Scientific Committee on Health and Environmental Risks

SCHER

Opinion on the environmental risks and indirect health effects of mercury in dental amalgam

The SCHER adopted this opinion at its 23rd plenary on 6 May 2008

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 the new or emerging problems which may pose an actual or potential threat.

They are: the Scientific Committee on Consumer Products (SCCP), 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 Evaluation Agency (EMEA), the European Centre for Disease prevention and Control (ECDC) and the European Chemicals Agency (ECHA).

SCHER
Questions relating to examinations of the toxicity and ecotoxicity of chemicals, biochemicals and biological compounds whose use may have harmful consequences for human health and the environment.

In particular, the Committee addresses questions related to new and existing chemicals, the restriction and marketing of dangerous substances, biocides, waste, environmental contaminants, plastic and other materials used for water pipe work (e.g. new organics substances), drinking water, indoor and ambient air quality. It addresses questions relating to human exposure to mixtures of chemicals, sensitisation and identification of endocrine disrupters.

Scientific Committee members
Herman Autrup, Peter Calow, Wolfgang Dekant, Helmut Greim, Wojciech Hanke, Colin Janssen, Bo Jansson, Hannu Komulainen, Ole Ladefoged, Jan Linders, Inge Mangelsdorf, Marco Nuti, Anne Steenhout, Jose Tarazona, Emanuela Testai, Marco Vighi, Matti Viluksela

Contact:

European Commission
Health & Consumer Protection DG
Directorate C: Public Health and Risk Assessment
Unit C7 - Risk Assessment
Office: B232 B-1049 Brussels

Sanco-Sc8-Secretariat@ec.europa.eu

The opinions of the Scientific Committees present the views of the independent scientists who are members of the committees. They do not necessarily reflect the views of the European Commission. The opinions are published by the European Commission in their original language only.

http://ec.europa.eu/health/ph_risk/risk_en.htm

ACKNOWLEDGMENTS

Members of the working group are acknowledged for their valuable contribution to this opinion:

Prof. W. Dekant, Universität Würzburg, Germany

Prof. C. Janssen, (Chairman and Rapporteur), Ghent University, Belgium

Prof. Ole Ladefoged, Institute of Food Safety and Nutrition, Denmark

Prof. J. Tarazona, Spanish National Institute for Agriculture and Food Research and Technology, Spain

Keywords:

SCHER, scientific opinion, dental amalgam, mercury

Opinion to be cited as:

SCHER scientific opinion on the environmental risks and indirect health effects of mercury in dental amalgam, 6 May 2008

TABLE OF CONTENTS

1. BACKGROUND

The Community Strategy Concerning Mercury[1] was adopted in January 2005 with the key aim to reduce mercury levels in the environment and to reduce human exposure. Mercury and its compounds are highly toxic to humans, ecosystems and wildlife. A main concern is human exposure from methyl mercury in fish.

Mercury is released to air, water and soil due to the use of dental amalgam. Once released into the environment mercury could change into methyl mercury in the aquatic environment, the most toxic form, and in this way be a health problem when people are eating fish. Another problem is the presence of mercury in sewage sludge, which is incinerated or used for land application as agricultural fertilizer to close the cycle of nutrients.

Mercury demand in the EU was around 440 tonnes in 2005. The demand is expected to decrease but some significant uses remain. As the chlor-alkali industry phases out mercury cells, dental amalgam will become the EU's major mercury use with a demand of around 90 tonnes per year.[2] It is therefore appropriate to re-examine the scope for substitution.

Amalgam has been used as a tooth-filling material since the 1800s. Today alternatives to dental amalgam are available on the market and in many EU-25 countries dental use of mercury is declining due to awareness of the toxicity of mercury and for aesthetic reasons. In some countries (e.g. Sweden[3], Denmark[4], Finland[3], Norway[3] and Japan[5]) the use of dental amalgam is very limited and only used for some specific cases. Despite the development towards alternative fillings the use of dental amalgam has increased slightly, in EU-25[2]. This is a result of better access to dental care in some countries where dental amalgam is still the main material used. At present amalgam fillings are considered less expensive than the alternative. However, this is debated since the cost of treatment does not cover the cost of releasing mercury in the environment. An investigation from Sweden shows that the material cost only stands for about 5-10 % of the total cost for the dental treatment[3]. Also many dental practitioners seem to be hesitant to change long-standing methods of treatment, are less aware of environmental risks, or they may be less familiar with the newer mercury free alternatives.

Two actions in the Strategy are related to dental amalgam:

Action 4: "*The Commission will review in 2005 Member States' implementation of Community requirements on the treatment of dental amalgam waste, and will take appropriate steps thereafter to ensure correct application.*"

Action 6: *"In the short term the Commission will ask the Medical Devices Expert Group to consider the use of mercury in dental amalgam, and will seek an opinion from the Scientific Committee on Health and Environmental Risks, with a view to considering whether additional regulatory measures are appropriate."*

[1] COM(2005) 20 final, 28 January 2005

[2] Mercury Flows and Safe Storage of Surplus Mercury, report prepared for DG Environment by Concorde East West, August 2006, http://www.ec.europa.eu/environment/chemicals/mercury/pdf/hg_flows_safe_storage.pdf

[3] Mercury – investigation of a general ban, Swedish Chemicals Inspectorate, Report 4/04 2004

[4] 'Assessment of Technological Developments and Improved Product Control and Product Management Measures', Sufficiency and Effectiveness Review of the 1998 Protocol on Heavy Metals, UNECE Convention on Long-range Transboundary Air Pollution (LRTAP), Report prepared by the Task Force on Heavy Metals, June 2006.
http://www.unece.org/env/tfhm/third%20meeting/PostOttawa/HMProtocol_Review_Products_final%20report_0615.pdf

[5] Statistics from the Ministry of Health, Labour and Welfare in Japan: Mercury use in dental clinics was about 5.2 tonnes in 1970, 700 kg in 1999 and 314 kg in 2004.

