SCHER preliminary opinion on "The environmental risks and indirect health effects of mercuryfrom dental amalgam (update)"

YOUR IDENTITY	
1. Do you write as an individual or on behalf of an organization? -single choice reply-(compulsory)	Organisation
If you write on behalf of an organisation, please specify the following: -single choice reply-(compulsory)	NGO
2. Your name or the name of your organization: -open reply-(optional)	Elena Lymberidi- Settimo on behalf of the European Environmental Bureau, the World Alliance for Mercury Free Dentistry and the Mercury Policy Project
3. Your email address: -open reply-(compulsory)	elena.lymberidi@eeb.org

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

4. YOUR COMMENTS: Do you agree with the observations made by the Scientific Committees? -single choice reply-(compulsory)	Disagree
Explain why: -single choice reply-(compulsory)	Other

Please specify -open reply-(optional)

In summary, knowing the characteristics of Hg and its transformations to MeHg and the toxicity of MeHg, it is hardly possible to reach any other conclusion than that Hg released from dental amalgam into the environment, in the same way as Hg released from other sources, “could cause serious effects on human health”. Calculations presented for the worst case scenario as well as the revised calculations on the average case at elevated apparent methylation indicate that the methyl mercury content in fish may already reach levels which are hazardous to human health if consumed. For full references please see our full position submitted by email.

5. Please provide the evidence to improve the overall report (with complete references): -open reply-(compulsory)

The opinion needs to be revised due to: overestimated control technology reductions of dental mercury release pathways; and underestimation of overall EU dental mercury releases, which has resulted in SCHER underestimating methylmercury exposure risks in the EU. Our conclusions are derived from our findings, including but not limited to the following: I. Given the clear reported air release values in the BIOIS report, which the SCHER acknowledge, we believe that a range should be presented for air emissions from crematoria and other air release pathways of dental Hg and these releases should be factored in to MeHg exposure in the EU. II. The Hg quantities involved in soil are far more significant than in the current SCHER report. They are significant enough for SCHER to perform a screening setting the upper and lower limit of Hg possibly reaching the soil and such a revised estimate should be presented by the SCHER. III. Our calculations indicate the following for determining efficiencies of amalgam separators: • Considering all aspects, for best case scenario, we would consider a lower rate of installed separators, but with also smaller than the required efficiency (see Annex 2). Therefore the mercury recovery rate by amalgam separators from the waste water stream would be 80.1% under a best case scenario. • At the average case scenario considering the lower efficiency of separators, our estimate would give, 52.5% mercury recovery (75% separator coverage and 70% efficiency as stated in BioIS, 2012) (see Annex 1). IV. By including the actual efficiency of the separators, the calculated inorganic Hg concentration in effluent increased to 0.102 µg/L (from 0.054 µg/L) for the average case and to 7.3E-5 µg/L (from 1.8E-5 µg/L) for the best case, respectively. Also the Hg concentration in surface water (after dilution) increased when considering the reduced efficiency of the separator, resulting in calculated Hg concentrations of 0.01 and 7.3E-6 µg Hg/L for the average case and best case, respectively.The revised values of Hg in surface water, obtained by including the actual efficiency of separators (see Annex 1), the Hg concentration in surface water at the average scenario (10.23 ng/L), is not one order of magnitude below the AA EQS value

(50 ng/L) but merely five times below. This smaller marginal at average scenario should be considered in the risk assessment. V. Comparing the re-calculated values of methyl mercury concentration in water and accumulation in fish allows the following conclusions: • Average case: calculated concentrations show that the WFD proposed threshold (20 µ Hg/kg fw) for secondary poisoning is exceeded already at methylation rates lower than 0.1 % (0.053%). The presently accepted level in food (500 µ Hg/kg fw) is exceeded at methylation rates higher than 1.35 %. The CONTAM Panel recently established the JEFCA TWI for methylmercury of 1.3 µg/kg b.w., expressed as mercury (EFSA, 2012). This is an adjustment down from the former value of 1.6 µg/kg b.w. This reduction would correspond to a revised, accepted level in food of 400 µ Hg/kg fw, which in the average case correspond to 1.05% methylation (Annex 1). VI. BPA is not a direct ingredient in dental sealants and composites as many studies indicate. Instead, dental resins are composed primarily of BPA derivatives, commonly BPA glycidyl dimethacrylate (bis-GMA), rather than pure BPA. No scientific studies have been identified to date which show that Bis-GMA can be converted into BPA. While more research can always be done on every product , this is not what SCHER was asked to do. SCHER was asked to do a comparative risk assessment based on current scientific knowledge – which consistently indicates that the alternatives are not a risk to the environment. For full references please see our full position submitted by email.

