



## **Results of the public consultation on SCENIHR's preliminary Opinion on the safety of dental amalgam and alternative dental restoration materials for patients and users**

A public consultation on the preliminary Opinion was opened on the website of the Scientific Committees from 9 September to 16 November 2014. Information about the public consultation was broadly communicated to national authorities, international organisations and other stakeholders.

Twenty five contributors- representing industry associations, universities, professional organisations, national authorities, non-governmental organizations and individuals- participated in the public consultation providing input to the main scientific questions (in total 102 contributions were received).

Each submission was carefully considered by the SCENIHR and the scientific Opinion has been revised to take account of relevant comments. The literature has been accordingly updated with relevant publications. The scientific rationale and the Opinion section were clarified and strengthened.

The SCENIHR thanks all contributors for their comments and for references sent during the public consultation.

**The table below shows all the comments made about each of the questions posed in the Opinion and SCENIHR's response to them. It is also indicated if the comment resulted in a change of the Opinion.**



**Comments received during the public consultation on the SCENIHR preliminary opinion on the safety of dental amalgam and alternative dental restoration materials for patients and users**

No	Name of individual/ organisation	Table of content to which comment refers	Comment	Scientific Committees Response
1	Rooney James, Trinity College Dublin, jrooney@rcsi.ie	ABSTRACT	<p>Page 4, paragraph 5: "The most recent in vitro evidence provides new insight into the effects of mercury on developing neural brain cells at concentrations similar to those found in human brain. The effects of genetic polymorphism concerning mercury elimination may influence the degree of individual susceptibility in regard to mercury internal exposure and toxicity. They therefore raise some concern for possible effects on the brain of mercury originating from dental amalgam. However, so far such effects have not been documented in humans." Comment: There is evidence from epidemiological studies of numerous genetically predisposed subgroups who do suffer subtle neurobehavioural effects on exposure to mercury. This has been demonstrated in both dental workers and children partaking in amalgam trials. Key findings are summarized in recent review papers.(1,2)</p> <p>Page4, paragraph 6: "As with any other medical or pharmaceutical intervention, caution should be exercised when considering the placement of any dental restorative material in pregnant women." Comment: It is not clear from this statement whether mercury is contraindicated in pregnant women or not. SCENIHR should show leadership here and clearly define pregnancy as a contraindication to amalgam placement.</p>	<p>Concerning the two cited references, please consider that: Basu et al., 2014 is a review; no original data are presented. However, the reference it is now included in the text Ref 2 is again a review, presenting a re-evaluation of data from the Casa Pia Study (cited in the opinion). In a reply of the authors to a former re-evaluation of the Casa Pia study, the method used for re-evaluation was criticised by the authors of the Casa Pia study (DeRouen T, Woods J, Leroux B, Martin M: Critique of reanalysis of Casa Pia data on associations of porphyrins and glutathione-S-transferases with dental amalgam exposure. Hum Exp Toxicol. 2014 Jul 8.): the paper is referred to in the text. The problem of post-hoc analyses was addressed in the Opinion: "As Friedman et al. document, there are numerous examples of such post hoc findings not being confirmed in subsequent trials."</p> <p>The issue of polymorphism is treated in more detail in the main text of the Opinion; not too many details can be added here in the abstract. Furthermore, the issue is still controversial, since the amount of available information has grown over the last years and has not yet been well consolidated. In addition, the evidence of genetic factors impacting Hg dynamics comes from a single research team.</p> <p>In the specific commented paragraph, reference is made specifically to direct effects on the brain that have not been documented. To make the text clearer and in order to address</p>