The European Parliament has asked the Commission to come forward by end of 2007 with a proposal to restrict the use of mercury in dental amalgam.[6]

It necessary that The Scientific Committee on Health and Environmental Risks is therefore requested to investigate the environmental risks and indirect health effects connected to the use of dental amalgam.

2. TERMS OF REFERENCE

The SCHER is asked for an opinion – based on an evaluation of reports prepared by Germany, Denmark and Sweden (available as supporting documents) - on environmental risks and indirect health effects from use of dental amalgam. The evaluation should not exclusively be restricted to the reports from these Member States but should also take into account the much wider information on risks related to mercury available from other Member States of the EU 25.

The opinion should take into consideration – as far as the required information is available in the supporting documents - all possible mercury emissions resulting from the use of dental amalgam during the products whole life cycle (e.g. dental clinics, sewage disposal systems, crematoria).

If the necessary information is available, the committee is also asked to compare the use of mercury in dental amalgam with other available alternatives.

In their evaluation of the supporting documents, the SCHER should in particular address -to the extent possible- the following:

1. 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.
2. 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?
3. Comparison of environmental risks from use of mercury in dental amalgam and use of alternatives without mercury.
4. If the Committee under its work finds out that more information is needed, for one or more of the questions, the Committee is asked to provide a detailed list on what kind of information is needed to carry out the task.

3. OPINION

Preface:

A preliminary report of this opinion was released for public consultation on 29 November 2007. The consultation ran from 14 January to 22 February 2008 and all comments received were subsequently evaluated by the SCHER. Based on the comments related to scientific aspects of the risks posed by Hg in dental amalgam, the committee has made - where appropriate - modifications to the preliminary report. This has lead to the final opinion presented here.

3.1 Question 1

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 from air, water and soil from fillings placed in patients should be taken into account.

[6] European Parliament resolution on the Community strategy concerning mercury (2005/2050(INI)) March 2006

3.1.1 General comments

Over the past decade, the mercury releases to the environment due to dental amalgam use and disposal, and the potential consequences (risks) for human and environmental health has received increased attention. Although numerous publications are available describing one or more aspects of this issue, 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. This type of risk assessment requires, next to extensive general information on the effects to humans and (various) environmental species, more detailed information on possible regional-specific differences in the use, release and fate of Hg originating from dental amalgam. This includes 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.

As this type of information is not available to SCHER, a comprehensive risk assessment cannot be performed by the Committee. However, SCHER will attempt at addressing the question posed by the Commission based on individual reports made available and a screening level risk assessment performed according to EU Technical Guidance Procedures (TGD, 2003). It should be that the EUSES program was not developed for assessing metals, thus, the scenario used in the present assessment was implemented in Excel for allowing the subsequent probabilistic assessment. TGD default values (WWTP characteristics, dilution factor, etc.) were employed; the equations representing environmental distributions were adapted to the specific considerations of metals as suggested in previous opinions of the CSTEE and SCHER on metals. The values used in this assessment, other than TGD defaults, are mentioned in the relevant sections of this opinion.

The only report known to SCHER which has specifically assessed the environmental risk of Hg originating from dental amalgam is the RPA study published in 2002 (Floyd et al., 2002). The report concluded that the use of Hg in the products studied – including dental amalgam – were unlikely to pose significant risks to human health and the environment. These authors did, however, clearly state that the results of their study should be treated with caution as the model (EUSES) used for calculating the environmental Hg concentrations is not directly suitable for use with metals. The CSTEE were requested to evaluate this report and concluded in their opinion of 12 November 2003, that due to the high uncertainty associated with the model calculations and thus the high uncertainties regarding predicted environmental and human exposures, no science-based conclusions concerning the risk of the studied products could be made (CSTEE, 2003).

Several studies report on a mass flow analysis of Hg in the environment and have assessed the consumption and release of mercury used in dental amalgam.

The Danish Environmental Protection Agency has performed a detailed analysis of the consumption – in relation to its various uses - of mercury in Denmark during 2002-2003 (Danish EPA, 2004). It is reported that the greatest intentional use of this metal is in dental fillings with a yearly use of 1200 (+/- 100) kg Hg. This corresponds to 34% of the total mercury consumption in Denmark. From this value, it is estimated that dental clinics discharge between 190 and 260 kg of Hg/y in their wastewater. The same study also estimated that a total of 120 to 180 kg Hg/y is disposed off in the form of extracted and lost teeth, 20-30% of which will enter the waste stream. Each year, approximately 170 kg of Hg is released to the atmosphere as a result of cremation and 70 kg enters the soil compartment as a result of burial. Finally it is reported that between 120 and 680 kg Hg is collected from strainers and extracted teeth, of that 50-140 kg enters the refuse stream and the remainder is collected and exported.

