of life of amalgams, future mercury releases from burial are likely to remain stable and will occur for several decades. Concerning mercury emissions from cremation, a stabilisation seems to have occurred since 2005, but future trends are difficult to predict due to several factors likely to produce contradictory effects. Mercury emission reduction efforts achieved through a progressive increase in the proportion of crematoria equipped with mercury abatement devices are likely to be offset by the increasing cremation rate and the increasing proportion of deceased people that have amalgam fillings in their mouths (see also Section 2.3.2.1). In this baseline scenario, it is therefore assumed that EU mercury emissions from cremation will remain at a similar level as today over the next 15 years.

Environmental impacts due to current and future use of dental amalgam depend upon future trends in dental amalgam use in the EU (see Section2.6.1.2) as well as possible improvements in mercury emission control strategies. If no further EU policy action is taken, the current use of dental amalgam will continue to generate environmental impacts that will occur over the whole lifetime of the amalgam fillings; a large part of the associated environmental emissions would occur during a period of 10 to 15 years after the placement of amalgam (this is the average lifetime of an amalgam filling)[82] but the actual environmental impacts (adverse effects to ecosystems) and possible indirect human health effects will occur for several decades. With regard to possible improvements in mercury emission control strategies, the baseline scenario's assumptions are similar to those described in the case of historical use of dental amalgam.

2.6.3 Economic aspects

In this section, the main economic aspects related to the use of dental amalgam are split according to the key actors concerned within the EU: manufacturers and suppliers of dental fillings, dentists, dental patients, waste management companies, EU taxpayers, crematoria and public authorities.

2.6.3.1 Manufacturers and suppliers of dental fillings

- **Current situation**

In this study, 57 main companies producing dental filling materials in the EU27 have been identified, of which 38 produce exclusively Hg-free materials and 19 produce both amalgam and Hg-free fillings. Of the 19 companies producing both types of fillings, 10 are based in Germany. Only two companies produce solely bulk mercury for applications in dental restorations[83]. A list of these companies is provided in Annex E. The majority of these companies are large companies, often EU subsidiaries of large multinational groups. Approximately 30 to 40% of these companies seem to be small or medium sized enterprises.

[82] Some amalgam restorations will last shorter (many last less than 2 years) while others have been reported to last up to 40 to 50 years (WHO (2010) Future use of materials for dental restoration)

[83] The Czech company Bome S.R.O. supplies bulk mercury directly to dental practices or to other manufacturers that produce dental amalgam capsules. The Italian company World Work Srl, produces dental amalgam capsules and dental products other than filling materials.

Future trends

Given the expected continued decrease in dental amalgam demand in future years, it is very likely that producers will substitute the production of dental amalgam with Hg-free materials or that they will increase their share in the global market of dental amalgam.

Given the fact that a large majority of dental filling manufacturers already produce Hg-free filling materials, the projected decrease in dental amalgam demand is not expected to have significant negative effects on this industry. On the other hand, revenues of the dental industry may increase given the higher sale prices of Hg-free filling materials. Besides, these companies tend to have a wide range of products other than dental filling materials.

Assuming that, on average, the average cost of the filling material for a dental restoration is 1 EUR for amalgam and 5 EUR for a composite or glass ionomer material[84], the increase in revenues for the EU dental fillings industry is estimated to be approximately EUR 2.3 billion for the period 2010-2025. This estimate is based on the assumption that: the share of the EU manufacturers of dental amalgam in the EU market will remain stable in the mid-term; for the period 2010-2025 the total dental amalgam demand substituted will be of approximately 350 t in total, representing approximately 580 million restorations (at 0.6 g Hg per filling); and the amalgam fillings will be substituted solely by Hg-free materials produced in the EU.

Unlike dental amalgam, Hg-free materials have been the subject of continuous technical improvements in the past years and this trend is expected to continue. The production of Hg-free materials is characterised by high-tech and more sophisticated processes. The projected demand increase for Hg-free materials is also expected to boost investments in R&D and innovation in the EU dental fillings industry, with the aim of improving material quality and decreasing production costs. Competition between dental fillings manufacturers may be increased as the production of Hg-free fillings is currently spread among more companies than the production of dental amalgam. Similar effects are expected to appear progressively in non-EU companies that have significant shares of the EU market.

2.6.3.2 Dentists

Costs incurred by dentists as a consequence of dental amalgam use mainly include costs for the installation and maintenance of amalgam separators and costs for the collection and treatment of amalgam waste as hazardous waste. These represent a part of the environmental costs of mercury pollution caused by dental amalgam ('environmental externalities'). These costs result from the need for dental practices to comply with EU waste legislation, which considers dental amalgam waste as hazardous waste. It can be assumed that such costs are to some extent included in the dentists' fees and therefore partially passed on to patients; however, to simplify, we consider here that they mainly affect dentists.

With regard to the costs related to dental restorations, it is assumed that they are fully passed on to dental patients (see Section2.6.3.3).

[84] Based on information provided by the German Dental Association (questionnaire reply). For composite, the material cost includes both the composite material as well as rubber dam, etchant and bond materials.

Current situation

In the EU27, there are approximately 62 dentists for every 100,000 inhabitants. In 2009, the total number of dentists in the EU27 was approximately 310,500[85]. Cyprus has the highest number of practising dentists per inhabitant (93 per 100,000 inhabitants in 2008) and Poland has the lowest population coverage (32 dentists per 100,000 inhabitants in 2009). Germany has the highest total number of practising dentists (approximately 62,000). Further data is provided in Annex E.

Costs of installing and maintaining amalgam separators

The cost of amalgam separators for dentists is in the range of EUR 400-500 per year, including installation, servicing, in-situ evaluation of filter efficiency and accreditation[27]. It is also estimated that there are approximately 130,000 to 210,000 dental clinics or dental offices. No statistics on the number or size of dental clinics in the EU could be found.

Annual costs of dental amalgam separators through their life cycle have been estimated by the US Environment Protection Agency (USEPA), including purchase or lease, installation, maintenance, replacement, transportation and waste recycling costs[86].Table 3 shows the estimated costs, per size of dental office and per life-cycle stage. The distribution of costs indicates that costs of amalgam separators are very much dependent on the size of dental offices as well as the installed model. In addition, the amount of wastewater discharged determines the needs for maintenance and replacements (e.g. of traps and filters).

Table 3: Estimated costs for amalgam separators by size of dental office in the USA (EUR)

Phase	Small (1-4 chairs)	Medium (5-12 chairs)	Large (+12 chairs)
Purchase	159-955	530-1,749	1,986-6,969
Installation	79-159	100-207	159- 794
Maintenance	0-159	0-159	0-159
Replacement of canisters	34-597	60-597	398-1,673
Estimated annual cost	147-748	204-767	1,387-3,227

Conversion rate: 1 EUR = 1.43 US$

Based on estimates reported by COWI/Concorde there are on average 2.1 practicing dentists per dental clinic. It is therefore more appropriate to consider the annual costs of small-sized dental clinics that are provided by the USEPA (approx. EUR 150 to 750). This estimate is consistent with the above-mentioned COWI/Concorde value, however with a much wider range. The COWI/Concorde estimates are based on the Danish market and therefore the US EPA costs might be more appropriate at the EU level where labour costs vary considerably among Member States. In addition, the USEPA considers all different types of separators (filtration,

[85] This number mostly includes practicing dentists. For countries where no information is available, the number of professionally active or licensed to practice dentists is used instead.

[86] USEPA (2008), Health Services Industry Detailed Study – Dental Amalgam (http://water.epa.gov/lawsregs/lawsguidance/cwa/304m/upload/2008_09_08_guide_304m_2008_hsi-dental-200809.pdf)

sedimentation, ion exchange, centrifugation and mix of these technologies) as well as different brands.

- Costs of collection and treatment of hazardous waste

The USEPA report provides estimates on the cost arising from recycling services related to amalgam separators. These services include the collection of amalgam waste form dental offices and the provision of related supplies, such as packaging, labels etc. The costs of these services as well as maintenance costs (including recycling) are estimated to range between $95 and $750 (EUR 66 to 523) per year. A previous study[87] in the US gives a lower estimate at $450 (EUR 314).

At the EU level, according to the stakeholders consulted, there is a significant variation of the costs incurred by dentists for the management of amalgam sludge: reported costs range between 100 and 600 EUR per year with an average cost of approximately 310 EUR per year and per dentist.

- **Future trends**

As explained in Section 2.3.2.1, it is highly unlikely that 100% of dental practices become compliant with the EU waste legislation in the short term without any further enforcement actions from public authorities. Only a slight increase in the number of dental clinics equipped with amalgam separators may be expected in the mid-term, due to the modernisation of equipment. In this baseline scenario, the costs incurred by dentists for managing dental amalgam waste are therefore not expected to change significantly in the mid-term. It must be noted that, even if the use of dental amalgam tends to decrease, this will not change the volume of sludge captured in amalgam separators and there is no efficient way to separate dental amalgam particles from mercury-free filling particles captured by the separator.

For some dentists which currently only perform dental amalgam restorations, the progressive increase in the demand for Hg-free restorations may oblige them to invest in additional equipment (except in the case of the ART technique which only requires hand instruments). Additional equipment required mainly consists of a polymer-curing lamp which costs EUR 540 to 1,620[27]. It is assumed that a vast majority of dental clinics are now equipped with such equipment, however the exact proportion is unknown.

2.6.3.3 *Dental patients*

The main economic aspect for dental patients is the cost of dental restorations. In the baseline scenario, the expected gradual change in dental filling restoration techniques will affect the costs incurred by dentists for performing the restorations and it is assumed that any changes in such costs will be fully passed on to dental patients. Dental restorations costs actually borne by the patients depend on four main factors:

[87] Walsh. 2007. Pepper Hamilton, LLP. The American Dental Association's (ADA) Comments on EPA's Study of a Pretreatment Requirement for Dental Amalgam. OW-2006-0771-0837. December 21.

- The cost of the filling material, which only represents a very small proportion of the total treatment cost[88].
- The labour cost, which is influenced by the time needed to perform a specific type of restoration and the hourly wage of the dentist. The time needed to perform a restoration may depend on the filling material used and on the specific skills of the dentist with regard to his/her ability to employ the different types of restoration techniques.
- The possible amount reimbursed to the patient by the national health insurance scheme, in countries where such schemes exist and cover dental restorations (further details provided in Table 25 in Annex E). It can be argued that even when costs are reimbursed, patients still bear these costs indirectly through their contributions to the national health schemes, however there are some redistribution effects.
- The longevity of the filling, which is an indirect but important cost factor.

Current situation

Responses to the study questionnaire showed large differences between Member States with regard to the cost of dental restorations for both dental amalgam and Hg-free materials. The differences in costs are mainly due to the differences in labour costs across the Member States and to the differences in the possible amounts reimbursed to patients by national health insurance schemes. The minimum, average, and maximum costs for dental amalgam and Hg-free restorations are presented in Figure 7 and Figure 8 below, covering Member States that provided information as part of the study (information was provided by national health authorities and/or dental associations). Average costs for EU12, EU15 and EU27 are also presented in Table 4 below. Detailed information is provided in Annex E (see Table 24). These costs correspond to the costs actually borne by the patients, i.e. taking into account the amounts possibly reimbursed by national health insurance schemes. These costs correspond to average restoration costs, considering the different types of restorations which may be performed (front teeth/rear teeth; 1, 2 or 3 surfaces; etc.). Hg-free restoration costs correspond to the use of composites or glass ionomers, i.e. the most common Hg-free materials used in the EU. The use of more expensive materials (e.g. ceramics or gold) has not been taken into account, as such materials cannot be compared with dental amalgam.

[88] For example, in Germany, the cost of the material is approximately 1 EUR per amalgam restoration and 5 EUR per composite restoration (Source: response to the study questionnaire)

Figure 7: Costs borne by patients for a dental amalgam restoration (EUR)

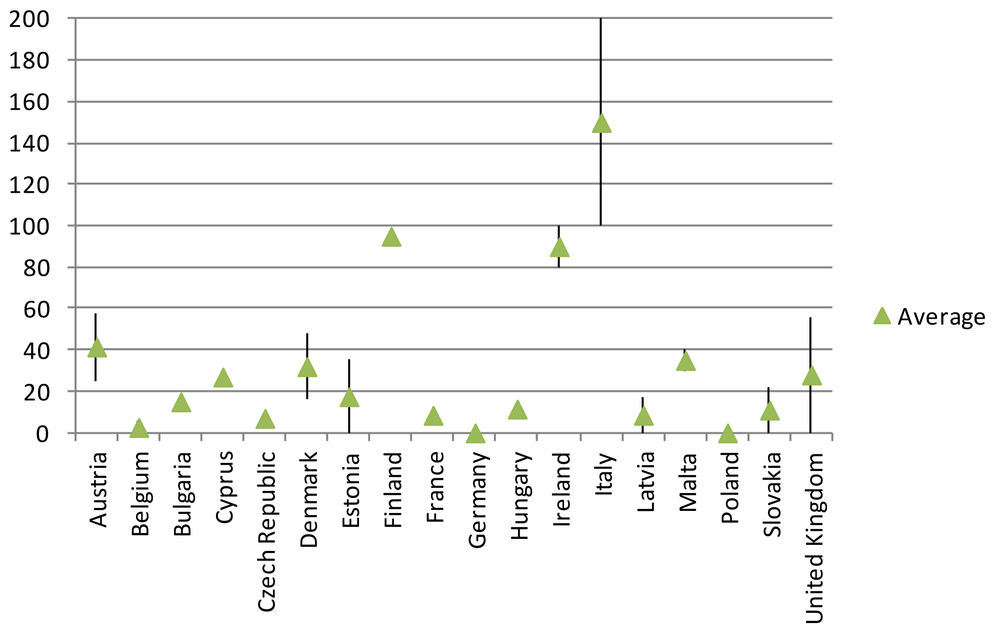


Figure 8: Costs borne by patients for a Hg-free restoration (EUR)

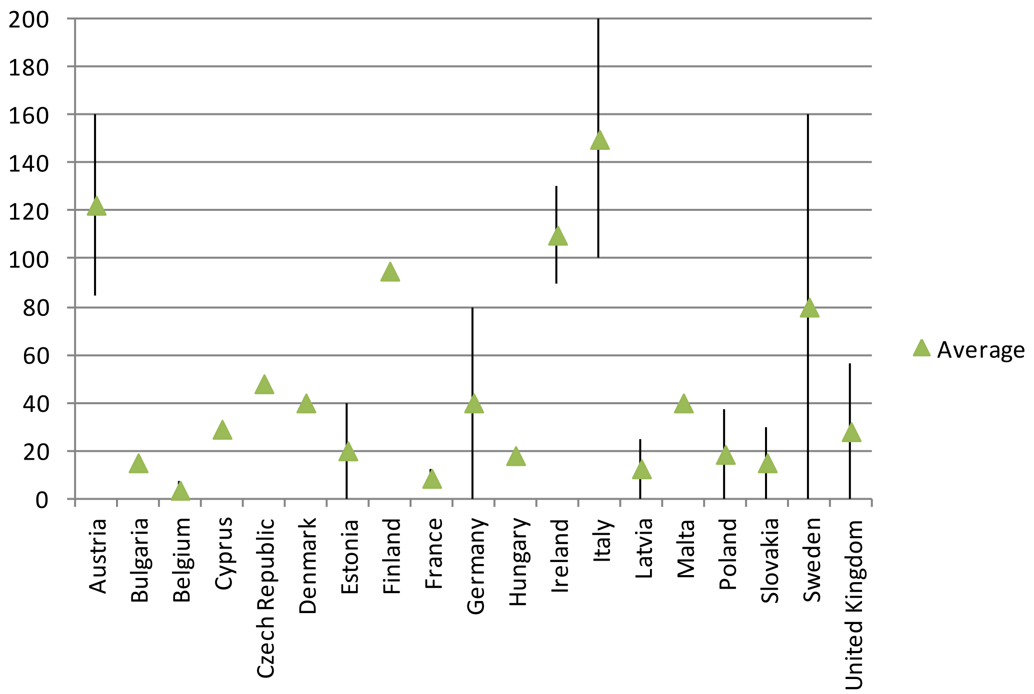


Table 4: Average dental restoration costs borne by patients

	Dental amalgam restoration cost (EUR)	Hg-free restoration cost (EUR)
EU27	32.2	47.0
EU15	49.7	67.8
EU12	14.7	24.0

According to the European Environmental Bureau (EEB)[89], in the USA the price of amalgam restorations has been rising faster than the price of composite restorations over the last few years, and there has been a decline in the price of mercury-free alternatives[90]. The least expensive Hg-free alternative appears to be ART (using glass ionomers): a restoration using ART costs about half the price of an amalgam restoration. At present, ART is not much used in the EU; however, in Sweden, glass ionomers using hand tools or ordinary instruments has increasingly become the first choice for restoring primary teeth[91,92].

- Time needed for restorations

The costs of dental restorations are greatly influenced by the time needed for the placement of the filling. Overall estimates on the time required for dental restorations vary considerably between the dentists. Some dentists claim that it takes longer to place a composite than an amalgam, e.g. the CED has estimated that it takes approximately 2.5 times longer to perform composite restorations, in comparison with amalgam restorations. However, dentists who use composites frequently say they can place a composite as fast as an amalgam. The WHO pointed out that staff training is a major component for success in using mercury-free alternatives[93]. In Sweden, where dental amalgam has been banned, it has been shown that the time needed to carry out a Hg-free restoration has reduced significantly as dentists have gained more experience in the handling of Hg-free materials. A 2011 study[94] revealed that '*over the past two decades, studies have been conducted in North and South America, Europe and Asia examining the teaching of resin-based materials for restoring posterior teeth. The findings of each study were similar, and concluded that the emphasis on teaching posterior resin composite placement had increased, but most dental graduates had minimal clinical experience with their placement*'.

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[89] Consultation to the present study

[90] The following study revealed that the price of amalgam has been rising faster than resins within the period 1975-1995: L. Jackson Brown & Vickie Lazar (1998) Dental Procedure Fees 1975 through 1995: How Much Have They Changed?, Journal of the American Dental Association (Sept. 1998), http://jada.ada.org/content/129/9/1291.short

[91] Sarmadi, Roxana (2010) ART. Public Dental Health Service, County of Uppsala.pdf

[92] Gabre, Pia (2010) Behandling av karies. Public Dental Health Service, County of Uppsala.pdf

[93] WHO (2010) Future Use of Materials for Dental Restoration (www.who.int/oral_health/publications/dental_material_2011.pdf)

[94] Zunliang Liew et.al. (2011), Survey on the teaching and use in dental schools of resin-based materials for restoring posterior teeth, INTERNATIONAL DENTAL JOURNAL available at http://onlinelibrary.wiley.com/doi/10.1111/j.1875-595X.2011.00003.x/pdf

Furthermore, to properly place an amalgam two visits to the dentist are required (one to place the filling and a second one to polish), making it the less efficient procedure. If left unpolished, amalgam restorations will have a lower lifetime. Also, the time required for a composite to replace a previous amalgam restoration is higher than for replacing a composite filling: a cavity originally prepared to receive an amalgam filling is typically larger and distinguished by various angles that would never be prepared for a composite, rendering the placement of a composite more difficult and time-consuming than it would otherwise have been.

- Longevity of restorations

A different longevity of the filling can indirectly affect the cost difference between amalgam and Hg-free restorations over the long term, as a shorter average lifetime of a dental filling means more frequent dental restorations. The longevity of the fillings depends on a multitude of factors, among which the type of filling material and the quality of the placement when composites are concerned (the quality of the placement is itself very much influenced by the experience of the dentist in handling composite fillings). While amalgam fillings used to have a longer average lifetime than composite fillings (10-15 years vs. 5-8 years for composites according to the WHO)[93], recent studies show that the longevity of both types of fillings tends to become similar thanks to recent technological improvements in composite materials and greater experience of dentists in handling such materials[95,96]. According to the WHO, '*recent data suggest that RBCs (resin-based composites) perform equally well as amalgam*' and '*composite resins have been reported to last 12-15 years*'[97]. According to a 2010 study over the course of 12 years, 'large composite restorations showed a higher survival in the combined population and in the low-risk group' and amalgam survived better only in specific circumstances (for 'three-surface restorations in high-risk patients, amalgam showed better survival'[98]. In addition, the longevity of ART restorations (which rely on glass ionomers) is now equal to or greater than that of equivalent amalgam restorations[99,100,101]. The operator performance is considered as crucial factor in relation to the level of void avoidance and therefore training is very important for the success of ART.

Another parameters is the annual failure rate. According to the WHO, dental amalgam and composites have a similar failure rate (around 2.2%), whereas other Hg-free materials have a higher failure rate; glass ionomers have the highest failure rate at 7.6%[93]. According to a 2005

[95] Christopher D. Lynch et al. (2011), Minimally invasive management of dental caries: Contemporary teaching of posterior resin-based composite placement in U.S. and Canadian dental schools, J AM DENTA ASSOC 2011; 142; 612-620 (http://jada.ada.org/content/142/6/612.abstract)

[96] Zunliang Liew et.al. (2011), Survey on the teaching and use in dental schools of resin-based materials for restoring posterior teeth, INTERNATIONAL DENTAL JOURNAL

[97] WHO (2010) Future Use of Materials for Dental Restoration, p.18

[98] N.J.M. Opdam, E.M. Bronkhorst, B.A.C. Loomans, and M.-C.D.N.J.M. Huysmana, 12-Year Survival of Composite vs. Amalgam Restorations, JOURNAL OF DENTAL RESEARCH, October 2010, Vol. 89, 10: pp. 1063-1067, available at http://jdr.sagepub.com/content/89/10/1063.abstract

[99] Mickenautsch S, Yengopal V, Banerjee A (2010). Atraumatic restorative treatment versus amalgam restoration longevity: a systematic review. Clin Oral Investig 14: 233-240

[100] Regia Luzia Zanataet al. (2010) Ten-year survival of ART restorations in permanent posterior teeth, CLINICAL ORAL INVESTIGATIONS, Volume 15, Number 2, 265-271 (2010), http://www.springerlink.com/content/w208655418q560g0/

[101] Frencken JE (2010) The ART approach using glass ionomers in relation to global health care. Dent Mater 26: 1-6

study published in the American Journal[102] of Dentistry, amalgam has a mean annual failure rate of 7.6% in children's primary teeth (compared to only 5.9% for composite, 3.3% for compomer, and 4.2% for resin-modified glass ionomer). The study determined that "the failure of amalgam restorations occurs more frequently in primary teeth, especially in small children, due 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. According to the Irish Dental Association, with Hg-free materials there is a higher risk of post-operation complications and there are more follow-up visits required in comparison to the dental amalgam restorations. These factors can also indirectly increase the cost of Hg-free restorations.

With regard to young children, longevity of the restoration is not a relevant concern since baby teeth will fall out long before the restoration fails. According to an ART specialist, ART will be an 'alternative to amalgam restoration especially in the primary teeth, whose life span is less than ten years'[103].

Given the results of recent studies comparing the longevity of different materials, it is considered here that the longevity of Hg-free fillings is no longer a factor increasing the overall cost of these types of restorations for patients.

- Other costs (externalities)

Finally, as pointed out in a UNEP report[104], it is important to note that the incremental cost of most Hg-free restoration techniques with regard to amalgam restorations would be lower if the environmental costs of mercury pollution were adequately factored in. Costs due to environmental pollution and indirect health damages from dental amalgam use are described in the other section of this baseline scenario; they affect dentists and their staff, EU taxpayers, crematoria, public authorities and the society at large.

[102] Reinhard Hickel et al. (2005) Longevity of occlusally-stressed restorations in posterior primary teeth, AMERICAN JOURNAL OF DENTISTRY, Vol. 18, No. 3, June 2005, available at http://www.amjdent.com/Archive/2005/Hickel%20-%20June%202005.pdf

[103] Dr. Prathip Phantumvanit Interview, DENTAL TRIBUNE available at http://www.dental-tribune.com/articles/content/id/3978/scope/news/region/asia_pacific

[104] UNEP (2008) Ad Hoc Open-ended Working Group on Mercury - Report presenting the costs and benefits for each of the strategic objectives (www.chem.unep.ch/mercury/OEWG2/documents/e52%29/English/OEWG_2_5_add_1.pdf)

Future trends

Estimates of the additional costs expected to be borne by patients for the period 2010-2025 are provided in Table 5 below.

Table 5: Additional costs borne by patients (EUR) in the baseline scenario, for the period 2010-2025

MS with cost differences	Average cost of a dental amalgam restoration (EUR)	Average cost of a Hg-free restoration (EUR)	Cost difference (EUR)	Total number of dental amalgam restorations substituted with Hg-free materials in 2010-2025 ('000)	Additional costs borne by EU patients in2010-2025 if no change in price difference (million EUR)	Additional costs borne by EU patients in2010-2025 with an annual decrease of the price difference by 1% (million EUR)
Austria	42	123	81	8,458	685	620
Czech Republic	7	48	41	38,062	1,561	1,412
Germany	0	40	40	28,652	1,146	1,037
Greece*	25	43	18	28,537	514	465
Hungary	12	18	7	2,643	17	16
Netherlands*	29	35	6	3,879	23	21
Poland	0	19	19	105,727	1,956	1,770
Luxembourg*	29	35	6	310	2	2
Portugal*	29	35	6	6,579	39	35
Romania*	25	43	18	54,177	975	882
Slovakia	11	15	4	13,694	55	50
Spain*	29	35	6	28,441	167	151
Latvia	9	28	20	1,684	33	30
Lithuania*	25	43	18	8,403	151	137
Ireland	90	110	20	5,434	109	98
Malta	35	40	5	1,046	5	5
Slovenia*	25	43	18	6,661	120	108
			EU27	342,388	7,557	6,838

* Estimated values. For these MS, the average cost difference is assumed to be equal to the average value for the group of MS they belong to.
NB: The average restoration costs take into account possible amounts reimbursed by national health insurance schemes, where they exist.

These additional costs are due to the progressive substitution of dental amalgam with Hg-free fillings in the baseline scenario. If one assumes that the average cost difference between amalgam and Hg-free restorations would remain similar in future years (which is a relatively pessimistic assumption), it is estimated that, in the baseline scenario, the overall cost borne by the patients will increase by some EUR 7.5 billion between 2010 and 2025 (cumulated cost over the 15-year period). In fact, dentists' skills in the handling of Hg-free filling materials are expected to improve with the increasing demand for such materials, leading to reduced restoration times for Hg-free materials and possibly reduced treatment costs. Assuming that cost difference between amalgam and Hg-free restorations would decrease by 1% annually for the above mentioned reasons, it is estimated that the overall cost borne by the patients will increase by some EUR 6.8 billion between 2010 and 2025. Based on these two estimates, the average cost per capita at the EU level is estimated to range between EUR 13.7 and 15.1 billion for the period 2010-2025.

In the estimates presented above, it is also assumed that the amounts or fee percentages possibly reimbursed by national health insurance schemes would remain stable in future years.

The expected increase in dental restoration costs, if not covered by existing national health insurance schemes, may benefit the private insurance as more EU citizens will be encouraged to subscribe to private insurance schemes covering dental treatment.

2.6.3.4 *Waste management companies*

Additional revenues for companies that manufacture, install and maintain amalgam separators as well as for companies that collect and treat dental mercury-containing waste are directly linked to the cost estimates for dentists presented in Section 2.6.3.2 (costs of amalgam separators and hazardous waste management). Some companies offer several or all of these services to the dentists.

2.6.3.5 *EU taxpayers*

- **Current situation**

Currently, the use of dental amalgam affects EU taxpayers mainly through their tax contributions to the costs of managing mercury-contaminated urban wastewater and municipal waste (usually included in local taxes).

Because a significant proportion of solid mercury-containing waste from dental practices is still not managed in compliance with EU waste legislation (i.e. separately collected and treated as hazardous waste), some mercury ends up in municipal and biomedical waste streams. The presence of mercury in municipal waste, partly due to the presence of dental waste, obliges certain municipal waste incinerators to operate specific flue gas treatment devices in order to comply with mercury emission limit values, which represents an additional cost to be borne by the municipalities and therefore by local taxpayers.

The residual quantities of mercury in dental effluents entering urban WWTPs also generate costs due to the lower potential for agricultural use of sewage sludge (usually the cheapest sludge management option) and/or the need to install mercury abatement devices in sewage sludge incinerators. Although these costs are first incurred by local authorities responsible for public wastewater treatment services, they are finally passed on to all taxpayers. These costs are likely to be higher in those Member States where only a small proportion of dental facilities are equipped with amalgam separators and/or where such separators are not well maintained.

Most of the mercury entering WWTPs ends up in sewage sludge. For WWTP operators, the consequence of too high mercury levels in sewage sludge is the impossibility for them to discard the sludge as fertilizer for agricultural use. Sludge spreading in agriculture is a relatively cheap option for WWTP operators; it is also an environmentally friendly option, as long as the sludge is exempt from potential soil contaminants. Mercury is one of the potential contaminants of sewage sludge, however, it is not the only one (other toxic heavy metals, organic pollutants and pathogens may cause concerns for the agricultural use of the sludge). Estimates on the cost of switching from agricultural use of sludge (landspreading) to other disposal routes are presented in Annex F. The Swedish Chemical Agency (KEMI) provided an example from the municipality of Eslöv in 2005: an amount of 1,210 t of sewage sludge was contaminated by approximately 25 ml of Hg and the sludge was no longer considered suitable for use in agriculture. The cost of landfilling of this sludge and the additional treatment required reached the amount of EUR78,000. According to KEMI estimations, if all sludge were to be incinerated in Sweden, this would result in an additional cost in the range of EUR 100-200 million per year.

The wastewater treatment organisations consulted during this study did not report that mercury was a significant limiting factor in itself for the agricultural use of sewage sludge, given the current regulatory limit values for the Hg content of sludge (which are relatively high in many Member States). However, one Spanish company, in charge of wastewater treatment for the city of Bilbao, reported that the presence of high mercury levels in sludge involved considerable extra costs for the treatment of sludge by incineration in 2010-2011[105]. In order to comply with legislation, the following had to be installed at the WWTP:

- Equipment (2 units) to analyse mercury in atmospheric emissions: EUR 140,000
- Special filters (2 units) with activated carbon and lime to remove mercury from atmospheric emissions: EUR 4,300,000.

Future trends

According to the wastewater treatment organisations consulted in the present study, the mercury content in sewage sludge is, in most Member States, not a legally limiting factor for the use of sludge in agricultural facilities, due to relatively high content of mercury allowed by current legislation on sewage sludge. In this respect, the reduction of mercury in the wastewater due to reduced use of amalgam in dental restorations is not expected to have a direct legal impact on the possibility to use sewage sludge in agriculture. However, mercury remains a limiting factor in the use of sludge in agricultural soils from both suitability and sustainability perspectives. Therefore any decrease in the levels of mercury in sludge can be considered indirectly as a positive economic aspect since the overall decreasing levels of mercury increase the potential for agricultural use of sludge in the long-term (assuming the levels of other sewage sludge contaminants would also decrease in the future).

[105] Information provided by the Bilbao wastewater treatment company

Another way by which EU taxpayers may be affected by future trends in dental amalgam use, in the baseline scenario, is through a possible increase in their financial contribution to national health insurance schemes. In the baseline scenario, it is assumed that the rules concerning the coverage of dental restoration by existing national health insurance schemes will not be modified between 2010 and 2025. As part of the study, information on the coverage of dental restorations by national health insurance schemes was obtained for 19 Member States (see Table 25 in Annex E). All these countries except CY, IT and MT have national health insurance schemes in place. Insurance schemes in the remaining 16 Member States cover both dental amalgam and mercury-free restorations, except in SE where dental amalgam is banned and with some limitations in the reimbursement of mercury-free fillings in some countries (e.g. only in children and pregnant women and/or only in front teeth).Information obtained on the amounts reimbursed is not always very accurate, thus only some general conclusions can be drawn from the information available. It appears that a majority of the 16 Member States reviewed apply fixed reimbursement tariffs whatever the material chosen (hence, if there is an extra cost for Hg-free restorations, it has to be borne by the patient). However, there are a few exceptions where a higher amount may be reimbursed for Hg-free restorations, for example in BE where the reimbursement is percentage-based. With the progressive substitution of dental amalgam by Hg-free materials, and given the currently higher cost of Hg-free restorations in most Member States, the financial contribution of some EU taxpayers may increase in those Member States where dental restoration costs are partly covered by a national health insurance scheme and where the scheme reimburses a higher amount for Hg-free restorations than for dental amalgam restorations. Based the above information, such a situation may be encountered in Belgium and possibly also in a few other Member States. However, under the assumption that there would be no changes to existing schemes, the majority of Member States is not expected to be affected by the progressive substitution of dental amalgam by Hg-free materials.

2.6.3.6 Crematoria

- **Current situation**

Environmental costs incurred by crematoria correspond to the installation and maintenance of technical devices to capture mercury in flue gases. According to DEFRA[106], such costs are partly or fully passed on to crematoria's customers.

Currently there are approximately 2,700 crematoria at the EU level and 2.5 million cremations per year. According to available information, approximately 40% of crematoria are equipped with mercury abatement devices (further details are provided in Annex C).

Costs of mercury abatement in crematoria are presented in Annex F. According to questionnaire responses of the present study, the cost for installing a mercury abatement system varies from EUR 250,000 to 350,000 per cremator. In addition, the cost for the collection and treatment of the mercury-containing residues is estimated at approximately EUR 3 per cremation.

Given the above figures, it can be roughly estimated that the current cost incurred by EU crematoria to control mercury emissions represents an existing investment in the range of EUR

[106] DEFRA consultations carried out in 2003 and 2004 concerning mercury abatement from crematoria in the UK

540 to 755 million (assuming 2 cremators per crematorium) and annual waste management costs of approximately EUR 2.9 million per year.

If all cremations taking place at present were subject to mercury abatement (this would be justified for environmental reasons), the total costs for crematoria would be in the range of EUR 1,350 to 1,890 million in terms of investment in abatement equipment and approximately EUR 7.3 million/year for waste management.

- **Future trends**

In four Member States for which information has been provided or identified (IT, NL, PL and PT) the number of cremations is predicted to rise in the forthcoming years. In most other Member States, a similar trend is likely to be observed. It is unclear whether this will affect the number of crematoria as well. In the same time, it can be assumed that the proportion of crematoria equipped with mercury abatement devices will continue to increase in future years, as a result of more stringent recent national legislations adopted in some Member States (e.g. FR and the UK) and the effect of the OSPAR Recommendation concerning mercury emissions from crematoria (which is still not followed by all Parties). Assuming the proportion of crematoria equipped with mercury abatement systems would double between 2010 and 2025 to reach 80% in 2025, this would result in 2,160 additional abatement systems to be installed (assuming 2 cremators per crematorium), representing an investment cost in the range of EUR 540 to 755 million.

2.6.3.7 Public authorities

The historical and current use of dental amalgam creates administrative burden for Member State environmental authorities due to the associated mercury emissions that need to be regulated and monitored in order to ensure the effective enforcement of the existing legal requirements. Enforcement efforts concern in particular mercury emissions from dental clinics, from urban WWTPs and from crematoria (in those Member States where such emissions are regulated). No information is currently available to quantify this administrative burden.

Even with the expected gradual decline of dental amalgam use in future years, a similar or even higher level of administrative burden will continue to exist in the baseline scenario, because of the need to enforce environmental requirements associated with mercury emissions from historical dental amalgam use and the recent adoption of more stringent mercury emission restrictions. For example, in some Member States (e.g. FR and the UK), legislation has been adopted recently to further regulate mercury emissions from crematoria, which will require additional enforcement efforts from public authorities.

2.6.4 Social aspects

The main social aspects related to the use of dental amalgam include employment in the dental fillings industry, occupational health and safety of dental personnel and public health and safety.

2.6.4.1 *Employment*

Current situation

In this study, it was not possible to estimate the total number of jobs associated with the production and supply of dental fillings in the EU, in the absence of specific information provided by the industry. However, the number of EU producers of dental fillings, with a breakdown by Member State and by type of filling materials, is presented in Annex E. No information could either obtained on the number of jobs associated with dental waste management.

Future trends

As it was pointed out in Section 2.6.3.1 , the progressive substitution of dental amalgam with Hg-free materials in the baseline scenario is not expected to induce major socio-economic changes in the dental fillings industry (including with regard to the number of jobs), since almost all manufacturers already produce Hg-free filling materials. Only two EU companies (one in CZ and one in IT) have been identified which only produce bulk mercury for dental amalgam; both are small sized and employ 10 to 20 persons.

2.6.4.2 *Occupational health and safety of dental personnel*

Current situation

Some air emissions may occur at dental practices during the handling of amalgam. This may include releases from accidental mercury spills, malfunctioning amalgamators, leaky amalgam capsules or malfunctioning bulk mercury dispensers, trituration, placement and condensation of amalgam, polishing or removal of amalgam, vaporisation of mercury from contaminated instruments, and open storage of amalgam scrap or used capsules[107]. Dental personnel may also be exposed to mercury vapours from dental effluents' treatment devices (chairside traps and amalgam separators).

However, the increasing use of pre-dosed capsules contributes to reducing emissions occurring during amalgam storage and preparation, and the exposure of dental personnel to these mercury vapours.

In the environmental assessment of dental amalgam use presented in Annex C, it was estimated that the handling of amalgam currently generates mercury air emissions of approximately 0.5 t Hg/year, while approximately 3 t Hg/year are emitted by dental effluents' treatment devices.

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[107] JADA (2003) 'Dental mercury hygiene recommendations,' ADA Council on Scientific Affairs, American Dental Association, Journal of the American Dental Association Vol. 134, November 2003 (as cited by Concorde/EEB)

Dental personnel may be exposed to these mercury vapours if protection measures are not used or are not efficient (e.g. exhaust ventilation). This may result in adverse health effects (see Annex D and Section 2.3.3) but there is some controversy on the actual magnitude of these health effects. It should be noted that many of the dental workers – including dental assistants, dental nurses, and hygienists – are women of childbearing age, which makes them particularly susceptible to the occupational hazards caused by mercury vapours.

- **Future trends**

With the expected gradual decrease in dental amalgam use in the baseline scenario, the exposure of dental personnel to mercury vapours from the handling of amalgam would reduce accordingly. However, as long as mercury is present in old fillings, dental personnel will continue to be exposed to mercury vapours from dental effluents and from solid mercury-containing waste if there are no adequate protection measures in place.

2.6.4.3 Public health and safety

- **Current situation**

  - Health aspects of dental amalgam

In the current situation, EU citizens are may be exposed to *indirect* health hazards from the presence of mercury from dental origin in the environment. As pointed out in the problem definition (see Section 2.3.2), certain EU population groups – and especially women of child-bearing age and children – are subject to unacceptable levels of exposure to mercury, principally through the ingestion of fish contaminated by methylmercury. This induces a risk of adverse effects on health, in particular affecting the nervous system and diminishing intellectual capacity.

In the Annex XV REACH Restriction Report concerning mercury in certain measuring devices (2010), ECHA conducted a review of available literature on health and environmental costs of mercury pollution[108]. It concluded that many studies have estimated rather high values of mercury pollution costs. These range from about EUR 5,000 to 20,000 per kg Hg emitted to air but can be much higher (e.g. EUR 250,000) if the less certain cardiovascular effects are included. Many of the values estimated to date relate to the costs of IQ losses resulting from mercury pollution. These values relate to emissions (to air) so they cover only one aspect of mercury pollution caused by dental mercury emissions.

As presented in Section 2.3.3, the possible *direct* health effects of dental amalgam fillings are a subject of scientific debate, with no consensus yet on the associated level of risk for human health.

  - Health aspects of mercury-free filling materials

With regard to mercury-free filling materials, both benefits and possible risks for human health have been reported to date.

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[108] ECHA (2010) Annex XV REACH Restriction Report concerning mercury in certain measuring devices – Appendix 2 (http://echa.europa.eu/doc/restrictions/annex_xv_restriction_report_mercury_en.pdf)

Outside the fact that they eliminate the need for mercury in dentistry, one main advantage of mercury-free restoration techniques are that they are less invasive and use filling materials which react with the tooth tissue to form new, permanent tissue with a composition close to the original one. Such techniques leave more intact tooth tissue in the treated tooth as compared with dental amalgam restoration. While dental amalgam placement tends to weaken the overall tooth structure (due to the significant amount of healthy tooth tissue that has to be removed), ART and other Minimally Invasive Techniques will most likely prolong the life of the tooth before implants (expensive) and/or extraction will be necessary. In a recent WHO report, it was concluded that '*fostering the philosophy of preserving the tooth structure and improving the survival of the tooth is imperative*'[93].

EU health authorities and dental associations consider that the use of non-metallic restoration materials is safe for patients (including pregnant woman and children) and dental health professionals. However, it is recognised that the use of alternative metallic restoration materials such as gold, nickel and titanium alloys may carry risks for children and adults which allergic and autoimmune diseases. To date, no evidence of adverse effects on human health of alternative materials has been established except for skin reactions of dental staff, who handled resin without gloves before it hardened. During in vitro experiments, it was observed that the very small amount of remaining compounds after the placement of alternative filling materials has toxic effects to pulp and gingival cells. Some induce DNA-damage or gene mutations in mammalian cells.

