Results of the public consultation on SCHER's preliminary opinion on the environmental risks and indirect health effects of mercury from dental amalgam (update 2014)

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

Information about the public consultation was broadly communicated to national authorities, international organisations and other stakeholders. Fifteen organisations and five individuals participated in the public consultation providing specific comments and suggestions on the scientific basis of the opinion. Out of the 15 organisations participating in the consultation, there were six NGOs, three national public authorities, three dentist associations, two businesses companies and one trade union.

Each submission was carefully considered by the Scientific Committee on Health and Environmental Risks and the scientific opinion has been reviewed to take into account relevant comments. The final opinion includes these changes; the literature has been updated with relevant publications, the scientific rationale and the opinion section were clarified and strengthened.

The three tables below show all the comments made about each of the questions posed in the opinion and SCHER's response to them. It is also indicated if the comment was taken into account in the opinion.

SUBMISSIONS					SCHER'S COMMENTS
No.	**Name of individual/ organisation**	**Do you agree with the observations made by the Scientific Committees?**	**Nature of disagreement**	**The evidence (s) with the reference(s)**	**SCHER's response**
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					
Q1.1.	Organisation NGO , Health Care Without Harm No agreement to disclose personal data	Uncertain		n/a	No reaction needed
Q1.2.	Individual No agreement to disclose personal data	Agree		Mark E Stone, Mark E Cohen, Lian Liang, Patrick Pang (2003), Determination of methyl mercury in dental-unit wastewater, Dental Materials, Volume 19, Issue 7, November 2003, Pages 675-679.	No reaction needed

Q1.3.	Individual No agreement to disclose personal data	Disagree	Relevant scientific and other information missing from the analysis	The german BuS manual for dentists dictates the use of amalgam separators (BGBl. I 2004, 1175). If the SCHER opinion is correct, it would imply that those amalgam separators would be unnecessary. However, since Mercury is highly toxic, I see the operation of amalgam separators as absolutely necessary. And I see you starting from the wrong side: what about the direct emissions from the source into the patient's mouth to the patient's body? That's the short way.	The terms of reference for this opinion are quite clear: review and update, if appropriate, the scientific opinion adopted in May 2008 on "The environmental risks and indirect health effects of mercury in dental amalgam ". Therefore what is asked for is out of the current mandate of the SCHER. The effects possibly rising from the direct emissions into the patient's mouth will be dealt with in another SCENHIR opinion under preparation.
Q1.4.	Organisation NGO, Elena Lymberidi-Settimo on behalf of the European Environmental Bureau, the World Alliance for Mercury Free Dentistry and the Mercury Policy Project , elena.lymberidi@eeb.org	Disagree	Other 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	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	I. - The BIOIS Report proposes an estimate of 3 t/y from crematoria in the EU. This estimate is the result of several data: • the ExIA (EC, 2005) proposes an estimate in the order of 2 to 2.3 tHg/year for 2002; • the Concorde/EEB report (2007) provided an estimate of 4.5 t Hg/year in 2004 on the basis of information from the Cremation Society of Great Britain; • a report by AMAP/UNEP provided an estimate of 3.5 t in 2005, noting the high uncertainty associated with this figure; • more recent estimates, from data reported under the OSPAR Convention (OSPAR, 2011) , indicate air emissions are in the order of 2.8 t Hg/year in 2011 for the 25 Member States for which data is available or could be estimated. In particular, for the most recent data, it appears that three MS (UK, Spain and France) are responsible for about 68% of the total.

			hazardous to human health if consumed. For full references please see our full position submitted by email.	presented by the SCHER.	Moreover, For the UK and France, more stringent legislation has been implemented recently.
				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).	As mentioned in the opinion, in the recent AMAP/UNEP global emission inventory (2013) the annual emissions from crematories were estimated to be 3.3 tonnes, in reasonable agreement with the value reported by the Bio Intelligence. The AMAP/UNEP inventory indicates a very wide potential range (from 1 to 12 t/year), supporting the large uncertainty of the assessment.
				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	On these bases, the value proposed by the BIOIS report seems an acceptable approximation of a recent situation. The possibility of increase due to the growing occurrence of cremations in the EU is mentioned in the report, but there are no elements for allowing a prediction. Moreover, no element are available for proposing a range different from those proposed by the AMAP/UNEP inventory. The same comments can be made on the other air releases proposed by the BIOIS report and summarised in the opinion. No information is provided for proposing a range, as well as for assessing the contribution to MeHg. II The EEB comments stated that: “SCHER’s added PECsoil values resulting from the contribution of dental clinic emissions, following the TGD default values, ranges from

