



Scientific Committee on Health and Environmental Risks

SCHER

Opinion on the environmental risks and indirect health effects of mercury from dental amalgam (update 2014)



SCHER adopted this opinion by written procedure on 10 March 2014

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### **SCHER**

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## ABSTRACT

In the 2008 Opinion on the environmental risks and indirect health effects of mercury in dental amalgam the Scientific Committee on Health and Environmental Risks (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 provided in 2008 opinion needs to be updated.

The concentration of mercury in surface water has been estimated considering three possible scenarios (worst, average and best case, as detailed in the main text). The Predicted Environmental Concentrations (PECs) calculated in the three scenarios have been compared with the Water Framework Directive (WFD) Environmental Quality Standards (Annual Average (AA) EQS and Maximum Allowable Concentration (MAC) EQS) that have been set for mercury. The comparison enables the conclusions stated below:

- best case scenario: the PEC is negligible in comparison to both EQS;
- average case scenario: the PEC is one order of magnitude below the AA EQS;
- worst case scenario: the PEC is substantially 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 following conclusions are derived:.

- best case scenario: all the calculated concentrations are far below the acceptable level in fish as well as the WFD threshold for secondary poisoning;
- average case scenario: all the calculated concentrations are far below the acceptable level in fish, however, the WFD proposed threshold for secondary poisoning is exceeded at methylation rates higher than 0.05%;
- worst case scenario: the acceptable level in fish is exceeded (or at least approached) at methylation rates higher than 0.1 %, while the WFD threshold for secondary poisoning is also exceeded at methylation rates higher than approximately 0.005%.

SCHER concludes that, in the worst case scenario, under extreme local conditions (maximal dentist density, maximal mercury use, absence of separator devices), 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.

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 in soil and air originating from dental amalgam use, it can be concluded that this emission fraction of Hg represents 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 0.005 %. 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.

With regard to human health, SCHER is of the opinion that the conclusions of the 2008-opinion are still valid. For health effects due to alternative materials particularly the potential leakage of bisphenol A (Bis-DMA), SCHER recommends referring to the SCENIHR opinion on the use of bisphenol A in medical devices.

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:

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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

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Actions 4 and 6 of the Mercury Strategy, both linked to dental amalgam, as areas where substantial improvement could still be achieved.

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 Union signed 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".

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 stated below.

*"... 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 European Union System for the Evaluation of Substances (EUSES) model for calculating environmental concentrations of a metal must be taken with caution, EUSES being 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. (Bio Intelligence Service, 2012)

**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.

1 **3.2.1.1. Concentration in surface water**

2 Sufficient data are available for SCHER to perform an estimation of the concentration of  
 3 mercury in the surface water compartment from the use of dental amalgam. Also in the  
 4 SCHER Opinion only for this compartment an estimation of Hg water concentration was  
 5 carried out (SCHER, 2008). SCHER has used the same calculation method as that used in  
 6 2008; several assumptions were replaced by new data that have become available. The  
 7 current version of the calculation method has been added as an Annex 1 to this opinion.  
 8 SCHER distinguished three scenarios to estimate the Hg concentration in surface water.  
 9 Table 2 gives an overview of the 3 scenarios.

10  
 11 **Table 2. Overview of assumptions used for estimating Hg surface water concentrations**  
 12 **due to the emission of mercury used in dental amalgam.**

13

	Worst case situation	Average case situation	Best case situation
Dentist discharge (g/dentist/y)	460*	160**	0.65*
Percentage of separators (%)	0 (in some countries no separation occurs)	75**	95 (estimated value since 100% can hardly be reached)
Efficiency of separator (%)	-	70**	95**
Number of dentists (N/10000 inhabitants)	12**	7**	3**
Average use of drinking water (L/d)	200***	200***	200***
Percentage in effluent water	10*	10*	10*
Dilution factor to surface water (-)	10***	10***	10***
Effluent concentration based on measurements (µg/L)	1*	0.05*	0.001*

14 \* Richardson et al., 2011  
 15 \*\* Bio Intelligence Service report, 2012  
 16 \*\*\* No change from 2008 (TGD 2003)

17  
 18 The meaning and the probability of occurrence of the three scenarios may be explained  
 19 considering the range of variability of the three major factors affecting Hg emissions: the  
 20 amount of Hg discharged per dentist, the percentage of installed separators and the  
 21 number of dentists per inhabitants. For all these factors the actual range of variability  
 22 has been taken from literature data. The three scenarios have been defined as described  
 23 below.

24 For the worst case scenario, the less favourable end of the range of variability for all the  
 25 three factors has been selected. This situation is possible at local level in some EU

1 countries or in some site-specific conditions. However, the probability of the presence of  
2 these three factors at the same time is difficult to quantify.

3 For the best case scenario, the more favourable end of the range of variability for all the  
4 three factors has been selected. As for the worst case, this situation is possible in some  
5 EU countries or in some site-specific conditions. Moreover, at least for the first two  
6 factors, it should represent the objective to be reached in the EU.

7 The average case scenario is based on realistic average values of the three factors.  
8 Though the probability of occurrence of this scenario in site-specific conditions cannot be  
9 quantified, it represents a realistic indication of the overall risk at EU level.