Mercury emissions from both natural sources and anthropogenic activities have also been assessed in detail by UNEP. Worldwide release of mercury to the atmosphere was estimated to be between 2,000 and 3,000 metric tons from anthropogenic sources and 1,400 to 2,300 due to natural sources. An assessment covering most likely uses of

mercury in the US (based on data from 1995) concluded that, mercury emissions to air from anthropogenic sources amount to 145 metric tons with dental preparations contributing 0.6 tons (UNEP, 2002). An updated assessment for the year 2000 estimated a total anthropogenic release of mercury to the atmosphere of 126 tons and a contribution of 4.5 tons due to the use of dental amalgams. This updated assessment also estimated mercury releases to water from anthropogenic activities (total of 46 tons, with 0.8 tons from intentional uses including 0.4 tons due to dental amalgams) and to soil (total of 2700 tons, with 106 tons from intentional uses including 28 tons due to dental amalgams) mostly from mining activities (Cain et al., 2007). Total mercury emissions to the atmosphere from intentional uses were estimated to be 239 tons (year 2000) in Europe with natural emissions of 177 t/y for Europe, with coal combustion being the major anthropogenic mercury source (Pacyna et al., 2006).

Very recently, the European Environmental Bureau has published a detailed mass balance analysis of mercury used in dental applications (EEB, 2007). This report has examined – in a quantitative manner and across the EU-27 - all sources of amalgam Hg and the pathways by which it can enter the environment. This report states that the EU-27 discharges 109 tonnes/y of mercury from dental practices and that mercury in the teeth of deceased persons contribute 14 tons Hg/y to the EU waste stream. The authors state that of this total of 123 tons, 77 tons will 'likely' end up in various environmental media: i.e. 30 tonnes in soil, 23 tonnes in the atmosphere, 14 tonnes in surface water and 10 tonnes in ground water.

The RPA report estimates that approximately 70 tons Hg/year is released (into the environment) by the EU-15 (Floyd et al. 2002). The value given for Denmark is 1 ton/y which is comparable to the values reported in above mentioned report (Danish EPA, 2004). No further comparisons of the use quantities, release patterns and possible (predicted) environmental concentrations could be made as the type of information and calculations provided in the various reports is too diverse in nature.

From the literature available to the SCHER it may be concluded that while dental amalgams may represent one of the major intentional uses of Hg today, the contribution of dental amalgams to Hg emission to air is only a small fraction of the total release of Hg to the atmosphere. Releases from dental amalgam to water may be more significant but the relative contributions of the various sources vary considerably depending on the literature source used. Information on the Hg releases of dental amalgam to the soil compartment is too scarce to assess it's relative importance and potential risks.

Finally, it should be noted that Hg releases associated with the present use of amalgams represent a small fraction of the total Hg emissions to atmosphere and the global Hg pool due to the much larger emissions from other sources (UNEP, 2002).

As mentioned above, although this type of mass balance data contributes to the understanding of the magnitude and sources of mercury contamination caused by dental applications, it does not allow to asses the risks of Hg in amalgam in a quantitative manner. Hence, SCHER has attempted to perform a screening level risk assessment according EU TGD procedures (TGD, 2003).

3.2 Screening risk assessment

Based on the available information, the screening risk assessment described below presents independent estimations for inorganic mercury and methylmercury exposure, and the potential risk associated to the methylation of inorganic mercury in the environment. It should be noted that all these risks should be combined for an overall evaluation of the added risk, and then the estimated added risk should be considered in conjunction with other Hg sources/exposures to perform a comprehensive risk assessment.

3.2.1 Direct risk for aquatic organisms: inorganic mercury

Information on emissions of mercury from dental practices can be assessed in a preliminary manner on the basis of Hg concentrations measured in dental clinic wastewaters. Two studies, covering current practice in Sweden and USA are available. The Swedish study (Hylander et al., 2006) presents measurements for several locations ranging from 0.77 to 74.1 mg Hg/l. It must be underlined that, due to legal requirements, Swedish clinics use amalgam separators prior to wastewater discharge. The efficiency of these systems was observed to be highly variable. Indeed, the wastewater concentrations measured after inspection and revision of these systems were about one order of magnitude lower, i.e. ranging from 0.23 to 6.6 mg Hg/l.

The concentrations measured in the USA (Stone et al., 2003) are similar to those reported for Sweden, ranging between 1.8 and 173 mg Hg/l for individual measurements. Site averages (5.4, 13.4 and 45.1 mg/l) were within the range observed for the Swedish locations. The presence of amalgam separators is not mentioned in the USA study, but the samples were collected from the liquid portion of the waste water (avoiding settled material).

Although the information used here is limited, it suggests that the large variability observed in the Swedish study covers operating conditions without separators or at least with separators that do not work efficiently. Therefore, it is suggested that the information used here cover those facilities and/or geographic areas for which a separator is not mandatory (this statements is supported by: (1) the significant reduction in the emissions observed after the maintenance of the separator and (2) the coincidence of the values used with the values reported in the US).

SCHER used the above information to estimate the releases of mercury to the wastewater system. The release range used here is intended to cover both “best case” (properly operating separators) and the “worst-case” conditions (inefficiently operating separators or no separator use).