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?

6. YOUR COMMENTS: Do you agree with the observations made by the Scientific Committees? -single choice reply-(compulsory)	Disagree
Explain why: -single choice reply-(compulsory)	Other

Please specify -open reply-(compulsory)

1) Knowing the characteristics of Hg and its transformations to MeHg and the toxicity of MeHg, it is evident that Hg released from dental amalgam into the environment could cause serious effects on human health in the same way as Hg released from other sources. While SCHER acknowledges potential health risks due to Hg released from dental amalgam into water, Hg released to air from burning amalgam containing solid waste, sewage sludge and cremation also significantly contributes to the environmental Hg pool. A certain fraction of this pool will methylate and partly bioaccumulate in biota and biomagnify throughout the food web, and similarly be released directly into waste water from dental clinics or households. 2) Based upon our revised calculations for “average case scenario” with correction for actual efficiency for amalgam separators, the methyl mercury content in fish which reaches the WFD threshold is already at 0.05 % methylation. 1% methylation rate results in levels even more hazardous to human health. This calculation is based on Hg from dental amalgam alone as the only mercury source in the model. In reality, mercury from different sources together contributes to increased mercury levels in fish. This indicates the absence of any safety marginal for potential methyl mercury poisoning via fish in many regions of EU, forcing the authorities to issue fish consumption advisories for many decades. 3) Fish and sea food is not the only source of MeHg to humans. Exposure via rice may be significant because of elevated levels of methyl mercury and large amounts eaten, as rice is a staple food. The presence of methyl mercury in rice may need to be considered at rice cultivation sites within the EU and also when importing rice from certain regions. 4) Inorganic Hg may also damage human health. The PTWI for inorganic Hg is 4 µg/kg b.w set up by EFSA (2012). EFSA also states that the TWI might be exceeded by inhalation exposure of elemental Hg from dental amalgam.

7. Please provide the evidence to improve the overall report (with complete references) -open reply-(compulsory)

1) The existence of significant mercury emissions from dental amalgam and knowledge about the continuously lowered limits for intake of methyl mercury, with a a PTWI of 3.3 µg Hg/kg bw before 2003 to the present PTWI of 1.3 µg/kg bw is a clear indication on potential serious effects on human health due to mercury releases and subsequent transformation to methyl mercury. Hg from dental amalgam should be added to other Hg sources to environment. Irrelevant to look at each source separately, because same element independent of source. EFSA (European Food Safety Authority). 2012. Scientific Opinion on the risk for public health related to the presence of mercury and methylmercury in food. http://www.mercury2013.com/news/-/16/ 2) Include efficiency of separators in the calculations MeHg limits reached No safety marginal Skare, I. & Engqvist, A. 1994. Human exposure to mercury and silver released from dental amalgam restorations. Arch. Environ. Health 49 (5): 384-394. Skerfving, S. 1972. Methyl mercury exposure, mercury levels in blood and hair, and health status in Swedes consuming contaminated fish. Toxicology, 2:3-23. Skerfving, S., Hansson, K., Lindsten, J. 1970. Chromosome breakage in humans exposed to methyl mercury through fish consumption. Preliminary communication. Arch-Environ-Health. 21(2): 133-139. 3) MeHg from rice. Horvat M, Nolde N, Fajon V, Jereb V, Logar M, Lojen S, Jaćimović, R., Falnoga, I., Liya, Q., Faganeli, J., Drobne, D. 2003. Total mercury, methylmercury and selenium in mercury polluted areas in the province Guizhou, China. Sci. Total Environ., 2003, 304, 231-256 4) Inorganic Hg PTWI 4 µg/kg b.w. The limit for a 70 kg-person is 40 µg inorganic mercury/day (4 µg * 70 kg / 7 days/week). Data from Skare (1995) indicate that persons with many amalgam restorations exceed this limit with up to a factor 3.

