



### **EEB/ZMWG** comments on the

SCHER Preliminary report on the environmental risks and indirect health effects of mercury in dental amalgam

Brussels

22 February 2008

### 1 Introduction

This paper comprises the European Environmental Bureau / Zero Mercury Working Group comments to the SCHER report entitled, *Preliminary report on the environmental risks and indirect health effects of mercury in dental amalgam*, approved for public consultation on 29 November 2007.

The EEB/ZMWG would like to express its surprise that there was no email notification from the European Commission - DG Health and Consumer affairs, at least to the main interested stakeholders, on the publication of this report and on the fact that a consultation period was launched. The EEB had already expressed its active interest in the topic, not only in line with its mercury campaign since November 2004, but also through submissions of information with respect to mercury use in dentistry, and mainly through its recent publication "Mercury in Dental use: Environmental implications for the European Union" – which is actually commented by the SCHER (p. 7).

We would therefore appreciate that EEB, as the biggest federation of environmental citizens' organisations, is informed when public consultations are launched, even at this stage of preliminary scientific comments, since these are very important milestones that may lead to subsequent policy developments. We would advise that notifications should be sent to the EEB and other interested bodies including governments, as is the procedure with regard to other issues (e.g. RoHS, etc).

Furthermore, to our knowledge the SCHER document was put up for public consultation only on 15 January 2008, with a deadline for responses of 22 February 2008. We consider that one month to comment on the two scientific studies (SCHER and SCENIHR) concerning dental amalgams is very little if we consider that the committees had a year to develop their preliminary opinion. We would appreciate if more time is provided for consultation in the future as is done with other consultations (e.g. RoHS review - 2 months).

We consider that the form this consultation has been set up is not appropriate. The consultation is restricting the length of responses <u>and</u> references to 4000 characters (spaces included) by question, making it very difficult to really provide all arguments justifying our response. We consider that this is not helpful nor for the public who is commenting, nor for the SCHER if the objective is to really receive thorough, scientific well justified comments.

#### 1.1 The Community Strategy Concerning Mercury

The Community Strategy Concerning Mercury<sup>1</sup> 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 methylmercury in fish.

Two actions in the Community Mercury Strategy are related to mercury in 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."

## 1.2 The EU process and the SCHER mandate

Several independent non-food related scientific committees provide the European Commission with the scientific advice it needs when preparing policy and proposals relating to consumer safety, public health and the environment.

The European Commission, on the basis of Actions 4 and 6 of the Community Strategy on Mercury, requested advice from these committees. DG Environment (DG ENV) prepared questions on the environmental impact of mercury in dental amalgam. DG Enterprise (DG ENTR) prepared questions on the health impacts of mercury in dental amalgam and its alternatives. Both sets of questions were sent to DG Health and consumer protection (DG SANCO). DG SANCO passed these questions to the relevant Scientific Committees. The questions on environment (DG ENV) were sent to the Scientific Committee on Health and Environment Risks (SCHER); the questions on health were sent to the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR).

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<sup>&</sup>lt;sup>1</sup> COM(2005) 20 final, 28 January 2005.

More specifically, the SCHER was asked by the European Commission for an opinion on environmental risks and indirect health effects connected to the use of dental amalgam. The opinion was to take into consideration the whole life cycle of mercury amalgam (e.g. dental clinics, sewage disposal systems, crematoria, etc.). The SCHER was asked *inter alia* to address the following:

- 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?

The SCHER report, *Preliminary report on the environmental risks and indirect health effects of mercury in dental amalgam*, was approved for public consultation at the 20th plenary on 29 November 2007. The comments in this paper respond specifically to that SCHER report and to the two above mentioned questions.

#### 2 Overview of NGO comments

In its comments, the EEB/ZMWG will address the following points, among others:

- Despite the SCHER's claim of large uncertainties and inadequate information to make a risk assessment of dental amalgam, the SCHER nevertheless concluded in a "screening level" risk assessment that the health risk due to environmental releases is "low."
- 2. Important information has been ignored by SCHER, including quantities of mercury released by dental amalgams, additional pathways of dental mercury to the environment and back to humans, the rate and extent of conversion of dental mercury to methylmercury, the rate and extent of bioaccumulation, etc.
- 3. The inclusion of various information ignored by SCHER, and the application of a more appropriate risk assessment methodology suggest different conclusions and significant health risks associated with environmental releases of dental Hg.
- 4. In the presence of compelling evidence of significant health risk (not to mention environmental risk) related to dental mercury releases to the environment, as cited in these comments, and until such time as this and other evidence is more carefully investigated, the SCHER is obliged to conclude that there is a potentially significant health risk.
- 5. Potential conflicts of interest of the SCHER team, and most importantly the four main authors with regard to assessing chemical and substance risks do not seem

to have been clarified in the report. Lacking transparency on this matter, whether the SCHER is to be independent experts, could be questioned. In addition, the specific expertise of the four main authors related to various aspects of mercury pollution, substance balances, etc., should be clearly stated in their report.

On the basis of the above, one can only have serious doubts about the SCHER's approach and conclusions with regard to the questions it was mandated to address. EEB/ZMWG understands that the European Commission needs to carry out a fair and objective analysis, data permitting, and in this spirit our specific concerns with regard to the SCHER report are addressed in the text below.

## 3 SCHER drew conclusions from inadequate information

#### 3.1 The SCHER assessment

With regard to the first question, "Are mercury releases caused by the use of dental amalgam a risk to the environment?," the SCHER wrote (pp. 6-7), "...a comprehensive EU wide assessment of the human health and environmental risks of the Hg used in dental amalgam is ... 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. [...] As this type of information is not available to SCHER, a comprehensive risk assessment cannot be performed by the Committee [emphasis added]."

Despite this general consensus of the SCHER team, they then "attempted" (their own word) what they referred to as a "screening level" risk assessment, which has virtually no scientific gravitas, and they then responded (rather precisely, in one case) to the questions posed by the European Commission, as detailed below.