The Swedish study also reports annual release estimations, ranging from 0.32 to 83.8 g Hg per dental chair and per year, with a mean value of 14.5 g. Considering an average EU value of 80 dentists per 100,000 inhabitants (Eurostat web page, 2007), and the default values for a wastewater treatment plant described in the TGD (2003), the concentration of Hg in the WWTP inflow due to dental practice is estimated to be in the range of 3.5 to 918 µg Hg/l with and average value of 159 µg Hg/l. Assuming a retention at the WWTP of 96% due to sludge adsorption and a default dilution factor of 10, the expected Hg contribution from dental clinics in river waters receiving municipal effluents is calculated to range between 0.000014 and 0.0037 µg Hg/l, with an average value of 0.00064 µg/l or 0.64 ng/l.

It is clear that this 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 Hg sources to fully assess the risks of Hg to the environment.

The comparison of these exposure estimations with the EC proposal for an Ecological Quality Standard for direct effects of mercury on aquatic organisms (0.05 µg Hg/l as annual average and 0.07 µg Hg/l as maximum permissible concentration) indicate that the added risk to aquatic organisms from the contributions from dental clinics to the total mercury should be considered low.

3.2.2 Direct risk for soil organisms: inorganic mercury

A similar approach, using the generic TGD scenarios and default values, can be used for the preliminary assessment of the potential risk for soil dwelling organisms of mercury released from dental practice. 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 as a consequence of releases from dental clinics is calculated to range between 0.001 and 2.4 mg Hg/kg dw with and average value of 0.42 mg/kg dw.

Considering that the reported EU average Hg concentration in sludge is 1.5 mg Hg/kg (EC 2004 web site: http://ec.europa.eu/environment/chemicals/mercury/summary of_legislation.pdf), it is suggested – based on this information – that the contribution of dental clinics represents about one third of the Hg total releases to the terrestrial compartment.

From a risk assessment perspective these values are well below the current EU legal limits established under Directive 86/218/EEC. However, it should be mentioned that these limits have not been updated based on current knowledge. The added PEC_{soil} resulting from the contribution of dental clinic emissions - following the TGD default values - ranges from 0.016 to 4.1 µg Hg/kg. These concentrations are well below the reported NOECs for soil dwelling organisms (e.g. Verbruggen et al., 2001; de Vries et al., 2007). Thus, based on this screening risk assessment, a low direct risk of dental Hg to the soil compartment is expected.

The atmospheric emissions of Hg from crematoria and further deposition close these installations should be considered as an additional contribution of mercury from dental amalgams. The few measurements which are available indicate a large variability. The contribution from this source may be significant in some local scenarios, while the environmental relevance cannot be assessed without an in-depth analysis of the soil fate and ecotoxicology of mercury in soils based on recent developments concerning the environmental risk assessment of metals (e.g. SCHER opinions on the RAR for several metals). Contrary to the sludge application in soil (which allows a simplified estimation of the initial PEC), the fate, transport and atmospheric deposition of mercury is complex and the simplified scenario described in the TGD requires in-depth modifications to allow correct PEC estimation. As such, this has not been covered in the screening risk assessment presented here.

3.2.3 Risks associated to the direct emissions of methylmercury from dental practice.

The concerns related to mercury in dental amalgams have been enhanced by the identification of methylmercury 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 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 methylmercury levels measured in the chair side wastewater where at least one order of magnitude lower that those measured in the tanks (Stone et al., 2003).

It should be noted that although the study was conducted in the USA, the levels of total mercury measured in the wastewater were similar to those reported for the EU.

Based on the percentage of total mercury released as methylmercury observed in the USA study (Stone et al., 2003), we selected the highest reported value of 0.2% as the generic estimation of the occurrence of MeHg. Using similar exposure estimations as those conducted for inorganic mercury, the concentration of methylmercury in the WWTP inflow due to dental practice is thus estimated to be in the range of 0.000007-0.0018 MeHg µg/l with and average value of 0.0003 µg/l. Assuming a retention at the WWTP of 96% due to sludge adsorption and a default dilution factor of 10, the expected contribution from dental clinics in river waters receiving municipal effluents is estimated to range between 7×10^{-9} to 1.8×10^{-6} µg/l, with and average value of 3.2×10^{-7} µg/l. Also here, this value needs to be added to the natural and historical background concentrations as well as to the contribution from any additional sources of methyl mercury - including the methylation in the environment of the inorganic mercury released by the dental clinics – to assess the overall risk of methylmercury.

The main environmental concern for methylmercury is its potential for bioaccumulation and food web biomagnification resulting in a risk for secondary poisoning in ictivorous

vertebrates. Thus, this screening risk assessment focused on secondary poisoning. It should be noted that the reported bioaccumulation factors (BAF) measured in the field for fish species collected at different locations range from about 20,000 to over 20,000,000. Using the larger values in this range, the releases of methylmercury (originating from dental amalgam) would exceed the EC proposal (within the WFD) of 20 µg methylmercury/kg in the prey of birds and mammals.