Some resin-based filling materials contain bisphenol A (BPA, a known endocrine disruptor). Some laboratory testing has suggested that BPA may affect reproduction and development in animals by mimicking the effects of the female hormone oestrogen, thereby raising concerns about its safety. Although these effects have not been observed in humans and are questionable at the exposure levels resulting from consumer products, some governments have recently taken a precautionary approach by banning the use of BPA in the manufacture of certain consumer products such as baby bottles (Canada, EU) and food containers (France). With regard to dental materials, studies conducted to date have found that exposure to BPA present in composite resins are far lower than tolerable daily intake values (e.g. those defined by Health Canada, the USEPA or the EU Scientific Committee for Food) and do not present a significant risk for estrogenic effects[109,110]. There is currently no scientific evidence to show that the very small concentration of BPA has any adverse health impacts[111,112]; the quantities released are indeed much lower than in other current applications of this widely used compound. It should be noted

[109] Richardson GM, Clark KE and Williams DR (1999) Preliminary estimates of adult exposure to bisphenol-A from food, dental materials and other sources. Environment Toxicology and Risk Assessment: Standardization of biomarkers for endocrine disruption and environmental assessment: Eight volume, ASTM STP 1364, DS Henshel, MC Black and MC Harrass, Eds., American Society for Testing and Materials, West Conshohocken, PA.

[110] Steven G. Hentges, Ph.D. Executive Director, Polycarbonate Business Unit, American Plastics Council, Bisphenol-A in Dental Composites, http://www.bisphenol-a.org/human/dental.html

[111] SCENIHR (2008) The safety of dental amalgam and alternative dental restoration materials for patients and users (http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_016.pdf)

[112] Van Landuyt et al. (2001) How much do resin-based dental materials release? A meta-analytical approach. Amalgam-related complaints and cognition. Dental Abstracts, Volume 56, Issue 2, March-April 2011, Page 83

that composite resins are widely available without BPA. In fact, according to the American Dental Association, BPA is rarely an ingredient in these mercury-free alternatives[113]. A few examples of BPA-free composite dental materials are listed in Table 6 below:

Table 6: Examples of BPA-free composite dental materials

Product	Manufacturer
Admira Flow	VOCO GMBH
Amaris	VOCO GMBH
Bisfil 2B	Bisco, Inc.
Bisfil II	Bisco, Inc.
Clearfil Core	Kuraray America Inc.
Construct	Kerr Manf. Co.
Filtek Supreme-XT	3M Corp.
Flow-Rite	Pulpdent Corp. of America
Grandio	VOCO GMBH
Grandio Flow	VOCO GMBH
Herculite XR	Kerr Manf. Co.
Luxapost	DMG
MIRIS	Coltene
Premise	Kerr Manf. Co.
Solitaire	Heraeus
Synergy D6	Coltene
Synergy Duo Shade	Coltene
Starfil	Danville Innovative Dental Products
TI- Core	Natural Essential Dental Systems

Future trends

The progressive substitution of dental amalgam with mercury-free alternatives, in line with the trends described in Section 2.6.1.2, will tend to reduce public exposure to indirect health hazards caused by mercury emissions from dental amalgam use. However, this improvement will only occur over a long period of time (i.e. decades), as there can be a significant delay between the time mercury is emitted to the environment and the time it triggers possible adverse health effects following inhalation of mercury vapours or ingestion of contaminated food by humans.

[113] ADA Council on Scientific Affairs, Statement on Bisphenol A and Dental Materials (July 2010), http://www.ada.org/1766.aspx

2.7 Policy objectives

The general objective of any future policies in relation to mercury in dental amalgam will be to reduce the environmental impacts from the use of mercury in dentistry and to reduce the contribution of dental amalgam to the overall mercury problem. In the long-term, this should contribute to achieving reduced mercury levels in the environment, at EU and global level, especially levels of methylmercury in fish. This general objective may take decades to be achieved, as the present levels of mercury in the environment are representative of past mercury emissions, and even without further emissions it would take some time for these levels to fall.

This long-term policy objective can be achieved through specific policy actions aiming to:

- Minimise mercury emissions from current and historical use of mercury in dentistry; and
- Minimise and, where feasible, eliminate the source of pollution, i.e. phase out dental amalgam use.

Chapter 3: Policy options

Policy options identified to address the environmental impacts of dental amalgam use are described in this chapter. These policy options have been identified on the basis of the evidence analysed as part of this study and presented in Chapter 2 as well as initial feedback received from the stakeholders, while taking into account the subsidiarity and proportionality principles. The rationale for each policy option is explained, as well as its main objective and the specific problems it could address. The analysis highlights options warranting further investigation and those which were excluded from the analysis, based on preliminary screening.

3.1 Policy options selected for further analysis

- **'No policy change' option**

In this option, no EU actions would be taken to reduce or ban the use of dental amalgam. The use of dental amalgam may continue to decline in the EU, mainly as a result of growing aesthetic concerns, although it is difficult to predict the speed of this decline. Dental amalgam may well continue to be used for many years in some of the less wealthy Member States.

In spite of Member States' efforts to improve the enforcement of the overall EU waste legislation, it is expected that application of such legislation in dental facilities would not improve significantly (as it is not currently considered as a priority by all Member States). It is also possible that mercury-related requirements of EU water legislation may not be properly anticipated by all Member States, preventing the achievement of long-term EU water quality objectives with regard to mercury.

The baseline scenario corresponding to a no policy change situation is described in detail in Section 2.6.

- **Option 1: Improve enforcement of EU waste legislation regarding dental amalgam**

In this option, the Commission would ask Member States to report on measures taken to manage dental amalgam waste in compliance with EU waste legislation (i.e. presence of amalgam separators in dental practices) and to provide evidence of the effectiveness of the measures in place (i.e. adequate maintenance of these separators in order to ensure a minimum 95% efficiency and amalgam waste to be collected and treated by companies with the adequate authorisation to handle this type of hazardous waste). Immediate action would be required from those Member States not able to demonstrate compliance of dental facilities with EU waste legislation requirements, with the possibility to impose administrative sanctions if corrective actions are not implemented within a short timeframe.

Option 2: Encourage Member States to take national measures to reduce the use of dental amalgam while promoting the use of Hg-free filling materials

In this option, the Commission would encourage Member States to take national measures aiming to reduce the use of dental amalgam (for example via a Communication) and Member States would have to report annually to the Commission on the measures taken and their effect. Such measures would include, in particular:

- Measures to improve dentists' awareness of the environmental impacts of mercury and the need to reduce its use
- Measures to review dental teaching practices so that Hg-free restorations techniques are given preference over dental amalgam techniques
- Measures to improve dentists' awareness and skills with regard to the Hg-free and cost-efficient Atraumatic Restorative Treatment (ART) technique
- Measures to improve public dental health so as to reduce the occurrence of cavities (such a measure should only be considered in association with other measures above).

The expected result of this policy option would be to accelerate the shift from dental amalgam to Hg-free materials by removing the cost barrier present in many Member States, by increasing awareness of current and future practitioners concerning the adverse environmental effects of dental amalgam and the benefits of Hg-free restoration techniques and by improving the skills of practitioners in Hg-free dentistry.

A higher awareness of dentists on the overall environmental consequences of using dental amalgam could help reduce dental amalgam use at EU level and the associated environmental impacts. In spite of awareness raising initiatives carried out by national dental associations, more can be done in some Member States.

A strengthening of dental health prevention policies across the EU would, in the long-term, lead to a reduced need for dental restoration and therefore a reduced consumption of dental amalgam and other filling materials.

In the present study, it is assumed that such a recommendation would be addressed by the Commission to the Member States in 2013.

Option 3: Ban the use of mercury in dentistry

One possibility for implementing this ban would be to add the use of mercury in dentistry to Annex XVII of the REACH Regulation[114], with the possibility to define limited exemptions to take into account specific medical conditions where dental amalgam cannot be substituted at present[115].

Similar exemptions as those defined in Sweden could be proposed, i.e. for use in adult patients in hospital dental clinics if: 1) The patient's specific medical condition makes use of alternative materials unsuitable 2) Alternative techniques do not provide adequate restorations and 3) The clinic has adequate equipment and routines with regard to the environmental impact of dental amalgam (amalgam separators, mercury waste management etc.). It can be noted that dental amalgam restorations carried out under the exemption defined in Sweden have represented a very small number of cases: only about 25 patients have been treated with dental amalgam in Sweden between June 2009 (when the general ban came into force) and June 2011. According to KEMI, in 2010, 16 dental amalgam restorations were carried out under this exemption, out of a total number of almost 3.3 million restorations in Sweden.

The ban would apply to the use of mercury in dental treatment in the EU but the manufacture of dental amalgam for export outside the EU would still be allowed.

In the present study, it is assumed that such a legal requirement would be adopted in 2013 and would become applicable 5 years later, i.e. in 2018, in order for all the stakeholders to anticipate the ban.

The aim of this policy option would be to accelerate the shift from dental amalgam to Hg-free restoration techniques and to ensure a rapid cessation of mercury emissions due to current use of dental amalgam in the EU, in line with the objective of EU legislation on water quality. It would also aim to accelerate the development of technical innovations in the field of Hg-free materials, in particular making them more affordable and increasing their longevity.

3.2 Policy options excluded from the analysis

Two other possible policy options were excluded from the analysis based on preliminary screening. The reasons for not considering them further in this study are explained below.

Establishing mercury emission thresholds in crematoria

Mercury emissions from crematoria remain small compared to other mercury emission sources, they seem to have stabilised over the last 5 years and there is currently no evidence that such emissions would increase significantly in future years. Therefore, it is questionable whether it would be proportionate to take additional action at the Community level for this relatively small problem, especially when the OSPAR Recommendation already covers the majority of

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[114] Regulation (EC) No 1907/2006 on Registration, Evaluation, Authorisation and Restriction of Chemicals – Annex XVII of the REACH Regulation contains the list of all restricted substances, specifying which uses are restricted.

[115] The choice of the most relevant policy instrument would need to be further investigated. Another possibility would be to see whether EU legislation on medical devices might address the environmental risks of dental amalgam.

cremations in the EU, large emitting countries such as the UK and France have recently implemented more stringent legislation and different types of legal requirements have been implemented in several Member States to tackle this problem (e.g. specific 'burden sharing scheme' in the UK, different types of Emission Limit Values defined in at least 8 Member States). Besides, the cultural and social sensitivities around cremation would suggest it might better be addressed at the Member State level, on the basis of subsidiarity.

- **Informing patients on the benefits and risks of dental restoration materials**

This policy option was not considered relevant given the complexity of communicating easily understandable information to patients on the environmental issues associated with dental amalgam. The focus of the present study is on the environmental impacts of dental amalgam and, with such a policy option, there is a risk of creating confusion among patients between direct health risks of dental amalgam on the one hand, and environmental and indirect health risks on the other hand.

Chapter 4: Analysis of impacts

The likely environmental, economic, and social impacts of policy options aiming to reduce the environmental impacts of dental amalgam use are analysed in this chapter. All the impacts discussed correspond to incremental positive or negative impacts with regard to the baseline scenario ('no policy change' option), meaning that they result from the implementation of new or altered policy actions.

4.1 Environmental impacts

4.1.1 Option 1

Based on the latest information provided by the Member States, it was estimated that approximately 25% of EU dental practices are still not equipped with amalgam separators. As described in Table 37 (see Annex H), the share of dental practices equipped with amalgam separators differs widely across the Member States. Besides, given that a number of the existing separators are suspected of not being adequately maintained, the average actual efficiency of separators was roughly estimated to be around 70% at present (instead of the standard 95% efficiency for which they are designed).

Based on the assumptions used to carry out the environmental assessment presented in Annex C, having 95% of mercury in dental effluents captured in 100% of dental facilities (under Option 1) instead of 70% of mercury captured in only 75% of dental facilities (current situation) would result in approximately 7 t/year of avoided mercury releases to urban WWTPs in the EU. This would represent a 30% reduction of the mercury load with regard to the baseline situation for 2015 (2015 is used as the reference year here, as it is assumed that the effect of Option 1 would be observed from this year).

The impact of this policy option will be more significant in those Member States where only a small proportion of dental facilities are equipped with amalgam separators (BG, EE, ES, GR, HU, IE, LT, LU, PL, RO and SK). In other MEMBER STATES, the impact will mainly be an improvement of separators' maintenance (ensuring a minimum of 95% efficiency is achieved) and the use of compliant waste handling and treatment options.

A co-benefit of this option would be to increase the capture of other metals present in amalgam and released from dental chairs (e.g. Ag, Sn, Cu, Sn); such metals have the potential to reduce the efficiency of urban WWTPs due to their toxicity to micro-organisms used in WWTPs, above certain concentrations[116].

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[116] Shraim A, Alsuhaimi A, Thamer Al-Thakafy J. (2011) Dental clinics: A point pollution source, not only of mercury but also of other amalgam constituents. Chemosphere, Volume 84, Issue 8, Pages 1133-1139

A full compliance of dental facilities with EU waste legislation will also increase the quantity of mercury-containing waste sent to hazardous waste treatment facilities (assuming 100% of the mercury waste generated will follow this route) and will avoid the presence of mercury in the municipal and biomedical waste streams. With all mercury-containing waste treated as hazardous waste, emissions of mercury to air and water due to inadequate waste handling and treatment will be avoided, which corresponds to approximately 7 t /year of avoided Hg emissions to air, 2 t/year of avoided Hg emissions to water and 11 t/year avoided Hg emissions to soil and groundwater (based on the assumptions used in the environmental assessment in Annex C). All mercury from dental waste will be either recycled or sequestered for long-term, thus the potential for such mercury to become bioavailable and accumulate in the food chain will be mostly eliminated.

4.1.2 Option 2

The actual impacts of this policy option are very difficult to quantify because of the non-mandatory nature of this option. Member States would be free to choose which measure or combination of measures they would implement to promote a reduction in dental amalgam use, with no binding target to achieve. There is also little quantified evidence available on the possible impacts of measures that can be recommended by the EU.

However, for the purposes of the present assessment, it is assumed that this policy option would achieve an intermediate result between the 'no policy option' and Option 3 (the most radical option). The key assumptions made here concern the threshold levels that would be reached by 2025 in terms of the share of dental amalgam restorations:

- Group 1 countries: the share of dental amalgam restorations would remain close to zero
- Group 2 countries: the share of dental amalgam restorations would stabilise between 0% and 10% of the total number of dental restorations
- Group 3 countries: the share of dental amalgam restorations would stabilise between 10% and 15% of the total number of dental restorations.

Under this policy option, the demand for dental mercury would stabilise around 20 t Hg/year in 2025 (instead of 35 t Hg/year in the baseline scenario), hence the avoided mercury use would be approximately 15 t Hg/year in 2025. However, it would be difficult to obtain any further decrease due to strong reluctance to completely phase out dental amalgam use in some Member States.

With such a decrease in dental amalgam use, it is estimated that mercury releases to the environment would be reduced by at least 3% with regard to the baseline scenario for year 2025 (according to the environmental assessment presented in Annex C and considering no change to other parameters such as waste and wastewater control measures).

4.1.3 Option 3

This option will lead to an almost complete cessation of mercury releases associated with the placement of new fillings, which will occur within a 5-year horizon following adoption of the ban, i.e. in 2018. However, as soon as the ban is adopted, i.e. in 2013, a significant decrease in dental amalgam use is expected to occur, as the stakeholders will tend to anticipate the change in legislation (the future ban will increase awareness on the environmental problems caused by dental amalgam, among dentists and patients, making dental amalgam a less favoured material). Within the transition period (2013-2017), it is assumed that the decrease in dental amalgam use will be four times greater than in the baseline scenario, at approximately 20% annually.

When the ban starts to apply, in 2018, the avoided mercury use is estimated at approximately 50 t Hg/year (in line with the expected slow decrease in amalgam use over time, described in the baseline scenario). Only very small amounts of mercury may still be used to treat specific medical conditions (the experience from Sweden shows that dental restorations temporarily exempted, until June 2012, from the mercury ban represent less than 0.0002% of the total number of annual restorations[117]).

This option, once implemented, will lead to an immediate decrease in environmental mercury releases. However, because there will still be mercury releases due to old amalgam fillings, it is estimated that, at the time the ban becomes applicable, mercury releases to the environment (air/water/soil) would only be reduced by approximately 15% with regard to the baseline scenario. Mercury releases will progressively decrease over the years in line with the decrease of mercury stocks in people's mouths. Given that the average lifetime of amalgam fillings ranges from 10 to 15 years, it is expected that mercury releases from historical amalgam use would have significantly decreased 15 years after the ban takes effects. Residual mercury releases would be mainly due to amalgam fillings borne by immigrants to the EU and possibly also some specific cremation practices such as the ones reported in Italy (according to the Italian crematoria association Federutility, in Italy approximately 20% of cremations are carried out on human remains and can take place 10 to 20 years after a burial).

The actual environmental impacts (e.g. adverse effects to ecosystems) would however continue to be observed for several decades, given the potential for elemental mercury to be transformed into methylmercury and to accumulate in biota.

[117] Calculations based on KemI. 2010. Government commission report on the effect of the general national ban on mercury (http://www.kemi.se/upload/Om_kemi/Docs/Regeringsuppdrag/Regeringsuppdrag_Hg_1009.pdf)

4.2 Economic impacts

4.2.1 Option 1

4.2.1.1 *Impacts on dentists*

- **Costs for the installation of amalgam separators**

The consequence of Policy Option 1 is that 100% of dental clinics will be equipped with amalgam separators in the short-term (instead of approximately 75% at present). The impact of this policy option will be more significant in those Member States where only a small proportion of dental facilities (assumed to be 20% on average) are equipped with amalgam separators (BG, EE, ES, GR, HU, IE, LT, LU, PL, RO and SK). In other MEMBER STATES, the remaining proportion of dental clinics to become equipped varies between 1% and 20%, according to available information. Assuming an average number of 2.1 dentists per clinic[27], we estimate that approximately 34,200 additional dental clinics across the EU will have to install a separator. By applying the costs that have been identified in Section 2.6.3.2 (EUR 150 to 750), it is estimated that installation and maintenance of separators in these additional 34,200 clinics will represent a total cost in the range of EUR 5.1 to 25.6 million per year (also including amalgam sludge treatment).

- **Increased waste management costs**

As explained in the problem definition, even in those Member States with a high proportion of dental clinics equipped with amalgam separators, there is evidence that many separators are not as efficient as the standard specifications (95% efficiency in general) due to a lack of adequate maintenance. Under Option 1, it is assumed that 50% of dental clinics currently equipped with amalgam separators (i.e. approximately 53,000 dental clinics) will need to significantly improve the maintenance of their equipment and the management of dental amalgam sludge from the separator. Given the average costs for the maintenance of separators and the management of hazardous waste (see Section 2.6.3.2), the additional cost for dentists is estimated to range between EUR 5.3 to 32 million per year at the EU level; approximately 20% of these costs correspond to maintenance works and 80% to waste collection and treatment.

It is important to remind that the costs of Option 1 for the dentists, as estimated above, should have been incurred at an earlier stage if EU waste legislation had been complied with.

4.2.1.2 *Impacts on waste management companies*

The cost of Option 1 for the dentists corresponds to additional revenues for waste management companies involved in the maintenance of amalgam separators and/or in the collection and treatment of dental amalgam waste. The economic impact of Option 1 for these companies is therefore positive.

4.2.1.3 Impacts on EU taxpayers

The implementation of Option 1 will result in a lower mercury content of dental effluents entering WWTPs. For example, this may reduce the need for municipalities to invest in expensive mercury abatement devices in sewage sludge incineration plants (see the example of Bilbao WWTP in Annex C). In certain cases, it may also increase the possibilities of using sewage sludge for agricultural purposes, a cheaper management option for sewage sludge. Overall, this will have a positive economic impact on municipalities, and finally on EU taxpayers, as it will reduce the environmental costs associated with the management of mercury pollution from dental amalgam.

4.2.1.4 Impacts on public authorities

Administrative costs of Option 1 for public authorities mainly correspond to increased awareness raising activities towards dental clinics and/or a higher frequency of inspections of dental clinics in order to ensure that EU waste legislation is fully complied with. It is difficult to quantify these costs in the absence of adequate data available. However, assuming that each inspection (including a visit and some time for reporting) would take approximately 4 hours and that 10% of EU dental clinics would be inspected each year, this would result in approximately 35,000 hours annually in EU27, corresponding to approximately 1 million EUR/year of labour cost for public authorities[118]. The actual administrative burden would be slightly lower since effective inspection schemes are reportedly already in place in some Member States (e.g. Germany, Sweden). If Member States impose financial penalties as a tool to enforce compliance, some revenues might also be generated through the collection of fines, which may partly offset the labour costs dedicated to inspection.

4.2.2 Option 2

4.2.2.1 Impacts on manufacturers and suppliers of dental fillings

As in the baseline scenario, negative economic impacts of Option 2 on the dental industry (i.e. revenue losses) are expected to be minimal since the necessary skills and equipment to manufacture Hg-free filling materials have already been acquired by the vast majority of companies. Nevertheless, because the substitution rate of dental amalgam by Hg-free materials will be more significant under Option 2 than in the baseline scenario, this may give a higher competitive advantage to companies that focus on the production of Hg-free materials with regard to companies that still have a significant market share in dental amalgam. The magnitude of this impact is difficult to estimate due to the uncertainties on the evolution of the global demand for dental amalgam. For example, an increased demand of dental amalgam in non-EU countries might encourage the EU dental industry to maintain high levels of dental amalgam production for exportation.

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[118] The cost per hour is taken from the EU Standard Cost Model, for Category 1 staff, in 2006 (average hourly wage for EU27: 31 EUR)

The increasing demand for Hg-free materials (composites and glass ionomers in particular) is expected to stimulate innovation concerning the production of these materials, which may lead to an improvement of technical characteristics, an increased durability of the materials and lower production costs.

By applying the same methodology as the one described in Section 2.6.3.1, it is estimated that the expected levels of substitution of dental amalgam by Hg-free materials under Option 2 will generate an increase in revenues for the EU dental fillings industry of approximately EUR 3.3 billion for the period 2010-2025, representing a 42% increase with regard to the value estimated in the baseline scenario. This value should only be regarded as a rough estimate as it is only based on the sale prices of amalgam and composites in the German market.

There is no specific data that can be used to estimate in quantitative terms the impact of Option 2 on the sale prices of Hg-free filling materials. However , it seems reasonable to assume that innovation and increased competition could reduce the difference in sale price between dental amalgam and Hg-free filling materials (composites or glass ionomers) by up to 25% by 2025, in which case the expected increase in revenues for the EU dental fillings industry would only range between EUR 1.7 to 3.3billion for the period 2010-2025, representing an increase in the range between 7% and 42%with regard to the value estimated in the baseline scenario.

4.2.2.1 Impacts on dentists

- **Acquisition of skills and equipment**

In comparison with the baseline scenario, the promotion of Hg- free restoration techniques by public authorities and the increase awareness of patients will presumably increase the need for dentists who are not skilled in these types of techniques to acquire such new skills. This will concern dentists in Group 3 countries and, to a lesser extent, dentists in Group 2 countries.

As explained in Section 2.6.3.2, the potential need for additional equipment is not expected to generate significant additional investment and operating costs for dentists.

Regarding ART restorations, the use of which is expected to be actively promoted by Member States under Option 2, currently many of the dentists are unaware of this technique. Therefore, the introduction of ART will require dentists to follow training sessions before being able to use it in their patients. Training costs are expected to be incurred by public authorities, as part of their activities to encourage a reduction in dental amalgam use. No additional investment in equipment is required to use ART (there is actually lower dental equipment maintenance costs in the case of ART).

Overall, the economic impacts for dentists associated with the acquisition of new skills, and possibly new equipment, are not expected to be significant.

- **Waste management costs**

Even if the use of dental amalgam in the EU decreases significantly, amalgam separators will continue to be required in dental clinics in the future, due to the time it will take for the amount of mercury stored in the mouths of EU citizens to be fully eliminated. In addition, amalgam will probably continue to be used in some non-EU countries, hence there will still be mercury releases from the teeth of EU immigrants[119]. It is difficult to estimate the long-term contribution from EU immigrants to mercury releases under Option 2; it can however be noted that, between 2002 and 2007, the foreign-born population in the EU increased by 1.2%, and in absolute terms this category of EU residents increased from 7.7% to 8.9% of the total EU population.

It should be noted that the progressive decrease in the silver content of amalgam separators' sludge, due to lower dental amalgam use, may slightly reduce the intrinsic value of this waste for waste management companies able to recycle silver (the mercury content of dental waste is too low to influence the value of dental waste); however, this is not expected to significantly affect the revenues of dental waste management companies and dentists' waste management costs[120].

4.2.2.2 Impacts on dental patients

Under Option 2, the substitution of dental amalgam with Hg-free restorations will be significantly greater than in the baseline scenario. Under this option, measures taken by Member States to promote Hg-free restoration techniques, including ART, are also expected to result in a significant decrease in the cost of Hg-free restorations borne by patients. This decrease in costs would be made possible through:

- An increased competition within the dental fillings industry and technological improvements leading to decreases in material costs
- Reduced average durations for carrying out Hg-free restorations due to improved dentists' skills, leading to a decrease in the labour costs of dental treatment
- A progressive increase in the use of ART, which costs about half less than the dental amalgam technique[121]; ART would be increasingly used in children but also for permanent teeth restorations.

By applying the same methodology as in the baseline scenario, it is estimated that in total approximately 490 million dental amalgam restorations will be substituted with Hg-free restorations between 2010 and 2025. If the average cost differences between dental amalgam and Hg-free restorations remained similar in the mid-term – which is a very pessimistic scenario – Option 2 would result in a cost of approximately EUR 10.7 billion (or EUR 21.5 per capita) for EU dental patients between 2010 and 2025, which represents a net cost of EUR 3.2 billion (EUR 6.4

[119] Given the current state of negotiations for the preparation of the global mercury treaty, the treaty may include a commitment to phase down global dental amalgam use at the global level, but probably not to phase it out.

[120] According to verbal information from a dental waste management company based in Sweden

[121] Although ART is currently mainly used in locations with limited infrastructure, it is cost-effective in the modern dental clinic as well. A recent study of the costs of ART use in clinics concluded that '*ART is also a cost-effective means of oral health care within a modern dental clinic; the ART approach can be undertaken at approximately 50% of the capital costs of conventional restorative dentistry'* (S. Mickenautsch et al. (2009) Comparative cost of ART and conventional treatment within a dental school clinic, Journal Of Minimum Intervention In Dentistry). Additionally, since ART is not painful, both the time and cost of administering anaesthetics is eliminated (F. J. T Burke et al. (2005) UK dentists' attitudes and behaviour towards Atraumatic Restorative Treatment for primary teeth, BRITISH DENTAL JOURNAL 199, 365 – 369)

per capita) with regard to the baseline scenario (see Table 7 below). If the cost differences between dental amalgam and Hg-free restorations decreased by 2% annually, in line with the above assumptions, Option 2 would result in a cost of approximately EUR 8.8 billion for EU dental patients between 2010 and 2025 (or EUR 17.6 per capita), which represents a net cost of EUR 2 billion (EUR 3.9 per capita) with regard to the baseline scenario.

As in the baseline scenario, it is assumed that the amounts or fee percentages possibly reimbursed by national health insurance schemes would remain similar in future years.

Table 7: Additional costs borne by patients under Policy Option 2, for the period 2010-2025

MS with cost differences	Total number of dental amalgam restorations substituted with Hg-free materials in 2010-2025 ('000)	Additional costs borne by EU patients in2010-2025 if no change in price difference (million EUR)	Additional costs borne by EU patients in2010-2025 with an annual decrease of the price difference by 2% (million EUR)
Austria	12,022	974	796
Czech Republic	54,101	2,218	1,814
Germany	40,726	1,629	1,332
Greece*	40,563	730	597
Hungary	3,757	24	20
Netherlands*	5,513	32	27
Poland	150,281	2,780	2,274
Luxembourg*	441	3	2
Portugal*	9,351	55	45
Romania*	77,007	1,386	1,134
Slovakia	19,465	78	64
Spain*	40,426	238	194
Latvia	2,393	47	38
Lithuania*	11,945	215	176
Ireland	7,724	154	126
Malta	1,487	7	6
Slovenia*	9,468	170	139
EU27	486,671	10,742	8,784

* Estimated values. For these MS, the average cost difference is assumed to be equal to the average value for the group of MS they belong to.
NB: The average restoration costs take into account possible amounts reimbursed by national health insurance schemes, where they exist.

The expected increase in dental restoration costs for patients is expected to affect the private health insurance industry in a positive manner, as it will increase the demand for insurance services covering dental treatment.

4.2.2.3 Impacts on EU taxpayers

As Option 2 addresses new and future use of dental amalgam, and not environmental impacts of historical use of dental mercury, the effect on the costs of solid waste and wastewater treatment will remain limited in the mid-term.

4.2.2.4 Impacts on crematoria

In the long-term, Option 2 will lead to a greater decrease in mercury emissions from crematoria than what would be expected in the baseline scenario. However, because Option 2 is not expected to result in a complete phase-out of dental mercury, mercury abatement equipment will continue to be required in crematoria, either as a legal requirement or as a good practice.

The economic impact of Option 2 on crematoria is therefore expected to be minimal.

4.2.2.5 Impacts on public authorities

Administrative costs of Option 2 for public authorities mainly correspond to increased awareness raising activities towards dentists and dental schools in order to discourage the use of dental amalgam and promote the learning and use of Hg-free restoration techniques.

The quantification of such activities is difficult as it can involve numerous actors and a variety of initiatives, and no adequate information is currently available. Regarding the actors involved, the measures taken under Option 2 would most likely involve EU and national health and environmental authorities, dental associations, NGOs, the media, dental schools, etc. As regards the specific communication tools which could be used, these could include the creation of websites, the organisation of conferences and training sessions, the mailing of brochures and other information material, etc. In order to achieve a significant reduction in the use of dental amalgam results, the overall administrative costs of such actions can be relatively high.

For example, an impact assessment that was carried out in relation to the ban on mercury-containing sphygmomanometers[122] estimated that the cost for contacting all EU doctors by sending letters to was between EUR 300,000 to 600,000. This action was targeted at 1.5 million doctors so if we consider that the number of EU practicing dentists is approximately EUR 300,000 and that, compared with doctors, a smaller number can be contacted through hospitals, then it is estimated that a similar campaign under Option 2 could roughly cost EUR 100,000 to 300,000.

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[122] European Chemicals Agency (2010), Annex XV Restriction report proposal for a restriction, substance name: Mercury

4.2.3 Option 3

4.2.3.1 *Impacts on manufacturers and suppliers of dental fillings*

On the one hand, the magnitude of the dental amalgam demand reduction under Option 3 will put significant pressure on dental fillings manufacturers with a high share of dental amalgam in their overall production. This pressure will be more significant than under Option 2, due to the limited time scale to substitute dental amalgam (within 5 years from the ban adoption) and the compulsory nature of the policy measure. On the other hand, companies with a high share of Hg-free materials in their production will gain an even greater competitive advantage than under Option 2.

Overall, since there are only two main EU companies producing bulk mercury for dental amalgam (and no Hg-free fillings), the economic impact on the industry is expected to remain limited.

The positive effect of Option 3 on innovation within the EU dental industry is expected to be greater than under Option 2, given the limited time scale to fully substitute dental amalgam.

For the reasons explained above, the effects of innovation and increased competition on prices of Hg-free dental filling materials under Option 3 are expected to be higher than those predicted under Option 2. In this context, it is assumed that the difference in sale price between dental amalgam and Hg-free materials (composites or glass ionomers) could be reduced by up to 50% on average by 2025. Under this assumption, the complete substitution of dental amalgam fillings with Hg-free materials would increase the revenues of the EU dental fillings industry by EUR 1.3 to 5.3billion between 2010 and 2025, representing an increase in the range between 14% and 128% with regard to the value estimated in the baseline scenario.

4.2.3.2 *Impacts on dentists*

- **Acquisition of skills and equipment**

One the one hand, in comparison with Option 2, the limited time to achieve a complete phase-out of dental amalgam as well as the compulsory nature of this measure may put more pressure on dentists that have no or little experience in carrying out Hg-free restorations, i.e. mainly dentists practising in Group 3 countries. These dentists will be obliged to obtain the necessary skills within a short timeframe; however, the proposed 5-year notice period before the ban becomes applicable should be sufficient to allow all EU dentists to get the necessary training required in due time. On the other hand, in the short term, this may generate a competitive advantage for dentists that are already fully skilled in Hg-free restoration techniques.

- **Waste management costs**

As in Option 2, the impact of Option 3 on waste management costs for dentists will be limited due to the time it will take for the amount of mercury stored in the mouths of EU citizens to be fully eliminated and due to the presence of dental amalgam in the teeth of EU immigrants.

4.2.3.3 Impacts on dental patients

Under Option 3, the substitution of dental amalgam with Hg-free restorations will be faster than under Option 2 and will be complete (dental amalgam to be phased out in 2018, i.e. 5 years after adoption of the ban assumed to be in 2013). Given the current higher cost of Hg-free restorations, Option 3 will tend to increase additional costs for dental patients. However, this effect is expected to be partly offset by a significant decrease in the cost of Hg-free restorations in the mid-term, for the same reasons as those explained under Option 2 (see Section 4.2.2.2) but leading to a more significant decrease in the average cost difference of dental restorations than in Option 2.

By applying the same methodology as in the baseline scenario, it is estimated that in total approximately 762 million dental amalgam restorations will be substituted with Hg-free restorations between 2010 and 2025. If the average cost differences between dental amalgam and Hg-free restorations remained similar in the mid-term – which is a very pessimistic scenario – Option 3 would result in a cost of approximately EUR 16.8 billion for EU dental patients between 2010 and 2025 (or EUR 33.6 per capita), which represents a net cost of EUR 9.3 billion (EUR 18.5 per capita) with regard to the baseline scenario (see Table 8 below). If the average cost differences between dental amalgam and Hg-free restorations decreased by 3% annually (more realistic scenario), Option 3 would result in a cost of approximately EUR 12.5 billion for EU dental patients between 2010 and 2025 (or EUR 25 per capita), which represents a net cost of EUR 5.7 billion (EUR 11.3 per capita) with regard to the baseline scenario.

As in the baseline scenario and under Option 2, it is assumed that the amounts or fee percentages possibly reimbursed by national health insurance schemes would remain similar in the future.

Table 8: Additional costs borne by patients under Policy Option 3, for the period 2010-2025

MS with cost differences	Total number of dental amalgam restorations substituted with Hg-free materials in 2010-2025 ('000)	Additional costs borne by EU patients in2010-2025 if no change in price difference (million EUR)	Additional costs borne by EU patients in2010-2025 with an annual decrease of the price difference by 3% (million EUR)
Austria	18,838	1,526	1,133
Czech Republic	84,772	3,476	2,581
Germany	63,814	2,553	1,896
Greece*	63,558	1,144	850
Hungary	5,887	38	28
Netherlands*	8,638	51	38
Poland	235,477	4,356	3,236
Luxembourg*	692	4	3
Portugal*	14,652	86	64
Romania*	120,662	2,172	1,613
Slovakia	30,499	122	91
Spain*	63,344	373	277
Latvia	3,750	73	54
Lithuania*	18,716	337	250
Ireland	12,103	242	180
Malta	2,330	12	9
Slovenia*	14,835	267	198
EU27	762,568	16,831	12,501

* Estimated values. For these MS, the average cost difference is assumed to be equal to the average value for the group of MS they belong to.
NB: The average restoration costs take into account possible amounts reimbursed by national health insurance schemes, where they exist.

The projected increase in dental restoration costs for patients is expected to affect the private health insurance industry in a positive manner, as it will increase the demand for insurance services covering dental treatment.

4.2.3.4 *Impacts on EU taxpayers*

- **Costs related to the national health insurance schemes**

Given the additional costs to be borne by dental patients (80% to 120% increase with regard to the baseline scenario for the period 2010-2025, as detailed in the above section), national health authorities may decide to increase the levels of reimbursement for dental restoration that are set by their national health insurance schemes (at least when dental restorations are reimbursed on a fixed amount basis).

At this stage, it is not possible to predict whether any additional costs due to a ban on dental amalgam would lead to changes in dental treatment coverage by the national health insurance schemes.

Given the current economic context in the EU and the expected decrease in the costs of Hg-free restorations, it has been assumed that all additional costs would be borne by the patients, with no impact on EU taxpayers.

- **Costs related to treatment of mercury-contaminated waste and wastewater**

As Option 3 addresses new and future use of dental amalgam, and not environmental impacts of historical use of dental mercury, the effect on the costs of solid waste and wastewater treatment will remain limited in the mid-term.

4.2.3.5 *Impacts on crematoria*

Option 3 will lead to an almost complete cessation of mercury emissions from crematoria. However, given the lifetime of dental amalgam restorations and the existence of specific cremation practices in certain Member States (e.g. some cremations occurring several years after burial in IT), this positive effect will only be observed in the long-term.

In the mid-term, Option 3 is not expected to reduce significantly mercury abatement costs incurred by crematoria. In the long-term, the dental amalgam ban will have a positive economic effect by avoiding the need for installing mercury abatement devices in new EU crematoria or operating the systems already in place (only small quantities of dental amalgam would still be used within the EU or could be found in the teeth of EU immigrants).

4.2.3.1 *Impacts on public authorities*

Option 3 will involve enforcing an additional restriction contained in the REACH Regulation (in the present study, it is assumed that the ban would be implemented by adding mercury use in dentistry to the list of restrictions in Annex XVII of REACH).

Currently there is no evidence that would allow a quantitative assessment of such administrative costs. The experience from Sweden cannot be considered as representative of the EU27, since before the ban on mercury came into force in 2009 there were other initiatives to discourage the use of dental amalgam. These included a voluntary agreement between the government and the country councils to phase out the use of amalgam in children and young people (adopted in 1995) and a decision to stop the reimbursement of amalgam restorations by the national health insurance scheme (came into force in 1999).

However, since this policy option would not require any transposition of legal provisions by the Member States and given that each Member State already has dedicated staff in charge of the enforcement of the REACH Regulation, a future ban on dental mercury use is not expected to increase the administrative burden of public authorities in a significant manner.

4.3 Social impacts

4.3.1 Option 1

- **Employment**

It can be expected that the requirement for adequate treatment of dental amalgam waste would have a positive impact in terms of jobs creation in companies that are involved in the manufacturing, installation and maintenance of amalgam separators as well as in companies specialising in the collection and treatment of dental mercury-containing waste. Many of these companies are based in the EU, although part of the amalgam separators may be manufactured outside the EU. It is difficult to estimate the number of jobs which may be created in the absence of information on the current level of employment in these companies. However, at a larger scale, it is recognised that better implementation of EU waste legislation would have a positive impact on EU employment: a recent study for the European Commission estimated that full implementation of EU waste legislation would increase the annual turnover of the EU waste management sector and recycling sector by EUR 42 billion and create over 400,000 jobs by 2020[123].

- **Occupational health and safety of dental personnel**

Option 1 is not expected to affect occupational health and safety, as it will not induce a decrease in mercury vapours from dental amalgam handling.

- **Public health and safety**

Option 1 will significantly reduce mercury releases to urban WWTPs, resulting in avoided mercury releases to the different environmental media, mainly depending on the fate of mercury in sewage sludge. In 2015, it is roughly estimated that avoided air emissions of mercury under Option 1 will be of approximately 7 t Hg/year (see Section 4.1.1). Considering health damage costs related to IQ loss of between EUR 5,000 to 20,000 per kg Hg emitted to air (see Section 2.6.4.3), this policy option would result in annual avoided health damage costs in the range of EUR 35 to 140 million per year in 2015. This should be considered as a minimum range, given that it does not consider possible impacts via ingestion and other types of health damages related to mercury exposure (e.g. impacts on nervous or cardiovascular systems).

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[123] BIO Intelligence Service, Ecologic Institute and Umweltbundesamt (2011) Implementing EU waste legislation for green growth (http://ec.europa.eu/environment/waste/studies/pdf/study%2012%20FINAL%20REPORT.pdf)

4.3.2 Option 2

- **Employment**

The impact of the measures taken by Member States under Option 2 is expected to be positive with regard to employment. Jobs may first be created in relation to awareness raising activities to be launched by the Member States, although these jobs may only be created only for a short period of time (the time of the awareness raising campaigns themselves). Jobs may also be created to train dentists in Hg-free restoration techniques, including the ART which is not yet widely spread in the EU. Finally, because Option 2 is expected to foster innovation in Hg-free filling materials (see Section 4.2.2.1), this may also generate new employment opportunities in R&D activities of the dental industry.

- **Occupational health and safety of dental personnel**

The expected decrease in dental amalgam use under Option 2 will reduce the volume of mercury vapours that may be inhaled by dental personnel, thereby reducing the health risks for these workers. However, as long as mercury is present in old fillings, dental personnel will continue to be exposed to mercury vapours from dental effluents and from solid mercury-containing waste if there are no adequate protection measures in place.