10 The results of the calculation are given in Table 3.

11

12 **Table 3. Estimated Hg concentrations due to the emission of mercury used in dental**  
13 **amalgam and measured Hg effluent concentrations.**

14

	Calculated in effluent (µg/L)	Measured in effluent* (µg/L)	Calculated Concentration in surface water after dilution** (µg/L)	
			From modelling	From measured data
Worst case scenario	1.2	1	0.12	0.1
Average case scenario	0.102	0.05	0.010	0.005
Best case scenario	3.6E-5	0.001	3.6E-6	0.0001

15 \* Based on Richardson (2000).

16 \*\* Assuming a dilution factor of 10

17

18 As Table 3 shows, the estimated Hg concentration due to the emission of mercury used  
19 in dental amalgam, including the calculated levels extrapolated from measured levels in  
20 the effluent match quite well, except for the best case scenario. This is due to the fact  
21 that conditions for the best case scenario are not fully implemented at the moment and  
22 therefore corresponding real values cannot be measured yet. Based on future  
23 developments, especially in the percentage of separators in use, the concentration in  
24 surface water is expected to reduce by a factor of about 50.

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

27

### 28 ***Methylation and bioaccumulation***

29 In the sheets in Annex 1, 2 and 3 the calculation results of the concentration for methyl  
30 mercury and its bioaccumulation in fish are also shown. The results are compiled in  
31 Table 4 for the three scenarios.

1  
2

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

Methylation (%)	Mercury concentration in surface water (µg/L)	Mean BAF* (-)	Methyl mercury concentration in fish (µg/kg fish)
Worst case scenario			
0.0001	1.2E-07	3.6E+06	4.2E-01
0.001	1.2E-06	3.6E+06	4.2E+00
0.01	1.2E-05	3.6E+06	4.2E+01
0.1	1.2E-04	3.6E+06	4.2E+02
1	1.2E-03	3.6E+06	4.2E+03
Average case scenario			
0.0001	1.0E-08	3.6E+06	3.7E-02
0.001	1.0E-07	3.6E+06	3.7E-01
0.01	1.0E-06	3.6E+06	3.7E+00
0.1	1.0E-05	3.6E+06	3.7E+01
1	1.0E-04	3.6E+06	3.7E+02
Best case scenario			
0.0001	3.6E-12	3.6E+06	1.3E-05
0.001	3.6E-11	3.6E+06	1.3E-04
0.01	3.6E-10	3.6E+06	1.3E-03
0.1	3.6E-09	3.6E+06	1.3E-02
1	3.6E-08	3.6E+06	1.3E-01

\* BAF = Bioaccumulation Factor.

3  
4

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

7 **3.2.1.2. Concentration in soil**

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

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

13 In the 2008 SCHER Opinion, a preliminary assessment of the potential risk for soil  
14 dwelling organisms of mercury released from dental practice was performed based on the  
15 generic TGD scenarios and default values. Based on a default average production of  
16 0.071 kg of sludge per person per day at the WWTP, the concentration of mercury in  
17 sludge, resulting from dental clinics is calculated to range between 0.01 and 2.4 mg  
18 Hg/kg dw with an average value of 0.42 mg/kg dw. These values are consistent with  
19 the mercury content of sewage sludge reviewed by BIO Intelligence Service (2012),  
20 ranging from 0.2 to 4.6 mg/kg dw (average value = 1.53 mg/kg dw). This range and  
21 average mercury concentration in sewage sludge is also consistent with observations  
22 made in the USA (US EPA 2009).

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

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

### 7 **3.2.1.3. Concentration in air**

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

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

15 In the on-going work to develop a global emission inventory for UNEP/AMAP (2012) the  
16 emissions from crematories in the EU were estimated to be 343 kg/y, ranging from 89 to  
17 1130 kg/y. Note that this value only represents cremation and not the handling,  
18 production and disposal of dental Hg. The same study estimated the global emissions  
19 from crematories at 3.3 tonnes (range 1-12), corresponding to 0.2% of total Hg  
20 emissions. This last figure was in reasonable agreement with those reported by the Bio  
21 Intelligence report (2012), indicating a value of about 2.8 tonnes for EU-27.

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

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

## 27 **3.2.2. Environmental risk assessment**

### 28 **3.2.2.1. Direct risk for aquatic organisms: inorganic mercury**

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

31 Annual Average EQS:	50 ng/L
32 Maximum Allowable Concentration EQS:	70 ng/L

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

- 35 • average case scenario: the estimated concentration of 10 ng/L is 5 times less  
36 than the AA EQS values;
- 37 • best case scenario: the estimated concentration of about 0.004 ng/L is negligible  
38 in comparison to EQS values;
- 39 • worst case scenario: the estimated concentration of about 120 ng/L is above both  
40 AA and MAC EQS values.

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

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

#### 5 **3.2.2.2. Direct risk for soil organisms: inorganic mercury**

6 The estimated concentrations of mercury in sewage sludge (0.01 and 2.4 mg Hg/kg dw)  
7 are far below the limit value for mercury concentration in sludge for use in agriculture  
8 (16 to 25 mg Hg/kg dw, Directive 86/278/EEC).