#### 3.2 The SCHER conclusions

With regard to the first question, "Are mercury releases caused by the use of dental amalgam a risk to the environment?" the SCHER concluded, despite the purported lack of adequate information:

- "...the added risk to aquatic organisms from the contributions from dental clinics to the total mercury should be considered low."
- "...a low direct risk to the soil compartment of dental Hg is expected."
- "...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 exceedance risk would rise to about 18%."
- "Although there are several models describing the bioaccumulation and biomagnification potential of mercury in different ecosystems, the variability ... is so high that no sound generic estimations can be done with the current level of knowledge."

With regard to the 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?" the SCHER concluded:

 "...the predicted indirect exposures of humans to methylmercury resulting from emissions due to dental amalgams are much lower than these tolerable limits indicating a low risk for serious health effects."

Apart from any other comments to the SCHER report, the EEB/ZMWG is astonished that after clearly stating that the SCHER lacked the information necessary to make a comprehensive risk assessment, the SCHER managed to conclude that the risk to the environment and to human health posed by mercury in dental amalgam (according to the balance of evidence presented in the SCHER conclusions quoted above) is generally "low" or "lower than low."

## 4 Important information ignored by the SCHER

In carrying out its investigation, the SCHER has ignored important sources of information that are directly relevant to its task. Some of the key information ignored includes the following:

- The SCHER methodology focused only on dental clinic mercury releases directly
  to water. As described below, there are various additional pathways of dental Hg
  to water, especially via atmospheric deposition of Hg from sludge
  incineration/disposal, municipal waste incineration, medical waste disposal,
  cremation, etc.
- 2. The occurrence of mercury in the wastewater stream of dental clinics is a particularly sporadic and discontinuous event. Rather than rely on incomplete numbers reported in a very small number of studies, it would be more robust for SCHER to rely on the many studies (references given below) that demonstrate that dental clinics are the origin of typically 40-50% of all Hg in the wastewater going to wastewater treatment plants.
- 3. When all pathways are considered, Hg releases to the atmosphere from dental use are highly significant, contributing probably 15-20% of total anthropogenic

- atmospheric Hg emissions in the EU (see references below).
- 4. As the dental use of mercury contributes a significant percentage of the total Hg emissions to both wastewater and the atmosphere in the EU, it is clearly a significant contributor to methylmercury generation and uptake by human and other organisms.
- 5. In conclusion, the percentage of methylmercury in surface waters that may be linked to mercury released by dental amalgams, and the associated health risks, contrary to the SCHER's conclusions, are significant.

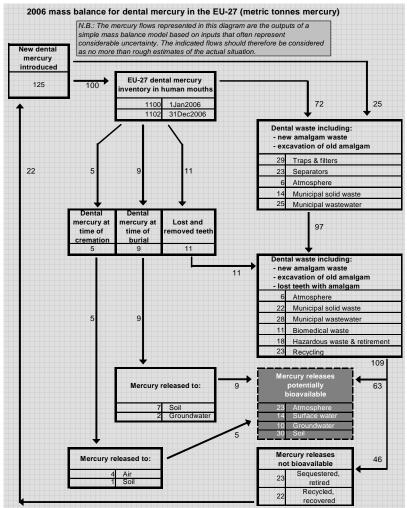
A range of information sources, and their significance to the questions of risk the SCHER was asked to address, are discussed further below.

#### 4.1 Important pathways ignored by the SCHER

The SCHER methodology focused almost exclusively on dental clinic mercury releases directly to water.

However, as described in the recent EEB report (EEB 2007) cited by the SCHER, mercury from dental amalgam can enter the environment via a number of pathways. For example, when amalgam waste is discarded in municipal waste, some mercury will be released into the atmosphere from landfill vapours or leachate, or the mercury will vaporize if the waste is incinerated. When amalgam waste is flushed through the wastewater system, the mercury typically adheres to wastewater sludge, which may be incinerated, instantly releasing the mercury vapour to the air. Or if the mercury-laden sludge is deposited to agricultural or other soil, some mercury will volatilize and other mercury will be carried away in runoff. Whatever mercury enters the atmosphere through these various means will travel through the atmosphere in a vaporized state before eventual deposition. Unfortunately, mercury fillings continue to pose a pollution problem even after death. About two-thirds of mercury in these fillings ends up in a cemetery, from where much of the mercury may eventually enter the soil and/or groundwater, while most of the rest is emitted to the atmosphere during cremation – meanwhile the rate of cremations is rapidly increasing across the EU (Reindl 2007).

Based on the quantities of dental amalgam used in the EU and the various pathways to waste and the environment, the EEB report (EEB 2007) cited by the SCHER estimated that every year some 30 tonnes of mercury from dental amalgam go to the soil, 23 tonnes to the atmosphere, 14 tonnes to surface water and 10 tonnes to ground water. These pathways are detailed in the figure below, and are not inconsistent with such sources as found in the *Journal of Dentistry* (Drummond *et al.* 2003).



Source: EEB 2007.

These releases to the environment are generally consistent with the findings of the RPA report (Floyd *et al.* 2002) cited by the SCHER. However, the SCHER completely dismissed the important implications of these dental mercury flows to the environment with the comment that the "type of information and calculations provided in the … reports is too diverse in nature" for the needs of the SCHER. This is an unnecessarily narrow reaction to these two reports, as both contain valuable information and copious references that could make a very useful contribution to the SCHER's mandate.

## 4.2 Mercury releases to the environment underestimated

#### 4.2.1 Releases of inorganic Hg to wastewater and surface waters

The occurrence of mercury in the wastewater stream of dental clinics is a particularly sporadic and discontinuous event. For its analysis, the SCHER relied heavily on

analyses of mercury in dental clinic wastewater reported in only two studies. This approach is highly problematic for several reasons:

- These two studies cannot be assumed to be representative of the EU situation as a whole;
- The SCHER assumed that wastewater is the only important pathway by which dental mercury is diffused in surface waters; however, as described above, there are many other pathways by which the mercury from dental amalgams gets into surface waters; and
- Subsequently, the quantity of mercury from dental amalgams that gets into surface waters is far higher than the SCHER analysis suggests.

