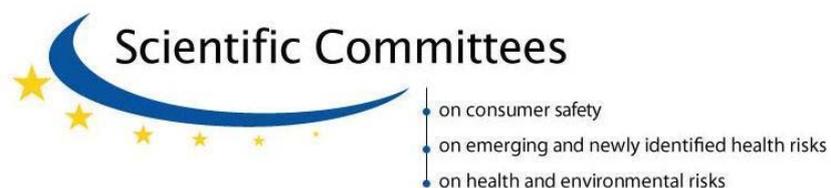




Scientific Committee on Health and Environmental Risks

SCHER

## Preliminary Opinion on the environmental risks and indirect health effects of mercury from dental amalgam (update)



SCHER approved this preliminary opinion for public consultation at the 2<sup>nd</sup> plenary of 28 June 2013

### **About the Scientific Committees**

Three independent non-food Scientific Committees provide the Commission with the scientific advice it needs when preparing policy and proposals relating to consumer safety, public health and the environment. The Committees also draw the Commission's attention to new or emerging issues which may pose an actual or potential threat.

They are: the Scientific Committee on Consumer Safety (SCCS), the Scientific Committee on Health and Environmental Risks (SCHER) and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) and are made up of external experts.

In addition, the Commission relies upon the work of the European Food Safety Authority (EFSA), the European Medicines Agency (EMA), the European Centre for Disease prevention and Control (ECDC) and the European Chemicals Agency (ECHA).

### **SCHER**

Opinions on risks related to pollutants in the environmental media and other biological and physical factors or changing physical conditions which may have a negative impact on health and the environment, for example in relation to air quality, waters, waste and soils, as well as on life cycle environmental assessment. It shall also address health and safety issues related to the toxicity and eco-toxicity of biocides.

It may also address questions relating to examination of the toxicity and eco-toxicity of chemical, biochemical and biological compounds whose use may have harmful consequences for human health and the environment. In addition, the Committee will address questions relating to methodological aspect of the assessment of health and environmental risks of chemicals, including mixtures of chemicals, as necessary for providing sound and consistent advice in its own areas of competence as well as in order to contribute to the relevant issues in close cooperation with other European agencies.

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## ABSTRACT

In the 2008 Opinion on the environmental risks and indirect health effects of mercury in dental amalgam the SCHER concluded that only a preliminary screening risk assessment was possible, based on existing knowledge at the time. As new evidence has become available, this has been evaluated to determine whether the risk assessment needs to be updated.

Exposure in surface water has been calculated considering three possible scenarios (worst, average and best case). The PECs calculated in the three scenarios have been compared with the WFD Environmental Quality Standards (AA EQS and MAC EQS) that have been set for mercury. The comparison allows the following conclusions:

- best case: the PEC is negligible in comparison to both EQS;
- average case: the PEC is one order of magnitude below the AA EQS;
- worst case: the PEC is above both AA and MAC EQS.
- Methylation in the aquatic ecosystem and mercury accumulation in fish have also been estimated. According to the three proposed scenarios and based on five hypothetical values for the methylation rate (between 0.0001 and 1 %), the calculation allows the following conclusions: best case: all the calculated concentrations are far below the acceptable level in food as well as the WFD threshold for secondary poisoning;
- average case: all the calculated concentrations are far below the acceptable level in food, however, the WFD proposed threshold for secondary poisoning is exceeded at methylation rates higher than 0.1 %;
- worst case: the acceptable level in food is exceeded (or approached) at methylation rates higher than 0.1 %, while the WFD threshold for secondary poisoning is also exceeded at methylation rates higher than 0.01 %.

It follows that a risk for secondary poisoning due to methylation cannot be excluded.

For the soil and air compartment a quantitative PEC cannot be estimated and an assessment of local risk is not possible.

Regarding the risk for human health due to environmental mercury coming from dental amalgam use, it can be concluded that emission of Hg to soil and in air represent a very minor contribution to total human exposure from soil and through inhalation.

Regarding the contribution of amalgam use to the concentrations of methyl mercury in fish, any calculation is affected by a high degree of uncertainty and based on a number of assumptions. However, a screening assessment was undertaken using a provisional risk assessment for surface water based on five hypothetical values for the methylation rate in three possible scenarios (worst, average and best case). In the best and the average cases, the expected methyl mercury concentrations in fish related to contributions of dental amalgam uses are well below maximum tolerable content of methyl mercury in fish. In the worst case scenario, the values obtained with the two highest methylation rates exceeded the threshold. Thus, in the worst case, mitigation measures are expected to be needed to reduce the risk. Further, the WFD's threshold for secondary poisoning is exceeded at methylation rates higher than 0.01 %. Therefore, compliance with the WFD threshold would contribute to the prevention of human health effects.

The information available on the Hg-free alternatives does not allow a sound risk assessment to be performed. For the human health, SCHER is of the opinion that the conclusions of the 2008-opinion are still valid, except for alternative materials containing bisphenol A-glycidyl methacrylate (Bis-GMA). For these materials SCHER recommends to

refer to an on-going SCENIHR mandate on the use of bisphenol A in medical devices, as soon as this opinion becomes available. For the environment, considering the probably low level of emissions and the relatively low toxicity of the chemicals involved, it is reasonable to assume that the ecological risk is low. However, it is the opinion of the SCHER that, at present, there is no scientific evidence for supporting and endorsing these statements. Therefore, more research on alternative materials is recommended.

Keywords:

SCHER, scientific opinion, dental amalgam, mercury

Opinion to be cited as:

SCHER preliminary scientific opinion on the environmental risks and indirect health effects of mercury from dental amalgam, 28 June 2013

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## 1. BACKGROUND

Dental amalgam and its substitutes are regulated under Council Directive 93/42/EEC<sup>1</sup> concerning medical devices, according to which they must comply with the essential requirements laid out in the directive, in particular in relation to the health and safety of patients.

Dental amalgam has been used for over 150 years for the treatment of dental cavities and is still used, in particular, for the treatment of large cavities due to its excellent mechanical properties and durability. Dental amalgam is a combination of alloy particles and mercury and contains about 50% of mercury in the elemental form. Overall, the use of alternative materials such as composite resins, glass ionomer cements, ceramics and gold alloys, is increasing, either due to their aesthetic properties or alleged health concerns in relation to the use of dental amalgam.

On 28 January 2005, the Commission adopted the Communication to the Council and the European Parliament on a Community Strategy Concerning Mercury<sup>2</sup>. The Strategy addresses most aspects of the mercury life cycle. Its key aim is to reduce mercury levels both in relation to human exposure and the environment. It identifies twenty priority actions to be undertaken, both within the EU and internationally. The Strategy was welcomed by Council Conclusions on 24 June 2005 as well as by a European Parliament Resolution on 14 March 2006. Pursuant to Action 6 of the Strategy, the use of dental amalgam should be evaluated with a view to considering whether additional regulatory measures are appropriate. The Commission services consulted two Scientific Committees on the use of dental amalgam, the Committee for Environmental and Health Risks (SCHER) and the Committee for Emerging and Newly Identified Health Risks (SCENIHR). The opinions<sup>3,4</sup> of both Committees were not conclusive regarding the appropriateness of additional regulatory measures to restrict the use of dental amalgam.

Concerning the environmental aspects, the SCHER opinion 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 of the EU 25/27", and identified a number of gaps that need to be addressed.

In the 2005 communication, the Commission had already expressed its intention to undertake a review of the Mercury Strategy by the end of 2010. To this effect, the Commission requested an external contractor, Bio Intelligence Service, to prepare a study, examining the progress of its implementation, assessing the success of the policies and corresponding measures, and proposing additional actions, if needed. The report produced, "Review of the Community Strategy Concerning Mercury"<sup>5</sup>, identified Actions 4 and 6 of the Mercury Strategy, both linked to dental amalgam, as areas where substantial improvement could still be achieved.