				five times below. This smaller marginal at average scenario should be considered in the risk assessment.	0.016 to 4.1 µg Hg/kg, are also markedly lower than using values reported by the BIO Intelligence (2012), which led to Hg concentrations in soil of about 2.6 and 7.9 µg/kg dw, using average and maximum concentrations in sludge, respectively." However, even these higher concentrations are well below the NOECs for soil dwelling organisms. A sentence has been added in the second paragraph of section 3.2.2.2 to reflect the comment. About the additional sources of contribution to soil (disposal of solid wastes and burial), it was opinion of the SCHER that no information is available to estimate a quantitative PEC and to assess local risk. No additional information is provided to perform the assessment. III. The value proposed for the best case scenario is based on several assumptions that are not easy to quantify. However, the concentration estimated in surface water for the best case is more than 4 orders of magnitude lower than the EQS. So changing the 95% rate, assumed by the SCHER, with the 80.1% proposed by EEB is fully irrelevant.
				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.	The average case scenario could be more relevant. However, even assuming a 70% of removal efficiency as an acceptable average at EU level (indeed this removal efficiency is reported in the BioIS report), the calculated concentration can be slightly increased, but it remains far below the AA EQS. The removal efficiency may be included in table 2 of the opinion. The concentration in surface water becomes 0.010 instead of 0.0054 g/L. Only minor and no substantial changes have been made in the risk assessment conclusions. The excel table for the average-case scenario has been revised. IV See answer above. As mentioned above, the revised calculation produces only minor and no substantial changes in the general conclusions: • the best case scenario, that may be referred to some EU countries where removal coverage and efficiency is particularly advanced, is 4 orders of magnitude below EQS; • the average case scenario, that may not be referred to specific EU countries but represents just an average of the EU situation, is 7 times below the MAC EQS and 5 times below AA EQS; • the worst case scenario, that may occur in some EU countries where removal is absent, indicate a risk for surface waters;

					V The recalculated values indicate that the WFD's threshold for secondary poisoning is exceeded at methylation rates slightly lower than 0.01% (exactly 0.005%). VI: dental materials are fabricated not only from bisphenol A glycidyl methacrylate (Bis-GMA) but also bisphenol A dimethacrylate (Bis-DMA).For dental materials, the leakage is limited to resins composed of Bis-DMA (bisphenol A dimethylacrylate) which has an ester linkage that can be hydrolysed to BPA, whereas the ether linkage in Bis-GMA (bisphenol A glycidyl methacrylate) was found to be stable. Measurements have shown that the release of BPA mainly occurs during the few hours directly after application while the BPA level is back to pre-treatment levels at 24 hours. Exposure to BPA released from dental materials is below the recently established t-TDI, also considering that the peak of release is limited to few hours after application. For further details on human health effects see the opinion on 'The safety of the use of bisphenol A in medical devices' for which a public consultation has been launched. BPA deriving from dental material can be of limited value for the environment, but whenever the use would have created any problem to human health cannot be ignored. This has been reflected in the opinion

Q1.5.	Organisation NGO, World Alliance for Mercury Free Dentistry No agreement to disclose personal data	Mostly disagree	Relevant scientific and other information missing from the analysis	The most pessimistic estimations must be taken into account in the calculation of fish impregnation. In fact: 1) A part of the population (especially heavy consumers of coastal areas, including pregnant women and children) exceeds the TWI (INRA AFSSA, 2006). Yet it is essential in order to protect the entire population. 2) Exposure to different types of mercury is cumulative. But the "worst case scenario" takes place in countries where the situation is most critical on dental mercury exposure, such as France and Poland (which both represent half of the EU consumption of dental mercury, as the first source of exposure (BIOIS 2012). In order to protect every one, the risk assessment should be based on the most worrying data and not on "average" values.	To the opinion of SCHER it is a misunderstanding that always the most pessimistic values should be taken into account in general risk assessment. SCHER has provided a general risk assessment taking into account some averaged information and also some worst case assumptions. It is good risk assessment practice to aim at a realistic worst case situation. If for every assumption the worst case value is selected the risk assessment becomes unrealistically worst case as all the worst case assumption do not apply in all situations. In that sense SCHER is of the opinion that its worst case scenario meets such practice. The typical situations in France and Poland have been taken into account in the definition of the realistic worst case scenario. In a general risk assessment sensitive groups in the population, like children and pregnant women are not considered. They may be taken into consideration at the next higher tier level in the risk assessment, which has not been carried out. SCHER is further of the opinion that such a higher tier level of risk assessment is not yet possible to be carried out as essential information for such a more detailed assessment is not available.