It is widely reported in the US that most municipal wastewater systems encounter significant levels of mercury, and it has been published that on average some 40-50% of that mercury originates from dental practices (Arenholt-Bindslev and Larsen 1996; AMSA 2002a; AMSA 2002b). Some US observations are summarized in the table below.

| City                    | Mercury load from dental offices |        |  |  |  |
|-------------------------|----------------------------------|--------|--|--|--|
| Duluth, Minnesota       |                                  | 36%    |  |  |  |
| Seattle, Washington     |                                  | 40-60% |  |  |  |
| Palo Alto, California   |                                  | 83%    |  |  |  |
| Greater Boston Area, MA |                                  | 13-76% |  |  |  |

Sources: Arenholt-Bindslev and Larsen 1996; AMSA 2002a; AMSA 2002b.

Lacking any better data for the EU, and observing that the number of dental amalgams placed annually in the EU (170-180 million) greatly exceeds that in the US (about 70 million), and until such time as 1) the majority of EU member states install and properly maintain separators (DG ENV 2007; Hylander *et al.* 2006a and 2006b), and 2) properly deal with amalgam waste as hazardous waste (DG ENV 2007), one may reasonably conclude that the EU wastewater situation, as regards mercury, is not much better than that in the US.

#### 4.2.2 Releases of mercury to the atmosphere

Mercury releases to the atmosphere related directly to the use of dental amalgam – probably the most important to any risk analysis of dental mercury – are not properly addressed by the SCHER. The recent EEB report (EEB 2007), peer-reviewed by a

number of experts<sup>2</sup> with extensive knowledge of mercury issues including mass flows of mercury in the environment, estimated that annually 23 tonnes of mercury from dental amalgam are released in the EU to the atmosphere. Until such time as more detailed studies are completed, it must be considered that this estimate may be roughly correct.

It is instructive to note that in the US, dental mercury related atmospheric emissions previously estimated by the US EPA have been recently challenged (Bender 2007), including from within US EPA (Cain *et al.* 2007), as serious underestimates. The 2002 EPA National Emissions Inventory (version 3) gave atmospheric emissions related to dental mercury as in the first column of the table below. The US EPA numbers are compared with those presented in the more recent analyses (Bender 2007; Cain *et al.* 2007), summarized in the second and third columns, which are given as ranges of emissions for the main categories of emission related to dental uses of mercury.

| Atmospheric emissions of dental mercury (short tons, i.e., 1 short ton = 908 kg) |   |   |  |  |  |  |
|--|---|---|--|--|--|--|
| Pathway  | EPA National<br>Emissions<br>Inventory 2002 | Congressional<br>Testimony 2005<br>(low estimate) | Congressional<br>Testimony 2005<br>(high estimate) |  |  |  |
| Human cremation  | 0.3   | 3.0   | 3.5  |  |  |  |
| Dental clinics   | 0.6   | 0.9   | 1.3  |  |  |  |
| Dental mercury sewage sludge incineration  | 0.6   | 1.5   | 2.0  |  |  |  |
| Dental mercury sludge spread on land and landfilled                              | n.a.  | 0.8   | 1.2  |  |  |  |
| Dental mercury MSW incineration and landfill                                     | n.a.  | 0.2   | 0.5  |  |  |  |
| Dental mercury infectious and hazardous waste                                    | n.a.  | 0.5   | 0.7  |  |  |  |
| Human respiration  | n.a.  | 0.2   | 0.2  |  |  |  |
| Total  | 1.5   | 7.1   | 9.4  |  |  |  |

Source: Bender 2007; Cain et al. 2007

It should be noted that the updated emissions estimates for dental mercury (columns 2 and 3 in the table above) appear to be some five times the emissions previously estimated by the US EPA (column 1).

## 4.3 Dental Hg emissions to water and air are significant

#### 4.3.1 Water

In Sweden, Norway, and Denmark amalgam separators are now used in the majority of

<sup>&</sup>lt;sup>2</sup> Experts from Uppsala University (Sweden); COWI AS (Denmark); a Stratton French certified hydrologist (US); etc.

dental clinics. Amalgam separators are also in wide use in Austria, Finland, the Netherlands and Switzerland, and increasingly in Belgium, Germany, France and the Czech Republic (Keml 2005; DG ENV 2007).

However, even where installed, their performance may be variable. Although amalgam separators have been required since 1979 in Sweden and have led to significant reductions in Swedish mercury emissions to wastewater, their effectiveness may be variable. A 1998 study found that one in four separators in Stockholm did not operate correctly, leading to excessive discharges, and more recent investigations have confirmed that problems persist (Hylander *et al.* 2006a and 2006b).

Even where amalgam separators are functioning properly, significant Hg releases may remain, due to previous accumulations of Hg in piping, inappropriate disposal practices with regard to disposal of amalgam removed from traps and separators, etc.

Assuming the placement of dental amalgams per capita in the EU is somewhat higher than that in the US (Reindl 2007), and assuming the incidence of separators in dental clinics is somewhat higher in the EU, the greater EU population density would suggest that dental mercury probably has a similar contribution to wastewater as that observed in the US, i.e., dental mercury probably comprises on average 40-50% of total Hg in EU wastewater going to municipal wastewater treatment plants.

#### 4.3.2 Air – outdoor

Despite regulations regarding the characterisation and disposal of mercury bearing wastes as hazardous wastes, most solid dental wastes in the EU still follow other routes of disposal (DG ENV 2007) such as municipal solid waste – disposed of in landfills or by municipal incineration. As described by EEB (EEB 2007), various other pathways of dental mercury to the atmosphere include medical waste treatment and incineration, incineration of wastewater treatment sewage sludge, releases of Hg from sewage sludges disposed to agricultural or other soils, releases during cremation, air releases from dental clinics, etc.