9 Moreover, the calculated added  $PEC_{soil}$  resulting from the contribution of amalgam to  
10 sewage sludge (from 0.016 to 4.1  $\mu\text{g Hg/kg}$ ) as well as those calculated using the  
11 maximum value reported by the Bio Intelligence Service report (7.6  $\mu\text{g Hg/kg}$ ) are well  
12 below the reported NOECs for soil dwelling organisms (e.g. Verbruggen et al., 2001; de  
13 Vries et al., 2007), which are all stated to be above 1.4 mg/kg. Thus, a negligible direct  
14 risk to the soil compartment is expected from the contribution of dental Hg in sewage  
15 sludge.”

16 As to the two additional sources of contribution to soil (disposal of solid wastes and  
17 burial), an estimate of the total European emission is available (Bio Intelligence Service,  
18 2012), but no information is available on the distribution patterns at the local scale.  
19 Therefore, a quantitative PEC cannot be estimated and an assessment of local risk is  
20 impossible.

#### 21 **3.2.2.3. Direct risk for the air compartment: inorganic mercury**

22 Total European emissions in the atmosphere from different patterns (sludge application,  
23 solid waste disposal, cremation) have been also estimated (Bio Intelligence Service,  
24 2012). However, as for soil, no information is available on the distribution patterns at the  
25 local scale. Therefore, a quantitative PEC cannot be estimated and an assessment of local  
26 risk is impossible.

#### 27 **3.2.2.4. Risks associated with methylation of inorganic mercury.**

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

38 Methylation of inorganic mercury may occur through two different patterns:

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

41 The concerns related to mercury in dental amalgams have been enhanced by the  
42 identification of methyl mercury in wastewater from dental units in the USA. The  
43 measured concentrations were particularly high in tanks from large clinics (up to 0.2% of  
44 the total mercury) suggesting methylation to occur within the tank. This may be the  
45 result of the activity of sulphate reducing bacteria, which are present in the oral cavity of  
46 humans, and can therefore be released during dental intervention. However, methyl  
47 mercury levels measured in the chair side wastewater were at least one order of  
48 magnitude lower than those measured in the tanks (Stone et al., 2003). In individuals  
49 with dental amalgam fillings, Hg-release may occur with time, influenced by individual



1 factors (i.e. gum chewing, tooth brushing, bruxism, dietary habits, and different rates of  
2 Hg releases from different amalgam types). In this situation, methylation may also occur  
3 in the human oral cavity as well in the gut, but the extent to which this happens and  
4 results in increased methyl mercury exposure is unclear.

5 A significant association has been found between annual urinary mercury levels and  
6 amalgams (Bellinger et al., 2006). The presence of dental amalgam fillings increases Hg  
7 excretion up to 3 µg (approximately 3.6 µg Hg/L) with respect to individuals with no  
8 amalgam fillings. It has been estimated that each amalgam filling will contribute an  
9 increase of around 0.1 µg Hg/L in urinary excretion. To put this value into context, this  
10 means that, at the German reference value of 1.4 µg Hg/L (reference value is mean Hg  
11 concentration in urine in the general population), up to 36 fillings may be necessary to  
12 exceed the HBM-I (defined as a urinary concentration without health risks based on  
13 presently available knowledge and applies to the general population).

14 It has been reported that the probability of exceeding the limits of mercury permitted in  
15 wastewater increased proportionally as the number of amalgam-filled surfaces increased  
16 and consequently that humans, especially in populated areas, can be a significant source  
17 of mercury pollutants (Leistevuo et al, 2002). However, the estimate was based on data  
18 coming from urinary excretion of total Hg, a marker which is strongly affected by dietary  
19 habits. Indeed, methyl mercury and even demethylated methyl mercury from seafood  
20 may significantly contribute to the mercury excreted in the urine (Johnnson et al.,  
21 2005; Sherman et al., 2013). By using an Hg isotope, Sherman et al. (2013) identified  
22 that while hair-mercury from dental professionals reflect isotope ratios typical for  
23 seafood, the urinary mercury differed from the ratio in the amalgam and tended to  
24 approach ratios in seafood as well, though with a wide variability that probably reflect  
25 differences in dietary habits.

26 The main environmental concern for methyl mercury is its potential for bioaccumulation  
27 and food web biomagnification resulting in a risk for secondary poisoning in ictivorous  
28 vertebrates. Consumption of fish and seafood as well as products for special nutritional  
29 uses are the most important sources for dietary exposure to mercury and methyl  
30 mercury, while other food products and drinking water are of minor relevance (EFSA,  
31 2012). As a threshold level, the EC proposal (within the WFD) of 20 µg methyl  
32 mercury/kg in the prey of birds and mammals may be used for safety evaluation. This  
33 threshold is much more conservative than the maximum acceptable concentration in food  
34 of 0.5 mg/kg ww (EC, 2006). It must be noted that the threshold in food refers to total  
35 mercury. However, it is reasonable to assume that most of mercury in fish is in the  
36 methylated form.