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<sup>1</sup> OJL169, 12.7.1993, p.1

<sup>2</sup> COM(2005)20 final

<sup>3</sup> [http://ec.europa.eu/health/ph\\_risk/committees/04\\_scher/docs/scher\\_o\\_089.pdf](http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_089.pdf)

<sup>4</sup> [http://ec.europa.eu/health/archive/ph\\_risk/committees/04\\_scenihr/docs/scenihr\\_o\\_016.pdf](http://ec.europa.eu/health/archive/ph_risk/committees/04_scenihr/docs/scenihr_o_016.pdf)

<sup>5</sup> [http://ec.europa.eu/environment/chemicals/mercury/pdf/review\\_mercury\\_strategy2010.pdf](http://ec.europa.eu/environment/chemicals/mercury/pdf/review_mercury_strategy2010.pdf)

The Commission issued a new Communication<sup>6</sup> to the European Parliament and the Council on the review of the Community Strategy Concerning Mercury on 7.12.2010. Given that some Member States have already substantially restricted the use of dental amalgam in their national health care systems and given that dental amalgam represents the second largest use of mercury in the EU, the Commission expressed its intention to further assess the use of mercury in dental amalgam with due consideration of all aspects of its lifecycle.

This assessment has been concluded under a contract with Bio Intelligence Service, including a stakeholder consultation in March 2012. The final report<sup>7</sup> focuses mainly on the environmental impacts of dental amalgam use and also seeks to address, to the extent possible, the gaps identified in the SCHER 2008 opinion.

There is an international dimension that needs to be considered too. In 2009 the Governing Council of the United Nations Environment Programme (UNEP) established an intergovernmental negotiating committee (INC) with the mandate to prepare a global legally binding instrument on mercury. The Committee started its work in 2010 and completed it, as planned, prior to the 27<sup>th</sup> regular session of the UNEP Governing Council in January 2013. The Commission represented the European Union in these negotiations and strived for a comprehensive multilateral environmental agreement. Dental amalgam is among the products to be regulated under the UNEP Convention on mercury, which the European Commission intends to sign on behalf of the EU, in October 2013. The Convention foresees a number of measures to be taken by the Parties in relation to dental amalgam in order to phase down its use, such as:

- (i) Setting national objectives aiming at dental caries prevention and health promotion, thereby minimizing the need for dental restoration;
- (ii) Setting national objectives aiming at minimizing its use;
- (iii) Promoting the use of cost-effective and clinically effective mercury-free alternatives for dental restoration;
- (iv) Promoting research and development of quality mercury-free materials for dental restoration;
- (v) Encouraging representative professional organizations and dental schools to educate and train dental professionals and students on the use of mercury-free dental restoration alternatives and on promoting best management practices;
- (vi) Discouraging insurance policies, and programmes that favour dental amalgam use over mercury-free dental restoration;
- (vii) Encouraging insurance policies and programmes that favour the use of quality alternatives to dental amalgam for dental restoration;
- (viii) Restricting the use of dental amalgam to its encapsulated form;
- (ix) Promoting the use of best environmental practices in dental facilities to reduce releases of mercury and mercury compounds to water and land

In light of the above, the Scientific Committee on Health and Environmental Risks (SCHER) is asked to update, if appropriate, the opinion adopted in 2008.

## **2. TERMS OF REFERENCE**

Taking into consideration recent developments, the SCHER is requested to review and update, if appropriate, the scientific opinion adopted in May 2008 on "The environmental risks and indirect health effects of mercury in dental amalgam".

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<sup>6</sup> Communication from the Commission to the European Parliament and the Council on the review of the Community Strategy Concerning Mercury, COM(2010)723final

<sup>7</sup> [http://ec.europa.eu/environment/chemicals/mercury/pdf/Final\\_report\\_11.07.12.pdf](http://ec.europa.eu/environment/chemicals/mercury/pdf/Final_report_11.07.12.pdf)

In particular, the Scientific Committee is requested to consider the following questions:

- Are mercury releases caused by the use of dental amalgam a risk to the environment? The fate of mercury released from dental clinics as well as the fate of mercury released to air, water and soil from fillings placed in patients should be taken into account.
- Is it scientifically justified to conclude that mercury in dental amalgam could cause serious effects on human health due to mercury releases into the environment?
- Comparison of environmental risk caused by the use of mercury in dental amalgam and that of the use of alternatives without mercury.

### 3. Opinion

#### 3.1. Introduction

In the 2008 SCHER Opinion on risks of mercury in dental amalgam a number of issues were raised leading to the conclusion that:

*“a comprehensive EU wide assessment of the human health and environmental risks of the Hg used in dental amalgam is – as far as could be established – not available”.*

In particular the lack of *“detailed quantitative information on the use and release pattern in all EU-27 countries, possible country-specific abatement measures, and differences in the fate of mercury due to regional-specific municipal wastewater treatment and sludge application practices”* was recognized.

Moreover, it was stated that the results of the use of the EUSES model for calculating environmental concentrations of a metal must be taken with caution, i.c. EUSES being the model developed for organic chemicals.

Therefore, the SCHER concluded that only a preliminary screening risk assessment was possible on the basis of the available information.

The aim of the present opinion is to evaluate if, in light of the new information available, a more scientifically sound assessment on the environmental risks and indirect health effects of mercury in dental amalgam, at local, regional and continental scale, is possible.

#### 3.2. First question

***Are mercury releases caused by the use of dental amalgam a risk to the environment? The fate of mercury released from dental clinics as well as the fate of mercury released to air, water and soil from fillings placed in patients should be taken into account.***

##### 3.2.1. Exposure assessment

In the 2008 SCHER Opinion several studies were examined on a mass flow analysis of Hg in the environment assessing the consumption and release of mercury used in dental amalgam. That original information has been updated with the results of some recent studies. In particular:

- AMAP/UNEP, 2013
- E-PRTR (European Pollutant Release and Transfer Register) 2011
- BIO Intelligence Service report (BIO Intelligence Service, 2012)

In order to provide an idea of the relevance of large scale emissions of mercury (global, continental), a synthesis is given in Table 1.

From the literature available, it may be concluded that nowadays dental amalgams may represent one of the major intentional uses of Hg. Emissions from the use of mercury in dental amalgam fillings can occur during the preparation of the amalgams and their subsequent removal and disposal in wastes. They can also occur when human remains with amalgam fillings are cremated. A mass balance of mercury emissions, in air, water and soil, from dental amalgam has been proposed by Bio Intelligence Service (2012).

This type of mass balance contributes to the understanding of the magnitude and sources of mercury contamination caused by dental applications. However, it does not allow to quantitatively assess the risks of Hg in amalgam, particularly if one considers that a non-

negligible risk from mercury in dental amalgam is likely to occur only at a local scale, close to relevant emission sites.

Table 1. Synthesis of the data on mercury emissions

| <b>Activity of Hg release</b>  | <b>Amount</b>             | <b>Reference</b> |
|--|---------------------------|------------------|
| Worldwide release of Hg to the atmosphere from anthropogenic sources (year 2010) | 1960 (1010 - 4070) tons   | AMAP/UNEP, 2013  |
| Worldwide release of Hg to the atmosphere from natural sources (year 2010)       | 825-1335 tons             | AMAP/UNEP, 2013  |
| Worldwide release of Hg to water from anthropogenic sources (year 2010)          | 185 (42.6 - 582) tons     | AMAP/UNEP, 2013  |
| Total Hg emissions to the atmosphere from intentional uses in Europe (year 2010) | 141.6 (68.2 - 253.4) tons | AMAP/UNEP, 2013  |
| Total Hg natural emissions to the atmosphere in Europe (27) (year 2010)          | 87.2 (44.5 - 226) tons    | AMAP/UNEP, 2013  |
| Hg releases to soil from anthropogenic sources in the USA (year 2000)            | 2700 tons                 | Cain et al. 2007 |
| Hg releases to soil from dental amalgams in the USA (year 2000)                  | 28 tons                   | Cain et al. 2007 |
| Total EU-27 emissions in air of Hg from dental practices                         | 19 tons/y                 | Biointell., 2012 |
| Total EU-27 emissions in soil of Hg from dental practices                        | 20 tons/y                 | Biointell., 2012 |
| Total EU-27 emissions in water of Hg from dental practices                       | 2 tons/y                  | Biointell., 2012 |

The quantification of mercury emissions from the use in dental amalgam fillings should take into account detailed information on specific issues, such as the density of dentists in a country, the specific amount of mercury used, the effectiveness of recovery through separation devices, etc.

Estimates have been reported for Canada (Richardson, 2000; Van Boom et al., 2003) and for the global scale (Pacyna et al, 2010). The latter report was prepared for the UNEP Governing Council. Collecting this amount of information for different European countries and situations in order to convert the mass balance analysis to an environmental concentration is impossible within the deadline proposed for this opinion. Too many site-specific factors influence the ultimate concentration of mercury originating from dental amalgam in WWTP receiving waters, to make the estimation of a single concentration feasible and/or realistic. However, considering the differences among EU-27 countries in terms of socio-economic and demographic conditions, presence of amalgam separators, WWTP facilities, etc., three possible extreme scenarios (worst, average and best case) may be developed in order to propose a range of possible environmental concentrations.