A preliminary risk estimation can be done by combining the TGD defaults with the individual values for each Swedish location and the field BAF (geometric means) reported in the WFD-EC document (EC, 2006). The Swedish values were considered as estimations of the expected releases to the WWTP. The default generic values of the TGD were used for estimating the predicted environmental concentrations (PEC) in water from these releases. The PECs were then multiplied by the BAF to estimate the expected concentration of mercury resulting from releases due to amalgam uses. Individual releases and BAF values were randomly combined using Monte Carlo analysis. The results are presented in Figure 1 and show that the risk of exceeding the EC proposal considering exclusively the direct emissions of methylmercury from dental facilities is of about 6%. If this contribution is assumed to represent about 10% of total anthropogenic contribution for methylmercury, the risk for exceeding the EC proposal would increase to about 18%.

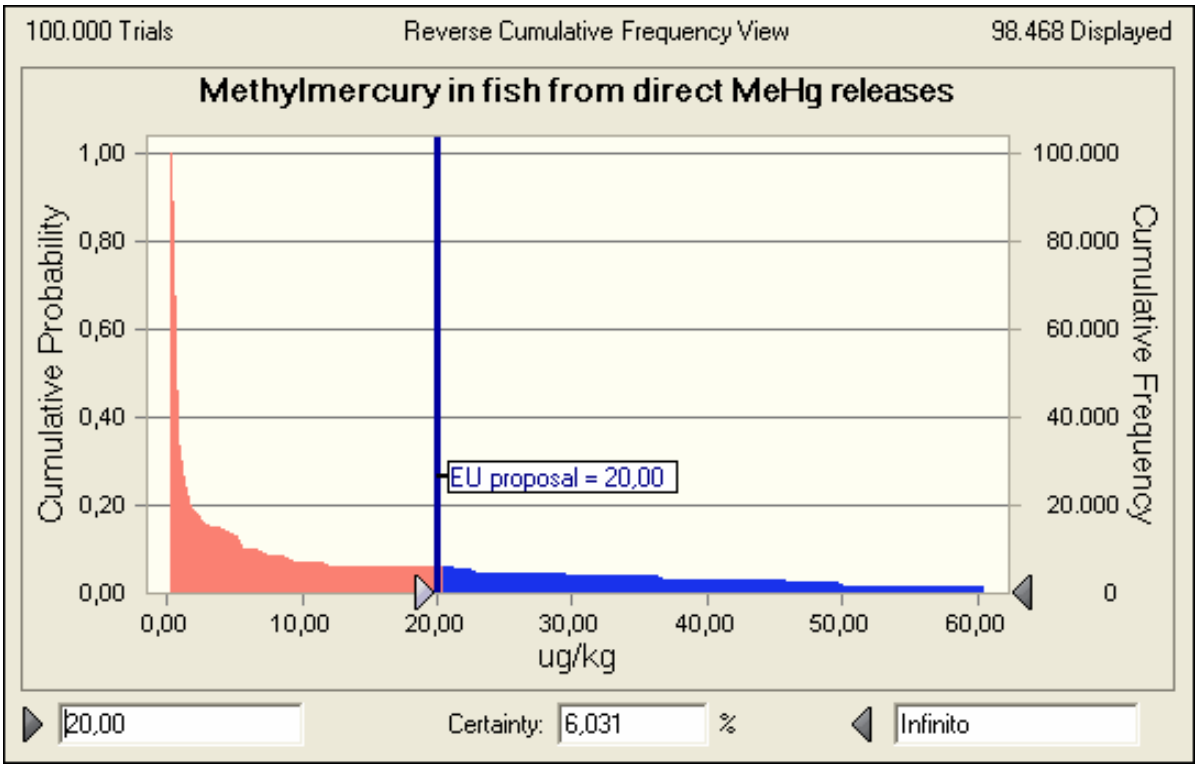

Figure 1 - Preliminary estimation of the risk for exceeding the EC proposal for the concentration of methylmercury in aquatic organisms as the result of the direct emissions of methylmercury from the dental use.

3.2.4 Risk associated to the environmental methylation of inorganic mercury: secondary poisoning, bioaccumulation and biomagnification potential for inorganic mercury releases.

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.

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.

The potential for bioconcentration of methylmercury in aquatic organisms is orders of magnitude higher than for inorganic mercury.

When the food-web bioaccumulation is considered, the overall bioaccumulation factor (ratio between the concentration in the organisms and the concentration in water) may be well above one million (cf. above).

Although there are several models describing the bioaccumulation and biomagnification potential of mercury in different ecosystems, the variability - in terms of both the methylation potential and the overall biomagnification - is so high that no sound generic estimations can be done with the current level of knowledge.

In fact, the conclusion presented by the European Commission within the process of setting Ecological Quality Standards for mercury under the Water Framework Directive was that "*Due to the different site specific factors driving bioaccumulation of mercury in aquatic food webs, it seems on the basis of the current knowledge not appropriate to derive a general* $QS_{secpois}$*, water. An in depth assessment of the uncertainties associated with the bioaccumulation potential of (inorganic and organic) mercury and its toxicity to predators is required in order to derive reliable quality standards depending on site specific factors. Thus, it is suggested to set the QS for methylmercury for the time being for the concentration in biota only*".

SCHER supports this conclusion for both the aquatic and soil compartments and hence considers that it is not possible to conduct a quantitative assessment of the risk of inorganic mercury releases from dental amalgams for top predators. Nevertheless, the development of probabilistic risk estimations offer alternatives, and the possibility for conducting sensitivity analysis should be investigated (see question 4).