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

- 39 • average case scenario: all the calculated concentrations are far below the  
40 acceptable level in fish, however, the WFD proposed threshold ( 20 µg Hg/kg) for  
41 secondary poisoning is exceeded at methylation rates higher than 0.05 %;
- 42 • best case scenario: all the calculated concentrations are far below the acceptable  
43 level in fish as well as the WFD threshold for secondary poisoning;
- 44 • worst case scenario: the acceptable level in fish is exceeded (or at least  
45 approached) at methylation rates higher than 0.1 %, while the WFD threshold for  
46 secondary poisoning is also exceeded at methylation rates higher than  
47 approximately 0.005 %.

48 SCHER concludes that, in the worst case scenario, under extreme local conditions  
49 (maximal dentist density, maximal mercury use, absence of separator devices in the  
50 water treatment process), a risk of secondary poisoning in ictivorous vertebrates due to  
51 methylation cannot be excluded. These risks depend on the methylation rate of inorganic  
52 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 and will be specifically dealt with in the upcoming SCENIHR opinion), include inhalation of mercury vapours 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-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 ( $\text{Hg}^{2+}$ ), only a small part of the dose ingested is absorbed from the gastrointestinal tract.  $\text{Hg}^{2+}$  absorbed or formed by oxidation of elemental Hg may be eliminated by excretion with urine and/or faeces. The elimination of elemental mercury or  $\text{Hg}^{2+}$  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  $\text{Hg}^{2+}$  results in kidney damage characterized by proximal tubular injury. In contrast, long term oral administration of  $\text{Hg}^{2+}$  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  $\mu\text{g}/\text{kg}$  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  $\mu\text{g}/\text{kg}$  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 other fish products. The middle bound (MB) methyl mercury dietary exposure in Europe varies from the lowest minimum of 0.06

1 µg/kg bw per week seen in elderly people to the highest maximum of 1.57 µg/kg bw per  
2 week in toddlers (EFSA, 2012). It is absorbed from the gastrointestinal tract and  
3 subsequently rapidly and evenly distributed in the organism. The biological half-life of  
4 methyl mercury in blood is around 70 days. The faeces are the most important route of  
5 excretion (approximately 90% of a single oral dose of methyl mercury is excreted in the  
6 form of mercuric mercury). Urinary total mercury might be a suitable biomarker of  
7 inorganic (and elemental) mercury, but not for methyl mercury exposure. Methyl  
8 mercury elimination in humans mainly occurs via the biliary route after conjugation with  
9 liver glutathione S-transferases (GSTs), which produce a stable glutathione-metal  
10 conjugate which is then eliminated mainly via faeces (Ballatori and Clarkson, 1985;  
11 Dutczak WJ, Ballatori N., 1994). GSTs are highly polymorphic in humans and an  
12 association between null GSTM1 and GSTT1 genotypes and the retention of the metal has  
13 been established (Mazzaron Barcelos et al., 2012). This genetic make up, together with  
14 allelic variants of metallothionein (MT) and the heme pathway enzyme  
15 coproporphyrinogen oxidase (CPOX) are reported to affect Hg toxicokinetics and  
16 individual susceptibility to mercury in adults. Two randomized, controlled, clinical trials  
17 evaluated the neurobehavioral effects of Hg from dental amalgam tooth fillings, one in  
18 New England that followed 534 children over 5 years (Bellinger et al. 2006) and one in  
19 Portugal (DeRouen et al. 2006) that followed 507 children, 8-12 years of age at baseline.  
20 Associations between Hg exposure, genetic variants and test performance in boys were  
21 in the direction of impaired performance. However, since urinary Hg reflects a composite  
22 exposure index that cannot be attributed to a specific source, the authors concluded that  
23 the findings do not support an association between Hg in dental amalgams specifically  
24 and the adverse neurobehavioural outcomes observed (Woods et al, 2012; 2013. Indeed,  
25 other factors, such as variants of Apolipoprotein E, a major protein transporter expressed  
26 in the brain, have been postulated to cause genetic predisposition to Hg-induced effects  
27 (Ng et al, 2013).

28 In humans, high dose poisonings resulted in effects that included mental retardation, and  
29 sensory and motor impairment: due to the developing stage of their nervous system,  
30 children may be particularly susceptible to this effect. Long term, low dose prenatal  
31 exposures to methyl mercury due to maternal fish consumption have been associated  
32 with more subtle endpoints of neurotoxicity. Results from animal studies also show  
33 effects on cognitive, motor and sensory functions indicative of neurotoxicity.

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

38 More recently EFSA (2012) identified a TWI for methyl mercury of 1.3 µg/kg bw/w,  
39 expressed as mercury. Data from human studies in children (NOEL from Seychelles Child  
40 Developmental Study and BMDL<sub>05</sub> from Faroese cohort 1 at age seven years) were used  
41 as the basis for the derivation of the TWI, by using toxicokinetic modelling and applying a  
42 total uncertainty factor of 6.4 (2 to account for variation in the hair to blood ratio 3.2 to  
43 account for interindividual variation in toxicokinetics) (EFSA 2012).