- **Public health and safety**

This policy option would reduce quantities of dental amalgam entering the market. In 2025, it would avoid the use of approximately 15 t Hg/year in 2025 (see Section 4.1.2) and the emissions of approximately 0.4 t Hg/year to the air. Considering health damage costs related to IQ loss of between EUR 5,000 to 20,000 per kg Hg emitted to air (see Section 2.6.4.3), this policy option would result in annual avoided health damage costs in the range of EUR 2 to 8 million per year in 2025. This should be considered as a minimum range, given that it does not consider possible impacts via ingestion and other types of health damages related to mercury exposure (e.g. impacts on nervous or cardiovascular systems).

4.3.3 Option 3

- **Employment**

Under this policy option, it is expected that new jobs would be created in relation to the training of dentists, some of which will need to improve their skills or acquire new skills in Hg-free restoration techniques within a short timeframe.

It is also expected that new jobs would be created to support R&D activities in the dental fillings industry, due to the need for companies to maintain a high level of innovation in Hg-free materials.

- **Occupational health and safety of dental personnel**

The ban on dental amalgam use will significantly reduce mercury-related health risks for dental personnel. Dental personnel may still be exposed to mercury vapours from dental effluents and from solid mercury-containing waste, if no adequate protection measures are in place, but this exposure will become negligible 10 to 15 years after the ban becomes applicable (10-15 years is the average lifetime of amalgam restorations).

- **Public health and safety**

At the time the ban becomes applicable (i.e. 2018), it is estimated that mercury releases to the environment would be reduced by approximately 5 t Hg/year with regard to the baseline scenario, including a reduction of approximately 3 t Hg/year to the air. Considering health damage costs related to IQ loss of between EUR 5,000 to 20,000 per kg Hg emitted to air (see Section 2.6.4.3), this policy option would result in annual avoided health damage costs in the range of EUR 15 to 60 million/year in 2018. This should be considered as a minimum range, given that it does not consider possible impacts via ingestion and other types of health damages related to mercury exposure (e.g. impacts on nervous or cardiovascular systems).

4.4 Other impacts

Because mercury pollution is a global issue, it is important to note that environmental and public health and safety benefits of Options 1, 2 and Option 3 are likely to extend outside the EU territory.

Furthermore, the adoption of a ban on mercury use in dentistry in the EU, under Option 3, may trigger the adoption of similar bans in some non-EU countries, especially given the context of ongoing international negotiations to adopt a legally binding instrument on mercury and given the fact that dental amalgam is among the main mercury uses worldwide.

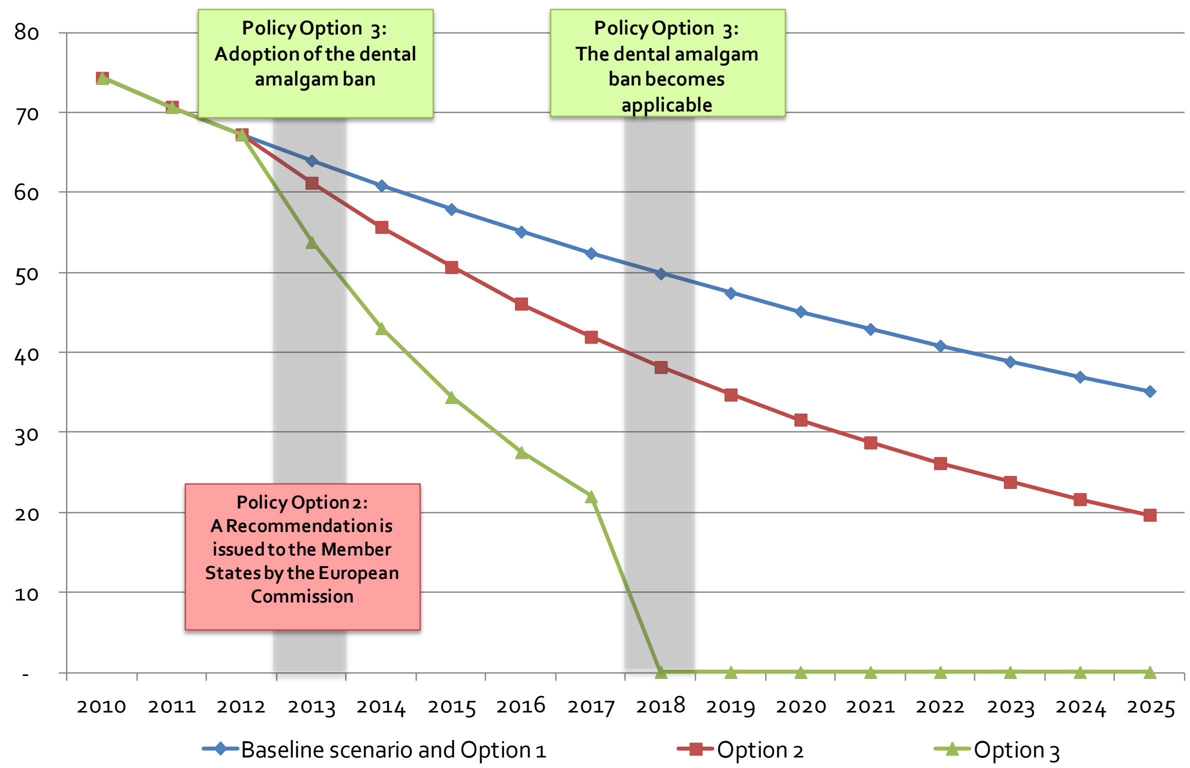
Chapter 5: Comparison of options and conclusions

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, taking into account effectiveness, efficiency and coherence criteria.

5.1 Comparison of policy options

Environmental and socio-economic impacts of the policy options are closely related to the projected trends for dental amalgam use in the EU, over the next 15 years. A comparison of the different projections developed in this study, for the different policy options, is presented in Figure 9 below. As explained previously, the assumptions used to develop these projections are based on the limited information currently available concerning the expected decline of dental amalgam demand in the EU and they carry a large part of uncertainty.

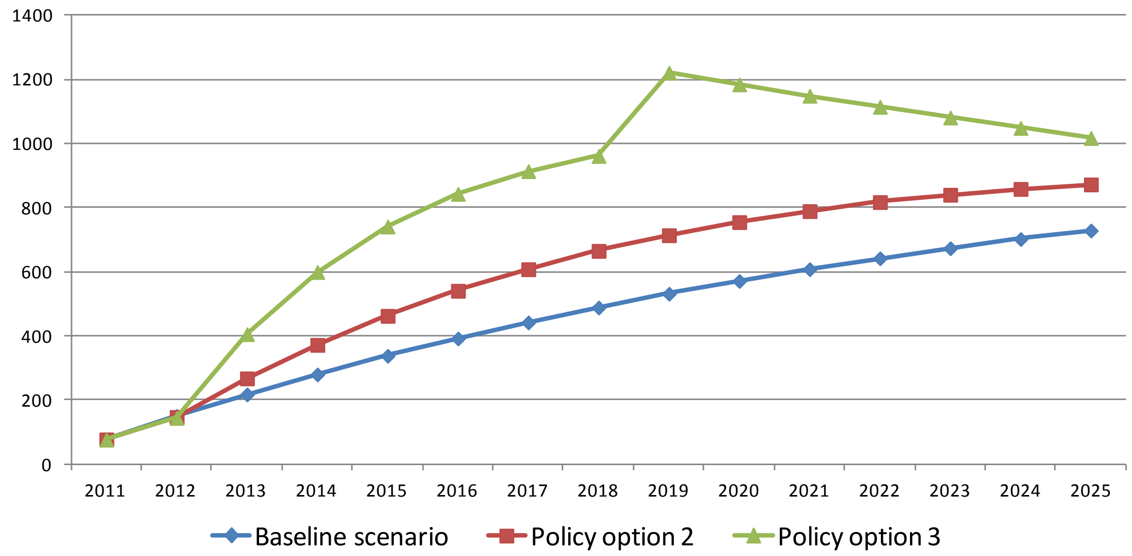
Figure 9: Projected annual demand for dental mercury in the EU (t Hg)



While the baseline scenario assumes a gradual decrease in dental amalgam demand over the next 15 years (approximately –5% demand per year) until a threshold of about 35 t Hg/year to be reached in 2025, Option 3 would result in a sharp decrease (approximately 20% annually) of dental amalgam demand from 2013 (when the ban is adopted) to reach zero demand in 2018 once the ban becomes applicable (in fact, very small amounts could still be used after 2018, in accordance with the allowed exemptions, but these are considered to be negligible). Option 2, as an intermediate option between the 'no policy change' and Option 3, would result in a more rapid decline in dental amalgam demand than in the baseline scenario (approximately –9% demand per year) until a threshold of about 19 t Hg/year to be reached in 2025.

The analysis of economic impacts revealed that another important indicator is the cost of dental amalgam substitution by Hg-free materials for EU dental patients. The projected evolution of such costs in the baseline scenario and under Options 2 and 3 is shown in Figure 8 below (costs of Option 1 would be similar to the baseline scenario). Projections shown below take into account a progressive decrease in the cost of Hg-free restorations, which was identified as the most realistic scenario. The graph shows that, in all policy options, the annual costs would increase (due to higher numbers of Hg free restorations); however, this increase would progressively slow down in the baseline scenario and Option 2 (due to the decreasing price difference between amalgam and Hg-free restorations). The annual costs tend to converge towards the end of the time period considered (2025).

Figure 10: Annual costs borne by EU dental patients due to the substitution of dental amalgam according to different policy options (million EUR)



A comparison of the four policy options, based on the key impacts or impact indicators analysed in this study, is presented in Table 9 below. The comparison of impacts is presented over a 15-year horizon (2010-2025), unless otherwise specified.

Table 9: Overview of key impacts associated with the policy options analysed, over a 15-year horizon (2010-2025)

Key impact indicators	'No policy change' (baseline scenario)	Option 1 Improve enforcement of EU waste legislation in dental practices	Option 2 Encourage MS to take national measures to reduce dental amalgam use	Option 3 Ban the use of Hg in dentistry
EU demand for dental amalgam	↘	↘	↘↘	↘↘↘ (reaching zero in 2018)
Environmental impact indicators				
Quantities of dental amalgam waste produced	↘	↘	↘↘	↘↘↘
% of dental amalgam waste treated as hazardous waste	≈	↗↗↗	≈	≈
Dental Hg emissions to air	↘	↘↘	↘ (within 15 years) to ↘↘ (within several decades)	↘↘ (within 15 years) to ↘↘↘ (within several decades)
Dental Hg emissions to water	↘	↘↘	↘ (within 15 years) to ↘↘ (within several decades)	↘↘ (within 15 years) to ↘↘↘ (within several decades)
Dental Hg emissions to soil and groundwater	↘	↘↘	↘ (within 15 years) to ↘↘ (within several decades)	↘↘ (within 15 years) to ↘↘↘ (within several decades)
Dental Hg accumulated in fish (in the form of methylmercury)	↘ (within several decades)	↘↘ (within several decades)	↘↘ (within several decades)	↘↘↘ (within several decades)
Economic impact indicators				
Revenues of dental fillings industry	≈ or ↗	≈ or ↗	↗ or ↗↗	↗ or ↗↗
Competitiveness of EU dental fillings industry	≈	≈	↗	↗↗
Level of innovation in dental filling materials	≈	≈	↗	↗↗
Costs borne by patients for dental	↗	↗	↗ or ↗↗	↗ or ↗↗

Key impact indicators	'No policy change' (baseline scenario)	Option 1 Improve enforcement of EU waste legislation in dental practices	Option 2 Encourage MS to take national measures to reduce dental amalgam use	Option 3 Ban the use of Hg in dentistry
restoration				
Costs borne by EU taxpayers (Hg pollution abatement)	≈	↘↘	↘	↘↘
Hg abatement costs for crematoria	↗	↗	↗	↘ (within several decades)
Administrative costs for public authorities	≈	↗	↗↗	↗
Social impact indicators				
Jobs in EU dental fillings industry	≈	≈	≈	≈
Occupational health risks for dental personnel	↘	↘	↘↘	↘↘↘
Public health risks due to *indirect* Hg exposure from dental amalgam	↘	↘↘	↘↘	↘↘↘
Public health risks due to *direct* Hg exposure from dental amalgam	?	?	?	?
Public health risks due to exposure to composite resins (possible presence of endocrine disrupting substances)	?	?	?	?

Legend:
≈ Expected to remain similar over the time horizon considered
↘ or ↗: Slight decrease or slight increase expected over the time horizon considered
↘↘ or ↗↗: Significant decrease or significant increase expected over the time horizon considered
↘↘↘ or ↗↗↗: Very significant decrease or very significant increase expected over the time horizon considered
?: Uncertain trend

5.2 Conclusions

The most effective way to reach the policy objective, i.e. reducing the environmental impacts of dental amalgam use, would be a combination of Options 1 and 3. While Option 1 tackles environmental impacts from both historical and current dental amalgam use, it focuses on releases from dental practices and is not sufficient in itself to address the whole range of mercury releases from the dental amalgam life cycle (it does not address mercury releases from the natural deterioration of amalgam fillings in people's mouths, from cremation and burial, and residual emissions to urban WWTPs). Option 3 would allow a significant reduction of dental mercury releases within the next 15 years and would virtually eliminate the environmental impacts of dental mercury in the longer term. However, because the cessation of mercury releases, under Option 3, would only be significant after about 15 years, Option 3 needs to be coupled with Option 1 in order to reduce mercury releases from historical use of amalgam in the short term.

Option 2 leaves more flexibility to Member States to implement national measures aimed at reducing dental amalgam use, which would allow them to take into account national specificities (e.g. current level of oral health, cost aspects, specificities of national health insurance schemes); however, the effectiveness of this option is subject to high uncertainty since there would be no binding targets to achieve. In order for this option to be effective in reducing environmental impacts, the administrative costs incurred by public authorities may be higher than in the case of Option 3 (significant awareness raising required in some Member States in order to induce a change in practices).

The 'no policy change' option cannot achieve a significant reduction of mercury pollution from dental amalgam. Even if the progressive substitution of dental amalgam with Hg-free materials is expected to continue in future years, a complete phase-out of dental amalgam use is very unlikely to happen for the reasons explained in the previous chapters. In this regard, it is interesting to note that, in Sweden, dentists' organisations and the National Board of Health and Welfare initially claimed that no legislative measures were needed to reduce amalgam use because it would vanish by itself; however, this did not happen after more than a decade, hence the decision of the authorities to introduce a ban. Following implementation of the ban, the use of dental amalgam was rapidly phased out without any problems.

The preferred combination of options is therefore Option 1 + Option 3. It would achieve the highest effectiveness, while the associated costs are considered to be reasonable for the various stakeholders especially as they are considered to be outweighed by the associated environmental and health benefits. The cost efficiency of Option 3 improves with the active promotion of cheaper Hg-free restoration techniques such as ART, the improvement of dentists' skills in Hg-free restoration techniques (resulting in reduced placement durations and therefore reduced labour costs) and a gradual decrease in the price of Hg-free filling materials thanks to continuous innovation and increased competitiveness within this industry sector. Another aspect to ensure the success of Option 3 is to take measures to avoid the presence of BPA and other known endocrine disruptors in composite resins, knowing that BPA-free filling materials are already available on the market. Implementing Option 1 should be relatively feasible from a political point of view as it is about enforcing existing legal requirements (rather than creating new requirements) and it is the logical follow-up of Action 4 of the EU Mercury Strategy ('*The Commission will review in 2005 Member States' implementation of Community requirements on the treatment of dental amalgam waste, and will take appropriate steps thereafter to ensure correct application*'). The implementation of Option 3 may be more challenging, not because of the actual costs of the changes required, but due to the changes in professional habits that need to occur among dentists, especially in some Member States, and the time required for all EU dentists to be well skilled at performing mercury-free restorations. The implementation of Option 3 can also be considered as a logical follow-up of Action 8 of the EU Mercury Strategy ('*The Commission will further study in the short term the few remaining products and applications in the EU that use small amounts of mercury. In the medium to longer term, any remaining uses may be subject to authorisation and consideration of substitution under the proposed REACH Regulation, once adopted'*) and seems necessary to achieve mercury-related requirements of EU legislation on water quality.

PART B: Assessment of policy options to reduce environmental impacts from mercury-containing batteries

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Chapter 6: Problem definition and objectives

This chapter describes the issues associated with mercury-containing batteries, the main drivers for these problems and the key actors affected. It also describes the current policy context, the current situation with regard to environmental and socio-economic aspects of the problem as well as the likely evolution of the problems in the absence of any further EU policy action. The reasons justifying public intervention at EU level are explained, taking into account subsidiarity and proportionality principles. Finally, the objectives of future policy action to address the issue of mercury-containing batteries are defined, in line with the problems and drivers identified.

6.1 Introduction

Button cell batteries are small, thin energy cells that are commonly used in watches, hearing aids, and other electronic devices. Because of their compact nature, button type batteries are very widely used as a source of electric power for the integrated circuits of electronic apparatus. Because of its miniature size, the button cell battery has to pack a lot of power in a small space. In the early 1980s, battery manufacturers began to decrease the amount of gasses and impurities within these types of energy sources by refining the zinc content. Battery manufacturers have used small amounts of mercury to suppress the formation of internal gasses that affect all batteries containing zinc electrodes (gassing can lead to leakage, possible rupture and/or short shelf life of batteries). Until a few years ago, the battery industry had developed alternative product designs that eliminated added mercury in all batteries except button cells; however Hg-free versions of button cell batteries have become available on the market in recent years.

The environmental impacts associated with the presence of mercury in batteries are mainly resulting from inadequate management of used batteries: only a limited proportion of waste batteries are currently separately collected in the EU, of which only a certain percentage can effectively be recycled. A significant proportion of Hg-containing batteries ends up in incineration plants or landfills for non-hazardous waste (if mixed with household waste).

6.2 Policy context

6.2.1 EU policy context

Mercury-containing batteries are classified as hazardous waste by Commission Decision 2000/532/EC. The use of mercury in batteries is already restricted by the Batteries Directive (2006/66/EC), however mercury content restriction for button cell batteries are much less stringent than for other types of batteries: the Directive prohibits the placing on the market of all batteries and accumulators containing more than 0.0005% Hg by weight, with the exception of button cells that are allowed up to a Hg content of 2% by weight. The Directive also imposes specific collection and recycling targets for waste batteries and requires that battery's packaging is labelled for the presence of mercury. The collection target is 25% by 2012 increasing to 45% by 2016. Minimum recycling efficiency targets vary between 50% and 75% depending on the battery types. When no viable end market for those metals is available, Member States are allowed to dispose of collected portable batteries or accumulators containing cadmium, mercury or lead in landfills or underground storage. These provisions are duplicated in the REACH Regulation (EC/1907/2006)[124].

The Environment Council, in its Council Conclusion of March 2011, invited the Commission to '*extend its investigation to mercury-containing button cell batteries that are still allowed on the EU market, and to assess the need for further risk management measures*'.

The Commission has reviewed in depth the Batteries Directive exemption clause regarding cadmium as required by the Directive, and has proposed a Directive repealing this exemption. This is not to be confused with the fully-fledged review of the Directive which will take place at a later stage, in 2016, when the Commission will have received Member States' implementation reports. This wider review will include an evaluation of the appropriateness of further risk management measures for batteries containing heavy metals.

The present study on mercury in button cell batteries aims primarily at gathering information on the current market situation, notably in view of the international negotiations on a global legally binding instrument on mercury which is likely to address the use of mercury in batteries (see Section 1.3). The information gathered through this study will also feed in the future policy and legislative reviews that the Commission will undertake (as stated in the 2010 Communication on the review of the Mercury Strategy[29], the mercury policy will be revisited after the conclusion of the Multilateral Environmental Agreement; the Batteries Directive will be reviewed in 2016).

6.2.2 International policy context

In addition to the global mercury treaty under preparation, which is likely to address the use of mercury in batteries (see Section 1.3), some initiatives to further restrict mercury use in button cell batteries are taking place in the USA and in China.

Three US States (Maine, Connecticut and Rhode Island) have enacted legislations to ban the sale of mercury-containing button cell batteries from mid-2011 (with an exemption for low sales volume silver oxide button cells until 1 January 2015 in the State of Maine, for economic reasons). In addition, all US battery manufacturers have voluntarily committed to eliminating mercury in button cell batteries sold in the USA by 2011.

China, one of the main countries producing alkaline manganese button cell batteries, issued 'Clean Production Guidelines' for the battery sector in December 2011. These guidelines recommend that companies should actively promote the production of mercury-free alkaline manganese button cell batteries.

[124] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:396:0001:0849:EN:PDF

6.3 Problem definition

6.3.1 The mercury problem

The mercury problem has been briefly described in the introduction to this report (Section 1.1). Further details can be found in the EU Mercury Strategy[28] or in the UNEP Global Mercury Assessment[125].

The fundamental problem in the current situation is that certain population groups – and especially women of child-bearing age and children – are subject to unacceptable levels of exposure to mercury, principally in the form of methylmercury through diet. This presents a risk of negative impacts on health, in particular affecting the nervous system and diminishing intellectual capacity. There are also environmental risks, for example the disturbance of microbiological activity in soils and harm to wildlife populations. According to calculations based on the critical load concept (mainly based on ecotoxicological effects and human health effects via ecosystems), more than 70% of the European ecosystem area is estimated to be at risk today due to mercury levels, with critical loads for mercury exceeded in large parts of western, central and southern Europe[126].

Mercury releases from mercury-containing products and processes contribute significantly to overall mercury releases from anthropogenic activities in the EU. The production of button cell batteries are one of the remaining uses of mercury in the EU.

6.3.2 Specific issues related to mercury-containing button cell batteries

Mercury-containing button-cell batteries are a source of mercury pollution mainly because of improper waste management at their end of life (i.e. waste not managed as hazardous waste). Non-hazardous waste treatment methods are not designed for battery waste; in the case of mercury-containing button cell waste, non-hazardous waste treatment methods have the potential to release mercury to air, water and soil. This mercury can then become bioavailable and accumulate in biota, leading to environmental and human health risks.

Increasing separate collection rates of batteries is a challenging task. Little data is currently reported by the Member States' compliance organisations on the collection of waste button cells. However, in 2009, the European Battery Recycling Association (EBRA) reported that 174 tonnes of button cells waste (most of which originated from the EU) was separately collected and

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[125] UNEP (2002) Global Mercury Assessment Report

[126] Hettelingh, J.P. et al. (2006). Heavy Metal Emissions, Depositions, Critical Loads and Exceedances in Europe. VROM-DGM report, www.mnp.nl/cce, 93 pp.; CEE Status Reports 2008 (Chapter 7, http://www.rivm.nl/thema/images/CCE08_Chapter_7_tcm61-41910.pdf) and 2010 (Chapter 8, http://www.rivm.nl/thema/images/SR2010_Ch8_tcm61-49679.pdf)

recycled in EU[127] (quantities collected correspond to 12% collection rate calculated as per the guidance provided in Battery Directive[128]). In other words, in 2009 approximately 88% of button cells waste escaped separate waste collection schemes and ended up with mixed non-hazardous waste. This represents approximately 5.5 tonnes of mercury[129].

The Battery Directive[130] sets the following minimum collection rates for portable batteries and accumulators (including button cells): 25% by September 2012 and 45% by September 2016. In fact, a high level of collection is unlikely to be achieved in the short-term at EU level. Thus, even a strong enforcement of the Battery Directive would not be sufficient to solve the problem of mercury pollution due to improper management of button cell waste.

The problem can be solved by substituting Hg-containing button cells by Hg-free alternatives. According to the stakeholders[131] (button cells manufacturers/importers/distributors) consulted in the present study, Hg-free versions are now commercially available for all applications of the four main types of button cells (Lithium, Silver oxide, Alkaline and Zinc-air) in EU. Majority of the stakeholders (5 out of 6 respondents to a questionnaire survey) confirmed that the performance parameters such as self-discharge, leak resistance, capacity and pulse capability of Hg-free button cells are the same for all application areas as compared to traditional Hg-containing button cells. The Hg-free alternatives also have a similar shelf-life as compared to the Hg-containing button cells. Costs of Hg-free alternatives are currently slightly higher (approximately 10%) than Hg-containing versions, however with a higher share of Hg-free button cells placed on the market, the extra cost of these button cells will tend to be offset.

Several factors, including market and regulatory failures have led to the current examination of the use of mercury in button cells in EU.

- **Market failures**

In the case of Hg-containing button cells, negative environmental and health externalities exist, which has created market failure, one of the underlying drivers of the problem. In the current situation, Hg-containing button cells are cheaper (by around 10%) than the Hg-free button cells. If not adequately controlled, the production, consumption and especially the end-of-life management of Hg-containing button cells may cause adverse environmental effects (mercury is particularly toxic for aquatic environments and organisms) and can create severe health

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[127] Source: EBRA, October 2010. EBRA member companies recycled 89% of overall EU button cells waste recycled in 2009.

[128] The Battery Directive (2006/66/EC) defines collection rate for a given Member State in a given calendar year, as the percentage obtained by dividing the weight of waste portable batteries and accumulators collected in accordance with Article 8(1) of this Directive or with Directive 2002/96/EC in that calendar year by the average weight of portable batteries and accumulators that producers either sell directly to end-users or deliver to third parties in order to sell them to end-users in that Member State during that calendar year and the preceding two calendar years.

[129] This estimate is calculated based on the assumption that the share of different button cells types in the collected waste is the same as the respective market shares of these batteries in EU in 2009 (i.e. 8% alkaline, 12% silver-oxide, 46% lithium and 34% zinc-air button cells). Using the average Hg content for each type of button cell in 2009 (0.45% in alkaline, 0.5% in silver oxide, 1% in zinc-air). In addition to the Hg-containing button cells types, the waste stream is likely to contain old mercury-oxide button cells (now prohibited) with higher levels of mercury, but also some Hg-free button cells.

[130] Directive 2006/66/EC

[131] See Annex A for further explanations

problems in humans, e.g. affecting the nervous system and diminishing intellectual capacity. These negative externalities are not included in the prices paid by retailers and end users.

- **Asymmetrical and incomplete information**

In 2003, the Commission published the "Impact assessment on selected policy options for revision of the Batteries Directive" stating that Hg-containing batteries are no longer a significant concern following the implementation of Directive 98/101/EC[132]. However, no viable substitutes for Hg-containing button cells appeared to be available at the time of drafting that report and the issue of mercury in button cells was not specifically addressed by this impact assessment.

Many stakeholders consider this situation is not acceptable, as new evidence has surfaced since the publication of the 2003 report indicating that today Hg-free button cells exist for all applications and appear fully competitive alternatives to Hg-containing button cells. Therefore, the present study examines the availability of commercially viable Hg-free button cells and the environmental justification for a restriction on the placing of Hg-containing button cells in the EU market, before assessing economic and social impacts.

6.4 Who is affected?

Mercury releases from the life cycle of button cell batteries contribute to the overall mercury pollution. All individuals are exposed to mercury pollution to some degree. However, some groups are particularly vulnerable to the health effects of mercury pollution:

- High-level fish consumers; for example, EU populations leaving in coastal areas are more likely to be exposed to higher levels of methylmercury;
- Children (in particular, due to the increased vulnerability of their developing nervous system);
- Women who are pregnant, breastfeeding or thinking of becoming pregnant (due to the increased vulnerability of the foetus).

Mercury pollution may also negatively affect some activity sectors such as the fishing industry, if levels of methylmercury affect the marketability of fish or consumer confidence.

Other key actors likely to be affected include:

- Companies involved in the production and sale of button cell batteries or products containing button cell batteries – Due to the revenue they get from their activities, and the associated jobs.
- Consumers – Due to possible price differences between Hg-containing and Hg-free versions of button cells.
- Companies involved in the recycling of button cell batteries – Due to the revenue they get from their activities, and the associated jobs.

[132] Directive 98/101/EC was repealed by the Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators

- Member State authorities – Due to the administrative burden associated with the enforcement of battery-related legislation.
- People handling button cell waste in third countries – Due to possible exposure to mercury in the case of improper treatment of battery waste or waste products containing batteries exported from the EU.

6.5 Baseline scenario

Current situation

The Batteries Directive has prohibited the placing of mercury-oxide button cells (containing more than 2% mercury by weight) on the EU market since January 2000. However, PRODCOM[133] reports that small quantities of mercury-oxide button cells (less than 0.05% of the overall button cell market) were still being placed on the EU market until 2007 (see Annex G). Due to a lack of other sources of information, the PRODCOM statistics on illegal placing of mercury-oxide button cells cannot be validated. For this study, it is assumed that, since January 2000, the market of mercury-oxide button cells ceased to exist in EU. It must however be noted that in spite of the banning of mercury-oxide button cells since January 2000, they are also still to be found in button cell waste generated in EU. It is so as the average age of the button cells in the collected waste is 5 years (as reported by two button cell recyclers based in Europe).

As per the import, export and production statistics reported by PRODCOM, the majority of the button cells placed on the EU market from 2004 until 2007 were manufactured locally (see Annex G). Many data points reported in PRODCOM are unknown, estimated, confidential and therefore not available. The limited level of precision, availability of data for recent years (last reported statistics correspond to 2007) and overall reliability of PRODCOM data render their use questionable for this study. Due to these reasons, it was necessary to investigate other sources of market and economic data. This information collected via stakeholder's feedback to a questionnaire and literature review.

The European Portable Battery Association (EPBA)[134] reported that its member companies placed 486.6 million button cells units on the EU market in 2010[135]. Germany is the largest market in EU representing 24% of EPBA members' overall button cells sales in EU. Germany, United Kingdom, France, Spain, Italy and Netherlands together represent 80% of EPBA members' button cells market in EU.

[133] PRODCOM data is based on manufactured goods whose definitions are standardised across the EU thus guaranteeing comparability between Member States (epp.eurostat.ec.europa.eu/portal/page/portal/prodcom/data/database)

[134] EPBA is the leading organisation representing the interests of primary and rechargeable portable battery manufacturers, those industries using portable batteries in their products and distributors of portable batteries active within the European Union, and beyond.

[135] The latest (year 2010) aggregated button cells sales data of the EPBA member companies by the 27 EU Member States is provided in Annex A.

EPBA remarked that currently there are many unknown factors which make it very difficult to estimate the overall market of button cells placed on the EU market[136]. An estimate is only available for Germany, where EPBA estimates that their member companies represent around 45% of the overall national button cell market[137]. For this study, in the absence of further information, it is assumed that, at the EU level, the market share of button cells represented by EPBA member companies is similar to their share of the German button cells market, i.e. 45%. Therefore, it can be estimated that the total button cells market in EU in 2010 was around 1,080 million button cell units[138].

Due to a lack of information, the current market share of the Hg-free button cells (of the overall button cell market) in EU cannot be quantified.

- **How will the problem evolve, if no further policy action is taken?**

The button cell market in EU is already experiencing a shift towards Hg-free button cells which is expected to continue in the coming years, driven by recent developments in the USA and environmental responsibility policies of the manufacturers; however, it is not known how fast a complete phase-out of mercury would occur[139]. With a higher share of Hg-free button cells placed on the market, the extra cost of these button cells will tend to be offset.

Increasing separate collection rates of batteries is a challenging task. In the absence of further policy actions, the button cells waste collection rate in EU is likely to progressively increase and reach the minimum thresholds set under the Battery Directive. It will probably take a long time before high collection and recycling rates are achieved in all Member States. In the present study, it is proposed to use the collection rate reported for 2009, i.e. 12% (waste collection scenario 1), as an estimate of the current situation (assuming no improvement since 2009 – which is relatively pessimistic) and the legislative target of 45% (waste collection scenario 2) as an estimate of the likely situation in 2016.

[136] EPBA underlined that the statistics reported by their member companies takes into account the direct sales of button cells to the end-users and the sales made to Other Equipment Manufacturers (OEMs) who place these button cells in the market as incorporated in various products. However, these sales only take into account the sales made to OEMs based in the European market. It does not include the button cells sales to OEMs outside EU, who may, later in turn place their products on the EU market. The quantity of button cells placed in EU market via import of products containing these button cells can be estimated based on the Member State implementation reports to the Commission as required by the Battery Directive. Member States are currently collecting this data. However, as the first report will only be available in June 2013, at the time of drafting this report, it is not possible to trace quantities of button cells introduced in EU by the import of products (in which these button cells are already incorporated).

[137] This estimate is based on the comparison of EPBA statistics for year 2010 with the overall button cell market data for Germany, published by GRS, the German battery take back scheme.

[138] It is important to acknowledge that this estimate of the overall market of button cells in EU only gives a partial view since differences will occur from one Member State to another. Even more as EPBA remarked that the button cells market share of its member companies in Germany is much higher as compared to in other Member States in EU.

[139] Five out of the six stakeholders who responded to the questionnaire survey expect the share of mercury-free button cells to increase in the coming years in EU.

6.6 Justification for an EU action

First of all, the mercury pollution issue is a transboundary issue, as airborne mercury can be transported over long distances (i.e. across continents). EU action is therefore more effective than uncoordinated action by the Member States to address this issue.

Furthermore, all Member States are affected by the use of mercury in button cells as these are freely circulating in the internal market – therefore the need for harmonisation and coordination of policies and implementing measures at the EU-level. Mercury content restrictions in batteries and accumulators have been harmonised in the Batteries Directive 2006/66/EC – hence any further restrictions should also be considered in a harmonised manner to avoid creating obstacles to the functioning of the internal market. Action at EU level on this issue is therefore justified by the necessity to ensure a level playing field for manufacturers and traders of button cells sold in the EU (i.e. establishing the same trade rules for all companies in all Member States).

6.7 Policy objectives

The general objective of any future policies in relation to mercury in button cell batteries will be to reduce the environmental impacts from the use of mercury in these products and to reduce their contribution to the overall mercury problem. In the long-term, this should contribute to achieving reduced mercury levels in the environment, at EU and global level, especially levels of methylmercury in fish. This general objective may take decades to be achieved, as the present levels of mercury in the environment are representative of past mercury emissions, and even without further emissions it would take some time for these levels to fall.

This long-term policy objective can be achieved through specific policy actions aiming to restrict and, where feasible, eliminate mercury from button cell batteries.

Chapter 7: Policy options

This chapter describes the two policy options that have been selected for further analysis, i.e. the "no policy change" option and a ban on the placing on the market of mercury-containing button cell batteries in the EU. The latter policy option has been selected on the basis of the evidence analysed in the previous sections of this study as well as initial feedback received from the stakeholders. This chapter also explains why some other policy options have been excluded from the analysis, based on preliminary screening.

7.1 Policy options selected for further analysis

- **Option 1: 'No policy change'**

In this option, no further constraints would be imposed concerning the placing on the EU market of mercury-containing button cell batteries. The shift to Hg-free button cells in the EU will probably continue in the coming years, driven by recent developments in the USA and environmental responsibility policies of the manufacturers; however it is not known how fast a complete phase-out of mercury would occur.

The baseline scenario is described in further details in Section 2.6.

- **Option 2: Ban the placing on the market of mercury-containing button cell batteries in the EU**

A legal ban would accelerate the transition to Hg-free alternatives and would accelerate the reduction of costs for the production of Hg-free button cells. This ban would involve deleting the exemption contained in (Article 4 (2)) of the Batteries Directive, concerning the maximum allowable mercury content of button cells[140]. No exemption to this ban is proposed here, based on the feedback received from industry stakeholders consulted as part of this study.

Besides, such a policy option would also encourage countries importing large amounts of button cells to the EU market, such as China (where most button cells are manufactured), to switch to the manufacture of Hg-free button cells, which could have a global impact on the use of mercury in this industry sector.

Similar to the 'No policy change' option, in this option it is assumed that the button cells waste collection rate in EU would progressively increase to reach the minimum thresholds set under the Battery Directive – a collection rate of 25% by September 2012 and 45% by September 2016.

It must however be noted that although this policy option restricts the placing of new Hg-containing button cells on the EU market, Hg-containing button cells waste will continue to

[140] Battery Directive 2006/66/EC, Article 4(2).

emerge in the collected waste for up to 5 years[141] on average after the implementation of the ban.

It is assumed that the ban would become applicable around 18-24 months after adoption of the legislative change, which corresponds to the time that is likely to be required by the industry for the implementation of this change[142].

7.2 Policy options excluded from the analysis

- **Voluntary commitment from the battery industry**

This policy option does not appear to be feasible since the number of different actors that would need to be involved in such an agreement would be relatively high and many of the companies producing batteries that are sold in the EU are not based in the EU. This option was therefore discarded.

[141] As per a stakeholder (button cell recycler), the average age of mercury-containing button cell waste collected for recycling in EU is 5 years

[142] Source: The estimate on time required for the implementation reflects the opinion of a button cell manufacturer in EU.

Chapter 8: Analysis of impacts

THis chapter analyses the potential direct and indirect environment, social, and economic impacts of the policy options listed in the previous section. The aim of this analysis is to provide clear information on the likely impacts of the policy options as a basis for comparing them against one another.

Stakeholder consultation and literature review are the main information sources for the analysis of environmental, economic and social impacts.

8.1 Selection of impact categories and indicators

One of the first steps required for analysing impacts of the different policy options is to select impact categories and where possible the associated measurable indicators. When considering impact categories and indicators, it is important to keep in mind the main life-cycle stages of the button cells, during which impacts occur.

Table 10 presents a selection of indicators that are used to guide the analysis of economic, social and environmental impacts of the proposed policy options. These indicators are mostly measured quantitatively and when data was not available (either through literature review or stakeholder consultation), a qualitative assessment was made.

Table 10: List of impact categories and the corresponding methods of evaluation

Impact category	Indicator	Unit (if applicable)	Method for evaluation
Environmental	Environmental emissions to air/water/soil/biota	Tonnes Hg	Based on Hg content of button cells placed on the EU market and the quantities of button cells not separately collected for recycling
Economic	Impact on industry (revenues, innovation, competitiveness)	Euros	Literature review and consultation with experts from the companies manufacturing/importing/trading Hg-containing/Hg-free button cells in EU
	Impact on retailers (revenues)	Euros	Expert consultation and literature review
	Impact on consumers (product prices)	Euros	Expert consultation and literature review concerning the cost difference between Hg-containing and Hg-free button cells and quantities of button cells placed on EU market
	Impact on button cells waste management industry (revenues)	Euros	Literature review and consultation with experts from the waste button cell collection and recycling companies

Impact category	Indicator	Unit (if applicable)	Method for evaluation
	Administrative burdens (MS authorities)	Euros	Expert consultation and literature review
Social	Employment generation	Semi-quantitative	Expert consultation and literature review concerning the number of companies manufacturing/trading Hg-containing/Hg-free button cells in EU and the companies involved in their end-of-life waste management
	Impact on public health	N.A.	Based on information on environmental emissions

8.2 Environmental impacts

8.2.1 Option 1 ('no policy change')

The environmental impacts resulting from the mercury contained in the button cells mainly occur during the end-of-life phase due to the landfilling or incineration of waste button cells which are not separately collected for recycling or disposal as hazardous waste. The recycling efficiency of mercury from waste button cells is more than 99% (by weight)[143]. The incineration or landfilling in facilities for non-hazardous waste generates environmental impacts, notably through mercury emissions to air, water and soil.

It is possible to calculate the quantity of mercury introduced in the EU economy via the button cells using the market data presented in the baseline scenario, Annex G and the following assumptions:

- The average weight of state-of-the-art button cells range between: 0.3 to 1.9 grams for zinc-air, 0.3 to 2.3 grams for silver-oxide and 0.8 to 3.3 grams for alkaline button cells.
- The average mercury content (by weight) of state-of-the-art button cells is: 1% for zinc-air, 0.5% for silver-oxide and 0.45% for alkaline button cells.

Using this information, an estimate of quantities of mercury introduced in the EU economy through button cells from 2006 until 2010 is presented in Table 11 below.

[143] Source: Based on feedback provided by a waste button cell recycler (Batrec, Switzerland)

Table 11: Mercury contained in button cells placed on EU market from 2006 until 2010

Year	Minimum quantity (in kg)	Maximum quantity (in kg)	Average quantity (in kg)
2006	1 883	11 831	6 857
2007	1 776	11 102	6 439
2008	1 923	12 124	7 024
2009	2 095	13 250	7 673
2010	2 317	14 449	8 383

NB: The above estimates may be slightly pessimistic as they assume that no mercury free alternatives to any of the button cells (ZnO, AgO and alkaline) were sold in EU during these years.

The total amount of button cell waste generated in EU in 2010 is estimated to be around 1 660 tonnes[144].

- **Waste collection scenario 1**

This scenario represents a waste button cell collection rate of 12% (as observed in 2009). This means, in 2010, around 200 tonnes of button cells waste was separately collected and recycled in EU. In other words, approximately 6.4 t Hg contained in the button cell waste escaped separate collection schemes and ended up with mixed non-hazardous waste.