Q1.6.	Individual , Florian Schulze (CAT-Berlin) florianschulze@hotmail.com	Mostly disagree	Relevant scientific and other information missing from the analysis	The report is taking the emission of methylmercury from dental practice(Point 3.2.2.4.) into account, which is not further specified. Oral methylation can take place by sulfate-reducing bacteria like Desulfomicrobium or Desulfobacter in subgingival dental plaque.[1] These genera are also the predominant sulfate-reducing bacteria in the human large intestine.[2] In correlation with elevated concentration of total mercury in stimulated saliva[3], which was studied in individuals with multiple dental amalgam fillings, humans, especially in populated areas, could be a significant source of mercury pollution. Even more, if there would be an increase of sulfate-reducing bacteria by prevalence or mutation, which could have effects on the methylation rate. Since the only reference in the report dates from 2003, I would claim for further analysis of this aspect and to take this comment into consideration. [1]Langendijk PS, Kulik EM, Sandmeier H, Meyer J, van der Hoeven JS. Isolation of Desulfomicrobium orale sp. nov. and Desulfovibrio strain NY682, oral sulfate-reducing bacteria involved in human periodontal disease. Int J Syst Evol Microbiol. 2001 May;51(Pt 3):1035-44. [2]J. S. van der Hoeven, C. W. A. van den Kieboom, M. J. M. Schaeken Sulfate-reducing bacteria in the periodontal pocket 19 DEC 2007 DOI: 10.1111/j.1399 302X.1995 .tb00156.x [3]Leistevuo J, Leistevuo T, Helenius H, Pyy L, Huovinen P, Tenovuo J. Mercury in saliva and the risk of exceeding limits for sewage in relation to exposure to amalgam fillings. Arch Environ Health. 2002 Jul-Aug;57(4):366-70.	The comment has been taken into account and some consideration are now included in the text of paragraph 3.2.2.4. More details about the effects possibly rising from the direct emissions of Hg and its methylation products into the patient's mouth will be dealt with in a SCENIHR opinion under preparation.

Q1.7.	Organisation , Business , Eight dental societies, all for MERCURY-FREE dentistry: Accademia Internazionale di Odontoiatria Biologica, British Society of Mercury-Free Dentists, Deutscher Berufsverband der Umweltmediziner, Deutsche Gesellschaft für Umwelt-Zahnmedizi, European Academy for Environmental Medicine	Mostly agree		All dentist members of our eight associations -- from Germany, Italy, Spain, Sweden, and the United Kingdom -- practice mercury-free dentistry. We support, and refer you to, the submission by European Environmental Bureau/World Alliance for Mercury-Free Dentistry/Mercury Policy Project, a comprehensive and thoroughly research report on how the SCHER report should be improved. Our contribution is in response to your question 9.	Similar to Q1-3

	e.V., International Academy of Oral Medicine & Toxicology--Europe, IAOMT-Sweden, MERCURIADOS (Dental Section) , charlie@toxicteeth.org				

Q1.8.	Organisation , Public authority , Swedish Chemicals Agency No agreement to disclose personal data	Disagree	Other Disagreement with the interpretation of the existing scientific and other data Relevant scientific and other information missing from the analysis	An over-all comment regarding the report is that it is very hard to follow the risk assessment. It has not been reported from where input parameters are derived. It is therefore hard to have an opinion on the outcome of the risk assessment. The worst case scenario for surface water seems not to be an extreme worst case as presented in the report, but rather a realistic worst case, since it is based on measured values. The difficulties to assess local scale scenarios are unclear. The mandate from the COM to SCHER includes "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". We are thus surprised that such information from the Biosis 2012 report was not used, e.g. Figure 12, page 153. We also find the figures in that report to be underestimated. The annual environmental release, through human urine and faeces, of mercury from existing amalgam fillings have been estimated to 12 kg for the 600,000 inhabitants in Stockholm. This now represents the major single source, around 60%, of mercury emissions to the waste water (Sörme, 2006; Lagerkvist, 2012). For the EU population this would roughly correspond to a yearly load of 10 tons of mercury to the waste water. A Finnish study confirms that emissions from human urine and faeces are in populated areas, a significant source of mercury pollutants to wastewater (Leistevuo, 2002). Although the use of dental amalgam has been phased out in Sweden, release of mercury from existing dental amalgam fillings will remain a significant source of	I. The worst-case scenario is not based on measured values. The result of the calculation has been compared with measured data. The scenario is based on the highest reported value of Hg dentist/year, the highest dentist density reported for EU countries and the total absence of separators. This is a situation that may be assumed as "not impossible to occur" in EU MS, but it is difficult to imagine a more extreme worst case. All the data from figure 12 of the BioIS report have been considered and reported in the opinion. However, they represent total emission at EU level and cannot be used at all for local scale scenarios. About the possibility of underestimation, the mentioned situation of Stockholm emission cannot be checked because in Swedish (Sörme, 2006) or personal communications (Lagerkvist, 2012). Moreover, a situation for a specific city cannot be assumed a representative for Europe. Some considerations about the issue of humans with dental filling as source of mercury/ methyl-mercury have been included in the text of paragraph 3.2.2.4. The leakage/erosion of mercury from amalgam fillings (and related excretion in urine) is not considered in the three scenarios of surface water emissions. It is estimated in the BioIS report as about 20% of the total emissions to urban WWTP on an European average.