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

53 In a detailed analysis of studies on effects of methyl mercury in humans and average fish  
54 consumption in the US, the US EPA has developed a fish tissue residue criterion  
55 (concentration in fish that should not be exceeded) of 0.3 mg methyl mercury/kg fish

1 (regarding human consumption) which is similar to a maximum tolerable content of 0.5  
2 mg methyl mercury/ kg fish for many fish species set by EU (EC, 2006). It must be noted  
3 that the EU threshold in food refers to total mercury, although it is expected that most of  
4 mercury in fish is in the methylated form.

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

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

14 The contribution of amalgam use to the concentrations of methyl mercury found in fish  
15 and formed from Hg<sup>2+</sup> dissolved in the oceans from non-anthropogenic sources is not  
16 known and consequently no clear conclusion on possible health risks is possible. Any  
17 calculation would be indeed affected by a high degree of uncertainty and based on a  
18 number of assumptions. However, a screening assessment can be attempted based on  
19 the provisional risk assessment for surface water, shown in Table 4, for which only the  
20 contribution of the emission of dentists was taken into account. Different situations can  
21 be evaluated on the basis of 5 hypothetical values for the methylation rate in three  
22 possible scenarios (worst, average and best case), with values spanning 4 -orders of  
23 magnitude. In the best and the average cases, the expected methyl mercury  
24 concentrations in fish related to contributions of dental amalgam uses are well below the  
25 thresholds of 0.3 – 0.5 mg methyl mercury/kg fish set by the US EPA and the EU. In the  
26 worst case scenario, those values obtained with a 0.1 % methylation rate exceed the US  
27 maximum tolerable content of 0.3 mg methyl mercury/kg fish and those obtained  
28 with 1% methylation rate exceed the EU maximum tolerable content of 0.5 mg methyl  
29 mercury/kg fish . Thus, the 'average' predicted indirect exposures of humans to methyl  
30 mercury resulting from emissions due to dental amalgams are much lower than the  
31 tolerable limits, although in the unlikely but not impossible worst case, mitigation  
32 measures are expected to be needed to reduce the risk. Therefore, compliance to the  
33 WFD threshold would prevent human health effects. On the other hand, methyl mercury  
34 in fish is the major contributor to the methyl mercury concentration in humans. It  
35 exceeds in a considerable proportion of children, safe limits, e.g. the limits set by US-EPA  
36 RfD and WHO-TDI, but not the limits set by EFSA. All additional sources which add to the  
37 methyl mercury burden in humans may increase the number of people at risk,  
38 Respecting the more conservative WFD threshold would contribute to the prevention of  
39 human health effects.

### 40 **3.4. Third question**

41

#### 42 ***Comparison of environmental risk from the use of mercury in dental amalgam*** 43 ***and the use of alternatives without mercury***

44

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

49 The composition of the most commonly used alternatives to dental amalgam is highly  
50 variable, represented by a matrix (e.g. a polymeric resin) and by several inorganic  
51 materials used as fillers (e.g. Al<sub>2</sub>O<sub>3</sub>, SiO<sub>2</sub>, metal oxides, metal fluorides, etc.).

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

- 2 1. *Composite resins*. They are composed of a polymerisable resin matrix, binding filler  
3 inorganic particles. The resin is initially a fluid monomer, which is converted into rigid  
4 polymer by a radical addition reaction. The most common resins used now are based  
5 on dimethacrylate (bisphenol A-glycidyl methacrylate: Bis-GMA and bisphenol A  
6 dimethylacrylate: Bis-DMA) or urethane dimethacrylate (UDMA). The inorganic  
7 materials used as fillers are silica-based glass fillers ( $\text{SiO}_2$ ), alumina glass ( $\text{Al}_2\text{O}_3$ ), and  
8 combinations of glass and sodium fluoride. They may also contain barium, strontium  
9 and boron.
- 10 2. *Glass ionomer (Glass polyalkenoate) cements*. They are a product of an acid-based  
11 reaction between basic fluoro-alumino-silicate and water-soluble polycarboxylic acid  
12 consisting of an organic-inorganic complex with high molecular weight (Wilson and  
13 McLean 1988; Davidson and Mjör 1999). The filler particles contain alumina ( $\text{Al}_2\text{O}_3$ ),  
14 silica ( $\text{SiO}_2$ ), metal oxides, metal fluorides, and metal phosphates. The metal ions  
15 usually selected are: aluminium (Al), calcium (Ca), strontium (Sr), zinc (Zn), sodium  
16 (Na), potassium (K), barium (Ba) and lanthanum (La).
- 17 3. *Resin-Modified Glass Ionomer Cement*. They are similar to the previous one, but  
18 water-soluble resin monomers (e.g., 2-hydroxyethylmethacrylate), capable of free  
19 radical polymerization, are added. Thus, resin-modified glass ionomer cement is a  
20 material that undergoes both the polymerization reaction and acid-base reaction.
- 21 4. *Compomers*. They are single-paste formulations consisting of fillers and a matrix,  
22 similar to a composite resin. The filler usually contains fluoro-alumino-silicate glass  
23 powder. Metal fluoride is also included in some materials for the same purpose. The  
24 glass powder contains strontium or some other metal. A compomer undergoes an  
25 acid-base reaction between the acidic monomer (e.g., polymerisable dimethacrylate  
26 resins such as urethane dimethacrylate) and ion-leachable basic glass filler in the  
27 presence of water from the saliva.
- 28 5. *Giomers*. They feature the hybridization of glass-ionomer and composite resins. They  
29 contain an adhesive promoting monomer and a bonding polymer catalyst, which allow  
30 bonding to hard tooth tissues.