### 3.2.1.1. Concentration in surface water

Sufficient data are available for SCHER to perform an estimation of the concentration of mercury in the surface water compartment from the use of dental amalgam. Also in the SCHER Opinion only for this compartment an estimation of Hg water concentration was carried out (SCHER, 2008). SCHER has used the same calculation method as that used in 2008; several assumptions were replaced by new data that have become available. The current version of the calculation method has been added as an annex to this opinion. SCHER distinguished three scenarios to estimate the Hg concentration in surface water. Table 2 gives an overview of the 3 scenarios.

Table 2. Overview of assumptions used for estimating Hg surface water concentrations due to the emission of mercury used in dental amalgam.

|   | Worst case situation                          | Average case situation                         | Best case situation                                   |
|---|---|--|---|
| Dentist discharge (g/dentist/y)                     | 460<br>(Richardson, 2011)                     | 160<br>(Bio Intelligence Service report, 2012) | 0.65<br>(Richardson, 2011)                            |
| Percentage of separators (%)                        | 0<br>(in some countries no separation occurs) | 75<br>(Bio Intelligence Service report, 2012)  | 95<br>(estimated value as 100% can hardly be reached) |
| Number of dentists (N/10000 inhabitants)            | 12<br>(Bio Intelligence Service report, 2012) | 7<br>(Bio Intelligence Service report, 2012)   | 3<br>(Bio Intelligence Service report, 2012)          |
| Average use of drinking water (L/d)                 | 200<br>(no change from 2008, TGD 2003)        | 200<br>(no change from 2008, TGD 2003)         | 200<br>(no change from 2008, TGD 2003)                |
| Percentage in effluent water                        | 10<br>(Richardson, 2011)                      | 10<br>(Richardson, 2011)                       | 10<br>(Richardson, 2011)                              |
| Dilution factor to surface water (-)                | 10<br>(no change from 2008, TGD 2003)         | 10<br>(no change from 2008, TGD 2003)          | 10<br>(no change from 2008, TGD 2003)                 |
| Effluent concentration based on measurements (µg/L) | 1<br>(Richardson, 2011)                       | 0.05<br>(Richardson, 2011)                     | 0.001<br>(Richardson, 2011)                           |

The results of the calculation are given in Table 3.

Table 3. Estimated and measured Hg surface water concentrations due to the emission of mercury used in dental amalgam.

|                        | Calculated in effluent (µg/L) | Measured in effluent* (µg/L) | Concentration in surface water after dilution (µg/L) |          |
|------------------------|-------------------------------|------------------------------|--|----------|
|                        |                               |                              | Calculated   | Measured |
| Worst case situation   | 1.2                           | 1                            | 0.12   | 0.1      |
| Average case situation | 0.054                         | 0.05                         | 0.0054   | 0.005    |
| Best case situation    | 1.8E-5                        | 0.001                        | 1.8E-6   | 0.0001   |

\* Based on Richardson (2011).

As Table 3 shows, the estimated and the measured values match very well, except for the best case situation. This is due to the fact that conditions for the best case scenario actually are not fully implemented and the future situation can in principle not be measured yet. Based on future developments, especially in the percentage separators, the concentration in surface water is expected to reduce by about a factor of 50.

In section 3.2.2 the calculated Hg values in surface water (Table 3) will be used for further risk assessment.

#### *Methylation and bioaccumulation*

In the EXCEL-sheet in Annex the calculation results of the concentration for methyl mercury and its bioaccumulation in fish are also shown. The results are compiled in Table 4 below for the three scenarios.

Table 4. Estimated concentrations of methyl mercury in surface water related to hypothetical methylation rates in 3 scenarios.

| Mercury concentration in surface water (µg/L) | Methylation (%) | Mean BAF (-) | Methyl mercury concentration in fish (µg/kg fish) |
|---|-----------------|--------------|---|
| Worst case scenario                           |                 |              |   |
| 1.2E-07                                       | 0.0001          | 3.6E+06      | 4.2E-01   |
| 1.2E-06                                       | 0.001           | 3.6E+06      | 4.2E+00   |
| 1.2E-05                                       | 0.01            | 3.6E+06      | 4.2E+01   |
| 1.2E-04                                       | 0.1             | 3.6E+06      | 4.2E+02   |
| 1.2E-03                                       | 1               | 3.6E+06      | 4.2E+03   |
| Average case scenario                         |                 |              |   |
| 5.4E-09                                       | 0.0001          | 3.6E+06      | 2.0E-02   |
| 5.4E-08                                       | 0.001           | 3.6E+06      | 2.0E-01   |
| 5.4E-07                                       | 0.01            | 3.6E+06      | 2.0E+00   |
| 5.4E-06                                       | 0.1             | 3.6E+06      | 2.0E+01   |
| 5.4E-05                                       | 1               | 3.6E+06      | 2.0E+02   |
| Best case scenario                            |                 |              |   |
| 1.8E-12                                       | 0.0001          | 3.6E+06      | 6.7E-06   |
| 1.8E-11                                       | 0.001           | 3.6E+06      | 6.7E-05   |
| 1.8E-10                                       | 0.01            | 3.6E+06      | 6.7E-04   |
| 1.8E-9  | 0.1             | 3.6E+06      | 6.7E-03   |
| 1.8E-8  | 1               | 3.6E+06      | 6.7E-02   |

In section 3.2.2 the calculated methyl mercury concentrations in fish will be used for further risk assessment.

### **3.2.1.2. Concentration in soil**

According to the Bio Intelligence report (2012), emissions patterns and quantities of Hg in soil from dental amalgam in the EU are:

- Spreading of sewage sludge on farmland or landfilled: 8 t/y
- Disposal of solid wastes: 8.5 t/y
- Burial: 4 t/y

In the 2008 SCHER Opinion, a preliminary assessment of the potential risk for soil dwelling organisms of mercury released from dental practice was performed based on the generic TGD scenarios and default values. Based on a default average production of 0.071 kg of sludge per person per day at the WWTP, the concentration of mercury in sludge, resulting from dental clinics is calculated to range between 0.01 and 2.4 mg Hg/kg dw with an average value of 0.42 mg/kg dw. These values are consistent with the mercury content of sewage sludge reviewed by BIO Intelligence Service (2012), ranging from 0.2 to 4.6 mg/kg dry matter (average value = 1.53 mg/kg). This range and average mercury concentration in bio-solids is also consistent with observations made in the USA (US EPA 2009).

The added  $PEC_{soil}$  resulting from the contribution of dental clinic emissions - following the TGD default values - ranges from 0.016 to 4.1  $\mu\text{g Hg/kg}$ . The same calculation when applied to the concentration in sludge reported by the BIO Intelligence report led to Hg concentrations in soil of about 2.6 and 7.9  $\mu\text{g/kg dw}$ , using average and maximum concentrations in sludge, respectively.

The Bio Intelligence Services report (2012) estimated a discharge of about 1.5 g Hg per person buried and the same value for cremations. For dental waste a total discharge was estimated to be 52 t Hg/y. These values cannot be used without many additional assumptions for a risk assessment purposes. Therefore, with respect to burial and waste containing mercury from dental amalgam, SCHER concludes that insufficient specific information is available to carry out a risk assessment.

### **3.2.1.3. Concentration in air**

According to the Bio Intelligence report (2012), emissions patterns and quantities of Hg in air from dental amalgam in the EU are:

- Losses during application and separation: 3.5 t/y
- Losses from sewage sludge: 6 t/y
- Losses from solid wastes: 4.5 t/y
- Cremation: 3 t/y
- Losses from fillings in use: 2 t/y

In the on-going work to develop a global emission inventory for UNEP/AMAP (2012) the emissions from crematories in the EU were estimated to be 343 kg/y, ranging from 89 to 1130. Note that this value only represents cremation and not the handling, production and disposal of dental Hg. The same study estimated the global emissions from crematories at 3.3 tonnes (range 1-12), corresponding to 0.2% of total Hg emissions. This last figure was in reasonable agreement with those reported by the Bio Intelligence report (2012), indicating a value of about 2.8 tonnes for EU-27.

The atmospheric emissions of Hg from crematoria and further deposition close to these installations should be considered as an additional contribution of mercury from dental amalgams.