- **Waste collection scenario 2**

This scenario corresponds to the legislative target set for 2016 by the Battery Directive, i.e. a waste button cell collection rate of 45%. If such a target had been reached in 2010 (which is highly unlikely, although no data is currently available to check this point), it would have resulted in around 745 tonnes of button cells waste separately collected and recycled in EU. In other words, approximately 4 t Hg contained in the button cell waste would have escaped separate collection schemes and ended up with mixed non-hazardous waste.

The quantity of mercury in button cell batteries potentially which ended up in the environment in 2010, due to inadequate waste management, is therefore assumed to be in the range of 4 to 6.4 tonnes. This mercury remains potentially bioavailable and may accumulate in the food chain in the form of methylmercury, leading to potential impacts to ecosystems and human health.

8.2.2 Option 2

Policy Option 2 will avoid the introduction of around 8.4 tonnes/year of mercury contained in the button cells into the EU economy[145] and the emissions of 4 to 6.4 t Hg/year in the environment (due to inadequate waste management). As the average age of button cell waste generated in EU is around 5 years, the Hg-containing button cell waste will still be present in the waste stream

[144] Calculated as per the guidance provided in the Battery Directive

[145] Based on the average amount of mercury contained in the button cells placed in the EU market in 2010.

even up to 5-10 years after the implementation of Policy Option 2. The actual environmental impacts of mercury from button cells, including adverse effects to ecosystems, will probably take several decades to fully disappear given the potential for the emitted mercury to be transformed into methylmercury and to bioaccumulate.

8.3 Economic impacts

8.3.1 Option 1 ('no policy change')

- **Impact on battery industry**

If there is no policy change, no additional costs over normal business functioning expenditure for the button cell industry are expected. It is important to note that in the baseline scenario there is already a natural shift of consumers towards Hg-free alternatives of button cells. In order to meet this natural market shift, it is expected that button cell manufacturers are already investing more in R&D and infrastructure development of Hg-free button cells and will continue to do so in the coming years. This natural investment in the baseline scenario needs to be considered while assessing the costs to button cell manufacturers in case the current exemption to restriction of mercury use in button cells was to be withdrawn. Due to a lack of information, the quantification of normal business functioning expenditure for button cells industry is not available. However, it does not affect the economic analysis presented here as the objective is to compare policy options and therefore only extra costs/benefits compared to the baseline scenario are required in this context.

- **Impact on public authorities**

If there is no policy change, no additional administrative burdens for the competent Member States authorities are expected.

8.3.2 Option 2

8.3.2.1 Impact on battery industry

Based on latest information provided by key stakeholders, Hg-free alternatives are now available for all applications (see Annex G). Therefore, no significant additional investments in Research and Development (R&D) of Hg-free button cell are expected by the manufacturers in Policy Option 2.

The manufacturers consulted as part of this study also remarked that the basic production method is the same for both Hg-containing and Hg-free button cells. They further commented that small changes are sufficient to convert existing assembly lines for making Hg-free button cells.

It also needs to be highlighted that the phase-out of mercury in button cells placed on EU market would create a level playing field for button cell manufacturers/importers/traders around the global market as Hg-containing buttons cells have already been banned in other parts of the world (e.g. US states of Maine, Connecticut and Rhode Island – See Section 6.2.2). The phase-out of mercury in button cells placed on EU market would therefore foster innovation and create business opportunities for button cell companies in EU to play a leading role in the global context.

8.3.2.2 Impact on retailers

It is assumed that the potential extra costs to the retailers due to the higher purchase price of the Hg-free button cells compared to the Hg-containing button cells will be entirely passed on to the consumers, therefore not impacting the retailers.

8.3.2.3 Impact on consumers

In the case of the restriction on use of mercury in button cells, consumers will potentially be impacted due to the higher selling price of alternative Hg-free button cells. Majority of the manufacturers pointed out that on an average the Hg-free button cells cost around 10% more compared to their Hg-containing substitutes. The impact of this increased cost when translated on the overall EU market of Hg-containing button cells (zinc-air, alkaline and silver-oxide) in 2010 results in an additional annual cost of around 143 million Euros (approximately an increase of around EUR 0.13 per unit of button cell sold in EU) for the button cell consumers in EU[146]. It must however be noted that this estimate of additional cost should only be considered as the highest possible cost for the consumers. In reality, the impact on consumers will be lower than this as the above presented estimate does not take into account the market share of the Hg-free alternatives that are already sold in the EU market, which is expanding. The above estimate also needs to adjusted for the natural evolution of Hg-free button cells market. Due to these reasons, it is concluded that the estimated additional cost for consumers presented above is subject to high uncertainty.

The manufacturers consulted as part of this study also remarked that the additional cost of Hg-free alternatives is due to the higher prices of raw material used and the production of low quantities of these Hg-free button cells at the moment when compared to their Hg-containing substitutes. In general, for the silver oxide, alkaline and zinc-air button cells, all six manufacturers who participated in the survey confirmed that the full conversion of their manufacturing facilities to single line production (Hg-free) will bring economies of scale (in purchasing, manufacturing, logistics, etc) hence leading to lowering the overall cost of Hg-free alternatives.

It is therefore expected that the economies of scale resulting as an outcome of Policy Option 2 will lead to decrease in the cost of production of Hg-free button cells resulting in a lower impact on consumers.

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[146] This calculation uses the following average sales price for each unit of button cell (based on stakeholder's inputs): zinc-air (€1.23/unit), alkaline (€2.78/unit) and silver-oxide (€2.76/unit). The lithium button cell sales volume are not considered while performing this calculation as all the lithium button cells sold in EU are already Hg-free.

8.3.2.4 *Impact on button cells waste management companies*

The compliance organisations that are involved in the collection of waste button cells in each of the Member States charge their members fees for the collection of waste batteries for every button cell placed by them on the market[147]. However, due to increased competition, information on fees is not public in most of the Member States. For the analysis in this study, it is assumed that there is no difference in collection costs between mercury-containing and mercury-free button cells.

Sorting of button cell waste into different types is usually done automatically by a sorting machine based on the difference in size of the button cells. At present, most of the time, Hg-containing and Hg-free button cells waste is not sorted from each other, hence resulting in similar treatment costs.

The cost of recycling waste button cells depends on various parameters, such as: their physical condition; recycling technology used; types of materials recovered; value of the recovered metals; and economies of scale. Button cell waste recycling process is comprised of two steps: the first step of the process extracts mercury from the waste and is followed by a second step to extract the remaining materials/metals. Two button cell waste recyclers (one based in Germany and the second in Switzerland) estimated the first process step to account for 30-40% of the overall cost of recycling button cell waste[148]. The reduced waste treatment costs (in the long-term) for the Hg-free button cell waste will therefore make their recycling more attractive to the recycling companies. This may in turn also affect the lowering of fees paid by the manufacturers to the compliance organisations.

The recyclers further commented that the first step of the process (i.e. Hg extraction from waste button cells) only represents 5-10% of their overall turnover and unavailability of such mercury-containing waste should not have a significant negative impact on their recycling activities.

8.3.2.5 *Impact on public authorities*

The restriction of mercury use in button cells placed on the EU market will require the competent Member State authorities to monitor and control their markets in order to ensure effective implementation of the ban. The Batteries Directive applies equally to all the Member States and it already requires each of them to regularly monitor the restriction of mercury use in portable batteries (other than button cells). To accomplish this, each Member State is expected to already have competent bodies, which can also handle the ban of Hg-containing button cells.

An additional body for monitoring is therefore not required as this task will most likely be handled by an already existing competent body, which monitors the restriction of mercury in

[147] For example, STIBAT in Netherlands charges its members €0.003 (excluding VAT) for every button cell battery placed by them on the market.

[148] The treatment of mercury-free batteries involves smaller costs for screening and classification of collected batteries and for flue-gas treatment, compared to mercury-containing batteries. In Germany, the costs of treatment of collected mercury-containing batteries (average mercury content 5.3%) were €3.03 per kilo in 2007 while the cost of treatment of mercury-free batteries was €0.80 to €1.35 per kg of batteries. (Source: Stiftung gemeinsames Rücknahmesystem Batterien, 2008, www.unece.org/env/documents/2009/EB/wg5/wgsr45/ece.eb.air.wg5.2009.8.e.pdf)

portable batteries (other than button cells). The implementation of Option 2 is therefore not expected to generate additional administrative burden for Member State authorities.

8.4 Social impacts

8.4.1 Option 1 ('no policy change')

- **Employment**

As there is no additional impact than normal business functioning on the industry stakeholders linked to button cells, there is no impact on employment generation.

- **Public health and safety**

Impacts to public health and safety are mostly related to the possible health damages due to exposure to mercury. If no further policy action is taken, only a slight reduction of mercury releases to the environment and possible associated health risks is expected to occur in future years, thanks to improved waste collection and treatment and the progressive substitution of mercury-containing button cells.

8.4.2 Option 2

- **Employment**

The phase-out of mercury in button cells may theoretically slightly affect the employment generation in EU (primarily related to production and end-of-life management of button cells). However, due to a lack of information concerning the extent of these impacts, their quantification is not possible.

- **Public health and safety**

The decrease in mercury releases to the environment expected to occur under this policy option (see Section 8.2.2) would result in avoided damages to public health, as exposure to mercury due to button cells will be eliminated in the long-term.

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Chapter 9: Comparison of options and conclusions

A comparison of the different policy options analysed, based on their respective environmental and socio-economic impacts, is presented in this chapter. The comparison highlights the advantages and disadvantages of these policy options, across the economic, social, administrative and environmental dimensions and it identifies their potential weaknesses and risks.

9.1 Comparison of options

To compare the two policy options, a semi-quantitative score matrix approach is adopted (see Table 12). The level of detail in the analysis depends on the amount of information gathered as well as their quality.

Table 12: Semi-quantitative score matrix

Legend	Likely effect with regard to the baseline scenario
++	Strongly positive impact
+	Positive impact
0	No significant effect (similar to the baseline)
-	Negative impact
--	Strongly negative impact
≈	Marginal/Negligible impact
?	Uncertain impact

Table 13 summarises the possible environmental, economic, social and administrative impact for implementation of the two policy options at the EU level. In each cell of the matrix a qualitative score is given, hence, forming the basis for identifying the most workable approach in an efficient and effective manner.

Table 13: Comparison of the two policy options according to economic, environmental and social indicators

Policy Option / Impact Indicator	Option 1 'No policy change'	Option 2 'Mercury ban in button cell batteries'
Environmental impact indicators		
Hg flows	o Approx. 4 to 6.4 t Hg/year contained in button cell waste escape separate collection schemes and end up with non-hazardous waste in EU (using year 2010 as basis for this analysis)	++ Introduction of around 8.4 t Hg/year contained in button cells placed on EU market will be avoided, as well as the resulting environmental emissions due to inadequate end-of-life management, when compared to Option 1
Economic impact indicators		
Costs for button cell manufacturers/importers/traders	o No additional cost or turnover loss	≈ Marginal or neutral cost related to investments in R&D and assembly lines adaptation for the button cell manufacturers in EU
Competitiveness of EU battery industry and innovation	o No impact on competitiveness and innovation	+ Option 2 would foster innovation and create additional business opportunities for EU button cell companies to play a leading role in the global context
Costs for retailers	o No additional cost or turnover loss	o Retailers will most likely pass on the increase in cost (of purchase of alternatives to Hg-containing button cells) entirely to consumers
Costs for consumers	o No additional cost	? An average Hg-free button cell sold in EU will cost 10% more (approximately an increase of around EUR 0.13/unit of button cell) to the consumer than the average Hg-containing button cell. This impact may however be lower given the current and natural evolution of market share of Hg-free button cells in EU (which is expanding)
Costs for waste collectors and recyclers	o No additional cost or turnover loss	+ Up to 30-40% lower recycling cost for the recycling of all button cell waste collected in EU, compared to Option 1.

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Policy Option / Impact Indicator	Option 1 'No policy change'	Option 2 'Mercury ban in button cell batteries'
Administrative burden for MS authorities	o No implementation costs for MS authorities	≈ Marginal or neutral cost since Hg restrictions in portable batteries (other than button cells) are already implemented in EU under the Battery Directive
Social impact indicators		
Employment generation (in button cell manufacturers, importers and traders; in MS implementation authorities; and in button cell battery waste collectors and recyclers)	o Does not increase/decrease jobs	≈ (?) Employment generation in EU may theoretically be slightly affected (primarily related to production and end-of-life management of button cells)
Public health quality	o No additional impact	+ In the long term, positive impact on public health due to elimination of exposure to mercury emissions associated with button cells

9.2 Conclusions

Based on the analysis conducted in this study, the ban on the placing on the market of mercury-containing button cells in the EU emerges out as a clear winner in terms of environmental benefits, with very limited adverse economic impacts as compared with the 'no policy change' option.

It also needs to be highlighted that the phase-out of mercury in button cells placed on EU market would create a level playing field for button cell manufacturers/importers/traders around the global market as Hg-containing buttons cells have already been banned in other parts of the world (e.g. US States of Maine, Connecticut and Rhode Island). The phase-out of mercury in button cells placed on EU market would therefore foster innovation and create business opportunities for button cell companies in EU to play a leading role in the global context.

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ANNEXES

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Annex A: Questionnaire to Member States

European Commission DG ENV

Study on potential for reducing mercury pollution from dental amalgam and batteries

(Ref. No. 07.0307/2011/594114/SER/C3)

Questionnaire to Member States (Environmental and Health Authorities)

Sept. 2011

This questionnaire aims to collect information to feed into the study on '**Potential for reducing mercury pollution from dental amalgam and batteries'** conducted by BIO Intelligence Service (BIO) for the European Commission (DG ENV). The questionnaire **focuses on dental amalgam** only, since most of the data gaps relate to this topic.

The objective of this study is to provide the Commission with a solid evidence base in order to inform future policy actions with a view to addressing the environmental problems posed by the use of dental amalgam. The study includes:

- An in-depth analysis of current amounts of mercury used in dental amalgam in EU and the associated environmental impacts; and
- An impact assessment of possible policy options to reduce mercury pollution from this use, with recommendations for further policy actions.

The present study aims to describe the full EU picture in a comprehensive manner, **with a breakdown of data per Member State (MS)**, allowing us to identify any significant contrasts between MS.

An active participation of MS in providing relevant data is thus essential to help us build a robust evidence base and take into account the variety of situations across the EU when identifying possible policy options.

This questionnaire also offers MS an opportunity to provide suggestions for policy options that should be considered as part of the impact assessment.

The questionnaire includes two parts:

- **Part 1** contains questions intended for **Environmental Authorities**
- **Part 2** contains questions intended for **Health Authorities**.

Member States may wish to coordinate responses from their authorities but can also send separate submissions to BIO.

- Existing information

In order to minimise the time needed to answer this questionnaire, we have compiled **information already available from previous studies and surveys in four annexes:**

- **Annex 1:** Analysis of Member States replies to a letter of DG ENV concerning the environmentally sound management of dental amalgam waste (2005)
- **Annex 2:** Data from the report for DG ENV on 'Options for reducing mercury use in products and applications, and the fate of mercury already circulating in society' (COWI, 2008)
- **Annex 3:** Compilation of data submitted by Parties to the OSPAR Convention, under the PARCOM Recommendation 2003/4 on 'controlling the dispersal of mercury from crematoria'
- **Annex 4:** Overview of policy measures

We are only interested in information updating and complementing what is presented in these Annexes.

- Supplementary material

If you have any **supporting documents and datasets that may be useful for this study**, we would be very grateful if you could submit this information with your reply to this questionnaire. You may also want to indicate specific **links to websites** containing useful information.

We thank you in advance for your time and participation.
Please do not hesitate to contact us for clarification or information regarding this questionnaire.

Kindly send the completed questionnaires to mercury@biois.com
at the latest by 10 October 2011

Alternatively, fax submission can be sent to:
+ 33 1 56 53 99 90 (BIO)
Hard copies of documents can be mailed to the following address:
20/22 Villa Deshayes – 75014 Paris – France
Contact persons: Shailendra Mudgal / Lise Van Long ☏ + 33 (0)1 53 90 11 80

PART 1: QUESTIONS FOR ENVIRONMENTAL AUTHORITIES

- Contact information
    - Name:
    - Position/Department/National Authority:
    - Country (MS):
    - Telephone:
    - E-mail:
- Mercury releases to water

Q1: What are the **legal requirements related to amalgam separators** in your country? *(Please tick the corresponding boxes – Existing information is summarised in Annex 1)*

☐ Amalgam separators required for *new* dental practices

☐ Amalgam separators required for *existing* dental practices

☐ Minimum efficiency of the amalgam separators required (please specify the min level required: _____)

☐ Maximum authorised concentration of mercury from separators (please specify the max concentration allowed: _____)

☐ Adequate maintenance of amalgam separators required by law

☐ Documented evidence of amalgam separators' maintenance required by law

☐ Periodic inspections of dental practices from public authorities concerning the management of dental amalgam waste

☐ Additional legal requirements (please specify): _____

Q2: What is the percentage of dental clinics equipped with **amalgam separators** in your country?

- Mercury releases to air

Q3: If estimates of **mercury emissions from crematoria** are available in your country, please provide the estimates by completing the tables below or the free text box.

NB: The data we already hold is compiled in Annex 3 (submissions under OSPAR Convention, 2009)

For crematoria applying mercury removal techniques:

Year	Number of crematoria	Number of cremations	Hg emissions (kg Hg)	Estimation method and information sources
_____	_____	_____	_____	_____

For crematoria not applying mercury removal techniques:

Year	Number of crematoria	Number of cremations	Hg emissions (kg Hg)	Estimation method and information sources
_____	_____	_____	_____	_____

Other information on emissions from cremation:

- Dental amalgam waste

Q4: Do you have any estimates of the **dental amalgam waste quantities** produced and treated in your country and/or exported? If so, please indicate available data in the table below.

*NB: The EU waste code for dental amalgam is **18 01 01**. Previous data for some MS is presented in Annex 2.*

	Waste quantities (kg/year)	Mercury quantities in waste (kg/year)	Year of the data
Total dental amalgam waste generated	_____	_____	_____
- *Of which:* Quantities collected **as hazardous waste**	_____	_____	_____
- *Of which:* Quantities **sent to recycling** within your country (hazardous waste)	_____	_____	_____
Quantities **landfilled** within your country (hazardous waste)	_____	_____	_____
Quantities **mixed with municipal waste**	_____	_____	_____
Quantities **mixed with medical waste**	_____	_____	_____
Quantities **exported** (please specify to which country(ies):_____)	_____	_____	_____

Additional information/comments concerning the above table:

- Existing policy measures going beyond EU legislation

Q5: Available information on existing **policy measures concerning dental amalgam going beyond EU legislation** is compiled in Annex 4 to this questionnaire. Please briefly describe any additional policy measures not covered by this Annex in the box below.

NB: We are particularly interested in any mercury-related provisions related to the transposition of the Water Framework Directive (2000/60/EC), the Directive on dangerous substances (2006/11/EC) and the Directive on Priority Substances (2008/105/EC)

- Cost comparison

Q6: Do you have any estimates of the **overall costs incurred by public authorities to manage environmental releases and waste from dental amalgam** in your country?

NB: This may include, for example, extra costs for landfilling or incinerating sewage sludge with excessive amounts of Hg rather than using it for agricultural purposes, installing mercury abatement devices to sludge incineration facilities, conducting inspections of dental practices, etc.

- Other information (optional)

Additional types of information that would also be very useful for our study are listed below. If such information is available for your country, could you please either give some details in the boxes below or indicate relevant public data/reports which we should review, or send us the relevant information as attachment.

Q7: Quantity of mercury **released to urban sewers** from **dental clinics** (after possible recovery in amalgam separators) in your country (**kg/year**)

Q8: Quantity of mercury **released to surface water after urban wastewater treatment,** in your country (**kg/year**)

Q9: Quantity of mercury **captured in sludge** from urban wastewater treatment plants that is spread to agricultural lands or incinerated, in your country (**kg/year**).

- Suggestions for future policy actions

Q10: If you have any suggestions concerning policy actions that should be considered in order to reduce mercury pollution from dental amalgam, please provide your comments below.

- Other comments

PART 2: QUESTIONS FOR HEALTH AUTHORITIES

- Contact information
    - Name:
    - Position/Department/National Authority:
    - Country (MS):
    - Telephone:
    - E-mail:
- Materials used for dental restoration

Q11: If you have information on **quantities of mercury for dental amalgam** used in your country (in the form of capsules and in liquid form), please provide the available data in the box below or indicate relevant public data sources/reports that we could review.

Q12: What is the **percentage of dental restorations** in which dental amalgam is used in your country? (vs. mercury-free alternatives)

Q13: If you have information on **quantities of mercury-free filling materials** used in your country, please provide the available data in the box below or indicate relevant public data sources/reports that we could review.

- Dental health

Q14: What is the average **number of dental restorations** (amalgam and alternative materials) **per person and per year** in your country?

In children: _____(please also specify the age range: _____)

In adults: _____

Q15: In future years, how is the **total number of dental restorations** (amalgam and alternative materials) expected to evolve? (reduce/stabilise/increase/unknown trend)

Q16: Do you have any estimate of national public expenses in **dental disease prevention policies (EUR/year)?** If so, please provide the available data in the box below with a brief description of these policies

- Cost comparison

Q17: What is the **average price for patients of a dental restoration?**

  - Using amalgam
  - Using mercury-free filling materials

- Reimbursement schemes

Q18: Are dental restoration treatments covered by a **national health reimbursement scheme** in your country?

☐ Yes

☐ No

If your answer is yes:

Is dental restoration using **mercury-free filling materials** reimbursed the same way as dental amalgam?

☐ Yes

☐ No

Please provide details on how the scheme works.

- Other comments

Annex B: Overview of policy measures concerning dental amalgam

The table below provides a summary of Member States' policies and best practices going beyond EU policy with regard to the management of environmental issues related to dental amalgam. Examples of international initiatives going beyond EU policy are also mentioned.

Table 14: Overview of MS and international legislation and best practices going beyond EU policy

EU policy measures	MS policies/best practices going beyond EU policy	International policies/best practices going beyond EU policy
Dental amalgam use		
–	**SE:** As part of the general ban on mercury-containing products, the use of dental amalgam is phased out in Sweden for all applications except for a time-limited exemption till 30 June 2012 for use in adults in hospital dental care if there are special medical reasons, if other methods of treatment do not provide a sufficiently good result in an individual case and the clinic is specially arranged from the environmental point of view for the use of dental amalgam. This exception will be evaluated after 31 December 2011, to make a standpoint on future use of dental amalgam[149]. **DK:** Ban on the use of dental amalgam for children's milk teeth and all front teeth **DE:** It is recommended not to use dental amalgam on children, pregnant and nursing women, people with kidney problems, when in contact with other metals, such as braces, and in people with mercury sensitivity	**NO:** As part of the general ban on mercury-containing products, use of dental amalgam is prohibited, except until end of 2010 for patients who must be treated under general anaesthesia or who are allergic to ingredients in other dental fillings **CH**: Use of dental amalgam exempted from the general ban if no substitutes are technically available; however Hg-free alternatives are widely used **JP**: Recommended to avoid the use of dental amalgam. **CA**: Health Canada directed its dentists to stop using amalgam in children, pregnant women, and people with impaired kidney function **AU**: Australia's National Health & Medical Research Council (NHMRC) says amalgam should be avoided in pregnant women, nursing mothers, children, and people with kidney disease. **UNEP partnership area on mercury reduction in products:** Objective to

149 The hospital dental care units are obliged to report their intention to use amalgam in order to evaluate the need for the exemption. The National Board of Health and Welfare must be notified before the first treatment with amalgam starts. Information must be noted on patient particulars, the medical reasons for using amalgam must be stated and the amount of amalgam used must be recorded. Since the general ban came into force (June 2009) and until June 2011, it was reported that only about 25 patients have been treated with dental amalgam (as part of hospital treatments).

EU policy measures	MS policies/best practices going beyond EU policy	International policies/best practices going beyond EU policy
	FR: AFFSAPS (French agency in charge of health products) recommended in 2005 to avoid dental amalgam use in pregnant and breastfeeding women (because of mercury vapours during placement). A similar recommendations had already been issued in 1998 by the French National Superior Hygiene Council. **IT**: A regulation entitled *Decreto Ministeriale sull'Amalgama* issued by the Ministry of Health in 2001 limits the use of amalgam in children under the age of 6, in pregnant and feeding women, in people with kidney injury and in people with allergy/sensitivity to one element of amalgam. **Catalonia, ES**: Since the end of 2007, there is a recommendation (by the Environmental and Health Catalan Departments) of not placing dental amalgam in pregnant women and children under 14 years old. **NL**: Dental amalgam is exempted from the general ban on mercury-containing products; however, its use is discouraged.	reduce the global demand for mercury in dental amalgam to less than 230 t/year, or a 15% reduction from status quo in 2015 **WHO (World Health Organisation)**: Supporting a global phase-down of dental amalgam use, as per their statement at INC1 in June 2010
Dental amalgam waste and emissions to water		
Directive 2008/98/EC (waste framework) and Decision 2000/532/EC (list of wastes): dental amalgam waste to be managed as hazardous waste Water Framework Directive (2000/60/EC), Decision 2001/2455/EC, Directive 2006/11/EC on dangerous substances and Directive 2008/105/EC on priority substances – Mercury considered as a priority hazardous substance, requiring a cessation of emissions, discharges and losses within 20	**AT, BE, CZ, DE, FR, FI, IT, LV, MT, NL, PT, SE, SI, UK**: Dental practices are required to be equipped with amalgam separators. Additional conditions are usually required such as: minimum Hg removal efficiency, equipment certification, Hg limit value in effluent, adequate maintenance. **DK:** Guidance only, but widely applied by dentists.	**NO**: Limit on discharges and requirement to have an approved amalgam separator (required to remove 95% of mercury from the wastewater) **CA**: Had set a target of 95% national reduction in mercury releases from dental amalgam waste discharges to the environment by 2005, from a base year of 2000 **Several US States**: Dental practices are required to be equipped with amalgam separators and to comply with environmental best management practices

EU policy measures	MS policies/best practices going beyond EU policy	International policies/best practices going beyond EU policy
years after adoption of measures. Environmental Quality Standards defined for Hg.		
Mercury air emissions from cremation		
–	**Parties to OSPAR Convention:** Recommendation to use BAT to reduce Hg air emissions and report on implementation (PARCOM Recommendation 2003/4). Covers BE, DE, DK, ES, FI, FR, IE, LU, NL, PT, SE, UK. **UK:** Abatement to be fitted covering 50% of cremations by end 2012, plus all new crematoria to have abatement[150] **DK:** All crematoria are since 01.01.2011 equipped with filters and the limit value for Hg emissions is 100 µg/m^3. **FR**: ELV of 0.2 mg/Nm^3 applicable from 2010 for new facilities and as of 2018 for existing facilities (Ministerial Order of 28/01/10) **CZ:** Sum of Cd, Hg and Th from crematoria shall not exceed 0.2 mg/Nm^3 **DE**: Some Länders have adopted ELVs for Hg (e.g. 0.2 mg/Nm^3 in Sachsen and 0.5 mg/Nm^3 in Brandenburg) **NL**: Hg abatement measures for new crematoria have been obligatory since 1999 and must be added by the end of 2006 or 2012 for large or small existing crematoria respectively. ELV of 0.05 mg Hg/Nm^3 **BE – Brussels Region**: ELV of 0.1 mg/Nm^3 **LU**: ELV of 0.1 mg/Nm^3 **IT**: A specific decree on crematoria defining ELVs for Hg in crematoria had to be taken in application of Law no 130 of 30 March 2001 but its	**PARCOM Recommendation 2003/4 (OSPAR Convention):** Recommendation to use BAT to reduce Hg air emissions and report on implementation **HELCOM Recommendation 29/1:** Recommended ELV for Hg air emissions 0.1 mg/Nm^3 (crematoria with a capacity > 500 cremations/year) **NO**: ELV of 0.5 mg/Nm^3

[150] In 2005, DEFRA and the Welsh Assembly Government established a 'burden sharing' system to reduce mercury emissions from existing crematoria. Under burden sharing, crematoria operators can choose whether to fit mercury abatement equipment or contribute to the costs of others doing so. Website of the organisation running the main burden sharing scheme: www.cameoonline.org.uk/

EU policy measures	MS policies/best practices going beyond EU policy	International policies/best practices going beyond EU policy
	adoption is still pending. At the moment, Hg emissions from crematoria are regulated by the legislation on incineration[151]. The ELV of the State regulation for mercury air emissions (which each crematorium must comply with) is 0.05 mg/m^3 as medium value registered for a period of sampling of 1 hour; however, the Local Authority may impose a more stringent ELV (which is often the case).	

[151] D.Lgs. N° 152 of 3 April 2006 and subsequent modifications and integrations ("Norms in the field of environment" – D.M. N° 124 of 25 February 2000 "Limit values of emission and technical norms regarding the characteristics and operating conditions of f incineration plants"

Annex C: Assessment of environmental emissions from dental amalgam use

The objective of this chapter is to provide a good evidence base in order to assess the extent to which dental amalgam use contributes to the overall mercury problem in the EU. In particular, this chapter presents information and data necessary to update and complement the findings from previous studies on the topic.

Following a description of the methodology employed, this section provides an overview of mercury releases from dental amalgam use and end of life phases and discusses the main aspects of the life cycle for which data was lacking or needed to be updated in order to provide a full and up-to-date EU picture of the problem. The additional data collected as part of the study is then presented and analysed. Existing data from previous studies and newly collected data are compiled to estimate mercury releases to the various environmental compartments. A comparison with contributions from other sources is finally carried out in order to estimate the scale of pollution caused by dental amalgam.

C.1 – Methodology

The objective of this part of the study was to identify and assess the potential environmental impacts associated with the use of dental amalgam, focusing on key stages of its life cycle.

A thorough review of existing literature and data was first carried out. Some key information sources are listed below:

- Summary of Member States responses to 2005 EC survey on management of dental amalgam waste
- SCHER (2008) Opinion on the environmental risks and indirect health effects of mercury in dental amalgam[44]
- COWI/Concorde (2008) Options for reducing mercury use in products and applications, and the fate of mercury already circulating in society[27]
- Concorde/European Environmental Bureau (EEB) (2007) Mercury in dental use: environmental implications for the EU[152]
- Report from the conference 'Dental sector as a source of mercury contamination' organised by NGOs (2007)[153]
- DEFRA consultation documents on mercury emissions from crematoria (2003, 2004)

[152] Concorde/EEB (2007) Mercury in dental use: environmental implications for the EU. Available from: http://www.zeromercury.org/index.php?option=com_phocadownload&view=file&id=17%3Amercury-in-dental-use-environmental-implications-for-the-european-union-&Itemid=70

[153] http://www.zeromercury.org/phocadownload/Developments_at_EU_level/Dental_Conference_Report_May07.pdf

- Latest mercury emission data from E-PRTR (2007, 2008, 2009)[154]
- Some waste data covering amalgam waste: data reported under the Basel Convention (2004-2005-2006)[155]
- OSPAR (2011) Overview assessment of implementation reports on OSPAR Recommendation 2003/4 on controlling the dispersal of mercury from crematoria[156].

Other data sources reviewed are mentioned in the following sections of this Annex.

Following a comprehensive review of existing literature on the topic, opportunities for updating and complementing estimates developed in previous studies were identified. Hence, the data collection and analysis tasks focused on data necessary to update and complement findings of previous studies, taking into account the gaps mentioned in the 2008 SCHER opinion.

Following the review of publicly available information, tailored questionnaires were sent to various types of stakeholders in order to fill the information gaps:

- Environmental and health authorities within Member States
- Industry stakeholders: dental associations, dental fillings suppliers, waste treatment industry, crematoria businesses and water treatment industry
- NGOs and academic experts.

In total, about 300 organisations/institutions were sent questionnaires and some follow-up telephone calls were also made. To date, we have received:

- Responses from environmental and/or health authorities from 20 Member States[157], with varying levels of detail
- 5 responses from national dental associations
- 2 responses from dental fillings suppliers
- 4 responses from cremation organisations
- 5 responses from water treatment organisations
- 4 responses from NGOs and academic experts.

In addition, several dental fillings manufacturers, national dental associations and researchers were contacted by telephone to obtain additional information and a telephone interview was also held with the Council of European Dentists (CED). Relevant findings extracted from previous studies have been summarised and references are provided in order for readers to have access to

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[154] European Pollutant Release and Transfer Register (http://prtr.ec.europa.eu/PollutantReleases.aspx).

[155] http://www.basel.int/natreporting/2005/compII/index.html

[156] http://www.ospar.org/documents/dbase/publications/p00532_Rec_2003-4_Overview_report.pdf

[157] AT, BE, BG, CZ, CY, DE, DK, EE, FI, HU, IE, LT, LU, LV, MT, PL, SE, SI, SK, UK. In addition, RO and CY advised that they were not able to provide any valuable information in relation to the study.

further details, the focus being placed on presenting updated and new information to inform future policy decisions.

One major challenge encountered is the general lack of reliable and up-to-date data on dental amalgam use in many Member States. Stakeholders active at the EU level (CED, FIDE[158], ADDE[159]) advised that they do not hold data on dental amalgam use in the EU or on the size of the EU market for dental amalgam.

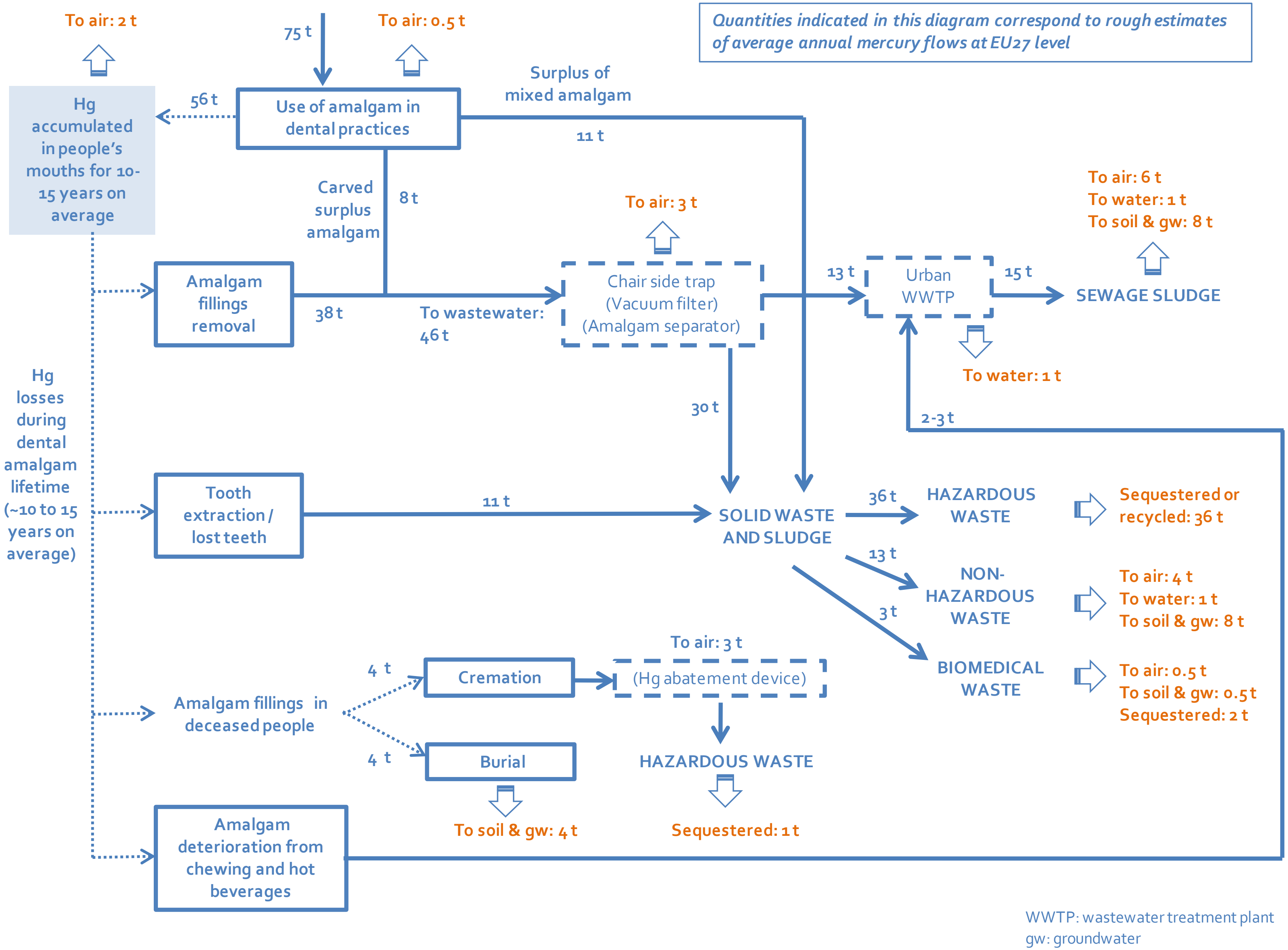
C.2 – Overview of mercury flows associated with dental amalgam

The main mercury flows investigated as part of this study are illustrated in Figure 11 below. As shown below, this study mostly focuses on mercury releases associated with current and historical mercury use in dentistry and the fate of mercury released by dental practices or by old fillings. Upstream releases associated with the supply of mercury for dental amalgam preparation have not been investigated in detail, considering that environmental issues related to these upstream steps (mercury supply and trade, production of mercury for dental applications) are less critical and better managed.

[158] Federation of the European Dental Industry

[159] Association of Dental Dealers in Europe

Figure 11: Main mercury flows associated with dental amalgam use (t Hg/year)



Mercury is consumed by dental practices in the form of pre-dosed capsules (containing approximately 50% elemental mercury) or in the form of elemental mercury sachets that are then mixed with alloy powder in a 1:1 ratio.

Mercury releases mainly occur during the following steps:

- Use of new amalgam: carved surplus of triturated amalgam is generated during the preparation of the amalgam while carved surplus of amalgam is generated during the placement of the filling
- Removal of old amalgam filling
- Loss or extraction of teeth with amalgam fillings
- Cremation/burial of people with amalgam fillings
- Deterioration of amalgam fillings due to chewing and hot beverages (ending up in human waste).

Most dental mercury waste results from the removal of previous fillings from patients' teeth. Together with waste from new fillings, removed teeth, etc., these dental wastes, in the form of solid dental amalgam particles, typically follow several main paths. They may be captured by the saliva pump (vacuum pump system) that leads to the general municipal wastewater system, they may be collected for subsequent recycling or disposal, they may be placed in special containers as medical waste, or they may be discarded in the waste bin as municipal waste[152].

As shown in the above diagram, next to each dental chair most dental facilities have a basic chairside filter (or trap) in the wastewater system to capture the larger amalgam particles, and some have secondary vacuum filters just upstream of the vacuum pump. An increasing number of clinics are also equipped with amalgam separators to capture dental amalgam particles.

Additional mercury releases to the wastewater occur as a result of amalgam deterioration due to chewing and ingestion of hot beverages, although quantities of mercury released are supposed to be smaller than those emitted by dental practices.

The main atmospheric emissions associated with the life cycle of dental amalgam occur during the cremation of deceased persons with mercury fillings. Some air emissions may also occur at dental practices during the handling and placement of amalgam and as a result of mercury discharged to the wastewater.

Finally, direct mercury releases to soil and groundwater may occur due to the burial of deceased persons with mercury fillings.

Further details on the main mercury flows are presented in the sections below.

C.3 – Main data gaps to be addressed

As mentioned in the introduction, the most recent study which attempted to assess the environmental impacts of dental amalgam use in the EU was carried out by the SCHER in 2008[44].The SCHER report used a number of previous studies on dental amalgam as a basis for their estimates. A number of data gaps were identified, which prevented the SCHER from conducting a comprehensive assessment of the environmental risks associated with dental amalgam. The purpose of the present study is therefore to fill the data gaps related to the estimation of mercury use, releases and fate. Additionally, because there are some expected changes in the use and releases of dental mercury across Member States due to changing behaviours, improved legal compliance or new policy initiatives, it was necessary to obtain up-to-date information on some of these aspects.

Consequently, the main aspects which needed to be investigated in further detail in this study, at Member State and EU level, are as follows:

- Latest data and trends on dental mercury use
- Latest data and trends on the percentage of dental practices equipped with amalgam separators
- Actual efficiency of amalgam separators
- Treatment options for solid dental amalgam waste
- Options for managing sewage sludge from urban wastewater treatment plants (WWTPs), in particular agricultural spreading practices
- Latest data and trends on mercury air emissions from crematoria.

Concerning the other aspects of the dental amalgam life cycle, estimates from previous studies have been used, as long as they were considered to be based on reliable data and reasonable assumptions.

C.4 – The human inventory of dental amalgam

The quantity of mercury contained in people's mouths in the EU-27 was estimated to be **over 1,000 tonnes** in previous studies[152]. This is based on the assumption that three-quarters of the EU population (500 million citizens) have an average of 3 g of mercury in their mouths, or that the **entire EU population has an average of 2.0-2.5 g of mercury in their mouths**. Amounts of mercury per citizen have been derived from figures previously estimated by several countries (BE, DK, DE, FR, NL, NO, SE, CH, UK, USA).