31  
32 The detailed composition of some of the most frequently used alternatives is described  
33 by Erdal (2012). This report concludes for the alternatives of amalgam that "there is no  
34 current evidence of significant personal or environmental toxicity".

### 35 *Human health*

36 From the human health point of view, there is no new relevant data available on  
37 alternatives compared to the opinion of SCHER in 2008 (SCHER, 2008). Therefore, SCHER  
38 confirms its position taken in the 2008 Opinion, except for alternative materials included in  
39 group 1. For dental materials, the leakage is limited to resins composed of Bis-DMA which  
40 has an ester linkage that can be hydrolysed to BPA, whereas the ether linkage in Bis-GMA  
41 was found to be stable. Indeed, the possible effects related to the use of bisphenol A-  
42 containing dental resins are included in the ToR of an on-going SCENHIR mandate on the  
43 the use of bisphenol A in medical devices. SCHER refers the reader to that opinion.

### 44 *Environment*

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

1 be excluded. However, regarding the possible contribution of BPA leakage from dental  
2 material, two recent reports indicate that environmental exposure to BPA is very limited  
3 and the major contribution for human exposure is at present represented by food and  
4 beverage consumption, from the use of BPA-containing medical devices and thermal  
5 paper (EFSA, 2013; SCENIHR, 2014).

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

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

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

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

22 The chemicals can be divided in five groups:

- 23 1. Monomers group 1 are the components of polymeric resins used in a large number  
24 of commercial products (more than 15 from the list of Erdal 2012), often in high  
25 percentages (even more than 70%);
- 26 2. Monomers group 2 are the components of polymeric resins used in a small number  
27 of commercial products (less than 5 from the list of Erdal 2012), in medium high  
28 percentages;
- 29 3. Monomers group 3 are the components of polymeric resins used only in one  
30 commercial product in medium low percentages (usually less than 10%);
- 31 4. Organic additives are organic chemicals added before the polymerization process  
32 with various functions (initiation, catalysis, etc.); they are usually present in  
33 relatively small amount (<5%); low toxicity solvents often present in the  
34 composition (e. g. ethanol, acetone) are not included in the list;
- 35 5. Inorganic additives are some metals that may be added as fillers (as oxides and  
36 fluorides) are listed; fluorine is also listed.

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

42 In many reports it is concluded that the ecological risk of the available alternatives to  
43 amalgam is very low, in any case lower than those of amalgam. A synthesis of these  
44 opinions is provided by a document of the World Alliance for Mercury-Free Dentistry  
45 (2012).

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1 Considering the relatively low toxicity of the chemicals involved, these views may be  
2 considered reasonable. However, it is the opinion of the SCHER that, at present, there is  
3 insufficient scientific evidence to support these statements.

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

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

14  
15 Finally, it should be noted that the assessment of environmental impacts of the substitutes  
16 would require two complementary studies: a comparative risk assessment for the relevant  
17 environmental compartments, and a life-cycle assessment covering non ecotoxicological  
18 impacts such as those related to energy and natural resources consumption, atmospheric  
19 emissions including greenhouse gases, waste production, etc.

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

	CAS	MW	WS mg/L	Log Kow	Ecotoxicology (E/LC50 mg/L)		
					algae	Daphni a	fish
					72h EC50	48h EC50	96h 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	<i>0.34</i> 7	<i>0.50</i>	<i>1.32</i>
triethyleneglycol dimethacrylate.	109-16-0	286. 33	366	1.88	222	224	294
urethane dimethacrylate (UDMA)	72869-86-4	470. 57	<i>0.11</i>	4.69	<i>0.57</i>	<i>0.79</i>	<i>1.98</i>
<b>Monomers group 2</b>							
3-trimethoxysilylpropyl methacrylate	2530-85-0	248. 35	<i>5490</i>	<i>0.75</i>	<i>2600</i>	<i>2304</i>	<i>2331</i>
bisphenolA polyethyleneglycoldietherdimethacryl.	41637-38-1	310. 44	<i>612</i>	<i>6.14</i>	<i>0.01</i> 3	<i>0.02</i>	<i>0.08</i>
glycerol 1,3-dimethacrylate	1830-78-0	228. 25	<i>1035</i> 0	<i>1.16</i>	930	864	960
methyl methacrylate	80-62-6	100. 12	1050 0	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	5000 0	0.81	42	33	19
tetrahydrofurfuryl methacrylate	2455-24-5	170. 21	<i>1790</i>	1.8	159	159	35
bisphenol A dimethacrylate	3253-39-2	364. 44	834	5.6	<i>0.05</i> 4	<i>0.08</i>	<i>0.26</i>
decamethylene dimethacrylate	6701-13-9	310. 44	612	5.4	<i>0.07</i> 3	<i>0.11</i>	<i>0.33</i>
ethoxylated bisphenol-A-dimethacrylate	56744-60-6	540. 66	<i>2500</i>	6.08	6	0.04	0.15
1-propanol-3,3'-[isopropylidenebis(p-phenyleneoxy)]di-dimethacrylate	27689-12-9	480. 61	<i>2990</i> 0	6.01	0.02 8	0.045	0.15 3
tricyclodocandimethanol dimethacrylate	43048-08-4	332. 44	<i>0.21</i>	5.35	0.08 7	0.13	0.38
dl-camphorquinone	10373-78-1	166. 22	<i>3230</i>	0.75	1741	1542	1560
<b>Organic additives</b>							
2,2-bis[4-(2-methacryloxy)ethoxy)phenyl]propane	24448-20-2	452. 55	<i>0.03</i>	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	75980-60-8	348. 38	<i>3.1</i>	3.87	2.77	3.51	7.29