Anthropogenic atmospheric emissions of Hg in greater Europe in 2000 have been estimated at 239 tonnes (see table below), of which over 50% was related to stationary (mostly coal) combustion. Of that total, no more than 150 tonnes was allocated to the EU-27 (Pacyna *et al.* 2006). With the recent application of more stringent controls on mercury emissions from municipal waste incinerators, anthropogenic atmospheric emissions for the EU-27 may in 2007 be estimated in the range of 120-130 tonnes, and

are expected to decline further by 2010 and afterwards as stricter controls on coal combustion emissions are applied.

Table 1
Emissions of total mercury and its major chemical species from anthropogenic sources in 10 European countries with the largest Hg emissions (tonnes/year)

| Country                     | Total | Hg0   | Hg2+ | Hg part, |
|-----------------------------|-------|-------|------|----------|
| Russian Federation (Europe) | 66.I  | 42.1  | 20.8 | 3.2      |
| Poland                      | 25.6  | 13.2  | 9.9  | 2.5      |
| Germany                     | 23.4  | 13.7  | 7.7  | 2.1      |
| Spain                       | 23.0  | 15.4  | 6.0  | 1.6      |
| Ukraine                     | 16.3  | 10.2  | 5.3  | 0.9      |
| France                      | 15.0  | 9.7   | 4.1  | 1.2      |
| Italy                       | 9.8   | 6.2   | 2.8  | 0.8      |
| United Kingdom              | 8.5   | 5.6   | 2.4  | 0.6      |
| Yugoslavia                  | 7.1   | 4.3   | 2.2  | 0.6      |
| Romania                     | 5.0   | 2.5   | 2.0  | 0.5      |
| Total Europe                | 239.3 | 146,3 | 75.7 | 17.2     |

Source: Pacyna et al. 2006

Therefore, the estimated 23 tonnes of atmospheric mercury emissions related to dental amalgam comprise in the range of 15-20% of total EU anthropogenic atmospheric mercury emissions. This contribution from dental amalgam can hardly be ignored as insignificant.

#### 4.3.3 Air – indoor – occupational exposures

Dental personnel may be exposed to the following sources of mercury vapours: "accidental mercury spills; malfunctioning amalgamators, leaky amalgam capsules or malfunctioning bulk mercury dispensers...; trituration, placement and condensation of amalgam; polishing or removal of amalgam; vaporization of mercury from contaminated instruments; and open storage of amalgam scrap or used capsules" (JADA 2003).

Dentists working with amalgam have been shown to have an increased Hg exposure (Harakeh *et al.* 2003; Tezel *et al.* 2001; Nylander & Weiner 1991). Studies on dental staff have demonstrated increased neuropsychological complaints (Aydin *et al.* 2003; Bittner *et al.* 1998; Echeverria *et al.* 2005, 2006; Heyer *et al.* 2006; Ngim *et al.* 1992; Ritchie *et al.* 2002) and pathological muscle biopsies (Nadorfy-Lopez *et al.* 2000). Visual evoked potentials in Hg exposed staff (among them dentists) show significant changes when compared to controls (Urban *et al.* 1999). A meta-analysis showed neuropsychological impairment in 686 persons exposed occupationally to mercury vapour compared to 579 controls (Meyer-Baron *et al.* 2002). Low level exposure to mercury vapour has been shown to lead to behavioural changes in adult mice (Yoshida

et al. 2004) and to the impairment of colour discrimination in humans (Urban et al. 2003).

# 4.4 Dental mercury conversion to methylmercury underestimated by SCHER

Based on a misuse of one source (Stone *et al.* 2003), the SCHER has assumed that 0.2% of the total mercury from dental clinics may become methylmercury. This is problematic for several reasons:

- A single reference paper can hardly be assumed to describe the EU situation as a whole;
- The SCHER has assumed that wastewater is the only pathway by which
  mercury from dental amalgams may be diffused as methylmercury; however,
  as described previously, there are many other pathways (especially
  atmospheric releases and deposition) by which dental amalgam contributes to
  methylmercury concentrations in surface waters and the food chain;
- The quantity of mercury released to surface waters through the use of dental amalgam – and therefore the quantity of methylmercury generated – is far higher than the SCHER analysis suggested; and
- While Stone et al. did measure methylmercury in the dental clinic waste stream, they did not presume to suggest that no other methylmercury could have been created during the rest of the life cycle of dental amalgam waste.

The SCHER made no attempt in its report to determine the total quantity of methylmercury currently present in the environment as a result of dental facility wastewater discharges. Rather, the authors assumed very small amounts of methylation of mercury in amalgams. Further, the SCHER did not present any evidence to show that all mercury entering wastewater from dental amalgams will not methylate, given long enough durations. Until such evidence can be produced, no serious attempt to translate total mercury from dental offices to methylmercury can be made. Meanwhile, ample evidence is presented below to warrant at least a precautionary stance.

# 4.5 Dental amalgam contribution to methylmercury exposure is significant

It has been shown previously that dental mercury contributes significantly both to the atmospheric burden, from where it eventually deposits on the soil and in waterways, and it is also released directly to waterways. It has been well established that as dental mercury releases increase the load of mercury to both the local and global environment,

such releases also increase human exposures to methylmercury through the fish that people eat (Mergler *et al.* 2007; US EPA 1997). As stated in a major report of the World Health Organisation (WHO 2007):

" reducing the concentrations [of methylmercury] in fish should be given a high priority. Reducing emissions to the atmosphere and longrange transport of pollution represents a means of achieving this aim."

The significant transformation of dental mercury to methylmercury, both in the human system and in the environment, and the important effects on the health of wild birds, mammals, and fish, is further supported by findings over 30 years of research, such as the broad range of research summarised by Scheuhammer *et al.* (2007). Some other landmark research is listed in Appendix 1 – Methylation of mercury.