SCHER concludes that with the scarce information available no estimation of the concentration in air due to the emission of dental amalgam is possible.

### **3.2.2. Environmental risk assessment**

#### **3.2.2.1. Direct risk for aquatic organisms: inorganic mercury**

According to the Water Framework Directive, the following Environmental Quality Standards have been set for mercury for all typologies of surface waters:

Annual Average EQS: 50 ng/L

Maximum Allowable Concentration EQS: 70 ng/L

The comparison of these EQS with the calculated exposure estimations in surface waters allows the following conclusions:

- average case: the estimated concentration of 5 ng/L is one order of magnitude below the AA EQS values;
- best case: the estimated concentration of about 0.002 ng/L is negligible in comparison to EQS values;
- worst case: the estimated concentration of about 120 ng/L is above both AA and MAC EQS values.

It is clear that the contribution of Hg originating from dental amalgam use should be added to the natural and historical background concentrations as well as to the contribution from other anthropogenic Hg sources, to fully assess the risks of Hg to the environment. However, it can be concluded that mercury from dental amalgam does not represent an overall risk for European surface waters. Nevertheless, in particular local conditions, a risk for the aquatic ecosystem is possible and the WFD EQS may be exceeded.

One must be aware that the latter scenario represents an extreme worst case (maximal dentist density, maximal mercury use, absence of separator devices). Although improbable, its occurrence is not impossible in some European countries or regions. In these cases, mitigation measures are needed to reduce the risk.

#### **3.2.2.2. Direct risk for soil organisms: inorganic mercury**

The estimated concentrations of mercury in sewage sludge (0.01 and 2.4 mg Hg/kg dw) are far below the limit value for mercury concentration in sludge for use in agriculture (16 to 25 mg Hg/kg dw, Directive 86/278/EEC).

Moreover, the calculated added  $PEC_{soil}$  values resulting from the contribution of amalgam to sewage sludge (from 0.016 to 4.1  $\mu\text{g}$  Hg/kg) are well below the reported NOECs for soil dwelling organisms (e.g. Verbruggen et al., 2001; de Vries et al., 2007), which are all above 1.4 mg/kg. Thus, a negligible direct risk to the soil compartment is expected from the contribution of dental Hg in sewage sludge.

As to the two additional sources of contribution to soil (disposal of solid wastes and burial), an estimate of the total European emission is available (Bio Intelligence Service, 2012), but no information is available on the distribution patterns at the local scale. Therefore, a quantitative PEC cannot be estimated and an assessment of local risk is impossible.

### **3.2.2.3. Direct risk for the air compartment: inorganic mercury**

Total European emissions in the atmosphere from different patterns (sludge application, solid waste disposal, cremation) have been also estimated (Bio Intelligence Service, 2012). However, as for soil, no information is available on the distribution patterns at the local scale. Therefore, a quantitative PEC cannot be estimated and an assessment of local risk is impossible.

### **3.2.2.4. Risks associated with methylation of inorganic mercury.**

The main concern related to the anthropogenic emissions of mercury into the environment is related to the well-known potential of this metal to bioaccumulate and biomagnify through the food chain resulting in high levels of exposure for top predators (including humans) and associated risk for secondary poisoning. The bioaccumulation of inorganic mercury in biota - although significant and described even for the mercury present in dental amalgams (Kennedy, 2003) - is generally regarded to be of low relevance compared to that of organic forms of mercury. The potential for biomagnification is, therefore, related to the methylation of inorganic mercury which may result from both abiotic and biotic processes. The later seems to be the most relevant under environmental conditions.

Methylation of inorganic mercury may occur through two different patterns:

- direct emission of methyl mercury from dental practice
- environmental methylation.

The concerns related to mercury in dental amalgams have been enhanced by the identification of methyl mercury in wastewater from dental units in the USA. The measured concentrations were particularly high in tanks from large clinics (up to 0.2% of the total mercury) suggesting methylation to occur within the tank. This maybe the result of the activity of sulphate reducing bacteria, which are present in the oral cavity of humans, and can therefore be released during the dental intervention. Methylation may also occur in the oral cavity but the methyl mercury levels measured in the chair side wastewater were at least one order of magnitude lower that those measured in the tanks (Stone et al., 2003).

The main environmental concern for methyl mercury is its potential for bioaccumulation and food web biomagnification resulting in a risk for secondary poisoning in ictivorous vertebrates. Consumption of fish and seafood as well as products for special nutritional uses are the most important sources for dietary exposure to mercury and methyl mercury, while other food products and drinking water are of minor relevance (EFSA 2012). As a threshold level, the EC proposal (within the WFD) of 20 µg methyl mercury/kg in the prey of birds and mammals may be used for safety evaluation. This threshold is much more conservative than the maximum acceptable concentration in food of 0.5 mg/kg ww (EC, 2006). It must be noted that the threshold in food refers to total mercury. However, it is reasonable to assume that most of mercury in fish is in the methylated form.

The comparison with the calculated value of methyl mercury accumulation in fish according to the three proposed scenarios allows the following conclusions:

- average case: all the calculated concentrations are far below the acceptable level in food, however, the WFD proposed threshold ( 20 µ Hg/kg) for secondary poisoning is exceeded at methylation rates higher than 0.1 %;
- best case: all the calculated concentrations are far below the acceptable level in food as well as the WFD threshold for secondary poisoning;
- worst case: the acceptable level in food is exceeded (or approached) at methylation rates higher than 0.1 %, while the WFD threshold for secondary poisoning is also exceeded at methylation rates higher than 0.01 %.

SCHER concludes that a risk of secondary poisoning due to methylation cannot be excluded. These risks depend on the methylation rate of inorganic mercury which may differ with exposure conditions.

### **3.3. Second question**

#### ***Is it scientifically justified to conclude that mercury in dental amalgam could cause serious effects on human health due to mercury releases into the environment?***

Mercury coming from dental amalgam as well as from many other sources is ubiquitously distributed in the environment and can be taken up by the general human population via food, water and air.

Potential sources of exposure to mercury, next to the direct exposure to mercury through dental treatments (which is out the scope of this opinion), include inhalation of mercury vapors in air which is mainly confined to closed ambient air, ingestion of drinking water and food contaminated with mercury. Dietary intake is the most important source of non-occupational exposure to methyl mercury, with fish and other seafood products being the dominant source of mercury in the diet. Most of the mercury present in fish or other seafood is methyl mercury (WHO 1990, 1991).

Taking these exposure considerations into account, for indirect intake of mercury from the environment due to the uses of dental amalgams, the toxicology of both inorganic mercury and methyl mercury is relevant for risk assessment. The toxicological profile of mercury is highly dependent on the route of administration and speciation of mercury (elemental mercury; inorganic salts of mercury; or methyl mercury). Indeed, the main concern related to the anthropogenic emissions of mercury into the environment is related to the potential of the organic forms of mercury to bioaccumulate and biomagnify through the food chain.

Aspects of the hazard assessment for inorganic and elemental mercury have been summarized in previous SCHER opinions on mercury (SCHER, 2010; 2012) and are described in detail in a number of monographs (ATSDR, 1997-1999; Clarkson and Magos, 2006; EFSA, 2012; IRIS, 2002; UBA, 2011; US-EPA, 2010; WHO/IPCS, 2002). Oral ingestion of elemental mercury results only in a very limited absorption (< 0.01 % of dose). Dermal absorption of liquid elemental mercury is also very limited. In contrast, approximately 80 % of the inhaled elemental mercury is absorbed in the lungs. Due to the high lipid solubility, elemental mercury rapidly penetrates alveolar membranes and is then distributed to all tissues of the body. Absorbed elemental Hg is oxidized in blood to Hg<sup>2+</sup>-ions, which cannot readily penetrate biological membranes. The potential exposure of humans to drinking water is explicitly included in EFSA (2012).

After consumption of inorganic mercury (Hg<sup>2+</sup>), only a small part of the dose ingested is absorbed from the gastrointestinal tract. Hg<sup>2+</sup> absorbed or formed by oxidation of elemental Hg may be eliminated by excretion with urine and/or faeces. The elimination of elemental mercury or Hg<sup>2+</sup> follows complex kinetics with half-lives in the range of 20 to 90 days. The major target organ for the toxicity of inorganic mercury is the kidney. Ingestion of high doses of Hg<sup>2+</sup> results in kidney damage characterized by proximal tubular injury. In contrast, long term oral administration of Hg<sup>2+</sup> to rodents causes glomerulonephritis as the most sensitive endpoint. Higher doses of inorganic mercury also cause neurotoxicity. IPCS has set a tolerable (oral) daily intake (TDI) for lifetime exposure to elemental and inorganic mercury of 2 µg/kg bw/day. The TDI also covers sensitive subgroups such as children (WHO/IPCS, 2002). Recently the EFSA CONTAM Panel established a tolerable weekly intake (TWI) for inorganic mercury of 4 µg/kg bw, expressed as mercury (EFSA, 2012).