A preliminary assessment covering apparent methylation rates (overall result of the processes covering methylation, demethylation and transport from water column to sediment and vice versa) ranging from 0.0001 to 1% is presented in Figure 2. These results clearly show that assessing the methylation rate is a key element for a correct evaluation.

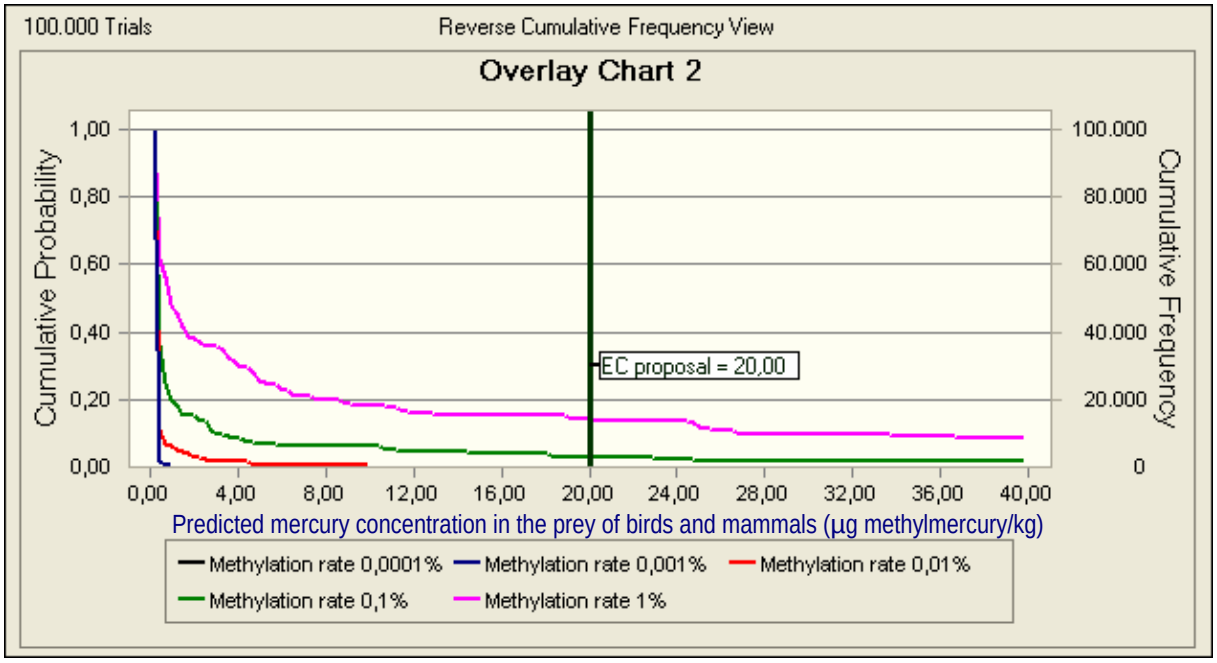

Figure 2 - Preliminary assessment of the role of environmental methylation when assessing the risk of inorganic mercury emissions from dental amalgams.

Conclusion on Question 1

The screening assessment presented here and which is based on the limited information suggests that a potential environmental risk associated to dental amalgams cannot be excluded. As expected, it is confirmed that methylation in the environment plays the key role. Therefore, a comprehensive risk assessment using higher tier techniques/procedures and probabilistic tools would be required for a proper assessment. This should results in a proper quantification of the likelihood and magnitude of the potential effects. This study should include comparative assessments of risks related to dental amalgam use and those related to other Hg sources.

3.3 Question 2

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 from many sources is distributed ubiquitously in the environment and can therefore be taken up by the general (human) population via food, water and air.

Potential sources of exposure to mercury include inhalation of mercury vapors in ambient air, ingestion of drinking water and food contaminated with mercury, and exposure to mercury through dental treatments.

Dietary intake is the most important source of non-occupational exposure to methylmercury, with fish and other seafood products being the dominant source of mercury in the diet. Most of the mercury consumed in fish or other seafood is methylmercury (WHO 1990, 1991) (Table 1).

Sources of exposure	Elemental mercury vapour	Inorganic mercury compounds	Methylmercury
Air	0.030 (0.024)	0.002 (0.001)	0.008 (0.0064)
Food			
Fish	0	0.600 (0.042)	2.4 (2.3)
Non-fish	0	3.6 (0.25)	0
Drinking water	0	0.050 (0.0035)	0
Dental amalgams	3.8 – 21 (3 – 17)	0	0
Total	3.9 – 21 (3 – 17)	4.3 (0.3)	2.41 (2.31)

Table 1: Estimated average daily intake and retention of total mercury and mercury compounds in the general population. Values given are the estimated average daily intake (µg/day) for adults. The figures in parentheses represent the estimated amount retained in the body of an adult.

Taking these considerations on exposure into account, for indirect intake of mercury from the environment due to the uses of dental amalgams, the toxicology of inorganic mercury and methyl mercury is relevant for risk assessment.

In general, the toxicology of mercury is highly depending on the route of administration and speciation of mercury (elemental mercury; inorganic salts of mercury; or methylmercury).

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. Elemental mercury is slowly oxidized in the blood.

After consumption of inorganic mercury (Hg^{2+}), only a small part of the dose ingested is absorbed from the gastrointestinal tract. 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 Hg^{2+} follows complex kinetics with half-lives in the range of 20 to 90 days.