C.5 – Mercury use in dental practices

There are two main ways to prepare dental amalgam: by using pre-dosed capsules or by mixing dental alloy and mercury purchased as separate products.

Plastic capsules contain two compartments, one with the alloy in the form of powder (alloy containing silver, tin, copper and other trace metals) and one with pure elemental mercury (400-800 mg in general, contained in a small plastic sachet called a 'mercury spill'). The membrane between the two compartments is broken during the process of mixing in a mechanical amalgamator used by the dentist. By mixing the capsule, the sachet breaks and metallic mercury reacts with the dental alloy to form dental amalgam, which can be used in patient within 10-12 minutes. This system ensures the exact mixing ratio between mercury and the dental alloy (1:1 in weight). Mercury spills present in the capsules are produced by specialised manufacturers and are supplied to the producers of dental amalgam capsules.

Alternatively, dentists can buy dental alloy in powder (standard packing 50-1,000 g) and dental metallic mercury (standard packing 100-1,000 g) as separate products. Metallic mercury is purchased in the form of a 'mercury spill' (plastic sachet) and produced by specialised manufacturers. A special mixer is then used by the dentist where both components are placed into separate compartments with the exact alloy/mercury ratio. The reason why some dentists still use this system is that buying alloy powder and mercury separately is cheaper than buying the easy-to-use capsules.

Mercury use for dental amalgam preparation in the EU-27 is estimated to range **between 55 and 95 t/year**, based on the most recent data collected as part of this study (further details are provided in the market review in Annex E). There is however significant uncertainty on this range of values.

C.6 – Mercury releases from dental practices

C.6.1 – Mercury releases to water

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.

The technical development of dental equipment with high-speed drills replacing more slowly rotating drills in the last decades in technically advanced nations has increased mercury emitted to air or released to water when removing or replacing amalgam fillings. This is caused by smaller particles created by the high-speed drills. In addition, the higher speed results in higher temperatures, increasing the emission rate. The temperature may to some extent be controlled by cooling with e.g. water. However, this results in larger amounts of mercury in the water leaving the clinic.

Mercury discharged in dental wastewater is present in many forms, including elemental mercury bound to amalgam particulate, inorganic (ionic) mercury, elemental mercury, and organic mercury (monomethyl mercury (MeHg)); the vast majority (>99.6%) of dental mercury discharges are in solid form (elemental mercury bound to amalgam particulate)[160].

Out of the total amount of mercury used by dentists in EU-27 (~ 75 t/year on average), it is generally assumed that approximately 56 t/year (i.e. 75%) end up in patients' teeth while 19 t/year (i.e. 25%) is wasted.

From the amount of amalgam ending up in patients' teeth, it has been previously estimated that about 70% is used to replace previous amalgam fillings (i.e. ~ 39 t Hg/year) while 30% is used to make new fillings (i.e. ~ 17 t Hg/year).

From the 19 t/year of wasted mercury, it can be estimated that approximately 11 t/year end up as solid waste (surplus of mixed amalgam) while 8 t/year are discharged to the wastewater (carved surplus of amalgam during placement) and 0.5 t/year is emitted to the air[161].

Since approximately 39 t/year of "new" mercury are used to replace old fillings, it can be estimated that the removal of old fillings releases almost the same amount of mercury (estimated here at 38 t) which goes into the waste stream[162]. In total the mercury content discharged to the wastewater comprises some 8 t of carved surplus amalgam plus some 38 t of removed amalgam, totalling about 46 t/year of mercury.

In addition to releases from current dental restoration works, the past accumulation of mercury in piping systems of the dental clinics over many years may constitute another source of continuous releases to wastewater. The slow dissolution and re-release of this mercury may be sufficient, even after dental clinic emissions have been greatly reduced, to exceed wastewater discharge standards, and may serve as a long-term source of mercury to urban WWTPs[152]. For example, large amounts of mercury were recovered (average 1.2 kg per clinic) during the remediation of 37 abandoned dental clinics in Stockholm in 1993–2003[163]. Similar accumulations were observed during more recent work in several Swedish dental clinics[164].

- **Treatment devices in dental facilities**

Most dental practices are equipped with chairside traps and vacuum filters able to capture a fraction of the larger amalgam particles.

An increasing number of dental practices are also equipped with amalgam separators, the use of which is necessary in order to comply with EU waste legislation (dental amalgam is considered as hazardous waste and should be collected as such for appropriate treatment).

[160] USEPA (2008) Health Services Industry Detailed Study – Dental amalgam (http://water.epa.gov/lawsregs/lawsguidance/cwa/304m/upload/2008_09_08_guide_304m_2008_hsi-dental-200809.pdf)

[161] Assumptions taken from the Concorde/EEB report (2007)

[162] It is assumed that previous fillings contained slightly less mercury at the time of removal, assuming some of the mercury has vaporised and the previous fillings were slightly smaller

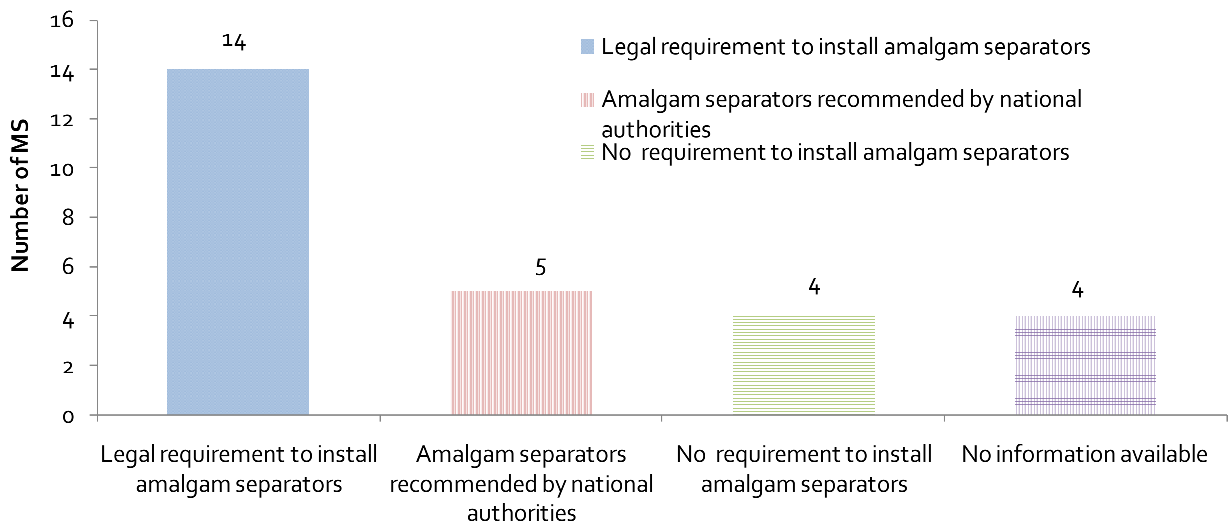
[163] Engman (2004) Kvicksilverförorening i avloppsrör i Lunds kommun. (Mercury contamination in wastewater pipes of Lund municipality). MSc thesis. Stockholm University, Stockholm, Sweden

[164] Hylander LD, Lindvall A and Gahnberg L (2006) High mercury emissions from dental clinics despite amalgam separators. Sci. Total Environ. 362:74-84

According to a survey carried out by the Commission in 2005 and the COWI/Concorde study (2008), no more than 30-40% of EU dental practices were equipped with amalgam separators in 2005 and the proportion of dental practices equipped with amalgam separators was much higher in northern Member States than in southern and eastern Member States. According to the latest survey by the Council of European Dentists (CED, 2010), 14 out of the 28 European countries surveyed had 99% of dental practices equipped with amalgam separators, while in a further 5 countries 80 to 99% of practices were equipped. The survey did not however specify which countries these values referred to, since it was anonymous (it was based on questionnaires sent to national dental associations).

As part of the present study, information on possible legal requirements concerning amalgam separators was obtained for 23 Member States (responses to the study questionnaires or data obtained from other sources). Among these 23 Member States, amalgam separators are required by law in 14 Member States (Figure 12). Usually, this requirement applies to both new and existing practices and a 95% minimum efficiency is required. Some Member States also impose Hg limit values in the effluent (usually between 0.005 and 0.03 mg Hg/l), documented evidence of proper maintenance and/or periodic inspections by local authorities. In some other Member States, amalgam separators are installed voluntarily under guidance provided by the national authorities (e.g. IE, DK). All Member States that responded to the study questionnaire reported that recently installed dental facilities are generally equipped with amalgam separators regardless of whether there are legal requirements in place.

Figure 12: Requirements concerning installation of amalgam separators (in % of MS)



An estimate of the share of dental facilities equipped with amalgam separators is available for 16 Member States (see Table 15 below).

Table 15: Share of dental facilities equipped with dental amalgam separators

Share of dental facilities equipped with amalgam separators	Member States
~100%	10 MS: AT, CZ, DK, FI, DE, LV, MT, PT, SE, UK
90-100%	5 MS: CY, FR, IT, NL, SI
80%	1 MS: BE
Unknown	11 MS: BG, EE, ES, GR, HU, IE, LT, LU, PL, RO, SK

Further details on the use of amalgam separators and the associated requirements are provided in Annex H.

It is difficult to provide a reliable estimate of the average share of dental facilities equipped with amalgam separators at EU27 level as information is still missing for Member States with large population (e.g. Poland, Spain). However, if one assumes that, in the 11 Member States where no data is available, only 20% of dental facilities are equipped with amalgam separators, the EU27 average would be in the order of **75% dental facilities equipped**[165]. This result suggests that there has been a significant increase in the proportion of dental facilities equipped with amalgam separators since the 2005 EC survey. Apart from the new legislation adopted is some Member States, this could also be explained by the fact that most new chairs on the market are equipped with separators.

In terms of the level of maintenance of the existing separators, several Member States reported that periodic inspections of the efficiency of equipment are undertaken by public authorities (CY, DE (every 3-5 years), DK, IE, MT (every year), SE, SI). Reportedly, an inspection programme is also being put in place in the UK.

Based on available information, the following assumptions have been made for the purposes of this assessment:

- 95% of the mercury discharged to the vacuum pump system goes to chairside filters, while 5% goes directly to the sewer (as most dental practices are equipped with chairside filters)
- Chairside filters have an average mercury removal efficiency of 45%[166]

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165 This average has been weighted by the number of dentists per MS (assumed to be proportional to the number of dental practices)

166 Assumption taken from Concorde/EEB study (2207)

- From the mercury present in the outflow of chairside filters, 70% goes to an amalgam separator while 25% goes directly to the sewer (assuming that, on average, 75% dental practices are equipped with amalgam separators in the EU)
- Amalgam separators have an average mercury removal efficiency of 70% (standard efficiency is usually higher, i.e. 95%, but actual efficiency is assumed to be lower due to a lack of proper maintenance observed in many cases[167])
- Approximately 3 t Hg/year are released from filters/separators to the atmosphere[168].

With the above assumptions, it can be roughly estimated that 30 t Hg/year are captured in filters and separators and potentially collected as solid waste, while 13 t Hg/year remain in the wastewater stream and enter urban WWTPs.

With regard to mercury concentration in the effluents, the SCHER report (2008)[44] used information from Swedish studies (Hylander 2006)[169,170] and a US study (Stone 2003)[171] to estimate releases of mercury to the wastewater system, in 'best case' conditions (properly operating separators) and 'worst-case' conditions (inefficiently working separators or no separator use): Hg concentration in the WWTP inflow due to dental practices was estimated to be in the range of 3.5 to 918 µg Hg/l with an average value of 159 µg/l.

C.6.2 – Mercury in solid waste

Solid mercury-containing waste generated by dental practices includes:

- Surplus amalgam from the preparation phase, which is directly discarded as waste (estimated above at approximately 11 t/year)
- Dental amalgam sludge recovered from the cleaning of chairside traps, vacuum filters and possible amalgam separators (estimated above at approximately 30 t/year), as well as from the cleaning of wastewater piping, during any maintenance activities
- Lost and extracted teeth, which are directly discarded as waste (estimated at approximately 11 t/year by a previous study[152]).

This represents a total of approximately **52 t Hg/year present in solid waste streams** from dental facilities.

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[167] See e.g. Hylander LD, Lindvall A and Gahnberg L (2006) High mercury emissions from dental clinics despite amalgam separators. Sci. Total Environ. 362:74-84

[168] 4 t/year were estimated by Concorde/EEB in 2007, but this was in relation to a higher dental amalgam use (125 t Hg/y)

[169] Hylander LD, Lindvall A and Gahnberg L (2006) High mercury emissions from dental clinics despite amalgam separators. Sci. Total Environ. 362:74-84

[170] Hylander, L. D., Lindvall, A., Uhrberg, R., Gahnberg, L., & Lindh, U. (2006). Mercury recovery in situ of four different dental amalgam separators. Sci. Total Environ. 366:320– 336

[171] ME Stone, ME Cohen, L Liang and P Pang (2003) Determination of methyl mercury in dental-unit wastewater, Dental Materials 19, 675–679, Elsevier Ltd

C.6.3 – Mercury releases to air

Air emissions from amalgam handling

Some air emissions may occur at dental practices during the handling of amalgam. This may include releases from accidental mercury spills, malfunctioning amalgamators, leaky amalgam capsules or malfunctioning bulk mercury dispensers, trituration, placement and condensation of amalgam, polishing or removal of amalgam, vaporisation of mercury from contaminated instruments, and open storage of amalgam scrap or used capsules[172].

However, the increasing use of pre-dosed capsules contributes to reducing emissions occurring during amalgam storage and preparation, and the exposure of dental personnel to these mercury vapours.

The Concorde/EEB study (2007) estimated up to 1 t/year of dental mercury emissions to the air for all of the EU-27, based on the assumption that occupational air concentrations of mercury inside dental clinics average about 15-20 µg/m^3 (derived from Echeverria et al. 1998)[173]. Given the lower dental amalgam use estimated in the present study and the increasing use of capsules in recent years, such air emission have been estimated at approximately **0.5 t Hg/year.**

Air emissions from the wastewater system

Mercury vapours may be emitted from the dental clinic effluents passing through the vacuum pump system. This system must be vented to the air, therefore mercury contained in the effluents has the potential to vaporise and be released into the atmosphere outside the dental clinic or into the sewer system, depending on the type of equipment used. Research carried out in the US in 1996[174] measured mercury releases from the wastewater system per dentist at about 60 mg/day. This value was extrapolated to EU27 by Concorde/EEB (2007), suggesting air releases in the order of 4 t/year. Given the lower dental amalgam use estimated in the present study, such air emission releases have been estimated at approximately **3 t/year.**

[172] JADA (2003) 'Dental mercury hygiene recommendations,' ADA Council on Scientific Affairs, American Dental Association, Journal of the American Dental Association Vol. 134, November 2003 (as cited by Concorde/EEB)

[173] D Echeverria, HV Aposhian, JS Woods, NJ Heyer, MM Aposhian, AC Bittner, Jr., RK Mahurin, and M Cianciola (1998) Neurobehavioral effects from exposure to dental amalgam Hgo: new distinctions between recent exposure and Hg body burden. The FASEB Journal Vol. 12 pp971-980

[174] PG Rubin and M-H Yu (1196) Mercury Vapor in Amalgam Waste Discharged from Dental Office Vacuum Units, Archives of Environmental Health Vol51 No.4, pp335-337

C.7 – Mercury releases associated with solid waste from dental practices

In accordance with the EU waste legislation[175], mercury-containing solid waste and sludge from dental clinics are considered as hazardous waste (EU waste code 18 01 10[176]). Such waste is to be collected separately from non-hazardous waste and treated in specific facilities dedicated to hazardous waste.

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. For example, a study in Greece reported that dental wastes were not managed properly by 80% of dentists in the Thessaloniki municipality in 2006[177]. While mercury emissions from hazardous waste treatment operations can be considered as negligible (since such treatment operations are designed for hazardous compounds like mercury), improper treatment of mercury-containing waste with non-hazardous waste or with medical waste may generate significant mercury emissions to air, water and soil/groundwater, as explained below.

A French study[178] estimated that, in 2005, a dental chair in France generated in the order of: 1 kg/year of wet sludge from amalgam separators with an average Hg content of 6%; 0.1 to 0.2 kg/year of dry solid waste (surplus mixed amalgam from preparation phase, assumed to contain 50% Hg); and some packaging waste that is mostly empty (1 to 1.5 kg/year of empty pre-dosed capsules).

There are no publicly available statistics on EU waste production for the waste code 18.01.10 ('dental amalgam waste'). Latest data available on dental amalgam waste production and treatment is provided in Annex I. Quantities of mercury contained in dental amalgam waste produced by the 17 Member States for which data is available amount to approximately 38 to 48 t Hg/year, with a high uncertainty on this range of values given the different information sources and the different methodologies used to estimate the mercury content of amalgam waste. This sample of Member States is not representative enough of the EU situation to allow an extrapolation for EU27. The estimate developed through the mass balance (i.e. 52 t Hg/year) is considered to be more reliable than an extrapolation of reported waste data; it is therefore used in the rest of this study.

The following assumptions are made in this study with regard to the destinations of dental amalgam waste:

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175 Directive 2008/98/EC of 19 November 2008 on waste and repealing certain Directives

176 Commission Decision of 3 May 2000 establishing a list of wastes, as amended

177 Kontogianni S, Xirogiannopoulou A and Karagiannidis A(2008). Investigating solid waste production and associated management practices in private dental units. Waste Management 28: 1441-1448

178 ASTEEE (2005) Vers une meilleure gestion des déchets mercuriels d'amalgames dentaires (http://www.astee.org/conferences/2005_paris/diaporamas/40.pdf)

- Surplus amalgam from the preparation phase: 70% managed as hazardous waste and 30% as non-hazardous waste (i.e. collected in mixture with general municipal waste);
- Dental amalgam sludge recovered from the cleaning of chairside traps, vacuum filters and possible amalgam separators: 80% managed as hazardous waste and 20% as non-hazardous waste;
- Lost and extracted teeth: 40% managed as hazardous waste, 30% as biomedical waste and 30% as non-hazardous waste[179].

With the above assumptions, it can be estimated that, out of the 52 t Hg/y of waste produced, around 36 t/y (i.e. 69%) are managed as hazardous waste, 3 t/y (i.e. 7%) as biomedical waste and 13 t/y (i.e. 24%) as non-hazardous waste (i.e. mixed with municipal waste).

- **Waste managed as hazardous waste**

Treatment options for mercury-containing waste mainly include recycling or landfilling in storage facilities for hazardous waste, and possibly also incineration.

In the case of mercury recycling (to recover elemental mercury), typical mercury recovery efficiency is around 99% according to the Waste Treatment Industries BREF document[180]. The remaining 1% mercury is mostly released to the air, while smaller amounts may be found in treatment residues, filters from flue gas cleaning, etc.

In the case of landfilling as hazardous waste (above or underground storage), environmental emissions of mercury are considered to be negligible as storage facilities are designed to be sealed and to minimise releases to the environment.

In the case of incineration as hazardous waste, environmental emissions of mercury can also be considered as negligible. According to the Waste Incineration BREF document[181], in a typical hazardous waste incinerator, 99.88 % of Hg present in hazardous waste is captured in solid residues for disposal.

- **Waste managed as municipal waste (non-hazardous waste)**

At EU level, treatment methods for municipal waste include landfilling (for 38% of municipal waste produced in 2009), incineration (20%), recycling (24%) and other methods including composting (18%)[182].

In the case of dental waste, these may be either landfilled or incinerated. Considering the above statistics, one can roughly assume that 70% of dental wastes ending up in the municipal waste stream are landfilled and 30% incinerated.

A French study[183] estimated that, in a typical municipal waste incinerator, 7 to 10% of the mercury contained in waste is emitted to the atmosphere. A large part of the mercury (around

[179] Assumption taken from Concorde/EEB study (2007)

[180] EC (2006) Reference Document on Best Available Techniques for the Waste Treatment Industries, Chap. 4.3.3.3

[181] EC (2006) IPPC - Reference Document on the Best Available Techniques for Waste incineration. Table 3.2 (http://eippcb.jrc.es/reference/)

[182] Sources: Eurostat, 2009 data ; EC (2010) Environmental statistics and accounts in Europe – 2010 edition (p. 121)

[183] AGHTM (2000) Rapport de synthèse des travaux du groupe de travail « Déchets mercuriels en France »

90%) remains in the slag or is captured by the flue gas cleaning systems (e.g. electrostatic filter, scrubber). The study estimated that the fraction discharged to water was very small (0.5-1%). Flue gas cleaning residues are usually stabilised and sent to hazardous waste landfills; short-term emissions from stabilised residues in such landfills are avoided, however there is limited knowledge on the behaviour of these residues over a long timeframe (several hundreds or thousands of years)[184]. Slag may be sent to landfills for hazardous or non-hazardous waste, and possibly also used for road backfilling works, leading to further possible emissions to water and soil. Values derived from this French study are given here as an example, which may not be representative of the whole EU (in some Member States, the proportion of mercury emitted to air from non-hazardous waste incinerators may be higher).

With regard to dental mercury-containing waste sent to municipal waste landfills, its behaviour is difficult to predict as it is very much dependent on the storage conditions. Mercury emissions to air, surface water, soil and groundwater may occur, as these landfills are not designed for the storage of such hazardous waste.

According to Concorde/EEB[152], a rough estimate of mercury emissions to the different environmental compartments arising from the presence of dental mercury in the municipal waste stream can be given as follows: 30% of mercury in waste emitted to the atmosphere; 10% emitted to surface water and 60% emitted to soil and groundwater. The same allocation rule has been used in the present study, in the absence of more accurate and up-to-date information.

- **Waste managed as medical waste**

A survey in the USA in 2000 discovered that 25-30% of dentists disposed of much of their dental amalgam waste as medical waste due to the potential presence of pathogens[185]. Typically, medical waste is disposed of by incineration, or sometimes by a sterilisation process known as 'autoclaving' (common in Ireland, for example). Medical waste incinerators are now supposed to operate according to EU regulations limiting emissions of mercury, although autoclaving remains less regulated and could result in mercury vapour releases, discharge of effluents to the wastewater system and/or eventual landfilling of autoclaved waste[186]. The Concorde/EEB study roughly estimated mercury emissions to the different environmental compartments arising from the presence of dental mercury in the biomedical waste stream, as follows[152]: 25% of mercury in waste emitted to the atmosphere; 5% emitted to surface water and 20% emitted to soil and groundwater; the remaining 50% are considered to be sequestered and no longer bioavailable (because handled as hazardous waste). The same allocation rule has been used in the present study, in the absence of more accurate and up-to-date information.

[184] COWI/Concorde (2002) Heavy metals in waste – Report for the European Commission (DG ENV)

[185] KCDNR (2000) – 'Management of Hazardous Dental Wastes in King County, 1991 – 2000,' King County Department of Natural Resources, Hazardous Waste Management Program, Water and Land Resources Division, Washington State, USA

[186] HCWH (2002) – 'Stericycle: Living Up To Its Mission? An Environmental Health Assessment of the Nation's Largest Medical Waste Company' Health Care Without Harm

C.8 – Mercury emissions from urban wastewater treatment plants

Most dental practices are connected to the municipal wastewater system, therefore mercury present in the dental effluents ends up in urban WWTPs. The **quantity of mercury entering urban WWTPs** was estimated above at approximately **13 t Hg/year**.

In addition to mercury discharges from dental practices, the deterioration of mercury fillings in people's mouths – due to chewing and consumption of hot beverages – also contributes to the mercury load received by WWTPs. This contribution was estimated at **2-3 t Hg/year** by Concorde/EEB[152], which is also the value used in the present study. As an example, for the city of Stockholm only, this mercury load was estimated in 2008 at 13-14 kg per year, which is about 40% of the total load entering the WWTP[187]. A previous study conducted on a sample of Swedish individuals in 1994 showed that the amounts of mercury excreted by each individual were comprised between 1.4 and as much as 209 µg Hg/day (median value of 62 µg Hg/day) and were correlated to the number of amalgam surfaces in the mouths[188]; extrapolating these values to the EU27 population gives a range of 0.3 to 38 t Hg/year (median of 11 t Hg/year) excreted by individuals and released to sewers, however it is unknown which exact proportion of this mercury is due to dental amalgam (the other main factor being the consumption of contaminated fish).

C.8.1 – Efficiency of treatment

Urban WWTPs are not specifically designed to capture mercury or other heavy metals. If mercury solids enter a treatment plant, they eventually wind up in the grit (the initial coarse screen/filter on incoming wastewater) and/or the sludge/biosolids. Treatment plant grit is typically landfilled, leading to possible problems with leaching and/or volatilization. Sludge is often incinerated, landfilled or applied to land as fertilizer or compost.

Mercury removal efficiencies of municipal WWTPs are usually higher than 95% (i.e. more than 95% of Hg is captured in the sewage sludge while less than 5% remains in the water)[189]. Applying this 95% efficiency ratio to the estimated mercury inflow (i.e. 16 t Hg/y), it can be roughly estimated that **15 t Hg/year are captured by the sewage sludge** and **1 t Hg/year is found in the WWTP effluent discharged to surface water**.

According to the latest data from the European Pollutant Release and Transfer Register (E-PRTR)[190], **urban WWTPs released 2.5 t Hg to surface water, 0.21 t Hg to the soil (via**

[187] Response from the Swedish Chemicals Agency to the Consultation on SCHER preliminary report on 'The environmental risk and indirect health effects of mercury in dental amalgam' (http://europaem.eu/politics/Response_Swedish_Chemical_Agency.pdf)

[188] Skare I et al. (1994) Human Exposure to Mercury and Silver Released from Dental Amalgam Restorations. Archives of environmental health, 49: 384–394

[189] Balogh S and Nollet Y (2008). Mercury mass balance at a wastewater treatment plant employing sludge incineration with offgas mercury control. Science of the total environment 389: 125-131.

[190] European Pollutant Release and Transfer Register (http://prtr.ec.europa.eu/PollutantReleases.aspx).Data reported under the E-PRTR covers industrial facilities (including urban WWTPs) with individual Hg water releases above certain thresholds: 10kg/year for Hg releases to air; 1 kg/year for Hg releases to water and 1 Hg kg/year for releases to soil.

agricultural spreading of sewage sludge) and 0.04 t Hg to the air in 2009. These should be considered as minimum values, as not all urban WWTPs may have been reporting data and data are only reported if above certain thresholds[191]. As a comparison, another information source estimated at 6 t the amount of mercury released to surface water from EU urban WWTPs in 2005[192].

Not all the mercury released by urban WWTPs comes from dental amalgam use: a study from 1996 estimated the contribution of dental clinics to total Hg load entering WWTPs at 13 to 78%[193]; more recent studies in the USA estimated the contribution of dental clinics to be around 50% [194,195].

In 2008, the SCHER[44] estimated the concentration of mercury in sludge as a consequence of releases from dental clinics ranged between 0.001 and 2.4 mg Hg/kg in dry weight with an average value of 0.42 mg/kg in dry weight[196]. Considering an average Hg concentration in sludge of 1.5 mg Hg/kg in the EU[197], the SCHER suggested that the contribution of dental clinics represented about one third of the Hg total releases to the terrestrial compartment. However, in certain Member States such as Sweden, the use of mercury in dental amalgam has been identified as the single largest source of mercury in sewage sludge.

The sludge can be managed in several different ways, as described below. In most cases, sludge management operations will only result in mercury being moved from one environmental medium to another and will not enable mercury to be sequestered for long-term.

C.8.2 – Releases from sewage sludge management

Different options exist for the management of urban sewage sludge, in particular agricultural use as fertilizer, incineration (either in dedicated facilities within WWTPs or in large coal combustion plants), digestion (to produce biogas) or landfilling.

According to a study by Pancon (2009)[198], EU sewage sludge is managed as follows: 45% is used for agriculture, 23% is incinerated, 18% is disposed of in the sea, 7% is landfilled and 7% is disposed of in other ways. However, sludge management options vary widely across Member

[191] Available data comes from 221 facilities across the EU and the reporting thresholds for Hg are 10 kg/year for releases to the air, 1 kg/year for releases to water and 1 kg/year for releases to the soil.

[192] Sundseth K, Pacyna JM, Pacyna EG, Panasiuk D (2011) Substance flow analysis of mercury affecting water quality in the EU. Water Air Soil Pollut. 223: 429-442

[193] Arenholt-Bindslev D and Larsen AH (1996). Hg levels and discharge in waste water from dental clinics. Water, Air Soil Pollut. 86: 93–99 (as cited by Concorde/EEB)

[194] ADA (2003) – Draft ADA Assessment of Mercury in the Form of Amalgam in Dental Wastewater in the United States, Environ report to the American Dental Association (as cited by Concorde/EEB)

[195] CCCSD (2006) – Dental Offices and Mercury Pollution, Central Contra Costa Sanitary District, Contra Costa, California, USA (as cited by Concorde/EEB)

[196] Taking a default average production of 0.071 kg of sludge per person per day at the WWTP

[197] EC 2004 web site: http://ec.europa.eu/environment/chemicals/mercury/summary of_legislation.pdf

[198] Pancon (2009) The EU sludge management (http://140.115.123.119/980626/sppt/2.pdf)

States (see Annex J). Another recent study by Milieu[199] projected the following management options for 2010 and 2020 under a business as usual scenario:

Table 16: Projections on sewage sludge management options in EU27 (in % of total sludge produced)

Year	Agricultural use	Incineration	Landfill	Other
2010	42%	27%	14%	16%
2020	44%	32%	7%	16%

According to the above projections, in a business as usual scenario the overall proportion of treated sludge recycled to agriculture across the EU will remain more or less the same up to 2020 while the share sent to incineration will rise slightly and the share going to landfills will be halved (due to EU legislation restricting organic waste going to landfill as well as public disapproval).

Agricultural use of sludge

In some Member States, a significant proportion of sewage sludge appears to be used for agricultural purposes, e.g. Bulgaria (56% of total sludge produced in 2009), Czech Republic (47% in 2008), Denmark (59% in 2007), Ireland (69% in 2007), Spain (83% in 2009), France (47% in 2008), Cyprus (50% in 2007), Lithuania (61% in 2009), Luxembourg (56% in 2008), Hungary (57% in 2007) or Portugal (87% in 2007) (for further details, please see Annex J).

The presence of mercury in sewage sludge can make it more difficult to use it as agricultural fertilizer. This option has been less and less favoured by operators of WWTPs, due to the presence of various potential contaminants – mercury among others. However, the wastewater treatment organisations consulted during this study did not report that mercury was a significant limiting factor in itself for the agricultural use of sewage sludge.

According to a recent report for the EC (Milieu 2010)[200], the mercury content of sewage sludge recycled to agriculture ranges from **0.2 to 4.6 mg/kg dry matter**; the highest concentrations being observed in Poland (4.6 mg/kg), Latvia (4.2 mg/kg), Cyprus (3.1 mg/kg) and Slovakia (2.7 mg/kg) (see further data in Annex K). Another report mentions average mercury contents between 0.3 and 3 mg/kg dry matter across the Member States (Pancon 2009)[201].

In Sweden, the phase-out of mercury use, the installation of amalgam separators in all dental clinics and the cleansing projects of mercury contaminated sewer pipes from dental clinics had led to a significant decrease in the mercury content of sewage sludge from approximately 1.1 mg/kg in 1995 to 0.6 mg/kg in 2008[202].

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[199] Milieu, WRC, RPA (2010) Environmental, economic and social impacts of the use of sewage sludge on land – Report for the EC, Part 1

[200] Milieu, WRC, RPA (2010) Environmental, economic and social impacts of the use of sewage sludge on land – Report for the EC, Part 2 (http://ec.europa.eu/environment/waste/sludge/pdf/part_ii_report.pdf)

[201] EC (2001) Disposal and recycling routes for sewage sludge – Scientific and technical report (http://ec.europa.eu/environment/waste/sludge/sludge_disposal.htm)

[202] Information provided by Sweden via the study questionnaire

In 1999, the average mercury content of sludge spread on EU agriculture soils was estimated at 1.5 mg/kg of dry matter, implying the introduction of **4.3 t Hg to EU agricultural land annually** (European Commission 2004)[203]. A new calculation based on more recent data shows that this mercury amount has remained stable (approximately 4.4 t Hg/year as estimated in Annex K).

Once the sludge is spread onto the soil, mercury present in the sludge may partly volatilise (some 30 to 60% of the mercury added to the soil, occurring in open field conditions)[204]. It may also be captured by the vegetation grown on the soil, immobilised in the soil or drained by surface runoff.

Sludge is regulated by Directive 86/278/EEC of June 1986, which dictates that Member States must prohibit the application of sewage sludge to soil where the concentration of one or more metals in the soil exceeds certain limit values. For mercury, the limit value in soil is 1 to 1.5 mg/kg of dry matter for spreading on soils with a pH higher than 6 and lower than 7. Member States must also regulate the use of sludge such that the accumulation of heavy metals in soil does not exceed the limit values; they can do this in one of two ways: a) by laying down the maximum quantities of sludge which may be applied per unit of area per year while observing limit values for heavy metal concentration in sludge – for mercury this limit value is 16 to 25 mg/kg of dry matter; or b) by observing the limit values for the quantities of metals introduced into the soil per unit of area and unit of time – for mercury this limit value is 0.1 kg/ha/yr.

Directive 86/278/EEC is currently under review and a study was carried out to analyse the impacts of several policy options to modify legislation on sewage sludge (Milieu 2010)[205]. Some of the options investigated by the study involve lowering the limit value for heavy metals in sludge used for agricultural purposes; for mercury, the proposed new limit values would be 10 or even 5 mg/kg of dry matter. In practice, several Member States have already implemented stricter limit values for mercury in sludge, for precautionary reasons. For the other Member States, considering the respective mercury contents of sludge currently used for agricultural purposes (0.2-4.6 mg/kg in dry weight, as presented above), the implementation of a lower limit value would not be a problem in most cases.

- **Sludge incineration**

The incineration of sewage sludge is becoming more widespread in the EU. Mercury present in sludge is partly captured by flue gas cleaning devices (depending on the abatement devices in place), the remainder being discharged to the atmosphere. Part of the mercury may be captured by conventional multi-pollutant abatement devices (e.g. dust filters, scrubbers), with varying efficiencies with regard to mercury removal. In order to improve the capture of mercury – among other micro-pollutants – some WWTPs have invested in activated carbon filters. For example, one large WWTP in Bilbao, Spain, reported that they recently invested in two activated carbon filters (4.3 million EUR investment) and two mercury emissions analysers (140 kEUR

[203] EC (2004) EU Legislation and Policy Relating to Mercury and its Compounds. Working Document of the European Commission, DG Environment. Prepared to inform the development of an EU strategy on mercury.

[204] EC (2001) Disposal and recycling routes for sewage sludge – Scientific and technical report (http://ec.europa.eu/environment/waste/sludge/sludge_disposal.htm)

[205] Milieu, WRC, RPA (2010) Environmental, economic and social impacts of the use of sewage sludge on land – Report for the EC (http://ec.europa.eu/environment/waste/sludge/pdf/part_ii_report.pdf)

investment)[206]; it is however not clear whether the Bilbao example should be regarded as best practice or as a common feature of many WWTPs in the EU.

As an example, a mercury mass balance was performed in 2007 by Balogh and Nollet[207] at a large metropolitan WWTP employing sludge incineration, which had been recently upgraded to provide for greater mercury control. The upgrade included a new fluidized bed sludge incineration facility equipped with activated carbon addition and baghouse carbon capture for the removal of mercury from the incinerator offgas. The results showed that mercury discharges to air from the plant represented less than 5% of the mass of mercury entering the plant, while the remaining mercury was captured in the ash/carbon residual stream exiting the new incineration process. It should be noted that such an example represents best practice rather than the average EU situation.

Solid residues from WWTP incinerators generally follow the same disposal routes as residues from non-hazardous waste incinerators (see Section C.7).

- **Sludge landfilling**

Landfill disposal of sludge has been the most widely used and lowest cost method of sludge disposal in Europe, but it is now widely recognised as being an unsustainable outlet due to concerns over pollution, loss of recyclable materials and loss of void for those wastes which cannot be recycled. The EC Landfill Directive (1999/31/EC) requires all Member States to develop national strategies to reduce biodegradable wastes going to landfill. In fact, a number of Member States have already introduced such measures, which when fully implemented in the next few years will effectively ban the disposal of sludge in landfill, unless it is as ash.

The behaviour of mercury contained in sludge going to landfill is difficult to predict as it is very much dependent on the storage conditions. Mercury emissions to air, surface water, soil and groundwater may occur, as these landfills are not designed for the storage of mercury-containing waste.

C.8.3 – Overall environmental releases from wastewater treatment and sludge management

According to Concorde/EEB[152], a rough estimate of mercury emissions to the different environmental compartments arising from the presence of dental mercury in the inflow of WWTP can be given as follows: 10% of mercury entering urban WWTPs is finally released to the air, 40% to surface water and 50% to soil and groundwater; none of this mercury can be considered as being sequestered for long-term. The same allocation rule has been used in the present study, in the absence of more accurate and up-to-date information.

[206] Information provided by the Bilbao wastewater treatment company via the study questionnaire

[207] Balogh, S. J., & Nollet, Y. H. (2008) Mercury mass balance at a wastewater treatment plant employing sludge incineration with off gas mercury control. Science of the Total Environment, 389, 125–131

C.9 – Mercury emissions from crematoria

C.9.1 – Estimates of atmospheric mercury releases

According to previous studies, cremation represents a significant contribution to mercury air emissions associated with the life cycle of dental amalgam.

In 2005, the Extended Impact Assessment (ExIA) of the EU Mercury Strategy provided an estimate of EU mercury emissions cremation in the order of 3 t Hg/year. The ExIA commented that '*although cremation is not an especially large source of emissions in relative terms, it is significant in some countries, and unlike the main industrial emissions it is not subject to any EU legislation'*; it was furthermore stated that '*mercury fillings are the larger reservoir of mercury in society behind the chlor-alkali industry, highlighting the possibility of significant total emissions over a period of many years*'. The Concorde/EEB report (2007) provided an estimate of 4.5 t Hg/year on the basis of information from the Cremation Society of Great Britain[208]. A report by AMAP/UNEP provided an estimate of 3.5 t in 2005, noting the high uncertainty associated with this figure[209].

Mercury emissions from this sector are not covered by current EU legislation but they are regulated in several Member States (Emission Limit Values (ELVs) for mercury and/or requirement for mercury abatement devices). In addition, Parties to the OSPAR Convention, which include twelve Member States, have proposed using Best Available Techniques to reduce mercury air emissions (OSPAR Recommendation 2003/4, as amended). Parties to the HELCOM Convention have also proposed to apply ELVs for mercury emissions from crematoria (HELCOM Recommendation 29/1). A summary of existing legislation in Member States is provided in Annex B.

Policy options to reduce mercury emissions from crematoria were investigated in the ExIA of the Mercury Strategy in 2005. It was concluded that Community-level action was not appropriate at that stage, mainly because such emissions were covered by an OSPAR Recommendation and by legislation in some of the remaining Member States that are not parties to the OSPAR Convention. The ExIA also noted that available data on the extent of emissions from cremation were limited and that future reporting required by the OSPAR Recommendation would provide an initial indication of the extent to which the Recommendation is being applied.

As part of this study, the following new data has been reviewed:

- Latest emission data reported under the OSPAR Recommendation 2003/4 (overview report issued in August 2011)[210]
- Data provided by the stakeholders contacted for this study (replies to the questionnaires)

[208] Cremation Society of Great Britain, 2004 statistics

[209] AMAP/UNEP (2008) Technical background report to the global atmosphere mercury assessment

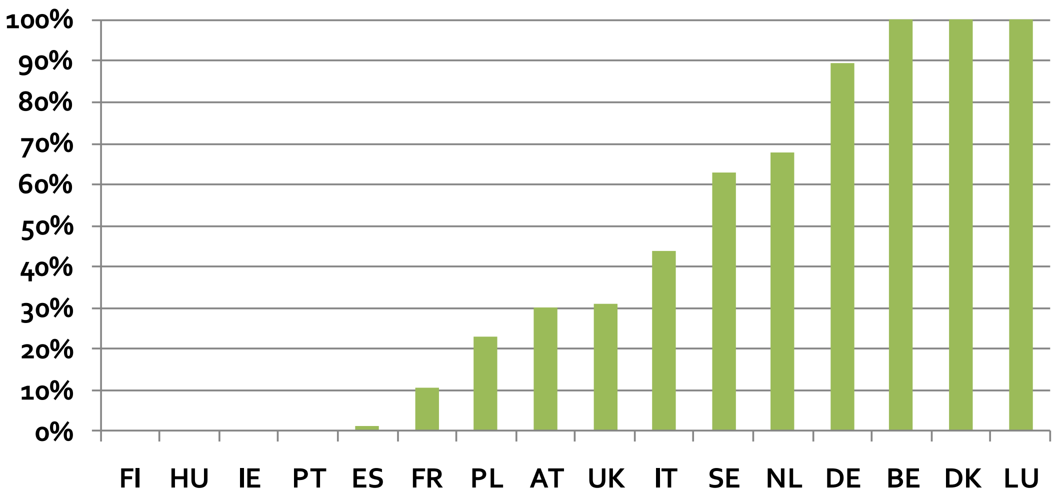
[210] OSPAR (2011) Overview assessment of implementation reports on OSPAR Recommendation 2003/4 on controlling the dispersal of mercury from crematoria (http://www.ospar.org/documents/dbase/publications/p00532_Rec_2003-4_Overview_report.pdf)

- Latest cremation statistics[211].