Methyl mercury is highly toxic. The diet is the most relevant source of exposure to methyl mercury, with fish meat being the main contributor to methyl mercury dietary

exposure for all age classes, followed by fish products. The middle bound (MB) methylmercury dietary exposure in Europe varies from the lowest minimum of 0.06 µg/kg bw per week seen in elderly people to the highest maximum of 1.57 µg/kg bw per week in toddlers (EFSA, 2012). It is absorbed from the gastrointestinal tract and subsequently rapidly and evenly distributed in the organism. The biological half-life of methyl mercury in blood is around 70 days. The faeces are the most important route of excretion (approximately 90% of a single oral dose of methyl mercury is excreted in the form of mercuric mercury). In humans, high dose poisonings resulted in effects that included mental retardation, and sensory and motor impairment. Long term, low dose prenatal exposures to methyl mercury due to maternal fish consumption have been associated with more subtle endpoints of neurotoxicity. Results from animal studies also show effects on cognitive, motor and sensory functions indicative of neurotoxicity.

Health based reference values for human exposures to methyl mercury have been established by US EPA in 2001; i.e. US EPA Reference Dose for Chronic Oral Exposure (RfD) 0.1 µg/kg bw/d and by WHO; i.e. TDI = 0.47 µg/kg bw/d [see: <http://www.inchem.org/documents/jecfa/jecmono/v52je23.htm>]

More recently EFSA (2012) identified a TWI for methyl mercury of 1.3 µg/kg bw, expressed as mercury. The mean dietary exposure does not exceed the EFSA derived TWI for methyl mercury, with few exceptions (i.e. toddlers in some surveys). Concentrations of mercury in blood and hair that correspond to the US EPA RfD and the WHO TDI can be calculated (FAO/WHO, 2003; NRC, 2000; Grandjean *et al.*, 2007). Recent biomonitoring data on mercury concentrations in hair from mothers and children recruited from the general population of 17 European countries indicate that methyl mercury exposure is generally below the EFSA derived TWI (EFSA, 2012) but more than 1.8 million children are born every year with MeHg exposures above the limit derived by US EPA, and about 200,000 births exceed the higher limit proposed by the WHO (Bellanger *et al.*, 2013).

In a detailed analysis of studies on effects of methyl mercury in humans and average fish consumption in the US, the US EPA has developed a fish tissue residue criterion (concentration in fish that should not be exceeded) of 0.3 mg methyl mercury/kg fish (regarding human consumption) which is similar to a maximum tolerable content of 0.5 mg methyl mercury/ kg fish for many fish species set by EU (EC, 2006). It must be noted that the EU threshold in food refers to total mercury, although it is expected that most of mercury in fish is in the methylated form.

Regarding the contribution of environmental mercury coming from dental amalgam use, it can be concluded that emissions of Hg to soil are not considered as a concern for human health. Indeed, the consideration of the calculated concentrations of 0.016 to 4.1 µg Hg/kg or the estimation that the emission of dental amalgam is about 1% of the total emission of Hg to soil as in the USA (Cain *et al.*, 2007), support the conclusion that dental amalgam represents a negligible contribution to total human exposure from soil.

Regarding inhalation, amalgam use will make only a limited contribution (around 1%) to the overall human inhalation exposure to Hg from anthropogenic sources (22%). Thus, this can also not be considered as a health concern.

The contribution of amalgam use to the concentrations of methyl mercury found in fish and formed from Hg<sup>2+</sup> dissolved in the oceans from non-anthropogenic sources is not known and consequently no clear conclusion on possible health risks is possible. Any calculation would be indeed affected by a high degree of uncertainty and based on a number of assumptions. However, a screening assessment can be attempted based on the provisional risk assessment for surface water, shown in Table 4, for which only the contribution of the emission of dentists was taken into account. Different situations can be evaluated on the basis of 5 hypothetical values for the methylation rate in three possible scenarios (worst, average and best case), with values spanning 4 -orders of magnitude. In the best and the average cases, the expected methyl mercury concentrations in fish related to contributions of dental amalgam uses are well below the

thresholds of 0.3-0.5 mg methyl mercury/kg fish set by the US EPA and the EU. In the worst case scenario, those values obtained with a 0.1 and 1% methylation rate exceeded the maximum tolerable content of 0.5 mg methyl mercury/kg fish. Thus, the 'average' predicted indirect exposures of humans to methyl mercury resulting from emissions due to dental amalgams are much lower than the tolerable limits, although in the unlikely but not impossible worst case, mitigation measures are expected to be needed to reduce the risk. On the other hand, the WFD threshold for secondary poisoning being more conservative is exceeded already at methylation rates higher than 0.01 %. Therefore, compliance to the WFD threshold would prevent human health effects. On the other hand, methyl mercury in fish is the major contributor to the methyl mercury concentration in humans. It exceeds in a considerable proportion of children, safe limits, e.g. the limits set by US-EPA RfD and WHO-TDI, but not the limits set by EFSA. All additional sources which add to the methyl mercury burden in humans may increase the number of people at risk, since the WFD threshold for secondary poisoning is exceeded already at methylation rates higher than 0.01 %. Respecting the more conservative WFD threshold would contribute to the prevention of human health effects.

### **3.4. Third question**

#### ***Comparison of environmental risk from the use of mercury in dental amalgam and the use of alternatives without mercury***

Currently, Hg-free materials are used more often than dental amalgam in the EU27. These materials are used in approximately 66% of all dental restorations and their use is growing (Biointelligence Service, 2012). Therefore, assessing the potential risks for these alternatives is a major issue.

The composition of the most commonly used alternatives to dental amalgam is highly variable, represented by a matrix (e.g. a polymeric resin) and by several inorganic materials used as fillers (e.g.  $\text{Al}_2\text{O}_3$ ,  $\text{SiO}_2$ , metal oxides, metal fluorides, etc.).

Erdal (2012) divides materials into the following five main classes.

1. *Composite resins*. They are composed of a polymerisable resin matrix, binding filler inorganic particles. The resin is initially a fluid monomer, which is converted into rigid polymer by a radical addition reaction. The most common resins used now are based on dimethacrylate (bisphenol A-glycidyl methacrylate: Bis-GMA) or urethane dimethacrylate (UDMA). The inorganic materials used as fillers are silica-based glass fillers ( $\text{SiO}_2$ ), alumina glass ( $\text{Al}_2\text{O}_3$ ), and combinations of glass and sodium fluoride. They may also contain barium, strontium and boron.
2. *Glass ionomer (Glass polyalkenoate) cements*. They are a product of an acid-based reaction between basic fluoro-alumino-silicate and water-soluble polycarboxylic acid consisting of an organic-inorganic complex with high molecular weight (Wilson and McLean 1988; Davidson and Mjör 1999). The filler particles contain alumina ( $\text{Al}_2\text{O}_3$ ), silica ( $\text{SiO}_2$ ), metal oxides, metal fluorides, and metal phosphates. The metal ions usually selected are: aluminium (Al), calcium (Ca), strontium (Sr), zinc (Zn), sodium (Na), potassium (K), barium (Ba) and lanthanum (La).
3. *Resin-Modified Glass Ionomer Cement*. They are similar to the previous one, but water-soluble resin monomers (e.g., 2-hydroxyethylmethacrylate), capable of free radical polymerization, are added. Thus, resin-modified glass ionomer cement is a material that undergoes both the polymerization reaction and acid-base reaction.
4. *Compomers*. They are single-paste formulations consisting of fillers and a matrix, similar to a composite resin. The filler usually contains fluoro-alumino-silicate glass powder. Metal fluoride is also included in some materials for the same purpose. The glass powder contains strontium or some other metal. A compomer undergoes an

acid-base reaction between the acidic monomer (e.g., polymerisable dimethacrylate resins such as urethane dimethacrylate) and ion-leachable basic glass filler in the presence of water from the saliva.

5. *Giomers*. They feature the hybridization of glass-ionomer and composite resins. They contain an adhesive promoting monomer and a bonding polymer catalyst, which allow bonding to hard tooth tissues.