Moreover, other impacts of the dental amalgam contribution to methylmercury contamination of fish must not be ignored, as below.

#### 4.6 Further environmental and human health impacts of MeHg

The contamination of fish with methylmercury is a serious consequence of environmental mercury pollution because consumption of fish is the primary pathway for human exposure to this highly toxic compound. The contamination of fish, therefore, has been viewed largely from a toxicological perspective with the focus on exposure and health effects.

Yet mercury pollution has also diminished the economic, recreational, nutritional, and cultural benefits derived from fishery resources. Almost half of the 83,000 lakes in Sweden contain game fish with mercury concentrations exceeding their national guideline (ICMGP 2006). In the far north, the consequences of contaminated fishery resources for indigenous communities that abandoned subsistence fishing have been particularly severe, and include adverse effects on lifestyle, culture, social cohesion, economic status, and health (Swain *et al.* 2007). In North America, mercury contamination now accounts for more than 80 percent of all fish-consumption advisories (ICMGP 2006). The socioeconomic losses caused by mercury contamination of fishery and other natural resources are discussed at length in Swain *et al.* (2007), and are highly relevant to policy considerations regarding, in particular, all sources of atmospheric emissions of mercury.

## 5 SCHER used inappropriate risk assessment methodology

Not only has the SCHER carried out a "screening level" risk assessment on the basis of what it considered inadequate data, but the methodology used is entirely inappropriate to the task, for all of the reasons cited previously about various dental mercury pathways to the environment, the extent of methylation over time of an accumulation of dental mercury in the environment, etc. Whether or not the SCHER eventually determines that it has enough data to carry out a proper risk assessment, we strongly suggest that the following important observations, among others, are kept in mind.

#### 5.1 Compelling evidence of risk

Leaving aside, for the moment, the significant contributions of dental mercury to the total mercury in the wastewater stream, we have shown above that dental mercury may contribute 15-20% – and an increasing percentage in years to come – to EU atmospheric emissions. Since atmospheric deposition of mercury is broadly proportional to atmospheric emissions (Lindberg *et al.* 2007), we must conclude that deposition in the EU is similarly significant. As recently reported (WHO 2007):

Atmospheric deposition is considered as the predominant source of mercury input to most soils and lakes in the boreal forest zone (Lindqvist et al. 1991). Such deposition has increased from 2-fold to more than 20-fold over the last few centuries because of anthropogenic emissions and subsequent dispersal at local, regional and global levels. For example, in Sweden, attention has focused on the alarmingly high mercury levels found in lake fish, as the values exceed the advisory health guidelines in tens of thousands of lakes (Håkanson et al. 1988, 1990; Lindqvist et al. 1991; Andersson & Lundberg 1995).

In connection with the development of concepts for critical load calculations for mercury, a model relating the concentrations in precipitation to the methylmercury concentrations in fish has been developed (Meili et al. 2003a, 2003b; UNECE 2004). The aim of the modelling is to estimate the mercury concentration in precipitation that is allowable in order to limit the methylmercury concentration in fish to <0.5 mg/kg (i.e. the EU recommended general limit value for fish). The model data indicate that the maximum tolerable concentration in precipitation is about 2 ng/l, which is about half the current level found in remote areas. More

recent evaluations of health impacts indicate that a lower limit value of 0.3 mg/kg (JECFA 2004; USEPA 2001) is more appropriate, which would suggest that the tolerable concentration in precipitation should be [still] lower.

More dramatically, in the words of Meili and co-authors writing about the Swedish situation (Meili *et al.* 2003a):

Critical receptors, ... even in remote areas, are humic waters, in which biotic Hg levels are naturally high, most likely to increase further, and at high long-term risk of exceeding the current levels of concern.... If environmental Hg concentrations are to be reduced and kept below these critical limits, virtually no man-made atmospheric Hg emissions can be permitted.

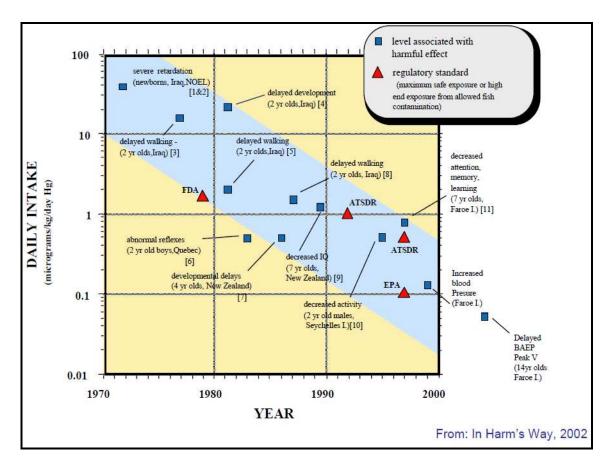
Therefore, if deposition in remote areas of the EU must be reduced by half and considerably more, then according to Meili *et al.* (2003a) EU anthropogenic emissions (which have a large but not exclusive contribution to EU deposition) must be reduced by 80-100% in order to decrease the methylmercury level in fish to tolerable levels for human consumption (Munthe *et al.* 2007a). It is evident that the large contribution of dental mercury to EU atmospheric emissions is not only a serious problem, but a serious contributor to health risk (Mergler *et al.* 2007).

For purposes of comparison, the United States Environmental Protection Agency (EPA) has recently approved a multi-state plan to reduce mercury in the waters of New York and New England. The goal of this multi-state plan is to reduce atmospheric deposition of mercury to the region by between 86 and 98 percent, which is the reduction deemed necessary in order to allow fish-tissue mercury levels to decline to a level where fish consumption advisories may be discontinued (NYS-DEC 2008). As in the EU, in the US the contribution of dental amalgam to atmospheric mercury deposition is significant (Bender 2007), and therefore an undeniably important factor in possible health risk.