In contrast to inorganic mercurial, most of an oral dose of methyl mercury is absorbed from the GI-tract. Absorbed methylmercury is rapidly and evenly distributed in the organism. The biological half-life of methyl mercury blood is around 70 days. The faeces are the most important route of excretion for mercury after short-term or long-term absorption of methylmercury (approximately. 90 % of a single oral dose).

The major target organ for the toxicity of inorganic mercury is the kidney. Ingestion of high doses of Hg^{2+} results in kidney damage characterized by proximal tubular injury. In contrast, long term oral administration of Hg^{2+} to rodents causes glomerulonephritis as the most sensitive endpoint. Higher doses of inorganic mercury also cause neurotoxicity.

Methylmercury is highly toxic. Human exposures following high dose poisonings resulted in effects that included mental retardation, and sensory and motor impairment. Long term, low dose prenatal exposures to methylmercury due to maternal fish consumption has been associated with more subtle endpoints of neurotoxicity. Results from animal

studies also show effects on cognitive, motor and sensory functions indicative of neurotoxicity.

Legal limits for human exposures to both Hg^{2+} and methyl mercury have been established by several organisations (Table 2).

Limit value	Refers to	Organisation
0.1 μg/kg/day (methyl-mercury)	„reference dose“	US EPA, 2001
0.3 μg/kg/day (Hg^{2+})	„reference dose“	US EPA, 1987
5 μg/kg/day total mercury, maximum of 1.6 μg/kg/day as methylmercury	Provisional weekly intake	JECFA, 2003

Table 2: Limits for the intake of $Hg2^{+}$ and methylmercury.

Expected methyl mercury concentrations in fish related to contributions of dental amalgam uses are in the range of up to 60 µg/kg based on the screening estimations conducted in section 3.1 (see Figures 1 and 2). This value has been derived by applying bioaccumulation factors measured in the field to the PEC_{water} estimated for the use of amalgam by dentists (see section 3.1 for details).

Tolerable limits for methyl mercury content of fish have also been set by different organisations. The US EPA, in a detailed analysis of studies on effects of methyl mercury in humans and average fish consumption in the US, 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.

For a group of fish including tuna, sword fish, and halibut a limit value of 1 mg/kg is established (Commission Regulation No 1881/2006). Therefore, the predicted indirect exposures of humans to methyl mercury resulting from emissions due to dental amalgams (i. e. up to 60 µg/kg bw of fish, see above) are much lower than these tolerable limits.

This indicates a low risk for serious health effects based on predicted contribution of amalgam uses to body burdens of methyl mercury. It should be noted that this screening assessment covers exclusively the release of mercury from the dental clinics wastewater (direct release of methyl mercury and methylation of released inorganic mercury in the environment).

3.4 Question 3

Comparison of environmental risks from use of mercury in dental amalgam and use of alternatives without mercury

Alternatives without amalgams for dental restoration often are resins generated by polymerisation processes. Data on toxic effects of resin monomers in animals and ecotoxicological data are not available from publicly accessible sources. However, since the materials used as a basis for resin generation are derivatives of methacrylic acids and glycidyl ethers, the well studied toxicology of methacrylate and its esters may be used as a basis for structure activity relationships to predict major toxicities.

Methylmethacrylate is rapidly absorbed after oral administration in experimental animals and is rapidly catabolized by physiological pathways to carbon dioxide. The major toxic effects of methylmethacrylate in animals are skin irritation and dermal sensitization. In repeated dose-inhalation studies, local effects on respiratory tissue were noted after methylmethacrylate inhalation. Neurotoxicity and liver toxicity were observed as systemic effects after inhalation of methylmethacrylate in rats and in mice to

concentrations above 3000 ppm for 14 weeks. No developmental toxicity after methylmethacrylate with a NOAEC > 2000 ppm was observed. Methylmethacrylate is also clastogenic at toxic concentrations (EU-RAR 2002).

Regarding glycidyl ethers a detailed overview of the toxicity of these compounds based mainly on unpublished study reports is available (Gardiner et al. 1992). Based on this report, skin irritation and skin sensitization are the major toxicities observed. In addition, positive effects in genetic toxicity testing were seen with many glycidyl ethers at comparatively high concentrations.

Due to the low mammalian toxicity of these compounds, indirect risks to human health from release of the alternatives without mercury are estimated as low.

Regarding the environmental risk, the available information is too limited for conducting a proper comparative assessment of amalgam alternatives. It should be noted that the assessment of environmental impacts of the substitute would require two complementary studies: a comparative risk assessments for the relevant environmental compartments, and a life-cycle assessment covering non ecotoxicological impacts such those related to energy and natural resources consumption, atmospheric emissions including greenhouse gases, waste production, etc.

3.5 Question 4

If the Committee under its work finds out that more information is needed, for one or more questions, the Committee is asked to provide a detailed list on what is kind of information is needed to carry out the tasks.

The responses given in the previous sections, it is clear that the information presently available does not allow to comprehensively assessing the environmental risks and indirect health effects from use of dental amalgam in the Member States of the EU 25/27.