The detailed composition of some of the most frequently used alternatives is described by Erdal (2012). This report concludes for the alternatives of amalgam that “there is no current evidence of significant personal or environmental toxicity”.

#### *Human health*

From the human health point of view there is no new data available compared to the opinion of SCHER in 2008 (SCHER, 2008). Therefore, SCHER confirms its position taken in the 2008 Opinion, except for alternative materials included in group 1. Indeed, the possible effects related to the use of bisphenol A-glycidyl methacrylate (Bis-GMA) are included in the ToR of an on-going SCENHIR mandate on the the use of bisphenol A in medical devices. SCHER refers the reading to that opinion.

#### *Environment*

For the environmental assessment, the statement of the Erdal report is not supported by SCHER. No attempt is made to estimate concentrations of different components in various environmental compartments and no ecotoxicological data is reported. Therefore, the available information is too limited for conducting a proper comparative risk assessment of the amalgam alternatives. However, it is reasonable to consider the risk determined by the polymeric resin as negligible or practically absent. Environmental risks associated with the release of monomers and from the leaching of filling materials can, however, not be excluded.

Therefore, the first questions to be answered for the development of an environmental risk assessment refer to exposure issues:

- What is the amount of monomers released during the treatment before the polymerisation process?
- Can monomers be released after dental filling disposal?
- What is the amount of inorganic fillers (e.g. metals) leached from the amalgam alternative?

Referring to effects, ecotoxicological information on the products in dental resins is practically absent.

Table 5 gives a list of chemicals (resin monomers or organic and inorganic additives) used in commercially available products (taken from Erdal 2012) is reported. Literature data on physical chemical properties (water solubility and log Kow) are available only for a few compounds. Most reported values have been estimated using the EPISUITE software<sup>8</sup>. The few acute toxicity data available for aquatic organisms reported in Table 5 are taken from the ECOTOX<sup>9</sup> database. Others ecotoxicity data were calculated using the QSAR equations for narcotic type chemicals (TGD EC, 2003).

The chemicals can be divided in five groups:

1. Monomers group 1 are the components of polymeric resins used in a large number of commercial products (more than 15 from the list of Erdal 2012), often in high percentages (even more than 70%);

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<sup>8</sup> [http://www.epa.gov/opptintr/exposure/pubs/updates\\_episuite\\_v4.11.revised.htm](http://www.epa.gov/opptintr/exposure/pubs/updates_episuite_v4.11.revised.htm)

<sup>9</sup> <http://cfpub.epa.gov/ecotox/>

2. Monomers group 2 are the components of polymeric resins used in a small number of commercial products (less than 5 from the list of Erdal 2012), in medium high percentages;
3. Monomers group 3 are the components of polymeric resins used only in one commercial product in medium low percentages (usually less than 10%);
4. Organic additives are organic chemicals added before the polymerization process with various functions (initiation, catalysis, etc.); they are usually present in relatively small amount (<5%); low toxicity solvents often present in the composition (e. g. ethanol, acetone) are not included in the list;
5. Inorganic additives are some metals that may be added as fillers (as oxides and fluorides) are listed; fluorine is also listed.

For many of the organic chemicals the estimated values show relatively low toxicity, often with E/LC50 values of some hundreds of mg/L. Among the monomers, the more toxic are those derived from bisphenol A. However, the uncertainty associated with these ecotoxicity data must be highlighted: they are estimated values calculated on the basis of estimated values of log Kow.

In many reports it is concluded that the ecological risk of the available alternatives to amalgam is very low, in any case lower than those of amalgam. A synthesis of these opinions is provided by a document of the World Alliance for Mercury-Free Dentistry (2012).

Considering the relatively low toxicity of the chemicals involved, these opinions may be considered reasonable. However, it is the opinion of the SCHER that, at present, there is no scientific evidence to support these statements.

Therefore the SCHER agrees with the conclusions of the Council of European Dentists (CED, 2012):

1. The scientific community is not yet fully able to demonstrate the relative emerging risks of the use of alternative materials;
2. Evidence about the toxicology of the alternative materials is a work in progress  
The profession should urge manufacturers to fully declare the chemical composition of the alternative materials;
3. The environmental data regarding the use of alternative materials is lacking and the profession should urge the decision-makers to know more;
4. More research on alternative materials is highly recommended.

Finally, it should be noted that the assessment of environmental impacts of the substitutes would require two complementary studies: a comparative risk assessment for the relevant environmental compartments, and a life-cycle assessment covering non ecotoxicological impacts such as those related to energy and natural resources consumption, atmospheric emissions including greenhouse gases, waste production, etc.

**Table 5. Physical-chemical and ecotoxicological characteristics of substances frequently used in commercially available products (from Erdal 2012). Figures in italics are estimated using EPISUITE or QSAR equations.**

|  | CAS        | MW     | WS<br>mg/L | Log<br>Kow | Ecotoxicology<br>(E/LC50 mg/L) |             |             |
|--|------------|--------|------------|------------|--------------------------------|-------------|-------------|
|  |            |        |            |            | algae                          | Daphnia     | fish        |
|  |            |        |            |            | 72h<br>EC50                    | 48h<br>EC50 | 96h<br>EC50 |
| <b>Monomers group 1</b>  |            |        |            |            |                                |             |             |
| 2-hydroxyethyl methacrylate  | 868-77-9   | 130.14 | misc       | 0.47       | 2596                           | 2228        | 227         |
| bisphenol A diglycidyl methacrylate (Bis-GMA)                        | 1565-94-2  | 512.61 | 356        | 4.94       | 0.347                          | 0.50        | 1.32        |
| triethyleneglycol dimethacrylate.                                    | 109-16-0   | 286.33 | 366        | 1.88       | 222                            | 224         | 294         |
| urethane dimethacrylate (UDMA)                                       | 72869-86-4 | 470.57 | 0.11       | 4.69       | 0.57                           | 0.79        | 1.98        |
| <b>Monomers group 2</b>  |            |        |            |            |                                |             |             |
| 3-trimethoxysilylpropyl methacrylate                                 | 2530-85-0  | 248.35 | 5490       | 0.75       | 2600                           | 2304        | 2331        |
| bisphenolA polyethyleneglycoldietherdimethacryl.                     | 41637-38-1 | 310.44 | 612        | 6.14       | 0.013                          | 0.02        | 0.08        |
| glycerol 1,3-dimethacrylate  | 1830-78-0  | 228.25 | 10350      | 1.16       | 930                            | 864         | 960         |
| methyl methacrylate  | 80-62-6    | 100.12 | 10500      | 1.38       | 246                            | 234         | 276         |
| 1,6-hexanediol dimethacrylate  | 6606-59-3  | 254.33 | 6.1        | 3.6        | 3.8                            | 4.6         | 9.0         |
| trimethylolpropane trimethacrylate                                   | 3290-92-4  | 338.4  | 1.3        | 4.39       | 0.81                           | 1.09        | 2.56        |
| <b>Monomers group 3</b>  |            |        |            |            |                                |             |             |
| (dimethylamino)ethyl methacrylate                                    | 2867-47-2  | 157.21 | 50000      | 0.81       | 42                             | 33          | 19          |
| tetrahydrofurfuryl methacrylate                                      | 2455-24-5  | 170.21 | 1790       | 1.8        | 159                            | 159         | 35          |
| bisphenol A dimethacrylate   | 3253-39-2  | 364.44 | 834        | 5.6        | 0.054                          | 0.08        | 0.26        |
| decamethylene dimethacrylate   | 6701-13-9  | 310.44 | 612        | 5.4        | 0.073                          | 0.11        | 0.33        |
| ethoxylated bisphenol-A-dimethacrylate                               | 56744-60-6 | 540.66 | 2500       | 6.08       | 0.026                          | 0.04        | 0.15        |
| 1-propanol-3,3'-[isopropylidenebis(p-phenyleneoxy)]di-dimethacrylate | 27689-12-9 | 480.61 | 29900      | 6.01       | 0.028                          | 0.045       | 0.153       |
| tricyclodocandimethanol dimethacrylate                               | 43048-08-4 | 332.44 | 0.21       | 5.35       | 0.087                          | 0.13        | 0.38        |
| dl-camphorquinone  | 10373-78-1 | 166.22 | 3230       | 0.75       | 1741                           | 1542        | 1560        |
| <b>Organic additives</b>   |            |        |            |            |                                |             |             |
| 2,2-bis[4-(2-methacryloxy)ethoxy]phenyl]propane                      | 24448-20-2 | 452.55 | 0.03       | 6.63       | 0.01                           | 0.01        | 0.04        |
| 2,4,4'-trichloro-2'-hydroxydiphenyl ether                            | 3380-34-5  | 289.55 | 4.6        | 4.76       | 0.30                           | 0.42        | 0.30        |
| 2,4,6-trimethylbenzoyldiphenylphosphine oxide                        | 75980-60-8 | 348.38 | 3.1        | 3.87       | 2.77                           | 3.51        | 7.29        |
| 2,6-di-tert-butyl-p-cresol (BHT)                                     | 128-37-0   | 220.36 | 1.1        | 5.1        | 0.10                           | >0.17       | >0.57       |
| 2-benzotriazolyl-4-methylphenol                                      | 2440-22-4  | 225.25 | 338        | 3          | 13.3                           | 15.2        | 25.9        |
| acrylamidosulfonic acid  | 15214-89-8 | 207.25 | misc       | -2.19      | 18901<br>42                    | 1193973     | 61375<br>4  |
| dl-camphorquinone  | 10373-78-1 | 166.22 | 3230       | 0.75       | 1741                           | 1542        | 1560        |
| glutaraldehyde   | 111-30-8   | 100.12 | misc       | -0.18      | 8923                           | 7104.29     | 10.50       |
| maleic acid  | 110-16-7   | 116.07 | 788        | -0.78      | 41183                          | 30600       | 21760       |
| <b>Inorganic additives</b>   |            |        |            |            |                                |             |             |
| aluminium  |            |        |            |            | 0.04                           | 1.6         | 0.18        |
| lantanium  |            |        |            |            | -                              | 0.08        | 0.01*       |
| strontium  |            |        |            |            | -                              | 41.5        | 0.124*      |
| titanium   |            |        |            |            | 8.7                            | 3.3         | 2.3         |
| zinc   |            |        |            |            | 0.14                           | 0.37        | 0.22        |