It is widely accepted by the scientific community that mercury deposition and methylation are already far too high. Fish consumption advisories are pervasive (and increasing, as illustrated in Appendix 2 – More frequent EU alerts re mercury in fish) in order to reduce scientifically proven health risks. And dental mercury is a significant contributor to atmospheric emissions and deposition, not to mention its additional pathways directly to surface waters.

#### 5.2 SCHER failure to adequately account for uncertainties

Over the years, increasingly detailed studies have concluded that safety thresholds have chronically been overestimated, as demonstrated in the following figure. Methyl mercury exposure of children, in particular, has received special attention. Both Ponce *et al.* (2000) and Cohen *et al.* (2005) examined neurocognitive deficiencies associated with foetal MeHg exposures, and assumed that the deficiencies persist throughout the life of the affected individual. The US EPA has even put a cost to the loss of an individual's IQ points as a result of developmental mercury exposure (US EPA 1997). Developmental neurological disease is said to affect one of every six children in the US, not to mention unknown numbers of cases of degenerative neurological disease, cardiovascular disease, etc. (Mergler *et al.* 2007)



## 6 SCHER conclusions incomplete and incorrect

If the SCHER considers that these comments and references now provide enough data to assess the toxicological implications of dental amalgam for the EU population and environment, then the previous SCHER conclusions must be reassessed in their entirety.

On the other hand, if the SCHER believes it still lacks adequate information to perform a comprehensive risk assessment, at least it now has access to sufficient evidence of risk to warrant caution in the face of uncertainty.

## 7 Risk and uncertainty

In the presence of incomplete evidence of a significant risk to the environment or human health, despite some remaining uncertainty, it is clear that caution should be exercised. In other words, why should one gamble with human and environmental welfare when the available science suggests significant health and/or environmental risk, when the Community Mercury Strategy demands that unnecessary uses and releases of Hg must be reduced as a priority, and while highly acceptable Hg-free alternatives are available for virtually all dental applications? As recently published, with direct reference to mercury risk:

For decades, scientific uncertainties on mercury led to exaggerated controversies that delayed preventive action. However, when uncertainties are interpreted as support of the null hypothesis, the costs to human health and society can be enormous. We have a responsibility to combine our ... talents and insights with the courage to elicit preventive action against the harm caused by environmental chemicals. Emphasis on uncertainties amid scepticism from colleagues, regulatory agencies, or stakeholders should not allow us to forget to call attention to preventable risks (Grandjean and Choi 2008).

## 8 Concerns about conflicts of interest, authors' expertise

To the best of our knowledge, the main authors of the SCHER report comprise two toxicologists, a veterinarian and a researcher. Potential conflicts of interest with regard to this risk assessment should be clearly spelled out. Furthermore, the specific experience of the main authors with regard to mercury and its effects on humans or the environment, mercury transport in surface waters and the atmosphere, mercury use and disposal in dental clinics, mercury mass balances, etc., should be clearly stated in the SCHER report. The apparent lack of familiarity of the authors with some of these fields could help explain why they overlooked many of the pathways of dental mercury to the environment.

#### 9 Conclusions

The SCHER was asked by the European Commission for an opinion on environmental risks and indirect health effects connected to the use of dental amalgam. The opinion was to take into consideration the whole life cycle of mercury amalgam (e.g. dental clinics, sewage disposal systems, crematoria, etc.).

Contrary to the main thrust of SCHER's analysis and conclusions, a comprehensive response to the European Commission's request for advice should be laid out in the following simple and logical terms:

- Considering the whole life cycle (municipal waste incineration and landfill, medical waste disposal, wastewater treatment sludge incineration/disposal, cremation, etc.), dental amalgam is a significant continuous contributor to anthropogenic atmospheric mercury emissions in the EU – in the range of 15-20%, corresponding to an estimated 23 tonnes of mercury annually;
- Via another pathway to the environment, dental amalgam is also an important contributor to the mercury concentration in municipal wastewater, where the mercury originates from dental clinics as well as (large quantities of) human wastes carrying (low concentrations of) mercury released by normal wear of amalgam fillings;
- In general terms, atmospheric mercury emissions are directly linked to subsequent mercury deposition and runoff;
- 4. The mercury carried by deposition and runoff is directly reflected in increased concentrations of mercury in surface waters;
- 5. The total mercury burden in surface waters, including not only dental mercury via the pathways described above, but also contributions from dental mercury accumulated in the environment (in sediments, wastewater piping systems, leaching from landfills, etc.) during previous years, is directly reflected in the methylmercury burden in surface waters;
- 6. Since not all pathways above were taken into account, the amount of mercury and therefore methylmercury in the environment is underestimated, considering that to the direct methylmercury emissions we need to add the methylmercury from transformation.
- 7. The main source of methylmercury exposure to humans and wildlife is fish and other aquatic organisms, whose uptake of methylmercury is proportional to the methylmercury burden in surface waters;
- 8. It has been well established that as dental mercury releases increase the load of mercury to both the local and global environment, such releases also increase human exposures to methylmercury through the fish that people eat.

- 9. There is a broad scientific consensus that anthropogenic mercury emissions need to be drastically reduced (e.g. calculations from Sweden call for a reduction of 80% in some areas and close to 100% in others; similarly, the Northeast region of the US has set targets of 86-98% reduction) in order to reduce the food-chain related methylmercury risks to a level where there would be little or no concern for effects on humans;
- 10. Likewise, there is ample and accumulating evidence that the methylmercury burden in surface waters is directly responsible for excessive methylmercury exposure of wildlife, and is causing significant harmful effects to a range of species;
- 11. Therefore, as long as dental amalgam remains a significant contributor to anthropogenic mercury emissions and, in turn, to the methylmercury burden in surface waters, then dental amalgam is also heavily implicated in health and environmental risks;
- 12. Finally, and importantly, it has been demonstrated that it is far more cost effective to reduce mercury emissions related to dental amalgam use<sup>3</sup> than it is to pursue other opportunities for significantly reducing mercury emissions (Hylander and Goodsite 2006). Major reduction of amalgam related releases may be achieved in the near term by greatly expanding the use of separators, and in the near to medium term by phasing out amalgams, for which there are economically viable alternatives (Keml 2005).