oxide							
2,6-di-tert-butyl-p-cresol (BHT)	128-37-0	220. 36	1.1	5.1	0.10	>0.17	>0.5 7
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	1890 142	11939 73	6137 54
dl-camphorquinone	10373-78-1	166. 22	3230	0.75	1741	1542	1560
glutaraldehyde	111-30-8	100. 12	misc	-0.18	8923	7104.2 9	10.5 0
maleic acid	110-16-7	116. 07	788	-0.78	4118 3	30600	2176 0
<b><i>Inorganic additives</i></b>							
aluminium					0.04	1.6	0.18
lantanium					-	0.08	0.01 *
strontium					-	41.5	0.12 4*
titanium					8.7	3.3	2.3
zinc					0.14	0.37	0.22

1 \* 28d LC50

#### 2 **4. COMMENTS RECEIVED DURING THE PUBLIC CONSULTATION**

3 A public consultation on this opinion was opened on the website of the EU non-food  
4 scientific committees from 25 September to 20 November 2013. A public hearing took  
5 place on 6 November 2013 in Luxembourg to receive contributions on the topic of the  
6 preliminary opinion.

7 Information about the public consultation was broadly communicated to national  
8 authorities, international organisations and other stakeholders. Fifteen organisations and  
9 five individuals participated in the public consultation providing input to the three main  
10 scientific questions (in total 60 contributions were received). Out of the 15 organisations  
11 participating in the consultation, there were six NGOs, three public authorities, three  
12 dentist associations, two businesses and one trade union.

13 Each submission was carefully considered by the Working Group and the scientific opinion  
14 has been revised to take account of relevant comments. The literature has been updated  
15 with relevant publications. The scientific rationale and the opinion section were clarified  
16 and strengthened.

17 All contributions received and the reaction of the Scientific Committee on Health and  
18 Environmental Risks (SCHER) can be downloaded at:  
19 [http://ec.europa.eu/health/scientific\\_committees/consultations/public\\_consultations/scher](http://ec.europa.eu/health/scientific_committees/consultations/public_consultations/scher_cons_06_en.htm)  
20 [\\_cons\\_06\\_en.htm](http://ec.europa.eu/health/scientific_committees/consultations/public_consultations/scher_cons_06_en.htm)

21

#### 22 **5. MINORITY OPINION**

23 None

## 6. LIST OF ABBREVIATIONS/ACRONYMS

1		
2		
3	BAF	Bio-Accumulation Factor
4	Bis-DMA	bisphenol A dimethacrylate
5	Bis-GMA	bisphenol A-glycidyl methacrylate
6	BMD	Benchmark Dose (An exposure due to a dose of a substance associated
7		with a specified low incidence of risk, generally in the range of 1% to 10%,
8		of a health effect; or the dose associated with a specified measure or
9		change of a biological effect).
10	BMDL	A lower one-sided confidence limit on the BMD
11	bw	Body weight
12	CAS	Chemical Abstract System
13	CSTEE	Scientific Committee on Toxicity, Ecotoxicity and the Environment
14	dw	dry weight
15	EC	European Commission
16	EC50	Median effect concentration (in relation to specific endpoint)
17	ECDC	European Centre for Disease prevention and Control
18	ECHA	European Chemicals Agency
19	EEB	European Environmental Bureau
20	EFSA	European Food Safety Authority
21	EMA	European Medicines Agency
22	EPA	Environmental Protection Agency
23	EQS	Environmental Quality Standard
24	EQS AA	Annual Average Environmental Quality Standard
25	EQS-MAC	Maximum Allowable Concentration Environmental Quality Standard
26	EU	European Union
27	EUSES	European Union System for the Evaluation of Substances
28	Hg	Mercury
29	INC	Intergovernmental Negotiating Committee
30	Kow	Octanol-water partition coefficient
31	LC50	Mean lethal concentration
32	MW	molecular weight
33	NO(A)EC	No Observed (Adverse) Effect Concentration
34	NOEL	No Observed Adverser Effect Level
35	PEC	Predicted Environmental Concentration
36	QSAR	Quantitative Structure Activity Relationship
37	RAR	Risk Assessment Report
38	RfD	Reference Dose
39	SCCS	Scientific Committee on Consumer Safety
40	SCENIHR	Scientific Committee on Emerging and Newly Identified Health Risks ( )
41	SCHER	Scientific Committee on Health and Environmental Risks
42	TGD	Technical Guidance Document
43	TDI	Tolerable Daily Intake
44	ToR	Terms of reference
45	TWI	Tolerable Weekly Intake
46	UNEP	United Nations Environment Programme (established an (INC)