According to international cremation statistics[212], the use of cremation has increased in EU countries over the last few years: in 2009 approximately 51% of deceased persons were cremated[213] vs. approximately 42% in 2005[214]. Countries with the highest rates of cremations in 2009 were the Czech Republic (80%), Sweden (77%), Slovenia (75%) and the UK (73%). The use of cremation has increased in all EU countries for which data is available, with significant increases noted in some Member States such as Portugal (+13% between 2005 and 2009) or Slovenia (+7.5%). In Poland, the rate of cremation is expected to double between 2006 (5%) and 2020 (10%)[215]. In Greece, Lithuania and Cyprus, there are no crematoria.

Recent estimates of mercury air emissions from crematoria in the Member States are presented in Annex L, covering 25 Member States[216]. Some of these estimates correspond to data reported under the OSPAR Convention while others were obtained through the study questionnaires or were estimated by BIO using the most recent cremation statistics. In these 25 Member States, there are **about 2,700 crematoria**. Based on data for 15 Member States, it can be estimated that **approximately 40% crematoria are equipped with mercury abatement devices**, but this proportion varies greatly across Member States as shown in Figure 13 below.

Figure 13: Share of crematoria equipped with mercury abatement devices in 16 MS[217]



[211] Cremation Society of Great Britain (http://www.srgw.demon.co.uk/CremSoc4/Stats/index.html)

[212] Cremation Society of Great Britain (http://www.srgw.demon.co.uk/CremSoc4/Stats/index.html)

[213] Based on data from 14 MS

[214] Based on data from 18 MS

[215] NILU Polska (2010) Cost-benefit analysis of impact on human health and environment of mercury emission reduction in Poland – Stage 1 (http://www.gios.gov.pl/zalaczniki/artykuly/etap1_20101022.pdf)

[216] MS not included are BG, MT

[217] CY, GR, LT: no crematoria. For other MS, no information is available on the share of crematoria equipped with Hg abatement devices.

It is difficult to know how EU emissions have evolved over the last few years, due to a lack of data in a number of Member States. However, the following national trends can be noted based on information reviewed to date:

- **UK:** Reported emissions have more than doubled between 2002 (~400 kg) and 2010 (~940 kg)[218]. In 2004, the UK Department for Environment, Food and Rural Affairs (DEFRA) estimated that the amount of mercury from cremations would increase in the UK by two-thirds between 2000 and 2020, accounting for over 25% of the national mercury emissions to the air in 2020, in the absence of further abatement measures[219].
- **France:** Reported data shows an increase in emissions between 2002 (200 kg) and 2009 (307-407 kg)[220].
- **Sweden:** Although the number of crematoria applying mercury removal techniques has increased between 2004 and 2009[221], overall mercury emissions from crematoria have increased during this time period (from 58 kg in 2004 to 114 kg in 2010), partly due to a higher number of cremations occurring in crematoria not equipped with abatement devices.
- **Netherlands:** A significant decrease can be observed between 2002 (80 kg) and 2010 (33 kg)[222], with an increasing share of crematoria equipped with mercury abatement devices.
- **Germany:** A decreasing trend is observed between 2002 (42-168 kg) and 2008 (39 kg)[223], although there was significant uncertainty on the 2002 estimate.
- **Denmark:** Emissions were estimated at 60 kg in 2002 and 70-104 kg in 2008[224] but are expected to have significantly decreased in 2011, as all crematoria are now fitted with mercury abatement devices to comply with national legislation (compliance deadline was January 2011).
- **Belgium:** Between 2006 and 2009, mercury emissions have remained stable (while the number of cremations has slightly increased both in crematoria with and without mercury abatement).

[218] Sources: 2002 value from OSPAR overview report published in 2003; 2010 value provided by CAMEO (Crematoria Abatement of Emissions Organisation) for this study. In addition, the value reported for 2009 was 730 kg (according to OSPAR overview report published in 2011)

[219] DEFRA (2004) Mercury emissions from crematoria. Second consultation on an assessment by the Environment Agency's Local Authority Unit

[220] Source: OSPAR overview reports published in 2003 and 2011, respectively

[221] 2004 data for Sweden available here: http://cdr.eionet.europa.eu/resultsdataflow?dataflow_uris=http%3A%2F%2Frod.eionet.eu.int%2Fobligations%2F492&years%3Aint%3Aignore_empty=&partofyear=&country=&sort_on=reportingdate&sort_order=reverse; 2010 data provided by KEMI as part of this study

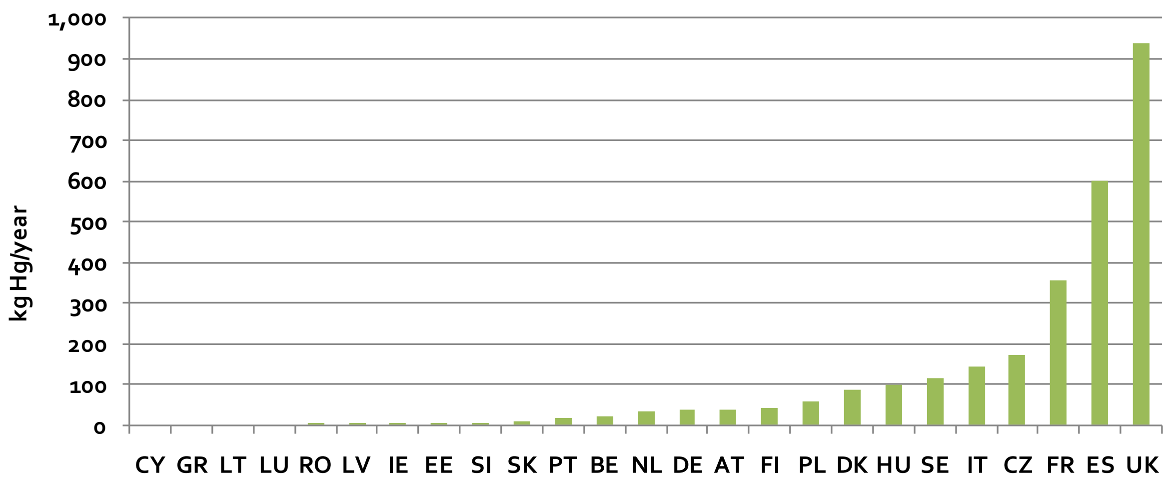
[222] Source: OSPAR overview reports published in 2003 and recent data provided by the Ministry of Environment for this study

[223] Source: OSPAR overview reports published in 2003 and 2011, respectively

[224] Source: OSPAR overview reports published in 2003 and 2011, respectively

For the 25 Member States for which data is available or could be estimated, it is roughly estimated that total mercury air emissions are **in the order of 2.8 t Hg/year**[225] (for the OSPAR Convention area alone, the 2011 OSPAR overview report provided a rough and provisional estimate of between 1 and 2 t Hg/year). This should be considered only as a rough estimate, as there is significant uncertainty on national mercury emission estimates. As mentioned by the OSPAR overview report, several measurement/estimation methodologies are currently used and the reliability of some these methodologies is questionable. In spite of some upwards trends observed in some Member States, this result suggests that overall EU mercury emissions have not increased since 2005. Estimated emissions per Member State are presented in Figure 14 below.

Figure 14: Estimated annual Hg emissions from crematoria in 25 MS



Data source: see Annex L.

The three Member States with the greatest emissions and showing significant increases in emissions over the last few years are the UK, Spain and France. For the UK and France, more stringent legislation has been implemented recently:

- **UK:** Requirement for abatement to be fitted covering 50% of cremations by end 2012, plus all new crematoria to have abatement from 2005[226].
- **France:** A Ministerial Order from January 2010 introduced an emission limit value of 0.2 mg Hg/Nm^3 applicable as of 2010 for new crematoriums and as of 2018 for existing ones[227].

No information is available on the actual or projected environmental impacts of the above regulations, however it can be assumed that the more stringent legal requirements implemented in these two countries would greatly contribute to stabilising emissions (or at least slowing down emissions increase) within the OSPAR Convention Area, after 2020.

[225] MS for which no estimates could be made, due to a lack of data, are: BG, MT

[226] Environment Permitting Regulations 2007 (January 2005)

[227] Ministerial Order of 28 January 2010 concerning emissions from crematoriums

In spite of the decreasing emission trends that can be expected from these measures, there are two main parameters that tend to counteract emission abatement efforts:

- A growing trend towards the use of cremation (rather than burial), particularly in big cities, as mentioned in the OSPAR report of 2011[228]. Crematoria companies who responded to the study questionnaire also reported upward trends[229].
- An increasing proportion of deceased people having amalgam fillings.

C.9.2 – Mercury deposition from crematoria

Little data is currently available on the possible impacts resulting from mercury deposition around crematoria. A study was conducted in the UK in 2008, on behalf of the UK Food Standards Agency[230], which demonstrated that, based on a highly conservative risk assessment, the potential exposure of members of the public to mercury arising from crematoria stack emissions via foodstuff consumption is almost certainly indistinguishable from the existing background concentrations of mercury existing in the UK population diet. The study concluded that there is no observed impact of mercury emissions from crematoria on human health via foodstuff consumption.

C.10 – Mercury emissions from other sources

- **Emissions from people's mouths**

A rough estimate of around **2 t Hg/year** exhaled by EU-27 citizens was given by a previous study[152].

- **Emissions from burial**

The burial of deceased persons with mercury fillings eventually leads to mercury releases to the soil and groundwater, however it is difficult to estimate the magnitude of such releases in the absence of any data.

It is assumed that deceased persons have an average of 1.5 g Hg in the mouth (older people are supposed to have slightly less mercury in their mouth than the average EU population, due to fewer remaining teeth). Given the number of deceased persons in EU27 (approximately 4.9

[228] OSPAR (2011) Overview assessment of implementation reports on OSPAR Recommendation 2003/4 on controlling the dispersal of mercury from crematoria

[229] In Italy, the Federal Utility company estimated an increase by about 4,000 to 5,000 cremations per year in the next 5 years. In Portugal, the national funerals association estimated an increase from 14 crematoria and 8,752 cremations in 2010 to approximately 25 crematoria and 15,000 cremations/year in 2016. In the Netherlands, a slight increase in the number of cremations, in the order of 0.5% per year, is expected by the Facultatieve Technologies group.

[230] Michael D. Wood, Adrian Punt and Richard T. Leah (2008) Assessment of the mercury concentrations in soil and vegetation, including crops, around crematoria to determine the impact of mercury emissions on food safety. Report for the UK Food Standards Agency (http://foodbase.org.uk/admintools/reportdocuments/323-1-574_C02070_27_april_09.pdf)

million in 2010)[231] and considering that about half are buried[232], this corresponds to approximately **3.7 t of Hg/year**.

Considering that the other half of deceased people are subject to cremation, a similar amount of mercury would be emitted from crematoria if there were no mercury abatement devices (the total amount of mercury air emissions from crematoria, estimated using another methodology in Section C.9.1, is of approximately 2.8 t Hg/year).

C.11 – Contribution to overall mercury releases

By summing up amounts of mercury released to air/water/soil as estimated in the previous sections, it can be roughly concluded that the current and historical use of dental amalgam leads to[233]:

- ~ 16 to 23 t Hg/year emitted to the air
- ~ 2 to 4 t Hg/year emitted to surface water
- ~ 16 to 24 t Hg/year emitted to the soil and groundwater
- ~ 31 to 46 t Hg/year sequestered for long-term or recycled.

The above estimates suggest that **34 to 50 t/year of mercury from current and historical use of dental amalgam are emitted to the environment with some potential for becoming bioavailable**, while **31 to 46 t/year** can be considered as being either **sequestered for long-term (i.e. no longer bioavailable) or recycled**.

Once in the environment, changes in pH, oxygen availability, temperature, presence of other ions and actions of abrasion and corrosion can allow the mercury in amalgam to be used by bacteria, which are able to convert it to the more toxic organic methyl-mercury[234,235]. Organic mercury is readily bioavailable and once entering the food web, it tends to accumulate in the organisms. The organism concentrations of methyl mercury increases (biomagnifies) when passing the food web to reach highest concentrations in top predators such as certain birds and piscivorous fishes, being popular for human consumption[236,237]. Methylation to methylmercury already starts in the wastewater before reaching its recipient[238].

[231] http://epp.eurostat.ec.europa.eu/statistics_explained/index.php?title=File:Number_of_deaths,_EU-27,_(1)_(million).png&filetimestamp=20111018093516)

[232] International cremation statistics 2009 (http://www.srgw.demon.co.uk/CremSoc5/Stats/Interntl/2009/StatsIF.html)

[233] The figures below take into account a +/-20% uncertainty range

[234] Kao RT, Dault S and Pichay T (2004). Understanding the mercury reduction issue: the impact of mercury on the environment and human health. J Calif Dent Assoc 32: 574–9.

[235] Jones DW (2004). Putting dental mercury pollution into perspective. Br Dent J 197: 175–7.

[236] UNEP (2002) Global mercury assessment report

[237] Zhao X, Rockne KJ, Drummond JL, Hurley RK, Shade CW and Hudson RJM (2008) Characterization of Methyl Mercury in Dental Wastewater and Correlation with Sulfate-Reducing Bacterial DNA. Environmental Science & Technology 42: 2780 -2786

[238] Zhao X, Rockne KJ, Drummond JL, Hurley RK, Shade CW and Hudson RJM (2008) Characterization of Methyl Mercury in Dental Wastewater and Correlation with Sulfate-Reducing Bacterial DNA. Environmental Science & Technology 42: 2780 -2786

Mercury emission estimates from dental amalgam use can then be compared with overall mercury releases to air/water/soil in the EU, in order to assess the relative contribution of dental mercury to the overall mercury problem in the EU. This comparison is presented in Table 17 below.

Table 17: Comparison between dental Hg release estimates and overall Hg releases in the EU

Environmental media	Hg releases from dental amalgam use (t/year)*	Available data on overall anthropogenic Hg releases in the EU (t/year)	Dental amalgam use contribution to EU releases
Air	16 - 23	EU report under UNECE Convention on LRTAP[239]: 73 t in 2009 E-PRTR[240]: 31.3 t in 2009 (only industrial facilities). The main contribution is from coal combustion plants (16.1 t, i.e. 51%) Sunseth et al.[241]: 105 t in 2005	Based on LRTAP data: 21 - 32%[242]
Surface water	2 - 4	E-PRTR[243]: 6.33 t in 2009 from industrial facilities (including urban WWTPs contributing 2.52 t, i.e. 40%) Sunseth et al.[244]: 27 t in 2005 (urban WWTPs estimated to contribute 6 t, i.e. 22%)	Based on Sunseth et al. data: 9 - 13%[245]
Soil and groundwater	16 - 24	E-PRTR[246]: 0.26 t in 2009 from industrial facilities (including urban WWTPs contributing 0.213 t, i.e. 82%), however this value only covers a very small proportion of overall Hg releases to soil	Not quantifiable

* Estimates developed in the present study include a +/- 20% uncertainty range.

The above comparison suggests that mercury emissions from the current and historical use of dental amalgam, expressed in terms of total Hg concentrations, still represent a significant

[239] EEA (2011) European Union emission inventory report 1990–2009 under the UNECE Convention on Long-range Transboundary Air Pollution (LRTAP), Table 2.13 (http://www.eea.europa.eu/publications/eu-emission-inventory-report-1990-2009)

[240] European Pollutant Release and Transfer Register (http://prtr.ec.europa.eu/PollutantReleases.aspx). Covers facilities releasing more than 10 kg/year of Hg to the air.

[241] Sundseth K, Pacyna JM, Pacyna EG, Panasiuk D (2011) Substance flow analysis of mercury affecting water quality in the EU. Water Air Soil Pollut. 223: 429-442

[242] The LRTAP value is chosen to estimate this ratio, because it is the most recent value available for overall EU air emissions from anthropogenic activities

[243] European Pollutant Release and Transfer Register (http://prtr.ec.europa.eu/PollutantReleases.aspx). Covers facilities releasing more than 1 kg/year of Hg to water.

[244] Sundseth K, Pacyna JM, Pacyna EG, Panasiuk D (2011) Substance flow analysis of mercury affecting water quality in the EU. Water Air Soil Pollut. 223: 429-442

[245] The value from Sunseth et al. (2011) is chosen to estimate this ratio, because it covers a wider scope than the E-PRTR value for direct mercury discharges to the aquatic environment

[246] European Pollutant Release and Transfer Register (http://prtr.ec.europa.eu/PollutantReleases.aspx). Covers facilities releasing more than 1 kg/year of Hg to soil.

contribution to overall EU mercury releases to air and surface water. Part of the mercury emitted to the air may actually be deposited after some time, and may enter other environmental compartments (surface water, soil and groundwater, vegetation). Contribution of dental amalgam use to mercury releases to soil and groundwater is difficult to quantify in the absence of any relevant data concerning total EU releases to soil and groundwater.

One important limitation to the assessment of environmental impacts from dental mercury is that mercury uses and releases can only be estimated in terms of total elemental Hg loads, while the actual environmental impacts depend on the mercury species involved and, in particular, the quantities of bioavailable methylmercury released in the environment (methylmercury is one of the most toxic forms of mercury, which also accumulates and biomagnifies in the food chain). Because the mercury methylation and demethylation processes are not very well understood at present, it is not possible to accurately model the possible biochemical transformations of mercury originating from dental amalgam and its environmental impacts. However, the comparison presented above shows that dental amalgam is a significant contributor to overall anthropogenic mercury releases in the EU. According to calculations based on the critical load concept (mainly based on ecotoxicological effects and human health effects via ecosystems), more than 70% of the European ecosystem area is estimated to be at risk today due to mercury levels, with critical loads for mercury exceeded in large parts of western, central and southern Europe[247]. As a significant source of mercury in the environment, the current and historical use of dental amalgam contributes to this environmental risk.

[247] Hettelingh, J.P., J. Sliggers (eds.), M. van het Bolcher, H. Denier van der Gon, B.J.Groenenberg, I. Ilyin, G.J. Reinds, J. Slootweg, O. Travnikov, A. Visschedijk, and W. de Vries (2006). Heavy Metal Emissions, Depositions, Critical Loads and Exceedances in Europe. VROM-DGM report, www.mnp.nl/cce, 93 pp.; CEE Status Reports 2008 (Chapter 7, http://www.rivm.nl/thema/images/CCE08_Chapter_7_tcm61-41910.pdf) and 2010 (Chapter 8, http://www.rivm.nl/thema/images/SR2010_Ch8_tcm61-49679.pdf)

Annex D: Literature review on health effects of using dental amalgam

The literature review presented in this annex aims to provide an overview of the ongoing scientific debate on health aspects of using dental amalgam, focusing on the most recent developments after the publication of the SCENIHR opinion in 2008 as well as previous publications of interest not reviewed by the SCENIHR.

Publications of interest have been obtained using specialised databases and internet searches, using the key words 'dental' and 'mercury' (in the text of the articles). Literature reviewed in this study includes scientific literature (experimental work, patents, scientific reviews) as well as grey literature.

INTRODUCTION

Dental amalgam has been used for over 150 years for the treatment of dental cavities and is still used, in particular in large cavities due to its relatively good mechanical properties and durability (even if those are not optimal when considering the associated risks of cracked teeth with large fillings). Dental amalgam is a combination of alloy particles and mercury that contains about 50% of mercury in the elemental form (SCENIHR, 2008[248]). It is estimated that several tens of tonnes of mercury are placed in people's mouths through amalgam worldwide (Enestrôm and Hultman, 1995[249]; Bates, 2006[250]).

Dental amalgam has been controversial ever since it was introduced, early in the nineteenth century, because of its mercury content, and the controversy is still open (LSRO, 2004)[251]. Recent evidence that small amounts of mercury are continuously released from amalgam fillings has fuelled the controversy (Skare, 1995)[252]. Several publications show that amalgams are by far the main contributors to mercury body burden (Palkovicova et al., 2007[253]; Drasch et al., 1994[254]; Da

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[248] SCENIHR (2008) The safety of dental amalgam and alternative dental restoration materials for patients and users. Available from: http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_016.pdf

[249] Enestrôm S and Hultman P (1995). Does amalgam affect the immune system? A controversial issue. Int. Arch. Allergy Immunol. 106: 180–203.

[250] Bates M (2006). Mercury amalgam dental fillings: An epidemiologic assessment. Int. J. Hyg. Environ.-Health 209: 309–316.

[251] Life Sciences Research Organisation (LSRO) (2004) Review and analysis of the literature on the health effects of dental amalgam – Executive summary (http://www.lsro.org/amalgam/frames_amalgam_report.html)

[252] Skare I (1995). Mass Balance and Systemic Uptake of Mercury Released from Dental Amalgam Fillings. Water, Air Soil Pollut. 80(1-4):59-67.

[253] Palkovicova L, Ursinyova M, Masanova V, Yu Z and Hertz-Picciotto I (2007). Maternal amalgam dental fillings as the source of mercury exposure in developing fetus and newborn. Journal of Exposure Science and Environmental Epidemiology 18: 326–331.

[254] Drasch G, Schupp I, Höfl H, Reinke R and Roider G (1994). Mercury burden of human fetal and infant tissues. European Journal of Pediatrics 8: 607-610.

Costa et al., 2005[255]). Although there is some consensus on the fact that people with amalgam fillings are exposed to some mercury released from the amalgam, the magnitude of this exposure is subject to controversy. A number of alternative materials are available, although in most cases their safety has not yet been evaluated in a comprehensive manner (Bates, 2006[250]).

HEALTH EFFECTS OF DENTAL AMALGAM

The main direct exposure pathway to inorganic Hg (acute exposure) in individuals having dental amalgams occurs during the placement or removal of the amalgam[256] (Clarkson, 2006)[257]. The release rate of mercury vapour is dependent on several parameters, including: filling size, tooth and surface placement, chewing, hot beverages, food texture, tooth grinding, and brushing teeth, as well as the surface area, composition, and age of the amalgam (Bates, 2006[250]; Skare and Engqvist 1994[258]). Moreover, mercury from amalgam may be transformed into organic mercury compounds by microorganisms in the oral cavity and gastrointestinal tract (Björnberg et al. 2006[259]; Leistevuo et al., 2001[260]; Heintze et al., 1983[261]; Yannai et al., 1991[262]).

The SCENIHR report stressed that Hg exposure of individuals having Hg fillings is between 5 and 30 times lower than limit values for occupational exposure (SCENIHR, 2008[248]). However, the method used to determine this exposure – which is generally the concentration of mercury in urine and blood – has been often criticized (Mutter et al., 2007; Mutter, 2011)[263] (Richardson et al., 2011)[264]. Some scientists have observed that mercury concentrations in blood and urine do not adequately represent the mercury levels in body tissues. A number of experiments with animals and humans showed that despite normal or low mercury levels in blood, hair, and urine, high mercury levels were found in critical tissues like brain and kidney (Danscher et al., 1990[265];

[255] Da Costa SL, Malm O and Dórea JG (2005). Breast-milk mercury concentrations and amalgam surface in mothers from Brasília, Brazil. Biological Trace Element Research 106: 145-151.

[256] The assessment for mercury (Hg) exposure is often based on blood and/or urinary concentration of Hg.

[257] Clarkson TW and Magos L (2006). The toxicology of mercury and its chemical compounds. Crit. Rev. Toxicol. 36: 609– 662.

[258] Skare, I and Engqvist, A (1994). Human exposure to mercury and silver released from dental amalgam restorations. Arch. Environ. Health 49 (5): 384-394.

[259] Björnberg KA, Vahter M, Englund GS (2006). Methylmercury, Amalgams, and Children's Health: Björnberg et al. Respond. Environ Health Perspect 114:A149-A150.

[260] Leistevuo J, Leistevuo T, Helenius H, Pyy L, Österblad M, Huovinen P and Tenovuo J (2001). Dental amalgam fillings and the amount of organic mercury in human saliva. Caries Res. 35: 163–166.

[261] Heintze U, Edwardsson S, Derand T and Birkhed D (1983) Methylation of mercury from dental amalgam and mercuric chloride by oral streptococci in vitro. Scand. J. Dent. Res. 91: 150– 152.

[262] Yannai S, Berdicevsky I and Duek L (1991) Transformations of inorganic mercury by Candida albicans and Saccharomyces cerevisiae. Appl. Environ. Microbiol. 57: 245–247.

[263] Mutter J, Naumann J, and Guethlin C (2007). Comments on the Article 'The Toxicology of Mercury and Its Chemical Compounds' (2006) by Clarkson and Magos. Critical Reviews in Toxicology 37: 537–549. Mutter J (2011). Is dental amalgam safe for humans? The opinion of the scientific committee of the European Commission. Journal of Occupational Medicine and Toxicology 2011, 6:2.

[264] Richardson GM et al (2011) Mercury exposure and risks from dental amalgam in the US population, post-2000. Science of The Total Environment. [Available online, not printed yet]

[265] Danscher G, Hørsted-Bindsley P and Rungby J (1990) Traces of mercury in organs from primates with amalgam fillings. Exp. Mol. Pathol. 52: 291–299.

Drasch, 1997[266]; Hahn et al., 1989[267], 1990; Hargeaves et al., 1988[268]; Holmes et al., 2003[269]; Lorscheider et al., 1995[270]; Opitz et al., 1996[271]; Vimy et al., 1990[272]; Weiner and Nylander, 1993[273]).

Indirect exposure can occur once the mercury contained in amalgams is released into the environment (e.g. the aquatic environment). Dental clinics reportedly contribute by 13 to 78% to the total Hg load to local wastewater treatment facilities (Arenholt et al., 1996[274]). Some studies in the US revealed that a dental clinic can generate up to 4.5 g of Hg waste per day, or approximately 1 kg Hg per year on a per-chair basis (Drummond et al. 2003 a[275] et b[276]).

In the environment, mercury from dental amalgam can be chemically transformed into methylmercury (MeHg) by sulfate-reducing bacteria (Zhao et al, 2008[277]) . MeHg is the most toxic form of mercury for living organisms, damaging the central nervous system. It may also cause cardiovascular disease (Houston, 2011[278]), cancer and genotoxicity (UNEP, 2002[279]). Top predators and humans are the most affected by MeHg since it can be bioaccumulated in the body and biomagnified in the food web. The exposure to environmental MeHg most frequently occurs through fish and seafood consumption (ingestion). Recent studies suggest that several genes

[266] Drasch G, Wanghofer E and Roider G (1997). Are blood, urine, hair, and muscle valid bio-monitoring parameters for the internal burden of men with the heavy metals mercury, lead and cadmium? Trace Element Electrolytes 14: 116–123.

[267] Hahn LJ, Kloiber R, Vimy MJ, TakahashiY and Lorscheider FL (1989). Dental 'silver' tooth fillings: A source of mercury exposure revealed by whole-body image scan and tissue analysis. FASEB J. 3: 2641–2646.

[268] Hargreaves RJ, Evans JG, Janota I, Magos L and Cavanagh JB (1988). Persistant mercury in nerve cells 16 years after metallic mercury poisoning. Neuropathol. Appl. Neurobiol. 14:443–452.

[269] Holmes AS, Blaxill MF and Haley BE (2003). Reduced levels of mercury in first baby haircuts of autistic children. Int. J. Toxicol. 22: 277–285.

[270] Lorscheider FL, Vimy MJ and Summers AO (1995). Mercury exposure from 'silver' tooth fillings: emerging evidence questions a traditional dental paradigm. FASEB J. 9: 504–508.

[271] Opitz H, Schweinsberg F, Grossmann T, Wendt-Gallitelli MF and Meyermann R (1996). Demonstration of mercury in the human brain and other organs 17 years after metallic mercury exposure. Clin. Neuropathol. 15: 139–144.

[272] Vimy MJ, Takahashi Y and Lorscheider FL (1990). Maternal–fetal distribution of mercury (203 Hg) released from dental amalgam fillings. Am. J. Physiol. 258: 939–945.

[273] Weiner JA and Nylander M (1993). The relationship between mercury concentration in human organs and different predictor variables. Sci. Total Environ. 138: 101–115.

[274] Arenholt-Bindslev D and Larsen AH (1996). Hg levels and discharge in waste water from dental clinics. Water, Air Soil Pollut. 86: 93–99.

[275] Drummond JL, Cailas MD and Croke K (2003). Hg generation potential from dental waste amalgam. J. Dent. 31: 493–501.

[276] Drummond JL, Liu Y, Wu TY and Cailas MD (2003). Particle versus Hg removal efficiency of amalgam separators. J. Dent. 31: 51–58.

[277] Zhao X, Rockne KJ, Drummond JL, Hurley RK, Shade CW and Hudson RJM (2008) Characterization of Methyl Mercury in Dental Wastewater and Correlation with Sulfate-Reducing Bacterial DNA. Environmental Science & Technology , 42: 2780 -2786.

[278] Houston MC (2011). Role of Mercury Toxicity in Hypertension, Cardiovascular Disease, and Stroke. J Clin Hypertens (Greenwich); 13:621–627.

[279] UNEP Chemicals. Global Mercury Assessment. (2002) Report no. 54790-01. Geneva, Switzerland. 258 p.

mediating the toxicokinetics of mercury are polymorphic in humans and may influence inter-individual variability in mercury accumulation (Goodrich et al., 2011[280]).

Exposure to Hg contained in amalgams can cause allergies such as urticaria, asthmatic seizures, hearing loss at high frequencies and can even result in anaphylaxis (Rothwell et Boyd, 2008)[281], (SCENIHR, 2008[248]; Weidinger et al., 2004[282]) or orofacial granulomatosis (Tomka et al., 2011[283]). In more than 90% of the cases, the allergic reactions recover by removal of amalgam (Guttman-Yassky et al., 2003[284]).

It has also been suggested that exposure to Hg contained in dental amalgam may increase the risk of peripheral neuropathy, neurological diseases and other systemic diseases such as Alzheimer disease[285] (Grosman and Picot, 2009[286]), kidney diseases (Mortada et al. 2009[287]), autism (Mutter et al., 2005[288]), autoimmune diseases (Gallagher et al., 2012[289]; Bartova et al., 2003[290]; Berlin, 2003[291]; Hultmann et al., 1994[292] and 1998[293]; Pizzichini et al., 2003[294]; Pollard et

[280] Goodrich, Jaclyn M., Wang, Yi, Gillespie, Brenda, Werner, Robert, Franzblau, Alfred, Basu and Niladri (2011) Glutathione enzyme and selenoprotein polymorphisms associate with mercury biomarker levels in Michigan dental professionals, Toxicology and Applied Pharmacology. Doi: 10.1016/j.taap.2011.09.014

[281] Rothwell J and Boyd P (2008). Amalgam dental fillings and hearing loss. Int J Audiol. 47: 770-776.

[282] Weidinger S, Kramer U, Dunemann L, Mohrenschlager M, Ring J and Behrendt H (2004). Body burden of mercury is associated with acute atopic eczema and total IgE in children from southern Germany. J. Allergy. Clin. Immunol. 114: 457–459.

[283] Tomka M, et al (2011). Orofacial granulomatosis associated with hypersensitivity to dental amalgam. Oral Surg Oral Med Oral Pathol Oral Radiol Endod. [available online, not printed yet].

[284] Guttman-Yassky E, Weltfriend S and Bergman R (2003) Resolution of orofacial granulomatosis with amalgam removal. J. Eur. Acad. Dermatol. Venerol. 17: 344–347.

[285] Several mechanisms explaining these disturbances have now been clearly identified: induction of oxidative stress, destruction of neuronal cytoskeleton, inhibition of the activity of enzymes which play a vital role in brain functions, disturbances in glutamate -a neuromediator- metabolism, etc. Moreover, The distribution of AD worldwide globally corresponds to that of tooth decay and to the use of dental amalgams.

[286] Grosman M and Picot A (2009). Environmental factors and Alzheimer's disease: Mercury strongly under suspicion. Médecine and Longévité 1: 12-21.

[287] Mortada WL, Sobh MA, El-Defrawy MM and Farahat SE (2002). Mercury in dental restoration: is there a risk of nephrotoxicity? Journal of Nephrology 15: 171-6.

[288] Mutter J, Naumann J, Schneider R, Walach H and Haley B (2005). Mercury and autism: Accelerating evidence? Neuro. Endocrinol.Lett. 26: 431–437.

[289] Gallagher C and Meliker J. Mercury and thyroid autoantibodies in U.S. women, NHANES 2007–2008. Environment International Volume 40, April 2012, Pages 39–43

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[291] Berlin M (2003). Mercury in dental-filling materials—An updated risk analysis in environmental medical terms. The Dental Material Comission—Care and Consideration. www.dentalmaterial.gov.se/mercury.pdf.

[292] Hultman P, Johansson U, Turley S, Lindh U, Enestrom S and Pollard K (1994). Adverse immunological effects and autoimmunity induced by dental amalgam and alloy in mice. FASEB J. 8: 1183– 1190.

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al., 2001[295]; Prochazkova et al., 2004[296]; Stejskal and Stejskal, 1999[297]; Stejskal et al., 1999[298]; Sterzl et al., 1999[299]) such as Amyotrophic Lateral Sclerosis (Stankovic, 2006[300]; Bates 2004[301]), psychological conditions, chronic fatigue syndrome, male or female fertility, obstetric parameters and birth defects. Some of these toxic effects may be mediated by binding of mercury to sulfhydryl groups of enzymes (Agency for Toxic Substances and Disease Registry, 1999[302]).

However, there is no scientific consensus on these effects. For some scientists, existing studies show little evidence of effects on general chronic disease incidence or mortality (SCENIHR, 2008[248]), (Bellinger et al, 2007[303]), (Lauterbach et al, 2008[304]; Bates 2006[250]).

Certain populations have been the subject of several studies (pregnant women, children) concerning the dental restoration with amalgams, because the developing brain of foetuses and children is more susceptible to lower exposure levels when compared with the rest of the population (Al-Saleh and Al-Sedairi, 2011[305]; Bellinger et al., 2007[306]; Bellinger et al., 2006[307]; Björnberg et al. 2005[308]). For instance, evidence of neurotoxicity from prenatal methylmercury exposure is now considered sufficient for high exposure levels, but more research is needed for

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low exposure levels (Röösli, 2011[309]; Watson et al. ,2011[310]). A number of research works have demonstrated that mercury from maternal amalgam fillings leads to an increase in mercury concentration in the tissues and the hair of fetuses and newborn children. Moreover, placental, fetal, and infant mercury body burden in addition to mercury levels in amniotic fluid (Luglie et al., 2003)[311] and breast milk (Drasch et al., 1998[312]; Oskarsson et al., 1996[313]; Vimy et al., 1997[314]) correlate with the numbers of amalgam fillings of the mothers (Ask et al., 2002[315] ; Drasch et al., 1994[316] ; Holmes et al., 2003[269]; Morgan et al., 2002[317]; Takahashi et al., 2001[318], 2003[319]; Vather et al., 2000[320]) and the number of amalgam fillings have been shown to correlate with age, education, smoking habits, and BMI (Body Mass Index) of pregnant women (Lygre at al., 2010)[321]. However, there is no consensus on the health effects related to such exposure. A case-control study of 1117 low birth weight infants and 4468 controls in Washington State, for instance, found no association between low birth weight and dental amalgam restorations in the mothers during pregnancy (Hujoel et al., 2005[322]). In a randomised clinical trial, exposure to elemental mercury in amalgam at the levels experienced by the children who participated in the trial did not result in significant effects on neuropsychological function within the 5-year follow-up period (Bellinger et

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al., 2007[306]). Similarly, in a recent study, no correlation between Hg exposure and autism markers was found in autistic children (Woods, et al., 2010)[323].

Many studies on health effects of mercury concluded that further research is needed into whether health effects occur in children (Counter and Buchanan, 2004; Bates, 2006[250]; Barregard et al., 2008[324]; Burbure et al., 2006[325]).

No link has been observed between Hg exposure and negative health effects with respect to dentist mortality, although the Hg blood level is higher in dentists than in a reference population (SCENIHR, 2008[248]), (Atesagaoglu et al, 2006[326]; Harakey et al., 2003[327]; Tezel et al., 2001[328]; Nylander and Weiner, 1991[329]). However, adverse health effects on dental nurses' reproductive health were observed in New Zealandian dental nurses who handled amalgam without stringent measures to protect them from exposure to Hg vapours (Jones, 2004[330]). Appropriate handling can significantly reduce exposure to mercury (e.g. Jokstad 2011[331]), however amalgam is still handled without sufficient protection from mercury exposure in many dental offices, especially in developing countries; reporting on this issue is incomplete (Munaz et al., 2010)[332]. When considering self-reported symptoms, studies on dental staff workers show increased neuropsychological complaints (Aydin et al., 2003[333]; Bittner et al., 1998[334]; Echeverria et al.,

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Visible health improvement or recovery of the previously mentioned diseases and symptoms has been reported after amalgam removal, also in cases where protective measures had been taken to minimise mercury exposure (Kidd, 2000[343]; Lindh et al., 2002[344]; Engel, 1998[345]; Huggins et al., 1998[346]; Prochazkova et al., 2004[347]; Siblerud et al., 1994[348]; Stejskal et al., 1999[298]; Sterzl et al., 1999[349], 2006[350]; Stromberg and Langworth, 1998[351]; Valentine-Thon et al., 2006[352]; Wojcik et al., 2006[353]).

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Self-reported cognitive symptoms are frequent in persons with amalgam-related complaints, but few studies have focused on their cognitive function. In a recent study, participants with amalgam-related complaints reported more symptoms, mainly musculoskeletal and neuropsychological disorders, compared with control individuals. However, the results revealed no significant difference between the amalgam and control group for any of the cognitive tests used (Sundström et al., 2010)[354]. Moreover, another study showed that negative life events could play a vital role in understanding and explaining amalgam-related complaints (Sundström et al., 2010)[355].

FURTHER RESEARCH NEEDS

Small number of subjects, inadequate exposure data and inadequate control recruitment methods are common limitations for the evaluation of health effects of dental amalgams (Bates, 2006)[250]. Timing of amalgam placements or dental treatment history is often ignored or difficult to track (Roberts et al, 2009[356]). Many of the suspected diseases can also be triggered by several environmental factors (multi-exposure).The toxic effects of all filling materials may also be dependent on dentine permeability and residual dentine thickness (SCENIHR, 2008[248]).

Better designed studies are therefore needed, particularly for investigation of neurodegenerative diseases and effects on infants and children. Sex-related differences in Hg handling and susceptibility to Hg toxicity need to be further investigated. Studies on long-term health effects of dentists' occupational exposure are also needed.

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Annex E: Additional data from the market review on dental amalgam and mercury-free alternatives

The objective of this market review was to gather and analyse information and socio-economic data on the market for dental amalgam and mercury-free alternatives, which could be used to conduct the assessment of policy options.

The data search covered the following key aspects:

- Identity and key characteristics of companies producing and selling dental fillings in the EU
- Number of dentists per Member State
- Number of dental restorations, by type of material used, in each Member State
- Amounts of dental filling materials used in each Member State, by type of material, and future trends
- Costs of dental restorations, by type of material, in each Member State
- Influence of national health insurance schemes on dental restoration costs

Following a review of existing literature and public databases, additional data was mainly collected via tailored questionnaires sent to the various stakeholders as well as telephone interviews with several stakeholders.

E.1 – Demand for dental amalgam

No public EU market data on dental amalgam is available from Eurostat (the category 'Dental cements and other dental fillings, bone reconstruction cements' (Code 32.50.50.10) is too broad to be able to distinguish between the various materials used). Therefore, in order to collect data on dental amalgam demand, the dental fillings manufacturers were contacted directly. Specifically, a questionnaire was send to 24 European dental fillings manufacturers in which they were asked to provide information on the amounts and prices of dental amalgam and Hg-free materials sold in the EU. Follow-up calls were made to the largest companies, but only one company provided individual market data and none of them provided an estimate of the EU market size. The Association of Dental Dealers in Europe (ADDE) and the Federation of the European Dental Industry (FIDE) were contacted as well. Both ADDE and FIDE pointed out that currently they do not hold EU market data on dental filling materials.

Member States were also consulted by questionnaire to obtain data, but only limited data on dental amalgam use was received. Therefore, some of the values are based on assumed correlations between the number of inhabitants and the demand for dental amalgam, for three groups of countries. Member States were categorised in three groups, according to the estimated share of dental restorations performed with dental amalgam (vs. the total number of restorations):

- Group 1 - Dental amalgam is used in less than 5% of the restorations (this group includes Sweden, Denmark, Finland and Estonia, where the use of dental amalgam is either banned or very limited);
- Group 2 – The share of dental amalgam restorations is estimated at between 6% and 35%;
- Group 3 – The share of dental amalgam restorations is estimated at more than 35%.