4	Schulze Florian, World Alliance for Mercury free Dentistry, florianschulze@hotmail.com	ABSTRACT	<p>The report is analyzing the direct health impact of amalgam-fillings. It is proofed that mercury is constantly evaporating from the amalgam fillings and deposited in the human body. It is also proofed that under certain conditions a transformation from mercury into Methymercury can take place inside the human body. But since the inhaled amount of Mercury from amalgam fillings is very low, you are considering the burden for the general population as insignificant to cause health effects. Even though you have done exceptions for vulnerable people, you have not considered the synergetic effect of mercury with other elements like for example Lead(1). Many people do have a burden of lead, since it is diffused in the atmosphere by combustion and also by tap water due to tubes out of lead. The health impact would therefore be multiplied for a significant part of the population. Please take the attached studies into consideration for the report of direct health risks.</p> <p>1) J Toxicol Environ Health. 1978 Sep-Nov;4(5-6):763-76. Combined effects in toxicology--a rapid systematic testing procedure: cadmium, mercury, and lead. Schubert J, Riley EJ, Tyler SA. <a href="http://www.ncbi.nlm.nih.gov/pubmed/731728">http://www.ncbi.nlm.nih.gov/pubmed/731728</a></p> <p>2) Arch Med Res. 2003 Jan-Feb;34(1):50-5. Nephrotoxic effects of mercury exposure and smoking among Egyptian workers in a fluorescent lamp factory. El-Safty IA1, Shouman AE, Amin NE. <a href="http://www.ncbi.nlm.nih.gov/pubmed/12604375">http://www.ncbi.nlm.nih.gov/pubmed/12604375</a></p> <p>3) J Inorg Biochem. 2003 Feb 1;94(1-2):50-8. Enhanced conformational changes in DNA in the presence of mercury(II), cadmium(II) and lead(II) porphyrins. Tabata M1, Kumar Sarker A, Nyarko E. <a href="http://www.ncbi.nlm.nih.gov/pubmed/12620673">http://www.ncbi.nlm.nih.gov/pubmed/12620673</a></p> <p>4) Biol Trace Elem Res. 2001 Winter;84(1-3):139-54. Nephrotoxicity of simultaneous exposure to mercury and uranium in comparison to individual effects of these metals in rats. Sánchez DJ1, Bellés M, Albina ML, Sirvent JJ, Domingo JL.</p>	<p>SCENHIR agrees that the issue can be of relevance, but the synergistic effect of mercury with other elements is outside the mandate received from the Commission.</p> <p>In addition the comment refers to mercury/lead combinations, but the references provided do not show clinically relevant information for amalgam or mercury derived from amalgam, nor do the authors of these articles refer to the amalgam situation.</p> <p>Ref 1 refers to the general issue of interactions among chemicals. However, no data are provided for mercury from amalgam. Ref 2 refers to industrial workers and mercury exposure, not to amalgam. Ref 3 refers to <i>in vitro</i> test on different metals/metal porphyrins on DNA change. No mention of amalgam, no indirect relation to the subject. Ref 4 considers that mercury and uranium interaction in rat studies are not related to the topic. Ref 5 refers to seafood methyl mercury and PCB: possible synergistic effect, but does not include dental amalgam. In addition, methyl mercury effects are different from mercury in dental amalgam.</p>
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5	Zimmerman Clinton, self-also works with consumers for dental choice, clintonzim@aol.com	3.1. Introduction	<p>Scenihr conclusion: "The contribution of methyl mercury exposure when compared to inorganic exposure is expected to be limited" This unsupported scientific conclusion is completely unjustified. In recent testimony at the 2010 FDA hearings, Dr. Ann Summers microbiologist, a leading expert in this field and invited expert speaker who uses newer extremely sensitive tests for methyl Hg noted-as seen in the transcripts, that Hg from amalgam "vastly boosted the levels of methyl and dimethyl Hg found in the gut". The advanced methods used by Summers and her team were shortly published thereafter. See "Discovering mercury protein modifications in whole proteomes using natural isotope distributions observed in liquid chromatography-tandem mass spectrometry" Purvine,Zink,Lipton,Summers Mol Cell Proteomics 2011Aug:10(8) for a description of newer methyl mercury detection methods. This finding was uncontested by the expert FDA committee who showed great interest in these results. Hardly a consensus as stated by SCENIHR that mercury conversion from amalgam is insignificant in the human body. Therefore there is every reason to expect the contribution to be significant. The conversion of amalgam Hg to methyl and dimethyl, an extremely toxic form of Hg has also been documented by Haley in "The Relationship of the Toxic Effects of Mercury to the Exacerbation of the Medical Condition Classified as Alzhiemers Disease". SCENIHR excludes this important reference in the peer reviewed literature. There are numerous similar scientific</p>	<p>About the transformation of inorganic mercury to methyl mercury in the body, which is treated in the document, the comment makes reference to an open hearing, where individual Opinions could be presented. The SCENIHR recognises the importance of the outcome of FDA hearings. However, the SCENIHR can only cite definitive conclusions from such hearings when published on the FDA website. The SCENIHR cannot cite views presented at those hearings unless they are supported by scientific data in the open literature. Please take into account that the amount of methylmercury eventually formed from dental amalgam should be put into context, considering the exposure coming from the diet (especially fish). In the provided reference (Purvine et al, 2011), the topic of transformation of inorganic mercury originating from dental amalgam into methyl mercury is not mentioned. The topic of Alzheimer's and amalgam has been extensively covered. In a review paper, Mutter et al (2010) did not indicate that available data allowed judgement on an association between amalgam and Alzheimer's.</p>