Thus, amalgam fillings cannot be authorized by the authorities if striving towards a harmonized legislation. Skare I. 1995. Mass Balance and Systemic Uptake of Mercury Released from Dental Amalgam Fillings. Water, Air Soil Pollut. 80(1-4):59-67.

Question 3: Comparison of environmental risk from the use of mercury in dental amalgam and the use of alternatives without mercury

8. YOUR COMMENTS: Do you agree with the observations made by the Scientific Committees? -single choice reply-(compulsory)	Disagree
Explain why: -single choice reply-(compulsory)	Disagreement with the interpretation of the existing scientific and other data

9. Please provide the evidence with the overall report (with complete references) -open reply-(compulsory)

The only environmental issue with respect to composite and sealants seems to be the potential for BPA release. Unlike mercury, an EU risk assessment (EU RAR (2010) estimates that BPA is readily biodegradable and not bioaccumulative. Regarding human exposure via the environment, the assessment concludes that key human health effects via the environment were those following repeated exposure. But “Given the low levels of exposure and the large margins of safety for both the regional and local exposure scenarios, there are no concerns for repeated dose toxicity and reproductive toxicity.” As a result, “There is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied already.” The same conclusion applied when the worst case environmental exposure was combined with exposure to food contact materials. (Indirect environmental exposure to BPA is considered much less important than exposure from food packaging materials, which account for the majority of daily human exposure to BPA. Kemi 2008) BPA is not a direct ingredient in dental materials like sealants and composites.(Chen & Suh (2013) BPA from the impurity of BPA derivatives used in composite is usually very low and not detectable (<2 ppm). .(Chen & Suh (2013) No scientific studies identified to date show that Bis-GMA, the most common monomer in polymer-based dental materials, can be converted into BPA. Under any circumstances, far less material is needed for composite restorations than amalgam restorations (even accounting for repair and replacement); hence there is even less monomer available to potentially enter the environment.(BIOIS 2012, SCHER’s mandate called for a “Comparison of environmental risk from the use of mercury in dental amalgam and the use of alternatives without mercury.” Instead of responding to its mandate, SCHER asks questions (p.21) regarding precise quantities that cannot be answered with exactness until composite technology stops developing. While more research can always be done on every product, SCHER was asked to do a comparative risk assessment based on current scientific knowledge – which consistently indicates that the alternatives are not a risk to the environment. While SCHER claims that “the available information is too limited for conducting a proper comparative risk assessment of the amalgam alternatives,” Erdal, for example, used a model developed by the U.S. EPA to make the assessment. (Erdal . 2012) It is not clear why SCHER has dismissed Erdal’s model calculation. Refs: EU RAR (2010) European Union Risk Assessment Report, 4,4'-ISOPROPYLIDENEDIPHENOL (BISPHENOL-A),http://esis.jrc.ec.europa.eu/doc/existing-chemicals/risk_assessment/REPORT/bisphenolareport325.pdf Kemi 2008, BPA, http://www.kemi.se/en/Content/In-focus/Bisphenol-A/; NTP-CERHR – National Toxicology Program. 2008. NTP-CERHR Monograph on the potential human reproductive and developmental effects of bisphenol A, http://ntp.niehs.nih.gov/ntp/ohat/bisphenol/bisphenol.pdf#search=Bpa , page vii (“While air, dust, and water (including skin contact during bathing and swimming) are other possible sources of exposure, bisphenol A in food and beverages accounts for the majority of daily human exposure.”) Chen & Suh, Bisphenol A in Dental Materials: A Review, JSM Dent 1:1004 (2013), http://www.jscimedcentral.com/Dentistry/Articles/dentistry-1-1004.pdf BIOIS 2012 Page 77; JJM Roeters, ACC Shortall, and NJM Opdam, Can a single composite resin serve all purposes?, BRITISH DENTAL JOURNAL 199, 73 - 79 (2005), http://www.nature.com/bdj/journal/v199/n2/full/4812520a.html Erdal, (2012)Health Care Research Collaborative of the University of Illinois at Chicago School of Public Health, the Healthier Hospitals Initiative, and Health Care Without Harm, Mercury in Dental Amalgam and Resin-Based Alternatives: A Comparative Health Risk Evaluation (June 2012) http://www.noharm.org/lib/downloads/other/Mercury_in_Dental_Amalgam.pdf