Information on the share of dental restorations performed with dental amalgam was obtained via the study questionnaire, for twelve Member States. For the other Member States, it was assumed taking into account the following parameters:

- Possible restrictions in place concerning the use of dental amalgam (legal restrictions or recommendations by national authorities)
- Attention paid to aesthetic aspects
- Economic wealth

The estimation of the dental amalgam use in the countries for which data is not available is based on the average demand per capita calculated for the countries that belong to the same group. For example, the demand in Belgium is calculated by multiplying the population of Belgium by the average demand per capita for Germany+ Ireland. The results are shown in the table below.

Table 18: Estimation of annual dental mercury demand per Member State

Country	Data from questionnaires' replies or from previous studies	Estimated by BIO	Amount of Hg contained in dental amalgam (kg)
Group 1 - Share of dental amalgam ≤5%			
Denmark	X		87
Estonia		X	13
Finland		X	51
Sweden	X		0.02
Italy	X		200
Group 2 - Share of dental amalgam between 6% and 35%			
Bulgaria		X	502
Belgium		X	768
Cyprus		X	53
Germany	X		2,710
Hungary		X	250
Ireland	X		514

Country	Data from questionnaires' replies or from previous studies	Estimated by BIO	Amount of Hg contained in dental amalgam (kg)
Luxembourg		X	29
Netherlands		X	367
Portugal		X	622
Spain		X	2,690
Latvia		X	159
Group 3 - Share of dental amalgam > 35%			
Austria	X		800
Czech Republic	X		3,600
France	X		17,000
Greece		X	2,699
Lithuania		X	795
Malta		X	99
Poland	X		10,000
Romania		X	5,124
Slovakia		X	1,295
Slovenia	X		630
UK	X		4,000
		TOTAL EU27	**55,058**

E.2 – Demand for Hg-free filling materials

The estimation of the number of Hg-free restorations was based on the questionnaire responses by Member States. Germany, Ireland, Austria, and Sweden and Italy provided estimates on the share of dental restorations per dental filling material. Other countries (Estonia, Denmark, Bulgaria, Hungary, Latvia, Czech Republic, Slovakia Slovenia and the UK) provided estimates on the share of dental amalgam and Hg-free fillings without specifying the exact types of alternative fillings.

Averages values for the above countries were used to estimate the values for the remaining Member States. In this exercise, the same country groups as in the determination of dental amalgam use were used to define the total shares of dental amalgam and Hg-free restorations. The determination of the specific Hg-free restorations (as shares of total Hg-free restorations) was based on the average of all countries for which data exist, regardless of the group each country belongs to. It is therefore assumed that the relative shares of Hg-free restorations are similar in all Member States.

The estimated shares of dental amalgam and Hg-free materials restorations are applied to the dental amalgam demand estimated in the previous section. Specifically, the number of dental amalgam restorations are calculated by dividing the total Hg demand by the average amount contained in one dental amalgam filling (assumed at approximately 600 mg per restoration). The table below shows the results for each Member State.

Table 19: Estimated shares of restorations per filling material type and per Member State in 2010

Country	Dental amalgam	All Hg-free materials	Total dental amalgam restorations/year*	Total Hg-free materials restorations/year
Group 1				
Denmark	5%	95%	195,750	3,719,250
Estonia	5%	95%	28,696	545,217
Finland	3%	97%	114,588	3,322,772
Italy***	1%	99%	450,000	44,550,000
Sweden**	0%	100%	45	5,507,955
Group 2				
Belgium	32%	68%	1,727,391	3,670,705
Bulgaria	30%	70%	1,129,981	2,636,623
Cyprus	30%	70%	119,986	279,968
Germany***	10%	90%	6,097,500	54,877,500
Hungary	16%	84%	562,500	2,953,125
Ireland***	35%	65%	1,156,500	2,147,786
Luxembourg	26%	74%	66,077	183,944
Netherlands	10%	90%	825,407	7,428,667
Portugal	26%	74%	1,400,029	3,897,378
Spain	26%	74%	6,052,613	16,849,167
Latvia	32%	68%	358,289	761,364
Group 3				
Austria***	37%	63%	1,800,000	3,064,865
Czech Republic	92%	8%	8,100,000	675,731
Greece	57%	43%	6,073,066	4,607,669
France	50%	50%	38,250,000	38,250,000
Lithuania	57%	43%	1,788,347	1,356,829

Country	Dental amalgam	All Hg-free materials	Total dental amalgam restorations/year*	Total Hg-free materials restorations/year
Malta	57%	43%	222,599	168,887
Poland	57%	43%	22,500,000	17,070,876
Romania	71%	11%	11,529,405	8,747,424
Slovakia	71%	11%	2,914,249	2,211,057
Slovenia	71%	11%	1,417,500	698,172
United Kingdom	71%	11%	9,000,000	14,684,211

* Assuming 0.6 g Hg per restoration

**Overall shares of restorations with the different materials have been estimated based on data in Concorde/EEB (2007)

***For these MS, overall shares of restorations with the different materials were provided in the responses to the study questionnaire

E.3 – Future trends in demand for dental fillings materials

As part of the study, Member States and dental associations were asked about future trends concerning:

- The number of dental restorations per person and per year (regardless of the material used);
- The use of dental amalgam vs. mercury-free materials.

Based on the thirteen responses received, different trends are expected for the number of dental restorations, with most of the countries expecting an increase in future years. Future trends are influenced by several parameters:

- A continuous improvement of dental health (e.g. due to public health policies) is likely to decrease the need for dental restoration in the long term; however, in some Member States, this may first lead to an increased share of population having access to dental care, resulting in an increase in dental restoration needs in the short term.
- As older people tend to maintain their own teeth longer, more dental restoration treatments are needed for this category of population whose share is increasing.

Responses received are summarised in Table 20 below. Among the eight Member States that provided information on future trends for dental amalgam, the use of this material is expected to decrease or stabilise. Only in the UK, two different views were stated: the British Dental Association projected a stabilisation of the use of dental amalgam, whereas DEFRA projected a decline. Specifically, DEFRA pointed out that dental students in Wales are taught the techniques for alternative materials on posterior teeth and there is an increasing demand for cosmetic dentistry and development of non-amalgam materials. Information provided by these eight Member States cannot be extrapolated to the entire EU, as it is not a representative sample of Member States.

With regard to alternative materials, four Member States reported an expected increase in the share of restorations using composite materials, while no change is expected in Austria. For the other materials, future trends at EU level seem to be relatively uncertain.

Table 20: Expected future trends in dental restorations and use of dental filling materials (based on replies to study questionnaire)

Country	Number of dental restorations (all materials)	Amalgam	Composite materials	Glassionomers	Compomers	Ceramics
Austria	Decrease	Decrease	No change	No change	Decrease	Increase
Denmark	Decrease	Decrease				
Estonia	Unknown	Decrease				
Finland	Unknown					
Germany	No change or decrease	Decrease	Increase	Unknown	Unknown	Increase
Hungary	Unknown					
Ireland	Children: expected increase of non-mercury restorations Adults: no change	Decrease	Increase	No change		No change
Latvia	No change					
Malta	Decrease	Decrease				
Slovakia	No change	Decrease	Increase	Increase	Increase	No change
Slovenia	Increase					
Sweden	Slight increase					
UK	Decrease	Decrease / no change	Increase	No change	Decrease	Decrease

Future projections of dental amalgam use

The tables below provide an overview of the projections of dental mercury demand, in 2025. The calculation was based on the assumption that demand for dental amalgam will decline, so that dental amalgam restorations will represent the following shares of total restorations in 2025:

- In the baseline scenario and Option 1: 5% - 15% in Group 2 and 20% - 30% in Group 3;
- In Option 2: 0% - 10% in Group 2 and 10% - 15% in Group 3;
- In Option 3: 0 – 0.0001% in all groups.

Table 21: Estimated demand for dental mercury in 2025, in the baseline scenario (t)

Country	Min	Max	Average	Difference with 2010 levels
Group 2 countries (projected share of dental amalgam restorations in 2025: 5-15%)				
Bulgaria	113	339	226	451
Belgium	162	486	324	712
Cyprus	12	36	24	47
Germany*	1,829	3,659	2,744	914
Hungary	105	316	211	126
Ireland	99	297	198	495
Luxembourg	8	23	15	24
Netherlands	94	281	187	307
Portugal	159	477	318	522
Spain	687	2,061	1,374	2,257
Latvia	19	57	38	83
Total Group 2	3,302	8,075	5,688	6,009
Group 3 countries (projected share of dental amalgam restorations in 2025: 20-30%)				
Austria	584	876	730	350
Czech Republic	1,053	1,580	1,316	3,544
France	9,180	13,770	11,475	11,475
Greece	1,282	1,923	1,602	2,042
Lithuania	377	566	472	601
Malta	47	70	59	75
Poland	4,749	7,123	5,936	7,564
Romania	2,433	3,650	3,042	3,876
Slovakia	615	923	769	980
Slovenia	254	381	317	533
United Kingdom	2,842	4,263	3,553	1,847
Total Group 3	23,416	35,124	29,270	32,887
EU27	26,717	43,199	34,958	38,897

*In Germany, the share of amalgam restorations is currently 10% and therefore the maximum value is assumed to remain stable until 2025

Table 22: Estimated demand for dental mercury in 2025, in Option 2 (t)

Country	Min	Max	Average	Difference with 2010 levels
Group 2 countries (projected share of dental amalgam restorations in 2025: 0-10%)				
Bulgaria	0.00	226	113	565
Belgium	0.00	324	162	874
Cyprus	0.00	24	12	60
Germany	0.00	3,659	1,829	1,829
Hungary	0.00	211	105	232
Ireland	0.00	198	99	595
Luxembourg	0.00	15	8	32
Netherlands	0.00	187	94	402
Portugal	0.00	318	159	681
Spain	0.00	1,374	687	2,945
Latvia	0.00	67	34	181
Total Group 2	0.00	6603.10	3,302	8,396
Group 3 countries (projected share of dental amalgam restorations in 2025: 10-15%)				
Austria	292	438	365	715
Czech Republic	527	790	658	4,202
France	4,590	6,885	5,738	17,213
Greece	641	961	801	2,843
Lithuania	189	283	236	837
Malta	23	35	29	104
Poland	2,374	3,561	2,968	10,532
Romania	1,217	1,825	1,521	5,397
Slovakia	308	461	384	1,364
Slovenia	127	190	159	692
United Kingdom	1,421	2,132	1,776	3,624
Total Group 3	11,708	17,562	14,635	47,522
EU 27	11,708	24,165	17,936	55,918

Table 23: Estimated demand for dental mercury in 2025, in Option 3 (t)

Country	Min	Max	Average	Difference with 2010 levels
Group 2 countries (projected share of dental amalgam restorations in 2025: 0%-0.0001%)				
Bulgaria	0	0	0	678
Belgium	0	0	0	1036
Cyprus	0	0	0	72
Germany	0	0	0	3658
Hungary	0	0	0	337
Ireland	0	0	0	694
Luxembourg	0	0	0	40
Netherlands	0	0	0	495
Portugal	0	0	0	840
Spain	0	0	0	3632
Latvia	0	0	0	215
Total Group 2	0.00	0.07	0	9,531
Group 3 countries (projected share of dental amalgam restorations in 2025: 10-15%)				
Austria	0	0	0	1080
Czech Republic	0	0	0	4860
France	0	0	0	22950
Greece	0	0	0	3644
Lithuania	0	0	0	1073
Malta	0	0	0	134
Poland	0	0	0	13500
Romania	0	0	0	6918
Slovakia	0	0	0	1749
Slovenia	0	0	0	850
United Kingdom	0	0	0	5400
Total Group 3	0	0	0	50646
EU 27	0	0	0	73855

E.4 – Cost comparison between dental amalgam and alternative materials

The table below presents the unit costs of dental restorations using dental amalgam or Hg-free materials. These correspond to the actual costs borne by patients, i.e. taking into account possible amounts reimbursed by the national health insurance schemes in place. The data comes from replies to the study questionnaire or publicly available information.

Table 24: Overview of dental restoration costs per Member State (EUR)

Country	Dental amalgam restoration			Hg-free restoration (composite, glass ionomer)		
	Minimum	Maximum	Average	Minimum	Maximum	Average
Austria	25	58	41	85	160	122
Belgium	5	5	5	15	15	15
Bulgaria	15	15	15	7	7	7
Cyprus	27	27	27	29	29	29
Czech Republic	7	7	7	48	48	48
Denmark	16	48	32	38	42	40
Estonia	35	35	35	40	40	40
Finland	95	95	95	95	95	95
France	5	12	9	5	12	9
Germany	0	0	0	0	80	40
Hungary	11	12	12	16	20	18
Ireland	80	100	90	90	130	110
Italy	100	200	150	100	200	150
Latvia	0	17	9	0	25	13
Malta	30	40	35	40	40	40
Poland	0	0	0	0	37	19
Slovakia	0	22	11	0	30	15
Sweden				0	160	80
UK	0	56	28	0	56	28

Influence of national health insurance schemes

Reimbursement schemes strongly influence the actual costs borne by patients.

The coverage of dental restorations by reimbursement schemes in the 19 Member States that provided such information is summarised in the table below.

Table 25: Coverage of dental restoration by national health insurance schemes

Country	Coverage of dental amalgam	Coverage of Hg-free materials	Same amount reimbursed for both types of fillings[357]	Comments
Austria	X	X	No	Mercury-free filing materials are only reimbursed when placed in front-teeth.
Belgium	X	X	No (fixed %)	When Hg- free filling materials are used, these have to be fixed with an adhesive technique. A Hg-free restoration costs an average extra cost of 11 EUR. Depending on the socio-economic situation of the patient and the age of the patient (children or adult), the amount reimbursed is 100% or 75%.
Bulgaria	X	X	Yes	
Cyprus				There no reimbursement schemes in Cyprus.
Czech Republic	X	X	Yes	The cost of a dental amalgam restoration is 16 EUR out of which 50% is reimbursed
Denmark	X	X	Yes	Amalgam reimbursement: 8,5-12 EUR Glassionomer/plast reimbursement: 8,5 EUR
Estonia	X	X	Yes	Treatment is free of charge up to 19-years old, regardless of the material chosen
Finland	X	X	Yes	
France	X	X	Yes	National insurance scheme reimburses 70% of standard treatment costs whatever the filling material used. Conventional treatment costs range between 17 and 41 EUR depending on the cavity size (but regardless of the material used). Final costs for patients are therefore between 5 and 12 EUR if they use dentists applying conventional treatment costs.
Germany	X	X	Yes	Dental amalgam fillings fully reimbursed (actual cost 20-50 EUR)
Ireland	X	X	No	No reimbursement for mercury-free fillings on back teeth
Italy				There no reimbursement schemes in Italy.
Latvia	X	X	No	Dental treatment of children 0-18 years old is paid from the government. For filling of molars and premolars only amalgam fillings are reimbursed.

[357] If 'yes': possible extra cost for Hg-free materials are to be borne by the patient (or his private insurance)

Country	Coverage of dental amalgam	Coverage of Hg-free materials	Same amount reimbursed for both types of fillings[357]	Comments
Malta				There are no reimbursement schemes in Malta.
Poland	X	X	No	Dental amalgam restorations (actual cost 10-20 EUR) are fully reimbursed by the national health scheme. Hg-free restorations (actual cost 20-37 EUR) are only reimbursed in certain cases, e.g. in children and pregnant women.
Slovakia	X	X	No	Up to 18 years old: restorations are fully covered for amalgam (actual cost: 13-22 EUR), glass ionomer in whole dental arch and composites in front, teeth Adults: Hg-free restorations (actual cost: 13-25 EUR) fully or partially covered excluding ceramics
Slovenia	X	X	Yes	
Sweden		X	No	Dental amalgam is no longer used, except under a few and highly restricted circumstances, as part of the general ban on mercury in Sweden.
United Kingdom	X	X	Yes	Only certain categories of patients can receive free dental care (children, pregnant women, etc.). In Scotland, alternative filling materials are not covered by the national health scheme where the filling involves molar or premolar teeth. Hg-free fillings cost 55 EUR when covered by the national healthcare scheme whereas under private treatment the cost varies between 58 and 702 EUR.

Source: Member States' responses to the study questionnaire, completed by internet searches.

E.5 – Key actors

Dentists

Numbers of practising dentists per 100,000 inhabitants and total numbers of dentists are shown in the tables below. The definition of 'dentist' varies between Member States[358]. For this reason, Eurostat defines three different categories of dentists: practising dentists, professionally active dentists and dentists licensed to practice. In the context of this project, the number of practising dentists is considered as more appropriate to be used as a potential indicator. However, the other two categories are also considered when data on practising dentists is not available.

[358] The different definitions used by each Member States are outlined in Eurostat's Concepts and Definitions Database (available at: http://ec.europa.eu/eurostat/ramon/nomenclatures/index.cfm?TargetUrl=DSP_GLOSSARY_NOM_DTL_VIEW&StrNom=CODED2&StrLanguageCode=EN&IntKey=16451485&RdoSearch=CONTAIN&TxtSearch=dentist&CboTheme=&IntCurrentPage=1)

In the EU27, there are approximately 62 dentists for every 100,000 inhabitants. In 2009, the total number of dentists in the EU27 was approximately 310,500[359]. Cyprus has the highest number of practising dentists per inhabitant (93 per 100,000 inhabitants in 2008) and Poland has the lowest population coverage (32 dentists per 100,000 inhabitants in 2009). Germany has the highest total number of practising dentists (approximately 62,000).

Table 26: Statistics on the number of dentists, 2009 - Source: Eurostat

Country	Number of practising dentists per 100,000 inhabitants	Total number of practising dentists
Austria	55.2	4,619
Belgium	70.6	7,655
Bulgaria	85.8	6,493
Cyprus*	93.2	743
Czech Republic	67.5	7,092
Denmark*	80.1	4,414
Estonia	89.2	1,196
Finland*	75.6	4,007
France	64.6**	41,799***
Germany	78.6	64,287
Greece	130.7**	14,774***
Hungary	49.1	4,920
Ireland	60.5***	2,702**
Italy	51.8**	31,085***
Latvia	67.2	1,510
Lithuania	70.5	2,347
Luxembourg	80.5	404
Malta	43.3	179
Netherlands*	51.1**	8,420***
Poland	31.9	12,169
Portugal	72.0***	7,656**
Romania	58.0	12,448

[359] This number mostly includes practicing dentists. For countries where no information is available, the number of professionally active or licensed to practice dentists is used instead.

Country	Number of practising dentists per 100,000 inhabitants	Total number of practising dentists
Slovakia	48.5**	2,633***
Slovenia	60.4	1,236
Spain	58.1***	26,725**
Sweden*	80.5	7,449
United Kingdom	50.9	31,560

*Data corresponds to 2008
** *Professionally active dentists
**Dentists licensed to practise

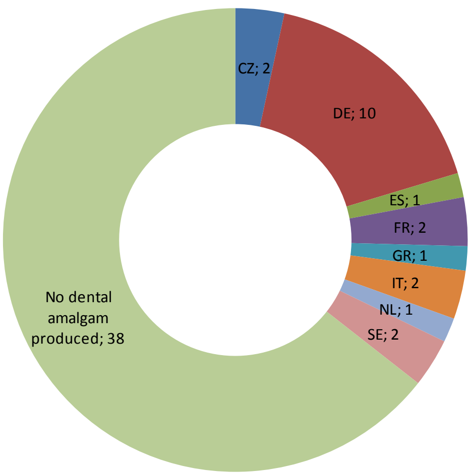
Dental filling manufacturers

It is estimated that 57 main companies produce dental filling materials in the EU, of which:

- 17 companies produce both dental amalgam and Hg-free materials
- 38 companies only Hg-free materials
- 2 companies produce only mercury for applications in dental restorations[360].

The figure below provides an overview of the dental filling producers in the EU. A list of these companies is provided in the table below.

Figure 15: Main dental filling producers in the EU (number by Member State)



[360] The Czech company Bome S.R.O. supplies bulk mercury directly to dental practices or to other manufacturers that produce dental amalgam capsules.

Table 27: Producers of dental filling materials in the EU 27

Company	Country	Dental amalgam	Hg-free 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
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

Company	Country	Dental amalgam	Hg-free materials	Website	Types of materials
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, compomeres, 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
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

Company	Country	Dental amalgam	Hg-free materials	Website	Types of materials
					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
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

Annex F: Additional data on environmental costs of dental amalgam use

This annex provides a compilation of data on costs associated with the environmental impacts of dental amalgam. In economic terms, such costs correspond to 'negative externalities' associated with the use of dental amalgam. Such costs are currently not fully reflected in the sale price of dental amalgam, however they are borne by different actors, in particular EU taxpayers.

Environmental costs incurred by dentists

Environmental costs incurred by dentists mainly include costs for the installation and maintenance of amalgam separators and costs for the collection and treatment of amalgam waste as hazardous waste. These costs result from the need for dental practices to comply with EU waste legislation, which considers dental amalgam waste as hazardous waste. It can be assumed that such costs are to some extent included in the dentists' fees.

Cost of amalgam separators

A study carried out by the US Environment Protection Agency (EPA)[361] estimated the cost of amalgam separators through their life-cycle, including purchase or lease, installation, maintenance, replacement, transportation and recycling costs. The table below shows the estimated costs, per size of dental office and per life-cycle stage. The distribution of costs indicates that costs of amalgam separators are very much dependent on the size of dental offices as well as the installed model. In addition, the amount of wastewater discharged determines the needs for maintenance and replacements (e.g. of traps and filters).

Table 28: Estimated annual costs for amalgam separators by size of dental office (2008)

Type of cost	Small (1-4 chairs)	Medium (5-12 chairs)	Large (+12 chairs)
Purchase	$228–$1,370 (€159-€955)	$760–$2,510 (€530-€1,749)	$2,850–$10,000 (€1,986-€6,969)
Installation	$114–$228 (€79-€159)	$143–$297 (€100-€207)	$228–$1,140 (€159- €794)
Maintenance	$0–$228 (€0-€159)	$0–$228 (€0-€159)	$0–$228 (€0-€159)
Replacement	$57–$856 (€34-€597)	$86–$856 (€60-€597)	$571–$2,400 (€398-€1,673)
Estimated annual cost	**$211–$1,073 (€147-€748)**	**$293–$1,110 (€204-€767)**	**$1,990–$4,630 (€1,387-€3,227)**

Source: USEPA (2008), Health Services Industry Detailed Study – Dental Amalgam

361 USEPA (2008), Health Services Industry Detailed Study – Dental Amalgam (http://water.epa.gov/lawsregs/lawsguidance/cwa/304m/upload/2008_09_08_guide_304m_2008_hsi-dental-200809.pdf)

A report for the European Commission in 2008[362], estimated the cost of amalgam separators at EUR 400-500 per year, including installation, servicing, in-situ evaluation of filter efficiency and accreditation, based on information from Denmark.

- **Costs of hazardous waste management**

The current and historical use of dental amalgam results in the need to separately collect and treat dental amalgam waste as hazardous waste. This mainly includes surplus amalgam waste from sludge accumulated in amalgam separators and chair-side traps and, to a lesser extent, solid waste from the preparation of new amalgam. Indicative annual waste management costs provided by some Member States as part of this study are shown in Table 29.

Table 29: Cost of dental amalgam waste management for dentists

Country	Average cost per year
Austria	100 EUR
Germany	0-600 EUR
Ireland	500 EUR
Malta	250 EUR
Sweden	100 EUR
UK	600EUR
Average	258 - 358 EUR

It is important to point out that these costs cannot be attributed solely to dental amalgam waste, since amalgam separators also trap waste from Hg-free materials.

[362] COWI/Concorde (2008) Options for reducing mercury use in products and applications, and the fate of mercury already circulating in society. Report for DG ENV

Environmental costs incurred by crematoria

Environmental costs incurred by crematoria correspond to the installation and maintenance of technical devices to capture mercury in flue gases and disposal of captured mercury as hazardous waste. According to DEFRA[363], such costs are partly or fully passed on to crematoria's customers.

Estimates of costs for different abatement measures are presented in the table below.

Table 30: Cost of strategies to avoid Hg pollution related to cremation

Option	Geographical scope/ year	Cost (EUR /kg Hg)	Reduction potential	Reference
Remove dental amalgam fillings at death	Sweden, estimated 2004	400	Large	Hylander et al, 2006[364]
Flue gas cleaning with carbon at crematoria	Sweden, estimated 2004	170,000–340,000	Medium/Large	Hylander et al, 2006
Flue gas cleaning with carbon at crematoria	UK, estimated 2004	29,000	Medium/Large	Hylander et al, 2006
Remove mercury from crematoria gases (cold start furnace)	OSPAR Convention Area, 2003	25,000 to 37,000	Medium/ Large	Derived from OSPAR 2003[365]
Remove mercury from crematoria gases (warm start furnace)	OSPAR Convention Area, 2003	25,000 to 37,000	Medium/ Large	Derived from OSPAR 2003

The report conducted by COWI/Concorde[366] for the European Commission provides estimates on the cost of bag filters with carbon injection in Denmark (considered as one of the most relevant technologies). The cost of this type of installation is more expensive in comparison to similar industrial installations due to additional costs that arise from works that are carried out to improve the aesthetics. For crematoria that already have bag filters installed, COWI/Concorde estimated the cost of adding a carbon dispenser at approximately EUR 8,000 per kg Hg (EUR 22 per cremation) in Denmark and approximately EUR 17,000 per kg Hg in the UK (EUR 45 per cremation) for a 90% Hg removal efficiency.

[363] DEFRA consultations carried out in 2003 and 2004 concerning mercury abatement from crematoria in the UK

[364] Hylander LD and Goodsite ME (2006) Environmental costs of mercury pollution. Science of the Total Environment, 368: 352-370 (http://www.elsevier.com/authored_subject_sections/P09/misc/STOTENbestpaper.pdf)

[365] OSPAR (2003) Mercury emissions from crematoria and their control in the OSPAR Convention Area. OSPAR Commission, London

[366] COWI/Concorde (2008) Options for reducing mercury use in products and applications, and the fate of mercury already circulating in society

A study carried out in 1999[367] in the UK estimates the additional cost per cremation if gas-cleaning techniques are installed in crematoria within the range £47-67 (EUR 33-46) per cremation. The exact value depends on the number of cremations carried out.

According to Federutility-SEFIT[368], in Italy a common technique for reducing mercury air emissions from crematoria is the injection of chemicals (normally sorbalite) before the filtration process. The additional average cost of such a system is estimated at EUR 80,000-100,000 (excl. VAT) whereas the total cost of a filtration system is estimated at EUR 250,000-300,000 (excl. VAT) per cremator. The costs of maintenance are not included. The cost of sorbalite is approximately EUR 3 per cremation.

The Dutch manufacturer of cremators Facultatieve Technologies[369] estimates the costs for the installation of FGT (Flue Gas Treatment) at about EUR 350,000 per cremator (excl. VAT).

The use of activated carbon or specific chemicals for capturing mercury in flue gases results in a significant increase in the volume of hazardous waste and thereby in the disposal cost, as compared to the same weight of mercury disposed of as mercury waste in dental clinics.

Environmental costs related to sewage sludge management options

Estimates on the cost of switching from agricultural use of sludge (landspreading) to other disposal routes are presented in Table 31 below.

Table 31: Costs to switch from agricultural use of sludge (landspreading) to other sludge management methods (EUR /t dry solids)

Member State	From land-spreading to landfill	From land-spreading to co-incineration	From land-spreading to mono-incineration
Austria	124	146	222
Belgium	130	152	233
Denmark	163	183	286
Finland	146	167	258
France	130	152	233
Germany	122	145	220
Greece	111	135	202
Ireland	148	169	261
Italy	124	146	222

[367] FBCA (2000), The Federation of British Cremation Authorities Statistics 1999, Resugram 43. 27-30, cited in DEFRA (2003) Mercury Emissions from crematoria, Consultation an assessment by the Environment Agency's Local Authority Unit

[368] Questionnaire sent in the context of this study.

[369] Questionnaire sent in the context of this study.

Member State	From land-spreading to landfill	From land-spreading to co-incineration	From land-spreading to mono-incineration
Luxembourg	136	157	242
Netherlands	121	144	218
Portugal	104	128	190
Spain	114	137	206
Sweden	133	155	238
United Kingdom	117	140	211
Bulgaria	64	91	126
Cyprus	107	131	195
Czech Republic	87	113	163
Estonia	93	118	172
Hungary	85	111	160
Latvia	90	116	168
Lithuania	81	107	154
Malta	94	119	174
Poland	84	110	158
Romania	76	102	145
Slovakia	85	111	160
Slovenia	99	124	183
EU average	110	134	200

Source: Milieu et al (2010), Environmental, economic and social impacts of the use of sewage sludge on land, Part II, Table 47. Report for DG ENV (http://ec.europa.eu/environment/waste/sludge/pdf/part_ii_report.pdf)

Annex G: Market review of button cell batteries in EU

PRODCOM data on button cells

PRODCOM classifies button cells in the category 31.40.11 "Primary cells and primary batteries". In its subcategories, different types of button cells are listed as presented in Table 32 below.

Table 32: PRODCOM classification of button cells

PRODCOM Code	PRODCOM category
31.40.11.12	Alkaline primary cells and primary batteries with a manganese dioxide cathode, button cells
31.40.11.17	Non-alkaline primary cells and primary batteries with a manganese dioxide cathode, button cells
31.40.11.25	Primary cells and primary batteries with a mercuric oxide cathode, button cells
31.40.11.35	Primary cells and primary batteries with a silver oxide cathode, button cells
31.40.11.52	Lithium primary cells and primary batteries, button cells
31.40.11.56	Air-zinc primary cells and primary batteries, button cells

Although PRODCOM statistics are used and referenced in other EU policy documents regarding trade and economic policy, it does have its limitations. Many data points are unknown, estimated, confidential and therefore not available.

At the time of drafting this report, PRODCOM statistics for category 31.40.11 were only available for years up to 2007 and not later. As shown in Figure 16 below, majority of the button cells placed on the EU market from 2004 until 2007 were manufactured locally.

Figure 16: EU import, export and production of button cells in million units (Source: PRODCOM)

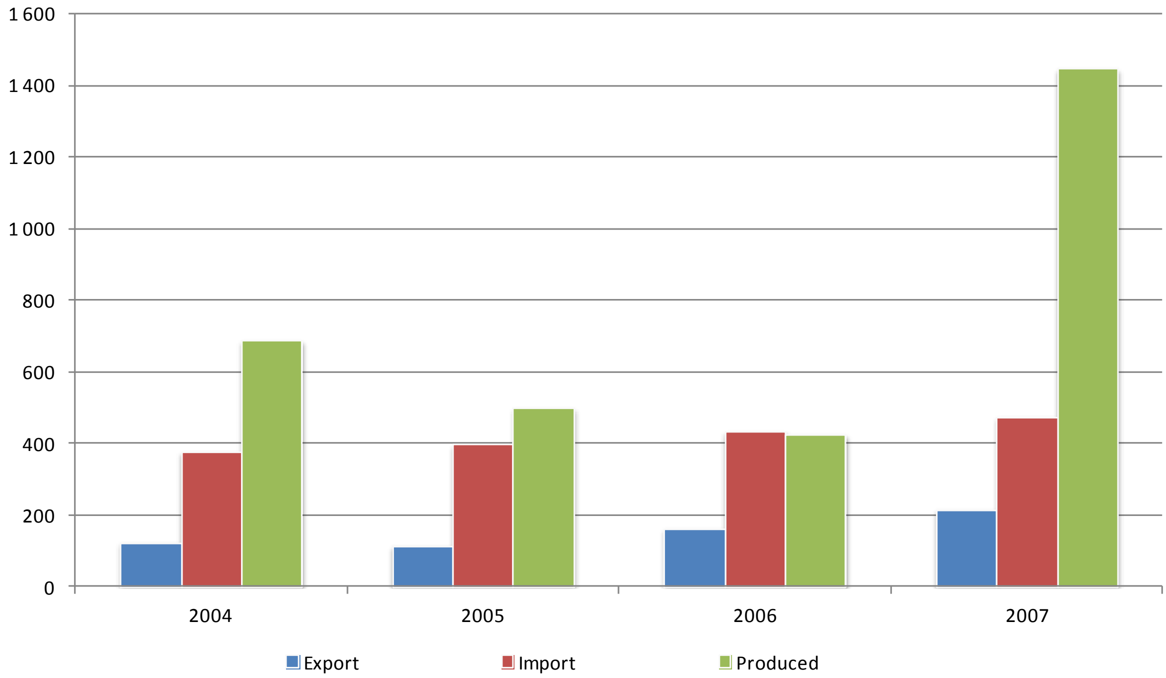


Table 33 presents the quantity (million units) of different types of button cells placed on the EU market from 2004 until 2007. The overall button cells market decreased by around 26% between 2004 and 2006. However, it is reported that from 2006 to 2007, the button cell market in EU grew by approximately 145%; this huge increase is in sharp contrast with the declining market trend from 2004 till 2006.

Since 2008, PRODCOM classifies button cells in the broad category NACE 27.20 'manufacture of batteries and accumulators' and there is, no longer a detailed level of segregation such as for the data reported under category 31.40.11 until 2007.

Table 33: Quantity (million units) of different types of button cells placed on the EU market from 2004 until 2007 (Source: PRODCOM)

Button cell type	2004	2005	2006	2007
Alkaline	287	266	368	465
Mercury oxide	0.12	1.02	0.35	0.29
Silver oxide	47	67	75	78
Lithium	163	205	194	191
Zinc air	447	243	60	973
Total	**943**	**782**	**697**	**1 706**

Stakeholders inputs on button cells market in EU

EPBA reported the sales of its member companies for different types of button cells placed on the EU market during the past seven (see Table 34 below). These trends show that the button cells market in EU in year 2010 was 29% higher than in 2004. They also show that, while the alkaline button cells market has been stable, the market for zinc-air and lithium button cells has increased since 2007.

Figure 17: Sales (in million units) of EPBA member companies for different types of button cells sold in EU for the period 2004-2010 (Source: EPBA)

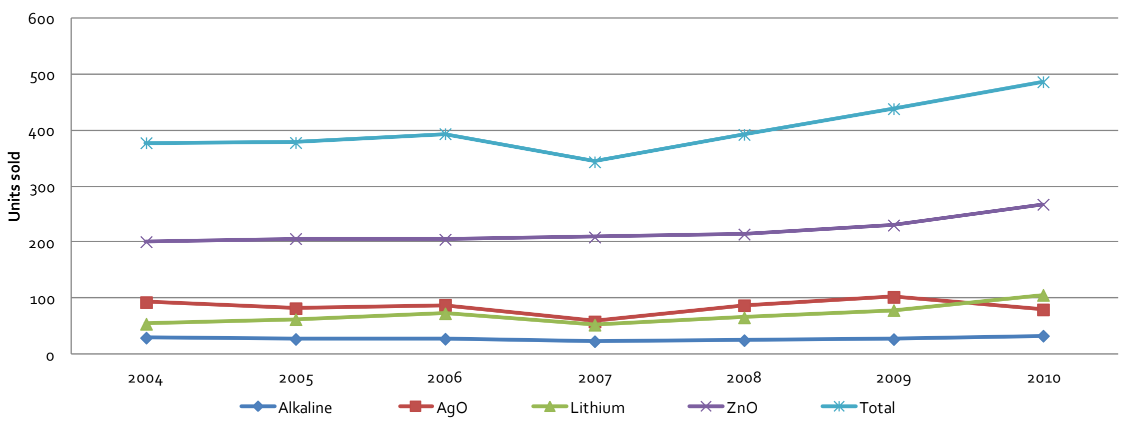


Table 34: Sales (in '000 units) of EPBA member companies for different button cell technologies in EU in 2010 (Source: EPBA)

Member State	Alkaline	Lithium	Zinc Air	Silver Oxide	Total
	Typical Hg content (% by weight)				
	0-0.9%	0%	0-2%	0-1%	
Austria	431	1 610	4 891	759	7 692
Belgium	1 118	3 101	4 111	3 845	12 175
Bulgaria	8	20	13	10	51
Cyprus	4	0	1	10	26
Czech Republic	723	1 296	1 824	1 185	5 027
Denmark	188	1 041	19 750	603	21 582
Estonia	10	17	14	89	503
Finland	552	1 697	1 685	479	4 413
France	4 825	12 172	36 827	10 370	64 194
Germany	6 246	38 382	53 792	20 684	119 105
Greece	563	1 145	1 605	2 226	5 539
Hungary	623	672	1 248	465	3 008

Member State	Alkaline	Lithium	Zinc Air	Silver Oxide	Total
	Typical Hg content (% by weight)				
	0-0.9%	0%	0-2%	0-1%	
Ireland	55	175	2 091	228	2 550
Italy	3 753	7 817	14 709	13 099	39 378
Latvia	254	164	0	32	450
Lithuania	19	22	8	7	57
Luxembourg	42	111	122	47	32
Malta	12	3	0	3	66
Netherlands	802	3 314	21 626	1 887	27 629
Poland	4 165	2 128	5 170	911	12 374
Portugal	18	422	3 361	65	4 615
Romania	403	597	1 080	495	2 575
Slovakia	245	502	365	527	1 638
Slovenia	86	254	360	200	900
Spain	1 711	3 628	26 301	5 410	37 050
Sweden	736	2 834	5 692	1 430	10 692
UK	4 693	22 557	60 863	13 680	101 792
EU-27	**32 818**	**106 284**	**267 902**	**79 601**	**486 605**

Nowadays an increasing number of manufacturers are producing mercury-free versions of various button cells types. It must however be noted that button cells with different chemistries generally are not interchangeable, e.g. hearing aids cannot be run with silver-oxide or lithium button cells. Therefore, the development of mercury-free alternatives must be carried out for each chemistry of button cells.

- **Lithium button cells**

All the lithium button cells sold in the EU market are already completely mercury-free.

- **Silver-oxide button cells**

Four out of the five manufacturers who responded to the questionnaire survey confirmed that the performance parameters such as self-discharge, leak resistance, capacity and pulse capability of mercury-free silver-oxide button cells are the same for all application areas as compared to traditional mercury-containing silver-oxide button cells. The mercury-free alternatives also have a similar lifetime during use phase as compared to the mercury-containing silver-oxide button cells. Although all the five manufacturers pointed out that at present, the cost of the mercury-free alternatives is a bit higher (approximately 10% higher) than the mercury-containing versions, the cost difference is decreasing. One of the manufacturers suggested that additional process steps could lead to overall improvement of productivity of the mercury-free button cells. The most significant parameter influencing the cost of these button cells is the high price of raw materials such as silver, which however has the same effect on the price of both mercury-containing and mercury-free button cells.

Four out of the five manufacturers who responded to the questionnaire survey expect the share of mercury-free button cells to increase in the silver-oxide button cells market in EU[370].

- **Alkaline button cells**

Four out of the five manufacturers who responded to the questionnaire survey confirmed that today it is technically feasible to replace mercury-containing alkaline button cells by their mercury-free alternatives for all applications. They remarked that the performance level of mercury-free alkaline button cells is already similar to the mercury-containing alkaline button cells.

One of the manufacturers pointed out that mercury-free alkaline button cells have some leakage issues and are therefore currently not safe to be used for certain specialised high drain applications requiring very low impedance. Another manufacturer who responded to the questionnaire survey however claimed that their company has successfully developed and introduced in the market mercury-free alkaline button cells for all applications.

Similar to mercury-free silver-oxide button cells, all five manufacturers commented that at present the cost of the mercury-free alternatives is a bit higher (approximately 10% higher) than the mercury-containing alkaline button cells.

Four out of the five manufacturers who responded to the questionnaire survey expect the share of mercury-free button cells batteries to increase in the alkaline button cells market in EU[371].

- **Zinc-air button cells**

Four out of the five manufacturers who responded to the questionnaire survey confirmed that today it is technically feasible to replace mercury-containing zinc-air button cells by their mercury-free alternatives for all applications. One of the manufacturers however pointed out that the capacity and pulse performance of mercury-free zinc-air button cells still needs to be improved to bring it to the level offered by mercury-containing zinc-air button cells.

Similar to mercury-free silver-oxide and alkaline button cells, all five manufacturers commented that at present the cost of the mercury-free alternatives is a bit higher (approximately 10% higher) than the mercury-containing zinc-air button cells. They further added that projected productivity improvements and economies of scale would however bring down the cost of manufacturing mercury-free zinc-air button cells to the same level as the mercury-containing ones.

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[370] For example: In 2005, Sony developed the first mercury-free silver oxide button cell and by 2007, Seiko Watch Corporation achieved the complete switchover from mercury-containing silver oxide button cells to their mercury free alternatives in quartz watches.

[371] For example in 2009, Sony developed the first Hg-free alkaline button cell. Today, most of the manufacturers of button cells are manufacturing mercury-free alkaline button cells and are primarily based in Asia (mainly China).

Four out of the five manufacturers who responded to the questionnaire survey expect the share of mercury-free button cells batteries to increase in the zinc-air button cells market in EU.