<sup>&</sup>lt;sup>3</sup> In particular, shifting to mercury-free alternatives, installing and maintaining amalgam traps and separators, and improving amalgam recycling and disposal practices.

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Note: A number of references not cited in the comments above are nevertheless included below to add to the general understanding of the issues addressed.

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## 11 Appendix 1 – Methylation of mercury

# 11.1 Typical references demonstrating methylation of dental Hg in the environment and effects on wildlife

There are many references demonstrating methylation and effects of dental Hg on the environment and animals, such as:

Aquarium tests with 1- and 2-summer old salmon (*Salmo salar*) at the Swedish National Environmental Protection Board (SNV) test lab revealed that granulated tooth amalgam releases mercury into the surrounding water in a form that can accumulate in fish. Test results gave a very uniform picture on this point. With 0.5 g of amalgam added for each liter of water, the content of mercury in the livers of test fish increased up to 60 times the original content after an exposure period of 28 days. The results also showed that the mercury was transferred from the livers of the fish into their musculature (Ekroth 1978).

The bioavailability and accumulation of mercury from external environmental exposure to mixed, cured, milled, sieved and proportioned dental amalgam was examined in the common goldfish, *Carassius auratus*. The fish were exposed to dental amalgam (particle size range from <0.10 to 3.15 mm) representative of the particle size and distribution of that found in the typical dental office wastewater discharge stream. Mercury was found in several tissues, and generally increased with exposure to higher amounts of dental amalgam. Compared to controls, concentrations in the whole body, muscle and liver of fish exposed for 28 days to the highest concentration of amalgam were 200-, 233-, and 40-fold higher, respectively. This study shows that mercury from an environmental exposure to representative samples of dental amalgam typically found within the dental wastewater discharge stream is bioavailable to fish and may accumulate in internal tissues (Kennedy 2003).

Research was carried out to establish whether monomethyl mercury (MMHg) is present in dental-unit wastewater, and if present, to determine the concentration relative to total mercury. In fact, environmentally important levels of MMHg were found to be present in dental-unit wastewater at concentrations that are orders of magnitude higher than seen in natural settings (Stone *et al.* 2003).

It has been demonstrated that the routine application of municipal sewage sludge to cropland significantly increases both total and methyl mercury in the surface soil (Carpi *et al.* 1997).

In parallel, while a smaller fraction of the mercury accumulated in boreal regions is anthropogenic in origin, in addition to the normal leaching process, larger assaults such as forestry operations and storm events can affect the environmental biogeochemistry of mercury, increase the mobilisation of both mercury and methylmercury, and increase the risks related to bioaccumulation in aquatic ecosystems. After direct atmospheric deposition, mercury leaching from forest soil is the most important source of mercury in surface waters, and such major assaults as described may result in a significant increase in the load of mercury on streams and lakes (Munthe *et al.* 2007b).

Increasingly worrying evidence of the effects of environmental mercury on the natural world is published almost daily. Very recent references include the following:

Scheuhammer and Sandheinrich (2008) – AM Scheuhammer and MB Sandheinrich, Recent advances in the toxicology of methylmercury in wildlife. *Ecotoxicology* 17(2): 67-68.

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Brasso and Cristol (2008) – RL Brasso and DA Cristol, Effects of mercury exposure on the reproductive success of tree swallows (*Tachycineta bicolor*). *Ecotoxicology* 17(2):133-141.

# 11.2 Typical references and abstracts demonstrating methylation of dental Hg in humans

It is well established that the anaerobic sulfate reducing bacteria (SRBs) are the major methylators of Hg in sulfur-rich freshwater and estuarine sediments. However, it is less well known that human commensal bacteria can methylate Hg(II). The following studies over the last 30 years, each done in slightly different ways in different laboratories, have observed methylation of Hg by either purified commensal bacteria or directly by saliva or feces:

The capacity of the oral bacteria *Streptococcus mitior*, *S. mutans* and *S. sanguis* to methylate mercury was investigated *in vitro*. Mercuric chloride and pulverized dental amalgam, respectively, in distilled water were used as sources of mercury. Methylmercury was found in the bacterial cells of all three tested strains. The results indicate that organic mercury compounds may be formed in the oral cavity (Heintze *et al.* 1983).

Leistevuo *et al.* (2001) found a correlation between the total amalgam surfaces and organic mercury – presumably as methylmercury (CH<sub>3</sub>Hg<sup>+</sup>) derived from oral bacteria biomethylation of inorganic mercury – in saliva. These results are compatible with the hypothesis that amalgam fillings may be a continuous source of organic mercury, which is more toxic than inorganic mercury, and almost completely absorbed by the human intestine.

The concentration of total mercury in stimulated saliva was studied in humans with dental amalgam fillings and in 2 non-amalgam groups. The probability of exceeding the limits of mercury permitted in wastewater increased proportionally as the number of amalgam-filled surfaces increased. The mercury limit for sewage is 0.05 mg/l (= 250 nmol/l) effluent according to the Council of European Communities directive 84/156/EEC. In neither of the non-amalgam groups was this limit exceeded, but 20.5% in the amalgam group exceeded the limit (p < .001). The risk of exceeding the limit increased 2-fold for every 10 additional amalgam-filled surfaces (odds ratio = 2.0; 95% confidence interval = 1.3, 3.3). These results demonstrated that humans, especially in populated areas, can be a significant source of mercury pollutants. As a consequence of mercury release, bacteria may acquire mercury resistance, as well as resistance to other antimicrobial agents, thus resulting in failure of antibiotic treatment (Leistevuo *et al.* 2002).