To allow this type of assessment, the following information is required:

- More specific information on possible regional-specific differences in the use, release and fate of Hg originating from dental amalgam. This includes detailed quantitative information on the use and release pattern in all EU-25/27 countries, possible country-specific abatement measures, and differences in the fate of mercury due to regional-specific municipal waste water treatment and sludge application practices.
- A comprehensive and updated data compilation on the effects to especially (various) environmental species of Hg and methylmercury.
- A more comprehensive evaluation of atmospheric emissions and further deposition of mercury from crematoria, taking into account EU-wide practices and possible region-specific local scenarios.
- A comprehensive literature review of the bioaccumulation and biomagnification of methylmercury under different EU conditions.
- A detailed comparison of the relative contribution of dental Hg to the overall mercury pool - originating from intended and non-intended Hg - in the environment.

4. LIST OF ABBREVIATIONS

BAF	Bio-Accumulation Factor
CSTEE	Scientific Committee on toxicity Ecotoxicity and the Environment
EEB	European Environmental Bureau
EPA	Environmental protection Agency

EQS	Ecological Quality Standard
EUSES	European Union System for the Evaluation of Substances
NO(A)EC	No Observed (Adverse) Effect Concentration
PEC	Predicted Environmental Concentration
RAR	Risk Assessment Report
RPA	Risk & Policy Analyst Ltd.
TGD	Technical Guidance Document
WFD	Water Framework Directive
WWTP	Waste Water Treatment Plant

5. REFERENCES

ATSDR (1999). Toxicological profile for mercury. Update. Agency for Toxic Substances Disease Registry, Atlanta, GA.

Cain A, Disch S, Twaroski C, Reindl J, Case CR (2007) Substance flow analysis of mercury intentionally used in products in the US. J Industrial Ecology 11: 61-75

CSTEE (2003). Opinion of the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) on 'Risks to health and the environment related to the use of mercury in products'. Adopted on 12 November 2003.

Danish EPA (2004). Mass flow analysis of mercury 2001. Environmental project 926.

de Vries W, Lofts S, Tipping E, Meili M, Groenenberg JE, Schütze G. (2007). Impact of soil properties on critical concentrations of cadmium, lead, copper, zinc, and mercury in soil and soil solution in view of ecotoxicological effects. Rev Environ Contam Toxicol. 191:47-89.

EC (2005) Common Implementation Strategy for the Water Framework Directive. Environmental Quality Standards (EQS) Substance Data Sheet Priority Substance No. 21 Mercury and its Compounds CAS-No 7439-97-6 Final version Brussels, 15 January 2005

EC (2006a) Proposal for a Directive of the European parliament and of the Council on environmental quality standards in the field of water policy and amending Directive 2000/60/EC. COM(2006) 397 final. 2006/0129 (COD) Brussels, 17 July 2006

EC (2006b) Commission regulation setting maximum levels for certain contaminants in foodstuffs. (EC) 1881/2006, OJ L364/519, 19 December 2006

EEB (2007) Mercury in dental use: environmental implications for the European Union. European Environmental Bureau (EEB)

EFSA (2004). Opinion of the Scientific Panel on Contaminants in the Food Chain on a request from the Commission related to mercury and methylmercury in food. The EFSA Journal 34, 1-14.

EU-RAR (2002). European Union Risk Assessment Report. Methyl methacrylate, CAS No: 80-62-6, EINECS-No. 201-297-1. European Commission

Floyd P., Crane M., Tarkowski S. and Bencko V. (2002). Risks to health and the environment related to the use of mercury products. Risk & Policy Analyst Ltd. Report prepared for the EU, DG Enterprise, pp. 119.

Gardiner, T. H., Waechter, J. M., Jr., Wiedow, M. A., and Solomon, W. T. (1992). Glycidyloxy compounds used in epoxy resin systems: a toxicology review. Regul Toxicol Pharmacol 15, S1-77.

Hylander L.D., Lindvall A. and L. Gahnberg L., 2006. High mercury emissions from dental clinics despite amalgam separators. Science Total Env 326:74-84.

IRIS (2007). Methylmercury. In: Integrated Risk Information System. Database, last revised. US-EPA 12 March 2002.

JECFA (2004). Methylmercury. In: Evaluation of certain food additives and contaminants. Sixty-first report of the Joint FAO/WHO Expert Committee on Food

Kennedy C.J., 2003. Uptake and accumulation of mercury from dental amalgam in the common goldfish, *Carassius auratus*. Environmental Pollution 121: 321-26.

TGD (2003) Technical Guidance Document on Risk Assessment, European Communities

UNEP (2002). Global Mercury assessment. United Nations Environment Programme - Chemicals, Generva.

US-EPA (1997). Mercury study Report to Congress. US Environmental Protection Agency, Office of Air Quality Planning & Standards and Office of Research and Development.

US-EPA (2001). Water quality criterion for the protection of human health: methylmercury. US Environmental Protection Agency, Washington.

Stone, M. E., Cohen, M. E., Liang, L., and Pang, P. (2003). Determination of methylmercury in dental-unit wastewater. Dent Mater 19, 675-9.

Verbruggen E.M.J., Posthumus R. and van Wezel A.P.(2001). Ecotoxicological Serious Risk Concentrations for soil, sediment and (ground)water: updated proposals for first series of compounds. RIVM report 711701 020. Bilthoven, 263pp.

WHO (1990). Methylmercury. World Health Organisation, International Programme on Chemical Safety, Geneva.

WHO (1991). Inorganic mercury. World Health Organisation, International Programme on Chemical Safety, Geneva.