\* 28d LC50

#### **4. MINORITY OPINION**

None

## 5. LIST OF ABBREVIATIONS

|         |  |
|---------|--|
| BAF     | Bio-Accumulation Factor  |
| Bis-GMA | bisphenol A-glycidyl methacrylate                                      |
| bw      | Body weight  |
| CSTEE   | Scientific Committee on Toxicity, Ecotoxicity and the Environment      |
| ECDC    | European Centre for Disease prevention and Control                     |
| ECHA    | European Chemicals Agency  |
| EEB     | European Environmental Bureau  |
| EFSA)   | European Food Safety Authority   |
| EMA     | European Medicines Agency  |
| EPA     | Environmental Protection Agency  |
| EQS     | Environmental Quality Standard   |
| EQS AA  | Annual Average Environmental Quality Standard                          |
| EQS-MAC | Maximum Allowable Concentration Environmental Quality Standard         |
| EUSES   | European Union System for the Evaluation of Substances                 |
| INC     | Intergovernmental Negotiating Committee                                |
| NO(A)EC | No Observed (Adverse) Effect Concentration                             |
| PEC     | Predicted Environmental Concentration                                  |
| RAR     | Risk Assessment Report   |
| SCCS    | Scientific Committee on Consumer Safety                                |
| SCENIHR | Scientific Committee on Emerging and Newly Identified Health Risks ( ) |
| SCHER   | Scientific Committee on Health and Environmental Risks                 |
| TGD     | Technical Guidance Document  |
| TDI     | Tolerable Daily Intake   |
| tw      | Dry weight   |
| TWI     | Tolerable Weekly Intake  |
| UNEP    | United Nations Environment Programme (established an (INC)             |
| WFD     | Water Framework Directive  |
| ww      | Wet weight   |
| WWTP    | Waste Water Treatment Plant  |

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**ANNEXES**

**Sheets for calculation of PECs in surface water**

**Annex 1 Average case**

**Annex 2 Best case**

**Annex 3 Worst case**

**Annex 1 Average case**

| <b>SCHER 2013 average case</b> |                              |                                       |            |                |         |                 |          |               |        |              |                        |   |
|--------------------------------|------------------------------|---------------------------------------|------------|----------------|---------|-----------------|----------|---------------|--------|--------------|------------------------|---|
| Assumptions                    |                              |                                       |            |                |         |                 |          |               |        |              | Remark                 |   |
| 0,05                           | μg/L                         | Better case concentration in effluent |            |                |         |                 |          |               |        |              |                        | Assume all Hg comes from dental amalgam   |
| 160                            | g Hg/dentist/y               |                                       |            |                |         |                 |          |               |        |              |                        | taken from Bio Intelligence report 2012 (calculated from total Hg use divided times the number of dentists) |
| 7                              | dentists/10000 inhabitant    |                                       |            |                |         |                 |          |               |        |              |                        | Average (BIO, 2012)   |
| 75                             | %                            | percentage amalgam separators         |            |                |         |                 |          |               |        |              |                        |   |
|                                |                              |                                       |            |                |         |                 |          |               |        |              |                        |   |
| mercury                        | dentist/10,000 in input WWTP | mercury                               | water      | mercury inflow | % water | mercury outflow | dilution | mercury river |        |              |                        |   |
| g Hg/dentist/y                 | g/y                          | mg/d (260d/y)                         | L/person/d | mg/L           |         | ug/L            |          | ug/L          | ng/L   |              |                        |   |
| mean                           | 40                           | 7                                     | 280        | 1076,923077    | 200     | 0,000538462     | 10       | 0,05384615    | 10     | 0,00538462   | 5,3846                 |   |
|                                |                              |                                       |            |                |         |                 |          | 0,05          | 10     | 0,005        | 5                      |   |
|                                |                              |                                       |            |                |         |                 |          |               |        |              |                        |   |
| methylmercury                  | dentist/10,000 in input WWTP | mercury                               | water      | mercury inflow | % water | mercury outflow | dilution | mercury river | BAF    | mercury fish |                        |   |
| g /dentist/y                   | g/y                          | mg/d                                  | L/person/d | mg/L           |         | ug/L            |          | ug/L          | ng/L   | ug/kg        |                        |   |
| mean                           | 0,08                         | 7                                     | 0,56       | 2,153846154    | 200     | 1,07692E-06     | 10       | 0,00010769    | 10     | 1,0769E-05   | 0,0108 3645423 39,2584 |   |
|                                |                              |                                       |            |                |         |                 |          |               |        |              |                        |   |
| % methylation field BAF fish   |                              |                                       |            |                |         |                 |          |               |        |              |                        |   |
| 0,2                            | 21700                        |                                       |            |                |         |                 |          | 1,0769E-05    | 0,0108 | 3645423      | 39,2584                |   |
| 0,001991944                    | 100000                       |                                       |            |                |         |                 |          | 1,0726E-07    | 0,0001 | 3645423      | 0,391                  |   |
| 0,200907806                    | 1600000                      |                                       |            |                |         |                 |          | 1,0818E-05    | 0,0108 | 3645423      | 39,4366                |   |
| 0,154392523                    | 6800000                      |                                       |            |                |         |                 |          | 8,3134E-06    | 0,0083 | 3645423      | 30,306                 |   |
| 0,0001                         | 33000                        |                                       |            |                |         |                 |          | 5,3846E-09    | 5E-06  | 3645423      | 0,01963                |   |
| 0,001                          | 120000                       |                                       |            |                |         |                 |          | 5,3846E-08    | 5E-05  | 3645423      | 0,19629                |   |
| 0,01                           | 680000                       |                                       |            |                |         |                 |          | 5,3846E-07    | 0,0005 | 3645423      | 1,96292                |   |
| 0,1                            | 27000000                     |                                       |            |                |         |                 |          | 5,3846E-06    | 0,0054 | 3645423      | 19,6292                |   |
| 1                              | 705478,561                   |                                       |            |                |         |                 |          | 5,3846E-05    | 0,0538 | 3645423      | 196,292                |   |
|                                | 200000                       |                                       |            |                |         |                 |          |               |        |              |                        |   |
|                                | 200000                       |                                       |            |                |         |                 |          |               |        |              |                        |   |
|                                | 6284902,545                  |                                       |            |                |         |                 |          |               |        |              |                        |   |