1	WFD	Water Framework Directive
2	WHO	World Health Organisation
3	US	United States
4	US EPA	US Environmental Protection Agency
5	WFD	Water Framework Directive
6	ww	Wet weight
7	WWTP	Waste Water Treatment Plant

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## ANNEXES

1	
2	
3	<b>Sheets for calculation of PECs in surface water</b>
4	
5	<b>Annex 1 Average case scenario</b>
6	
7	<b>Annex 2 Best case scenario</b>
8	
9	<b>Annex 3 Worst case scenario</b>
10	
11	

### Annex 1 Average case scenario

Assumptions				Remark											
0.05	µg/L	Better case concentration in effluent		Assume all Hg comes from dental amalgam											
160	g Hg/dentist/y			Richardson, 2011 and applying 75% separators											
70	dentists/100000 inhabitant			Average (BIO, 2012)											
75	%	percentage amalgam separators		BIO, 2012											
70	%	efficiency of separators		BIO, 2012											
	mercury	dentist/10,000 inhabitants	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		ug/L	ng/L				
mean	7.6E+01	7	5.3E+02	2.0E+03	200	1.0E-03	10	1.0E-01	10	1.0E-02	1.0E+01				
								0.05	10	0.005	5				
										methyl mercury river					
											mean BAF			methyl mercury fish	
										ug/L	ng/L			ug/kg	
mean										1.0E-08	1.0E-05	3.6E+06	3.7E-02		
	% methylation	field BAF fish													
	1.0E-04	2.2E+04								1.0E-08	1.0E-05	3.6E+06	3.7E-02	Methylation rate 0,0001%	
	1.0E-03	1.0E+05			input value					1.0E-07	1.0E-04	3.6E+06	3.7E-01	Methylation rate 0,001%	
	1.0E-02	1.6E+06			assumption					1.0E-06	1.0E-03	3.6E+06	3.7E+00	Methylation rate 0,01%	
	1.0E-01	6.8E+06								1.0E-05	1.0E-02	3.6E+06	3.7E+01	Methylation rate 0,1%	
	1.0E+00	3.3E+04								1.0E-04	1.0E-01	3.6E+06	3.7E+02	Methylation rate 1%	
	5.5E-02	1.2E+05								5.6E-06	5.6E-03	3.6E+06	2.1E+01	Methylation rate 0.055%	
		6.8E+05													
		2.7E+07													
		7.1E+05													
		2.0E+05													
		2.0E+05													
		6.3E+06													

### Annex 2 Best case scenario

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			BIO, 2012									
95	%	efficiency of separators			BIO, 2012									
	mercury	dentist/10,000 inhabitants	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	ug/L	ng/L	ug/L	ng/L			
mean	6.2E-02	3	1.9E-01	7.2E-01	200	3.6E-07	10	3.6E-05	10	3.6E-06	3.6E-03			
								0.001	10	0.0001	0.1			
										methyl mercury river				
											mean BAF	methyl mercury fish		
										ug/L	ng/L	ug/kg		
mean										3.6E-12	3.6E-09	3.6E+06	1.3E-05	
	% methylation	field BAF fish												
	1.0E-04	2.2E+04								3.6E-12	3.6E-09	3.6E+06	1.3E-05	Methylation rate 0,0001%
	1.0E-03	1.0E+05								3.6E-11	3.6E-08	3.6E+06	1.3E-04	Methylation rate 0,001%
	1.0E-02	1.6E+06								3.6E-10	3.6E-07	3.6E+06	1.3E-03	Methylation rate 0,01%
	1.0E-01	6.8E+06								3.6E-09	3.6E-06	3.6E+06	1.3E-02	Methylation rate 0,1%
	1.0E+00	3.3E+04								3.6E-08	3.6E-05	3.6E+06	1.3E-01	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 scenario

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			BIO, 2012								
0	%	efficiency of separators			BIO, 2012								
	mercury	dentist/10,000 inhabitants	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	ug/L	ug/L	ng/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										mercury river	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
	1.0E-03	1.0E+05			input value					1.2E-06	1.2E-03	3.6E+06	4.2E+00
	1.0E-02	1.6E+06			assumption					1.2E-05	1.2E-02	3.6E+06	4.2E+01
	1.0E-01	6.8E+06								1.2E-04	1.2E-01	3.6E+06	4.2E+02
	1.0E+00	3.3E+04								1.2E-03	1.2E+00	3.6E+06	4.2E+03
	5.0E-03	1.2E+05								5.8E-06	5.8E-03	3.6E+06	2.1E+01
		6.8E+05											
		2.7E+07											
		7.1E+05											
		2.0E+05											
		2.0E+05											
		6.3E+06											