- **Button cells waste management in EU**

Many compliance organisations in EU are involved in the collection of waste batteries in each of the Member States. The collected waste button cells are then sent to recycling plants. A list of the main recycling companies engaged in the recycling of different types of button cells waste arising in EU is provided in the table below.

Table 35: Main companies involved in the recycling of button cell batteries waste arising in EU[372]

Company	Country	Mercury oxide[373]	AgO	ZnO	Alkaline
		Typical Hg content (% by weight)			
		30-40%	0-1%	0-2%	0-0.9%
Batrec Industrie Ag	Switzerland	Yes	Yes	Yes	Yes
Recypilas S.A.	Spain	Yes	Yes	Yes	Yes
Claushuis Metaalmaatschappij B.V.	Netherlands	Yes	Yes		Yes
Engelhard	EU		Yes		
Indaver Relight Nv	Belgium	Yes	Yes	Yes	Yes
Inmetco	USA		Yes	Yes	
MBM	Germany	Yes	Yes	Yes	Yes
Mercury Recycling Ltd.	United Kingdom	Yes	Yes	Yes	Yes
NQR GmbH	Germany	Yes	Yes	Yes	Yes
Quicksilver Recovery Services	United Kingdom	Yes	Yes		Yes
Trienekens AG	Switzerland	Yes			
RECYKLACE EKOVUK	Czech Republic	Yes	Yes	Yes	Yes

Based on this list, from a technology point of view, it is evident that recycling technologies exist for all different types of button cells currently marketed in EU.

Quantities of button cell battery waste (as per country of origin) recycled in the EU by EBRA member companies for three Member States in 2009 are presented in the table below.

[372] Source : EPBA (2009)

[373] Mercury oxide button cell batteries are now prohibited except for a few specific applications, but such batteries are still present in the waste stream

Table 36: Quantities of button cell battery waste recycled (in tonnes) as per country of origin of button cell battery waste in 2009 (Source: EBRA)

Member State	Quantity recycled (in tonnes)
France	31
Netherlands	16
Spain	10

Annex H: Use of amalgam separators

Table 37: Use of amalgam separators in EU27

Country	Legal requirement to install amalgam separators	Estimated % dental clinics equipped with amalgam separators	Additional requirements	Maintenance requirements and actual efficiency levels	Information source
Austria	Yes	100%	Required in new and existing dental offices; 95% min efficiency; documented evidence of proper maintenance required; max concentration of Hg: 0.01 mg/l	Maintenance required by law, with documented evidence and periodic inspections of authorities concerning the management of waste.	Questionnaire 2011 (Dental Chamber and Ministry of the Environment)
Belgium	Yes	80% (in 2005)	Flanders: certification; max concentration of Hg: 0.01 mg/l Walloon Region: max concentration of Hg: 0.3 mg/l Brussels: max concentration of Hg: 0.03 mg/l	In Brussels: Maintenance required by law.	Questionnaire 2011 (IBGE Brussels) and 2005 EC survey
Bulgaria	No		Amalgam separators are advised but are not yet mandatory. However, all modern dental chairs are equipped with amalgam separators.		Questionnaire 2011 (Ministry of the Environment)
Czech Republic	Yes	100%	Required for new and existing practices. Min efficiency: 95% Hg limit value: 0.05 mg/l		Questionnaire 2011 (Ministry of the Environment) and EC 2005 survey
Cyprus	No	Most dental clinics have modern equipment and therefore amalgam separators		Periodic inspections are carried out by public authorities.	Questionnaire 2011 (Ministry of the Environment) and EC 2005 survey

Country	Legal requirement to install amalgam separators	Estimated % dental clinics equipped with amalgam separators	Additional requirements	Maintenance requirements and actual efficiency levels	Information source
Denmark	No	100%	No obligatory legal requirement, however in practice there are separators in every dental clinic due to a guidance document from the Ministry of The Environment. All municipalities follow this guidance, as they are in charge of the waste water treatment and surface water quality within their municipality.	Periodic inspections are carried out by public authorities.	Questionnaire 2011 (Danish EPA)
Estonia	No	Amalgam separators and filters installed only in a few facilities.			EC 2005 survey
France	Yes	90% (in 2005)	95% min efficiency		EC 2005 survey
Finland	Yes	100%	Required for new and existing dental practices. 95% min efficiency		Questionnaire 2011 (SYKE) and EC 2005 survey
Germany	Yes	100%	95% min efficiency; ISO 11143; max concentration of Hg: 0.005 mg/l	Inspection by qualified technicians of national authorities is carried out every 3-5 years.	Questionnaire 2011 (German Dental Association)

Country	Legal requirement to install amalgam separators	Estimated % dental clinics equipped with amalgam separators	Additional requirements	Maintenance requirements and actual efficiency levels	Information source
Greece	No	Amalgam separators installed in most recent facilities		A survey conducted in the Thessaloniki urban area in 2006, it was noted that none of the dental units used amalgam chariside traps or amalgam separators. Some had the appropriate equipment, but used the traps only to avoid clogging in the pipes, and the contents were washed out in the washstands of the dental units. Hg-bearing dental wastes were not managed properly by 80% of dentists and metalbearing waste was handled in accordance with internationally established best management practices by less than 50% of dentists[374].	EC 2005 survey; Kontogianni et al. 2008 (Survey on dental waste management in the Thessaloniki urban area)
Hungary	No	New and modern dental clinics tend to be equipped with amalgam separators.	The installation of amalgam separators is only recommended and therefore not uniformly applied.		Questionnaire 2011 (Ministry of the Environment)
Ireland	no (but voluntary initiatives)			Periodic inspections by public authorities are carried out.	Questionnaire 2011 (Ministry of the Environment)and EC 2005 survey
Italy	Yes	90%	Required in existing and new dental	Yearly Inspections by ASL (local	Questionnaire 2011 (Italian

[374] Dental waste mismanagement was found to be primarily due to the lack of general awareness among dentists that their waste is hazardous and should be managed properly and a lack of regulatory control and support by governmental agencies and dentistry associations.

Country	Legal requirement to install amalgam separators	Estimated % dental clinics equipped with amalgam separators	Additional requirements	Maintenance requirements and actual efficiency levels	Information source
			practices	health authority) on the waste procedures is requried by law	Dental Assoc.)
Latvia	Yes	100%	Required in existing and new dental practices	Maintenance required by law, with documented evidence.	Questionnaire 2011 (Ministry of the Environment)
Lithuania	No				Questionnaire 2011 (Ministry of the Environment)
Luxembourg	?	?			
Malta	Yes	100%		Documented evidence of amalgam separators' maintenance required by law. Yearly inspections by authorities are carried out and the results obtained show a good level of compliance. If a clinic does not comply it is shut down until it complies with specifications.	Questionnaire 2011 (Ministry of the Environment)
Netherlands	Yes	90% (in 2005)	95% min efficiency		EC 2005 survey
Poland	No		Recommended by the national authorities. A regulatory proposal was drafted to make it obligatory but has not been adopted to date.		Verbal information from the Polish Chamber of Physicians and Dentists
Portugal	Yes	90% (in 2005)			EC 2005 survey
Romania	?	?			
Slovakia	No	New facilities			EC 2005 survey

Country	Legal requirement to install amalgam separators	Estimated % dental clinics equipped with amalgam separators	Additional requirements	Maintenance requirements and actual efficiency levels	Information source
		only			
Slovenia	Yes	95%	Required for new and existing dental practices. 85% min efficiency Hg limit value: ,01 mg/L.	Periodic inspections are carried out by the public authorities.	Questionnaire 2011 (Ministry of the Environment)
Spain	?	?			
Sweden	Yes	100%	95% min efficiency	The dentists in Sweden have an obligation to inspect their own equipment. Inspections are also made by the local authorities and by the suppliers of amalgam separators.	Questionnaire 2011 (KEMI)
United Kingdom	Yes	99%	Required for new and existing dental practices 95% min efficiency Separators should meet the requirements of British Standard 'Dental Equipment – Amalgam Separators' (BS ISO EN 111:43 as amended by Cor. 1:2000) Documented evidence of proper maintenance required.	Adequate maintenance is required by law, with documented evidence of it. No inspections by public authorities to date, but a programme is in development.	Questionnaire 2011 (DEFRA)

Annex I: Amalgam waste data

Table 38: Estimated amounts of dental amalgam waste produced in EU Member State

Member State	Year	Dental amalgam waste produced (kg/year)	Mercury in waste produced (kg/year)*	Comments / Data sources
Austria	2010	700	42	Questionnaire 2011- Dental chamber 100% is recycled
Belgium	2005	5,000	300	COWI/Concorde 2008: the waste consists of amalgam + cassette from separator 100% collected as hazardous waste and exported for recycling Questionnaire 2011 - IBGE: 1,088 kg dental amalgam waste produced in the Brussels region in 2009
Bulgaria				
Czech Republic	2009	2,370	142	Questionnaire 2011 - Ministry of the Environment 78% collected as hazardous waste, of which 96% exported (to AT or SK)
Cyprus				
Denmark	2005		900-1,900	COWI/Concorde 2008: 0.8-1.7 t (90%) exported for recovery, 0.05-0.1 t landfilled or incinerated
Estonia	2010	20	1	Questionnaire 2011 - Ministry of the Environment 100% collected as hazardous waste, of which 15% exported
France	2005	42,800-58,000	2,568-3,480	Association Scientifique et Technique pour l'Eau et l'Environnement 2005 (ASTEEE) 100% recycled
Finland	2009	3,500	1,750	Questionnaire 2011 - Finish Institute for the Environment (SYKE) 100% collected as hazardous waste, of which 41% exported. A small amount of the waste is also recycled inside the country (unknown quantities). Hg content estimated at 50%.
Germany	2010	25,000-30,000	1,250-2,400	Questionnaire 2011 - German dental associations (BZÄK and VDDI). Hg content estimated at 5-8% of the waste. 100% recycled
Greece				
Hungary	2006	4	2	COWI/Concorde 2008 - Probably only covers solid waste (surplus of mixed amalgam from preparation) Landfilled or incinerated.
Ireland	2010	2,400	144	Questionnaire 2011 - Ministry of the Environment 100% exported to Germany. Information is based on a limited survey of commercial medical waste collectors and waste shipment brokers in relation to EWC 18 01 10.
Italy	2009	1,407	84	Questionnaire 2011 – Ministry of the Environment 80% of dental amalgam waste collected as hazardous waste is either landfilled or incinerated; 20% is recycled
Latvia				
Lithuania				

Member State	Year	Dental amalgam waste produced (kg/year)	Mercury in waste produced (kg/year)*	Comments / Data sources
Luxembourg				
Malta				
Netherlands	2003	3,900	2,000	COWI/Concorde 2008
Poland	2009	1,657	99	Questionnaire 2011 – Polish Bureau for Chemical Substances (Chemikalia). Based on reported data. The value seems very low in comparison with other MS, therefore the figure estimated by NILU has been used instead.
	2006		7,800	NILU Polska (2010) Cost-benefit analysis of impact on human health and environment of mercury emission reduction in Poland – Stage 3 (http://www.gios.gov.pl/zalaczniki/artykuly/etap3_20101022.pdf). Derived from estimates on dental amalgam use.
Portugal	2002	400	24	COWI/Concorde 2008
Romania				
Slovakia				
Slovenia	2009	2,537	152	Questionnaire 2011 - Ministry of the Environment and COWI/Concorde 2008. Data refers to EWC 18 01 10 In 2006: 68% collected as hazardous waste, of which 93% recycled in Slovenia, the rest being incinerated or landfilled
Spain				
Sweden	2009	6,440	3,220	Questionnaire 2011 - Swedish Chemicals Agency (KEMI). Only exported quantities (to DE) have been provided but there is also some domestic treatment. The total amount of dental amalgam produced may be higher than the value presented here. Hg content estimated at 50%.
United Kingdom	2008	94,192	5,652	Questionnaire 2011 - British Dental Association. Data for England & Wales only, corresponding to EWC Code 18.01.10. Treatment methods in 2008: 5.14 t - Incineration with energy recovery (5%) 1.312 t - Incineration without energy recovery (1%) 7.13 t - Recycling / reuse (8%) 66.76 t - Transfer (Disposal) (71%) 13.85 t - Transfer (Recovery) (14%)
		TOTAL (17 MS)	**38,027 – 47,777**	

*Shaded cells correspond to data estimated by BIO assuming an average Hg content of 6% (based on % found in DE and FR), most of the waste being assumed to consist of sludge from amalgam separators. Only for HU the Hg content was assumed at 50% since the small quantity of waste is supposed to be mainly surplus mixed amalgam from preparation.

Annex J: Sewage sludge management statistics

Table 39: Sewage sludge produced in the Member States and treatment methods 2006-2009 (Source: Eurostat)

1 - Agricultural use of sewage sludge from urban wastewater

2 - Composting of sewage sludge from urban wastewater

3 - Incineration of sewage sludge from urban wastewater

4 - Landfill of sewage sludge from urban wastewater

5 - Other methods of disposal of sewage sludge from urban wastewater

		2006						2007					
		1	2	3	4	5	total 2006	1	2	3	4	5	total 2007
Belgium	Millions of kg	10	0	68	0	44	122	11	0	69	0	45	125
	% of total	8%	0%	56%	0%	36%		9%	0%	55%	0%	36%	
Bulgaria	Millions of kg	12	0	0	16	0	28	6	0	0	21	0	27
	% of total	43%	0%	0%	57%	0%		22%	0%	0%	78%	0%	
Czech Republic	Millions of kg	48	90	0	14	23	175	55	80	0	9	28	172
	% of total	27%	51%	0%	8%	13%		32%	47%	0%	5%	16%	
Denmark	Millions of kg							83		22	8	27	140
	% of total							59%		16%	6%	19%	
Germany	Millions of kg	612	467	965	5	67	2116	593	444	1015	4		2056
	% of total	29%	22%	46%	0%	3%		29%	22%	49%	0%		
Estonia	Millions of kg	3	1	0	4	18	26	3	1	0	5	19	28
	% of total	12%	4%	0%	15%	69%		11%	4%	0%	18%	68%	
Ireland	Millions of kg							61			5	22	88
	% of total							69%			6%	25%	
Greece	Millions of kg	0	0	0	123	3	126	0	0	2	74	58	134
	% of total	0%	0%	0%	98%	2%		0%	0%	1%	55%	43%	
Spain	Millions of kg	687	0	41	168	169	1065	864					1153
	% of total	65%	0%	4%	16%	16%		75%					
France	Millions of kg												
	% of total												
Italy	Millions of kg												
Cyprus	Millions of kg							4	3	1	0	0	8
	% of total							50%	38%	13%	0%	0%	
Latvia	Millions of kg	9	2	0	0	10	21	8	2	0	0	9	19
	% of total	43%	10%	0%	0%	48%		42%	11%	0%	0%	47%	
Lithuania	Millions of kg	20	5	0	6	0	31	25	7	0	9	0	41
	% of total	65%	16%	0%	19%	0%		61%	17%	0%	22%	0%	
Luxembourg	Millions of kg	4	3	1	0	0	8	4	3	1	0	0	8
	% of total	50%	38%	13%	0%	0%		50%	38%	13%	0%	0%	
Hungary	Millions of kg			0				148	7	2	77	26	260
	% of total							57%	3%	1%	30%	10%	
Malta	Millions of kg												
	% of total												
Netherlands	Millions of kg	0	4	325	15	16	360	0	0	325	0	14	339
	% of total	0%	1%	90%	4%	4%		0%	0%	96%	0%	4%	
Austria	Millions of kg	39	74	98	25	18	254						
	% of total	15%	29%	39%	10%	7%							
Poland	Millions of kg	81	28	4	147	241	501	98	25	2	125	284	534
	% of total	16%	6%	1%	29%	48%		18%	5%	0%	23%	53%	
Portugal	Millions of kg							164			13	12	189
	% of total							87%			7%	6%	
Romania	Millions of kg	0	4		145	7	226	1	3		44	8	100
	% of total	0%	2%		64%	3%		1%	3%		44%	8%	
Slovenia	Millions of kg	0	0	5	9	6	20	0	4	5	9	4	22
	% of total	0%	0%	25%	45%	30%		0%	18%	23%	41%	18%	
Slovakia	Millions of kg	0	34	0	15	6	55	0	37	0	13	5	55
	% of total	0%	62%	0%	27%	11%		0%	67%	0%	24%	9%	
Finland	Millions of kg												
Sweden	Millions of kg	30		0			210	31					217
	% of total	14%		0%				14%					
United Kingdom	Millions of kg						1809						1825

estimated value

Blank cells: data not available

		2008						2009					
		1	2	3	4	5	total 2008	1	2	3	4	5	total 2009
Belgium	Millions of kg	19	0	72	0	44	135		0		0		
	% of total	14%	0%	53%	0%	33%							
Bulgaria	Millions of kg	11	0	0	18	0	29	14	0	0	11	0	25
	% of total	38%	0%	0%	62%	0%		56%	0%	0%	44%	0%	
Czech Republic	Millions of kg	103	69	3	27	18	220						
	% of total	47%	31%	1%	12%	8%							
Denmark	Millions of kg												
	% of total												
Germany	Millions of kg	588	386	1078	2		2054						
	% of total	29%	19%	52%	0%								
Estonia	Millions of kg	2	19	0	1	0	22	0	18	0	4	0	22
	% of total	9%	86%	0%	5%	0%		0%	82%	0%	18%	0%	
Ireland	Millions of kg												
	% of total												
Greece	Millions of kg	0	0	24	72	40	136	0	0	40	109	2	151
	% of total	0%	0%	18%	53%	29%		0%	0%	26%	72%	1%	
Spain	Millions of kg	927					1156	995					1205
	% of total	80%						83%					
France	Millions of kg	512	279	206	90		1087						
	% of total	47%	26%	19%	8%								
Italy	Millions of kg												
Cyprus	Millions of kg												
	% of total												
Latvia	Millions of kg												
	% of total												
Lithuania	Millions of kg	24	8	0	1	0	33	17	10	0	1	0	28
	% of total	73%	24%	0%	3%	0%		61%	36%	0%	4%	0%	
Luxembourg	Millions of kg	5	3	1	0	0	9						
	% of total	56%	33%	11%	0%	0%							
Hungary	Millions of kg												
	% of total												
Malta	Millions of kg							0	0	0	1	0	1
	% of total							0%	0%	0%	100%	0%	
Netherlands	Millions of kg	0	0	336	0	0	336						
	% of total	0%	0%	100%	0%	0%							
Austria	Millions of kg	40	57	91	21	43	252						
	% of total	16%	23%	36%	8%	17%							
Poland	Millions of kg	112	28	6	92	330	568	123	24	9	82	326	564
	% of total	20%	5%	1%	16%	58%		22%	4%	2%	15%	58%	
Portugal	Millions of kg												
	% of total												
Romania	Millions of kg	0	2		36	1	79	0	16		58	2	120
	% of total	0%	3%		46%	1%		0%	13%		48%	2%	
Slovenia	Millions of kg	0	2	7	8	3	20	0	0	17	5	5	27
	% of total	0%	10%	35%	40%	15%		0%	0%	63%	19%	19%	
Slovakia	Millions of kg												
	% of total												
Finland	Millions of kg												
Sweden	Millions of kg	56		1			214	50					212
	% of total	26%		0.5%				24%					
United Kingdom	Millions of kg						1814						1761

estimated value

Blank cells: data not available

Annex K: Mercury content of sewage sludge

Table 40: Estimates of mercury quantities introduced into agricultural soils

Member State	Sewage sludge used in agriculture (t/year of dry matter)[375]	Average Hg content (mg/kg of dry matter)[376]	Total Hg quantities (kg/year)
Austria	38,400	not available	unknown
Belgium	10,927	1.0	10.9
Bulgaria	11,856	1.2	14.2
Cyprus	3,116	3.1	9.7
Czech Republic	59,983	1.7	102.0
Denmark	82,029	not available	unknown
Estonia	3,316	0.6	2.0
Finland	4,200	0.4	1.7
France	787,500	1.1	866.3
Germany	592,552	0.4	237.0
Greece	56	not available	unknown
Hungary	32,813	1.7	55.8
Ireland	26,743	not available	unknown
Italy	189,554	1.4	265.4
Latvia	8,936	4.2	37.5
Lithuania	24,716	0.5	12.4
Luxembourg	3,780	not available	unknown
Malta	not available	not available	unknown
Netherlands	34	not available	unknown
Poland	88,501	4.6	407.1

[375] The data are for years 2006 or 2007, except for Denmark (2002), Finland (2005), Ireland (2003) and Estonia (2005)

[376] For year 2006

Member State	Sewage sludge used in agriculture (t/year of dry matter)[375]	Average Hg content (mg/kg of dry matter)[376]	Total Hg quantities (kg/year)
Portugal	225,300	1.0	225.3
Romania	0	not available	0
Slovakia	33,630	2.7	90.8
Slovenia	18	0.8	0.01
Spain	687,037	0.8	549.6
Sweden	30,000	0.6	18.0
UK	1,050,526	1.2	1,260.6
		Total (20 MS)	4,166
		Total EU27 (extrapolated)[377]	4,400

Source: Milieu, WRC, RPA (2010) Environmental, economic and social impacts of the use of sewage sludge on land – Report for the EC

- Data on sewage sludge production: Part I, Table 1 (http://ec.europa.eu/environment/waste/sludge/pdf/part_i_report.pdf)
- Data on Hg content in sludge: Part II, Table 51 (http://ec.europa.eu/environment/waste/sludge/pdf/part_ii_report.pdf)

[377] For the 7 MS where data on Hg content is missing, it has been assumed that this Hg content is equal to the average value calculated for the 20 other MS

Annex L: Mercury emissions from crematoria

The table below is a compilation of data on mercury emissions from crematoria. Information sources include national reports under the OSPAR Convention, the 2011 overview report issued by the OSPAR Convention ('Overview assessment of implementation reports on OSPAR Recommendation 2003/4 on controlling the dispersal of mercury from crematoria'), responses from stakeholders consulted as part of this study and international cremation statistics. The data includes some mercury emission estimates developed by BIO for those Member States which did not provide information.

Table 41: Estimates of mercury emissions from crematoria in the EU Member States

Country	Year	Crematoria applying mercury removal techniques				Crematoria not applying mercury removal techniques				Total Hg emitted (kg Hg)	Information sources
		Number of crematoria	Number of cremations	Hg emissions (kg Hg)	Comments	Number of crematoria	Number of cremations	Hg emissions (kg Hg)	Comments		
AT	2005	3				7		40	calc. Umweltbundesamt 2009	**>40**	Min. Env. (questionnaire reply)
BE (Wallonia)	2007					3	9,788	19.6		**19.6**	OSPAR report 2011
	2008					3	10,378	20.8		**20.8**	OSPAR report 2011
	2009					3	10,281	20.6		**20.6**	OSPAR report 2011
BE (Brussels)	2008		6,356	1.2	1 single concentration measurement; without filtration system					**1.2**	National report to OSPAR, 2009
	2009		6,348	1.3	4 concentration measurements; with filtration system but filters under calibration/setting					**1.3**	National report to OSPAR, 2009

Country	Year	Crematoria applying mercury removal techniques				Crematoria not applying mercury removal techniques				Total Hg emitted (kg Hg)	Information sources
		Number of crematoria	Number of cremations	Hg emissions (kg Hg)	Comments	Number of crematoria	Number of cremations	Hg emissions (kg Hg)	Comments		
	2010	1	6,119	0.15	2 concentration measurements; with filtration					**0.15**	IBGE Brussels (questionnaire reply)
BE (Flemish Region)	2006	6	28,905	1.0	Emission factor: 0.036 g Hg/cremation					**1.0**	OSPAR report 2011
	2007	6	29,877	1.0						**1.0**	OSPAR report 2011
	2008	6	31,690	1.2						**1.2**	OSPAR report 2011
CY		0				0				**0**	Min. Env. (questionnaire reply)
CZ	2009					27	86,583	173	No information on the existence of mercury removal techniques; Hg emissions estimated by BIO assuming 2 g Hg/cremation	**173**	International cremation statistics
DE	2009	137	462,103	25.4	Emission factor: 184 g Hg/crematorium per year	16	53 968	13.5	Emission factor: 844 g Hg/crematorium per year (for these crematoria: flue gas cleaning techniques in place but not considered as BAT)	**38.9**	OSPAR report 2011
DK	2008	2	7,223	0.4 – 0.7		29	34 565	69.1 – 103.7		**69.5- 104**	OSPAR report 2011

Country	Year	Crematoria applying mercury removal techniques				Crematoria not applying mercury removal techniques				Total Hg emitted (kg Hg)	Information sources
		Number of crematoria	Number of cremations	Hg emissions (kg Hg)	Comments	Number of crematoria	Number of cremations	Hg emissions (kg Hg)	Comments		
	2011	31		Not available		0				**Not available**	EPA (questionnaire reply)
EE	2009					2		6.6	No information on the existence of mercury removal techniques; Hg emissions estimated by BIO assuming 3.3 kg Hg per crematoria per year[378]	**6.6**	International cremation statistics
ES	2009	≈2				≈180		600	Hg emissions estimated by BIO assuming 3.3 kg Hg per crematoria per year	**600**	OSPAR report 2011
FI	2010	0			3 crematoria have plans to install Hg removal devices in 2012-2013	22	21,068	42	2 g Hg per cremation	**42**	SYKE (questionnaire reply)
FR	2010	10-15	19,500	< 6.7	Limit value of 0.2 mg/Nm^3 was used to estimate the load of mercury. This may be an over-estimate.	125-130	132 500	300-400		**307-407**	OSPAR report 2011
GR		0				0				**0**	

[378] This is an average ratio calculated on the basis of data avalable for all MS listed in this table, in the case of crematoria with no Hg removal devices

Country	Year	Crematoria applying mercury removal techniques				Crematoria not applying mercury removal techniques				Total Hg emitted (kg Hg)	Information sources
		Number of crematoria	Number of cremations	Hg emissions (kg Hg)	Comments	Number of crematoria	Number of cremations	Hg emissions (kg Hg)	Comments		
HU	2010					13	50,000	100	Hg emissions estimated by BIO assuming 2 g Hg/cremation	**100**	Min. Env. (questionnaire reply)
IE	2009	0				3	3,800	8.1		**8.1**	OSPAR report 2011
	2010	0				3	3,083	6.5	Emission Factor NAEI UK 2009 (2.125 g Hg/cremation)	**6.5**	Min. Env. (questionnaire reply)
IT	2010	39 (furnaces)[379]	48,058	48	Nb of furnaces applying Hg removal techniques is an estimate based on the Federal Utility company's knowledge of the market Hg emissions estimated by BIO assuming 1 g Hg per cremation (i.e. 50% capture of total average Hg body burden)	50 (furnaces)	47,709	95	Nb of furnaces applying Hg removal techniques is an estimate based on the Federal Utility company's knowledge of the market Hg emissions estimated by BIO assuming 2 g Hg per cremation	**143**	Italian funeral association – Federal Utility (questionnaire reply).
LU	2007		2,157	<0.004 g/h < 0.008 kg	Limit value : 0.1 mg/Nm³ Measured values : <0.001 mg/Nm³ Operating hours: 2,000 h/year	0	0			**≈0**	OSPAR report 2011
	2008		2,108								OSPAR report 2011
	2009		2,267								OSPAR report 2011
LT		0				0				**0**	Min. Env.

[379] One crematorium can have several furnaces

Country	Year	Crematoria applying mercury removal techniques				Crematoria not applying mercury removal techniques				Total Hg emitted (kg Hg)	Information sources
		Number of crematoria	Number of cremations	Hg emissions (kg Hg)	Comments	Number of crematoria	Number of cremations	Hg emissions (kg Hg)	Comments		
											(questionnaire reply)
LV	2009					1		3.3	No information on the existence of mercury removal techniques; Hg emissions estimated by BIO assuming 3.3 kg Hg per crematoria per year	**3.3**	International cremation statistics
NL	2008	38	49,850	1	Use of BAT reduces Hg emissions by 98 to 99.5 %	30	29,150	40	Assumption: 100% emission of mercury in amalgam fillings	**41**	OSPAR report 2011

Country	Year	Crematoria applying mercury removal techniques				Crematoria not applying mercury removal techniques				Total Hg emitted (kg Hg)	Information sources
		Number of crematoria	Number of cremations	Hg emissions (kg Hg)	Comments	Number of crematoria	Number of cremations	Hg emissions (kg Hg)	Comments		
	2010	48	57,439[380]	1.2	Nb of crematoria and cremations from LVC (Landelijke Vereniging van Crematoria) Hg emissions estimated based on data reported to OSPAR for 2009 (0.02 g Hg/cremation)	23	23,454	32	Nb of crematoria and cremations from LVC (Landelijke Vereniging van Crematoria) Hg emissions estimated based on data reported to OSPAR for 2009 (1.37 g Hg/cremation)	**33**	The Facultatieve Group (cremation company) (questionnaire reply)
PL	2011	3	7,621	8	Between 2008 and 2011, 3 new crematoria have been built: it is assumed that they are equipped with Hg abatement devices. Nb of cremations estimated by BIO based on data for 2008 (2,540 cremations per crematoria per year) Hg emissions estimated by BIO assuming 1 g Hg per cremation (i.e. 50% capture of total average Hg body burden)	10	25,402	51	Nb of cremations only available for 2008: 25,402 cremations for 8 crematoria. Hg emissions estimated by BIO assuming 2 g Hg/cremation	**59**	Nb of crematoria in 2008 and 2011 and nb of cremations in 2008 taken from a press article: http://www.newsweek.pl/wydania/1316/kogo-uwiera-urna,83710,1,1
PT	2010					14	8,752	17.5	0.015 to 0.04 mg Hg/Nm^3; Hg emissions estimated by BIO assuming 2 g Hg/cremation	**17.5**	Portuguese association of funerals professionals (questionnaire reply)

[380] Figures including 3,428 cremations from Belgium and Germany (for crematoria applying or not applying Hg removal techniques)

Country	Year	Crematoria applying mercury removal techniques				Crematoria not applying mercury removal techniques				Total Hg emitted (kg Hg)	Information sources
		Number of crematoria	Number of cremations	Hg emissions (kg Hg)	Comments	Number of crematoria	Number of cremations	Hg emissions (kg Hg)	Comments		
RO	2009					1	967	1.9	No information on the existence of mercury removal techniques; Hg emissions estimated by BIO assuming 2 g Hg/cremation	**1.9**	International cremation statistics
SE	2004	33	49,500	7.5		36	16,500	50		**58**	National report to OSPAR, 2004
	2009	41	46,500	7		27	19,500	60		**67**	OSPAR report 2011
	2010	41	≈49,000		Average emission factor: 1.63 g Hg/cremation	24	≈20,777		Average emission factor: 1.63 g Hg/cremation	**114**	KEMI (questionnaire reply)
SK	2009					3		9.9	No information on the existence of Hg removal techniques; Hg emissions estimated by BIO assuming 3.3 kg Hg per crematoria per year	**9.9**	International cremation statistics
SI	2011					2		6.6	No information on the existence of Hg removal techniques; Hg emissions estimated by BIO assuming 3.3 kg Hg per crematoria per year	**6.6**	Min. Env. (questionnaire reply)
UK	2007		All crematoria: 381,067	732			All crematoria: 381,067			**732**	National report to OSPAR, 2009

Country	Year	Crematoria applying mercury removal techniques				Crematoria not applying mercury removal techniques				Total Hg emitted (kg Hg)	Information sources
		Number of crematoria	Number of cremations	Hg emissions (kg Hg)	Comments	Number of crematoria	Number of cremations	Hg emissions (kg Hg)	Comments		
	2009	56	All crematoria: 413,431	unknown		194	All crematoria: 413,431	unknown	Emission factor used: 1.92 g Hg per cremation.	**860**	OSPAR report 2011
	2010	81	26,006	3.75	Information received from members of the CAMEO trading scheme. Emission factor applied to abated cremations is based on the UK NAEI (National Atmospheric Emission Inventory) and assumes 94% Hg removal efficiency.	182	387,774	933	Emission factor applied to unabated cremations is based on the UK NAEI derived emission factor for 2009 using dental amalgam statistics from the UK Department of Health.	**937**	Min. Env. / CAMEO (questionnaire reply)

Additional notes:

BE - Brussels-Capital Region: The environment permit mentions the following emission limit values: before 01/05/2008: 0.2 mg Hg/Nm^3; from 01/05/2008: 0.1 mg Hg/Nm^3

DE - The percentage of crematoria fitted with a mercury abatement technique (BAT) increased from 83.3% to 89.5% between 2004 and 2009. Within this period, the number of crematoria and cremations in Germany increased as well and therefore the total amount of mercury emitted increased from 36 kg to approximately 39 kg.

DK - An agreement was reached in 2007 between The Danish EPA and the Ministry of Ecclesiastical Affairs that existing crematories establish air abatement to reduce mercury emissions from 2011.

ES - Cremation is an increasing practice in the Spanish society, especially when considering increasing difficulties and costs of burials. Measures of mercury emissions from crematories are not included under the E-PRTR register and so, it is difficult to get information on this activity. Currently, there is some information that will be published in the SETAC-2010 regarding estimations of mercury releases from cremations in the Basque Country.

FR - The Ministerial Order of 28 January 2010 introduced an emission limit value for mercury at 0.2 mg/Nm^3. This value is immediately applicable to new installations. A period of 8 years (until 2018) is given to existing installations to become compliant.

IE - There is currently no specific national legislation regarding air emissions from crematoria. One of the crematoria is in the process of commissioning mercury abatement on their cremator (Sept 2011); this cremator accounts for one third of the national cremation figures.

LU- The operation of the crematorium is authorised by « Arrêté n°1/97/0407 » of 1st July 1999 issued by the Environment Ministry, in accordance with modified law of 9 May 1990 concerning hazardous facilities. Mercury emissions in the form of gases or particles are restricted to 0.1 mg/Nm3.

NL - In 2008, 59 % of the deceased were cremated. According to the national association of crematoria, by the end of 2009, 63 % of all cremations will be taking place in crematoria applying mercury removal (activated carbon filter).

SE – The Swedish Federation of Cemeteries and Crematoria (SKKF) considers that to put a selenium capsule in the oven, without subsequent filters, is a removal technique. This view is not shared by the Swedish EPA which makes information from SKKF difficult to use straight off. The official Swedish air emission statistics reports mercury emissions from crematoria at 114 kg 2010. This is a calculation using an emission factor of 1.63 g Hg/cremation. According to SKKF the emission of mercury from crematoria was 29.4 kg in 2010. The truth is possibly somewhere in between but for now the officially reported figure of 114 kg should be used.

UK - In England and Wales, all new crematoria are required to fit mercury control equipment but those conducting fewer than 750 cremations a year have till 2012 to do this In 2005, DEFRA and the Welsh Assembly Government established a 'burden sharing' system to reduce mercury emissions from existing crematoria. It specifies that 50% of cremations (using 2003 baseline figures) should be subject to mercury abatement by end-2012. In 2010, CAMEO (the Crematoria Abatement of Emissions Organisation) stated that it had 151 members, of which 81 said they were abating, 68 said they were not and 2 were still undecided. In 2011, the number of members increased to 168 and 75 have indicated that they will be abating by the deadline of the 1st January 2013 whilst 83 have stated that they will be burden sharing and 10 are still undecided. There are a further 95 crematoria in the UK who are not members of CAMEO so their intentions are not known.

According to DEFRA, Northern Ireland has 1 crematorium which carried out 2,732 cremations in 2010; although there are no data on Hg levels, a good level of compliance is expected with very occasional exceedences usually due to unapproved items left in coffins whilst with the undertaker.

<u>Notes on the data from the OSPAR 2011 overview report:</u>

Several methods are reported for calculating loads emitted from crematoria. The most common is to use an estimate for the amount of mercury in the fillings of each corpse and multiply this by the number of corpses incinerated. This ranges between 1 and 5 g Hg per corpse. Some countries also apply an abatement factor to account for the amount of mercury which is removed during cremation. Several countries which have mercury measurement devices for flue gases calculate the mercury emissions directly from these measurements based on the time the crematoria is operating.

Annex M: Statistics on dental health

The European Statistics of Income and Living Condition (EU-SILC) survey[381] provides data on people with unmet needs for dental examination by sex, age, reason and income quintile. The table below shows the percentage of population with unmet dental needs, whose income falls under the first quintile of equivalised income, and that state as a main reason the high cost of dental care.

Table 42: Share of EU population with unmet needs for dental examination by sex, age, reason and income quintile (%) – Source: Eurostat

GEO/TIME	2004	2005	2006	2007	2008	2009
European Union (EU6-1972, EU9-1980, EU10-1985, EU12-1994, EU15-2004, EU25-2006, EU27)		9.2	7.9	8.2	7.4	7.6
Belgium	5.4	5.0	3.6	4.2	5.1	3.9
Bulgaria				46.2	30.3	25.2
Czech Republic		1.3	1.4	0.9	2.4	1.8
Denmark	6.5	6.7	6.2	7.7	2.7	6.5
Germany (including former GDR from 1991)		14.2	10.5	9.0	5.5	5.8
Estonia	20.0	23.4	22.6	23.1	16.9	9.3
Ireland	2.2	1.9	2.7	3.2	2.5	1.7
Greece	6.9	9.6	8.3	10.1	10.0	11.2
Spain	10.9	7.0	5.5	4.7	6.0	6.5
France	7.3	6.6	6.3	7.5	7.8	8.9
Italy	12.2	11.9	11.7	11.3	13.8	11.8
Cyprus		11.2	11.8	13.1	9.5	7.7
Latvia		35.9	31.1	29.5	25.3	24.4
Lithuania		13.5	16.8	10.5	7.4	5.0
Luxembourg	2.2	1.5	2.3	2.2	1.4	1.5

[381] Available at http://epp.eurostat.ec.europa.eu/cache/ITY_SDDS/en/hlth_care_silc_esms.htm

GEO/TIME	2004	2005	2006	2007	2008	2009
Hungary		11.9	7.5	7.6	6.6	6.4
Malta		1.7	3.7	1.8	1.6	3.1
Netherlands		3.2	2.0	1.6	1.1	2.0
Austria	2.7	2.1	1.5	2.4	3.7	2.8
Poland		15.6	12.9	10.9	6.5	6.5
Portugal	13.8	16.0	15.8	6.4	12.5	20.3
Romania				20.2	16.4	17.8
Slovenia		0.5	0.7	0.3	0.3	0.9
Slovakia		7.5	6.4	5.1	1.9	2.7
Finland	4.9	6.5	3.5	2.2	3.0	2.0
Sweden	9.9	11.9	15.1	9.0	11.7	11.0
United Kingdom		1.0	1.3	0.9	0.6	0.8

Table 43 shows several health care indicators that have been extracted from Eurostat.

Table 43: Health care indicators by group of Member States[382]

Group of Member States	Practicing dentists per capita	Health care expenditure in offices of dentists (EUR per capita in 2009*)	Health care expenditure in offices of dentists (% per GDP in 2009*)	Public funding in (% of the total health care expenditure in 2009*)	Share of population with unmet needs for dental examination (% in 2009)	Share of population with unmet needs for dental examination because they cannot afford it (% in 2009)
Group 1 counties	74.9%	151	0,49%	37%	9.7%	3.9%
Group 2 countries	69.4%	101	0,40%	27%	8.9%	5.3%
Group 3 countries	60.8%	64	0,29%	29%	6.1%	3.1%

*AT, BG, CY, LV, LU and PT values refer to 2008

382 Source: Eurostat statistics on public health. Data on the unmet needs for dental examination derive from the European Statistics of Income and Living Condition (EU-SILC) survey

The following observations can be made:

- Healthcare expenditure in dental offices

There is a strong correlation between health care expenditure in dental offices and use of dental amalgam[383], both in terms of Euros spent per capita and as a percentage of the GDP. This correlation might be explained, at least partially, by the higher cost of Hg-free restorations and also by the fact that higher expenses normally entail a higher quality of service with regard to informing the patients on benefits (or drawbacks) of each restorative material. A correlation also exists on the percentage of public funding (as a share of the total health care expenditure) and the dental amalgam demand. It is not known which share of this public expenditure includes national health reimbursement schemes, but it can be assumed that the higher percentage in Group 1 occurs because of the higher cost of Hg-free dental restorations.

- Unmet needs for dental examination

The results of the European Statistics of Income and Living Condition (EU-SILC) survey indicate that unmet needs of dental examination appear mostly in countries with low dental amalgam demand. In addition, there does not seem to be a correlation between the type of dental filling material and the affordability of dental treatment. This aspect seems to correlate mainly with the wealth of the Member States. Specifically, the percentage of the population that cannot afford dental examination in EU15 is estimated at 3% whereas in the EU 12 this percentage rises at 5%.

[383] According to Eurostat, health expenditure includes: the medical care households receive (ranging from hospitals and physicians to ambulance services and pharmaceutical products) and their health expenses, including cost-sharing and the medicines they buy on their own initiative; government-supplied health services (e.g. schools, vaccination campaigns), investment in clinics, laboratories, etc.; administration costs; research and development; industrial medicine, outlays of voluntary organisations, charities and non-governmental health plans.

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