A study was conducted by analysing saliva samples from subjects with amalgam fillings and control subjects with no amalgams. Hg<sup>2+</sup> and MeHg were found in all samples, while Hg° was found only in the samples from subjects with amalgams. In the control group, the concentrations found before and after cleaning the mouth were equivalent. In the

amalgam group, concentrations of  $Hg^{2+}$  found before cleaning the mouth were 10 to 40 times higher than those found after cleaning, suggesting that the oxidation reaction of  $Hg^{2+}$  takes place. For MeHg, a similar but less pronounced pattern as  $Hg^{2+}$  was found, supporting methylation in the mouth (Liang and Brooks 1995).

Small amounts of methylmercury were produced during 7 days aerobic growth in the presence of sublethal amounts of mercuric chloride by certain bacterial species studied. Under the same conditions methylmercury was also formed by mycelium of the fungi investigated. The concentration of the methylmercury was of the same order of magnitude as that found in Swedish experiments with lake sediments. In bacteria most of the methylmercury formed was present in the culture liquid, whereas the remainder was in or on the cells. In contrast, methylmercury formed by fungi was for the greater part present in the mycelium (Vonk and Sijpesteijn 1973).

Most strains of staphylococci, streptococci, yeasts and *E. coli* isolated from human faeces, could synthesize methylmercury compounds. In contrast, few strains of obligate anaerobes could do so. Up to 6 ng methylmercury/ml were formed in 44 hours from 2 µg mercuric chloride (Rowland *et al.* 1975).

In other research, mercury was transformed to methylmercury by the microorganisms present in aquatic sediments and rat intestines, and examples of some of the important reactions were illustrated (Edwards and McBride, 1975).

Indeed, there is good evidence that a significant source of methylmercury in fish is not from the water column alone, but from methylation by their own intestinal bacteria of ingested inorganic Hg(II) from the water column (Rudd *et al.*, 1980).

## 12 Appendix 2 – More frequent EU alerts re mercury in fish

# Ecologistas en Acción alerta sobre el incremento de mercurio en el pescado

25-01-08

La organización Ecologistas en Acción ha alertado sobre el fuerte incremento de las notificaciones por contenido de mercurio en pescado durante el 2007. Esta situación es muy grave ya que los límites permitidos por la UE de mercurio en pescado no protegen suficientemente la salud, al no tener en cuenta el consumo medio, ni las características corporales de los consumidores.

Según Ecologistas en Acción durante el año 2007 se han incrementado de forma muy importante las notificaciones por contenido en mercurio en pescado, situación que era previsible, a la vista de los datos del primer semestre. Estas notificaciones son publicadas por el sistema de alerta rápida para piensos y alimentos (RASFF en sus siglas inglesas). La situación actual, con 130 notificaciones, 47 de ellas de alerta y 83 de información, concuerda con la tendencia observada en el informe anual del 2006, año en el que aumentaron las notificaciones sobre superaciones del nivel legal de contenido en mercurio en productos pesqueros con respecto a años anteriores. Las superaciones en el año 2006 fueron 71, 46 superaciones en 2005 y 45 en 2004.

Como en otras ocasiones, el pez espada fue la especie con un mayor número de la notificaciones en 2007 con 68, 27 de las cuales fueron de alerta. El país que ha efectuado un mayor número de denuncias ha sido Italia, con 66 notificaciones mientras que España destaca por ser el originario de las partidas de pescado con un mayor número de denuncias, hasta un total de 67, 31 de las cuales fueron de alerta y 35 de información.

Según la normativa comunitaria, el nivel máximo permitido de mercurio en los productos pesqueros es de 0.5 miligramos (mg) por kg. En ciertas especies (como el pez espada, el tiburón, o el atún) se permite un nivel máximo más alto, de un miligramo por kg.

Para Ecologistas en Acción la situación es mucho más grave, ya que si en lugar de los límites establecidos por la UE, utilizásemos los criterios establecidos por el Comité Mixto FAO/OMS de Expertos en Aditivos Alimentarios (JECFA), referidos a la ingesta máxima semanal de metilmercurio, 1,6 microgramos (µg) por kg de peso corporal por semana para proteger suficientemente al feto en desarrollo expuesto al metilmercurio a través de alimentos contaminados ingeridos por la madre embarazada.

Este nuevo límite recomendado sustituye a la recomendación precedente de 3,3 µg de metilmercurio en los alimentos por kg de peso corporal por semana, el cual se mantiene para el resto de personas adultas. Con esta propuesta, una mujer, en edad fértil, con un peso de 60 kg y que consuma unos 400 gramos de atún a la semana (media de consumo de pescado en Asturias [1]), no debería ingerir pescado con contenidos superiores a las 0,25 mg por kg para no superar los límites aconsejados por el comité de expertos.

El mercurio es un metal extremadamente volátil que puede ser transportado a grandes distancias una vez se ha emitido a la atmósfera. Una vez se ha depositado en un ambiente acuático, el mercurio se transforma en metilmercurio, una potente neurotoxina, que se acumula en los peces y en los animales y los humanos que los consumen. Cuando es ingerido por mujeres embarazadas, el metilmercurio atraviesa la placenta y se acumula en el cerebro y el sistema nervioso central del feto en desarrollo. Incluso cantidades relativamente despreciables pueden producir serios retrasos motores o de comunicación. El mercurio nunca desaparece del medio ambiente, asegurando que la contaminación de hoy seguirá siendo un problema en el futuro. <a href="https://www.ecoportal.net">www.ecoportal.net</a>

#### Ecologistas en Acción

http://www.ecologistasenaccion.org/

#### Más información:

Alertas por mercurio en pescado: <a href="http://www.ecologistasenaccion.org/spip.php?article7076">http://www.ecologistasenaccion.org/spip.php?article7076</a>

#### Notas:

[1] El consumo medio de pescado en España es de 28,4 kilogramos por persona y año, según datos del Ministerio de Agricultura, Pesca y Alimentación (MAPA). Asturias (36,3 kilos), Castilla y León (36,1), Aragón (34), La Rioja (33,5) y Navarra (32) son las CC AA donde se consume más pescado.