**Annex 2 Best case**

| SCHER 2013 best case |                            |                                     |            |               |                    |                |         |               |          |                      |          |                     |         |                          |
|----------------------|----------------------------|-------------------------------------|------------|---------------|--------------------|----------------|---------|---------------|----------|----------------------|----------|---------------------|---------|--------------------------|
| Assumptions          |                            |                                     |            |               |                    |                |         |               |          |                      |          |                     |         |                          |
| 0.001                | µg/L                       | Best case concentration in effluent |            |               | Remark             |                |         |               |          |                      |          |                     |         |                          |
| 0.64                 | g Hg/dentist/y             |                                     |            |               | Richardson, 2011   |                |         |               |          |                      |          |                     |         |                          |
| 3                    | dentists/10000 inhabitants |                                     |            |               | Poland (BIO, 2012) |                |         |               |          |                      |          |                     |         |                          |
| 95                   | %                          | percentage amalgam separators       |            |               |                    |                |         |               |          |                      |          |                     |         |                          |
|                      | mercury                    | dentist/10,000 in                   | input WWTP | mercury       | water              | mercury inflow | % water | mercury outfl | dilution | mercury river        |          |                     |         |                          |
|                      | g Hg/dentist/y             |                                     | g/y        | mg/d (260d/y) | L/person/d         | mg/L           |         | ug/L          |          | ug/L                 | ng/L     |                     |         |                          |
| mean                 | 3.2E-02                    | 3                                   | 9.6E-02    | 3.7E-01       | 200                | 1.8E-07        | 10      | 1.8E-05       | 10       | 1.8E-06              | 1.8E-03  |                     |         |                          |
|                      |                            |                                     |            |               |                    |                |         | 0.001         | 10       | 0.0001               | 0.1      |                     |         |                          |
|                      | methyl mercury             |                                     |            |               |                    |                |         |               |          | methyl mercury river | mean BAF | methyl mercury fish |         |                          |
|                      |                            |                                     |            |               |                    |                |         |               |          | ug/L                 | ng/L     | ug/kg               |         |                          |
| mean                 |                            |                                     |            |               |                    |                |         |               |          | 1.8E-12              | 1.8E-09  | 3.6E+06             | 6.7E-06 |                          |
|                      | % methylation              | field BAF fish                      |            |               |                    |                |         |               |          |                      |          |                     |         |                          |
|                      | 1.0E-04                    | 2.2E+04                             |            |               |                    |                |         |               |          | 1.8E-12              | 1.8E-09  | 3.6E+06             | 6.7E-06 | Methylation rate 0,0001% |
|                      | 1.0E-03                    | 1.0E+05                             |            |               |                    |                |         |               |          | 1.8E-11              | 1.8E-08  | 3.6E+06             | 6.7E-05 | Methylation rate 0,001%  |
|                      | 1.0E-02                    | 1.6E+06                             |            |               |                    |                |         |               |          | 1.8E-10              | 1.8E-07  | 3.6E+06             | 6.7E-04 | Methylation rate 0,01%   |
|                      | 1.0E-01                    | 6.8E+06                             |            |               |                    |                |         |               |          | 1.8E-09              | 1.8E-06  | 3.6E+06             | 6.7E-03 | Methylation rate 0,1%    |
|                      | 1.0E+00                    | 3.3E+04                             |            |               |                    |                |         |               |          | 1.8E-08              | 1.8E-05  | 3.6E+06             | 6.7E-02 | Methylation rate 1%      |
|                      |                            | 1.2E+05                             |            |               |                    |                |         |               |          |                      |          |                     |         |                          |
|                      |                            | 6.8E+05                             |            |               |                    |                |         |               |          |                      |          |                     |         |                          |
|                      |                            | 2.7E+07                             |            |               |                    |                |         |               |          |                      |          |                     |         |                          |
|                      |                            | 7.1E+05                             |            |               |                    |                |         |               |          |                      |          |                     |         |                          |
|                      |                            | 2.0E+05                             |            |               |                    |                |         |               |          |                      |          |                     |         |                          |
|                      |                            | 2.0E+05                             |            |               |                    |                |         |               |          |                      |          |                     |         |                          |
|                      |                            | 6.3E+06                             |            |               |                    |                |         |               |          |                      |          |                     |         |                          |

**ANNEX 3 Worst case**

| SCHER 2013 worst case |                            |                                      |            |               |                    |                |         |               |          |               |          |                     |         |         |         |                          |
|-----------------------|----------------------------|--------------------------------------|------------|---------------|--------------------|----------------|---------|---------------|----------|---------------|----------|---------------------|---------|---------|---------|--------------------------|
| Assumptions           |                            |                                      |            |               |                    |                |         |               |          |               |          |                     |         |         |         |                          |
| 1                     | μg/L                       | Worst case concentration in effluent |            |               | Remark             |                |         |               |          |               |          |                     |         |         |         |                          |
| 460                   | g Hg/dentist/y             |                                      |            |               | Richardson, 2011   |                |         |               |          |               |          |                     |         |         |         |                          |
| 13                    | dentists/10000 inhabitants |                                      |            |               | Greece (BIO, 2012) |                |         |               |          |               |          |                     |         |         |         |                          |
| 0                     | %                          | percentage amalgam separators        |            |               |                    |                |         |               |          |               |          |                     |         |         |         |                          |
|                       | mercury                    | dentist/10,000 in                    | input WWTP | mercury       | water              | mercury inflow | % water | mercury outfl | dilution | mercury river |          |                     |         |         |         |                          |
|                       | g Hg/dentist/y             |                                      | g/y        | mg/d (260d/y) | L/person/d         | mg/L           |         | ug/L          |          | ug/L          | ng/L     |                     |         |         |         |                          |
| mean                  | 4.6E+02                    | 13                                   | 6.0E+03    | 2.3E+04       | 200                | 1.2E-02        | 10      | 1.2E+00       | 10       | 1.2E-01       | 1.2E+02  |                     |         |         |         |                          |
|                       |                            |                                      |            |               |                    |                |         | 1             | 10       | 0.1           | 100      |                     |         |         |         |                          |
|                       | methyl mercury             |                                      |            |               |                    |                |         |               |          |               | mean BAF | methyl mercury fish |         |         |         |                          |
|                       |                            |                                      |            |               |                    |                |         |               |          | ug/L          | ng/L     | ug/kg               |         |         |         |                          |
| mean                  |                            |                                      |            |               |                    |                |         |               |          | 1.2E-07       | 1.2E-04  | 3.6E+06             | 4.2E-01 |         |         |                          |
|                       | % methylation              | field BAF fish                       |            |               |                    |                |         |               |          |               |          |                     |         |         |         |                          |
|                       | 1.0E-04                    | 2.2E+04                              |            |               |                    |                |         |               |          |               |          | 1.2E-07             | 1.2E-04 | 3.6E+06 | 4.2E-01 | Methylation rate 0,0001% |
|                       | 1.0E-03                    | 1.0E+05                              |            |               |                    |                |         |               |          |               |          | 1.2E-06             | 1.2E-03 | 3.6E+06 | 4.2E+00 | Methylation rate 0,001%  |
|                       | 1.0E-02                    | 1.6E+06                              |            |               |                    |                |         |               |          |               |          | 1.2E-05             | 1.2E-02 | 3.6E+06 | 4.2E+01 | Methylation rate 0,01%   |
|                       | 1.0E-01                    | 6.8E+06                              |            |               |                    |                |         |               |          |               |          | 1.2E-04             | 1.2E-01 | 3.6E+06 | 4.2E+02 | Methylation rate 0,1%    |
|                       | 1.0E+00                    | 3.3E+04                              |            |               |                    |                |         |               |          |               |          | 1.2E-03             | 1.2E+00 | 3.6E+06 | 4.2E+03 | Methylation rate 1%      |
|                       |                            | 1.2E+05                              |            |               |                    |                |         |               |          |               |          |                     |         |         |         |                          |
|                       |                            | 6.8E+05                              |            |               |                    |                |         |               |          |               |          |                     |         |         |         |                          |
|                       |                            | 2.7E+07                              |            |               |                    |                |         |               |          |               |          |                     |         |         |         |                          |
|                       |                            | 7.1E+05                              |            |               |                    |                |         |               |          |               |          |                     |         |         |         |                          |
|                       |                            | 2.0E+05                              |            |               |                    |                |         |               |          |               |          |                     |         |         |         |                          |
|                       |                            | 2.0E+05                              |            |               |                    |                |         |               |          |               |          |                     |         |         |         |                          |
|                       |                            | 6.3E+06                              |            |               |                    |                |         |               |          |               |          |                     |         |         |         |                          |