				mercury to the waste water (Lagerkvist, 2012 and 2013). Despite all efforts to reduce emissions of mercury to the environment the levels of mercury in lakes and sea water have still not reached a level in Sweden considered to allow for unrestricted consumption of all species of fish. (Swedish EPA, 2012). There are several air borne sources of mercury adding to the deposits to surface water, and all possible means of reducing these sources should be considered. Therefore any additional emissions from other sources must also be reduced, e.g. emissions from the dental amalgam via waste water treatment effluents as well as via the air. In countries without plans to phase out dental amalgam, emissions of mercury to water from dental clinics and patients will continue for a long time. For the exposure scenarios in the opinion we propose that emissions to waste water are evaluated in two separate streams, one from dental clinics and another from existing amalgam fillings. Our view is that the best case scenario in SCHERs calculations is an underestimation. This may be part of the explanation for differences between measured and calculated values in the assessment. We also find underestimations and lack of data in the draft opinion, e.g. the manufacturing of dental amalgam material and emissions from cremation. We consider the effectiveness of the amalgam separators to be overestimated regarding both installed devices and working efficiency (Stockholm Env Adm, 2007; Hylander, 2006a; Hylander 2006b). The installation of mercury separators is not compulsory in European dental clinics, their actual working efficiency	However, this component is included in the measured values in WWTP effluents and may be an explanation of the higher value of measured concentrations in comparison to calculated in the best case scenario. All other comments are qualitative and are not helpful for a quantitative local scale risk assessment. II. As mentioned under Comment Q1.4 IV, the best case scenario represents a situation where removal coverage is the maximum, dentist density is the minimum reported among EU MS and the Hg per dentist/y is at the lower hand of a range reported in the literature. Such a situation is based on a series of assumptions that, individually, are really occurring, even if the contemporaneous occurrence of all assumptions cannot be assumed as representative of a generalised European condition and the probability may be not high. However, this is the meaning of a “best case scenario”: a scenario not highly probable but not impossible in the EU (this is the same for the “worst case scenario”). It is not surprising that measured and calculated values are not corresponding. It means that the full implementation of all conditions assumed for the best case calculation is not frequent in the EU and should be assumed as an objective for future development of control measures.. The statement on the underestimation of

				needs to be assessed and routines for handling the mercury waste collected need to be standardized and regulated. The number of practicing dentists per inhabitant in the EU from 1999-2010 are readily available from the Eurostat database (Eurostat 2013). We understand that manufacturing of dental amalgam was not part of the task for this SCHER opinion. However, it is our opinion that an env. assessment of the use of dental amalgam should include this stage. Small companies in the dental sector may be connected to the municipal waste water systems. Refs to Qst1 (Full refs are sent by email) Sörme, 2006 Lagerkvist 2012. Lagerkvist 2013. Leistevuo 2002 Swedish EPA 2012 Stockholm Env Adm 2007 Hylander 2006a&2006b Eurostat 2013	emissions from cremation is not supported at all. Other issues, such as the variability of separator presence and the number of practicing dentists per inhabitant in EU MS, have been considered as assumptions for the development of the three scenarios. For the problem of effectiveness of separators, see response to Q1.4 III. As mentioned in the comment, emissions from manufacturing of dental amalgam were not in the mandate of the opinion.
Q1.9.	Individual No agreement to disclose personal data	Mostly agree		The literature needs to be updated. Simply stating that there is not enough empirical evidence is only driving more research and monitoring (income generators for the contractors involved in the report) rather than properly enabling policy making. The SCHER statement "From the human health point of view there is no new data available compared to the opinion of SCHER in 2008" appears to not be well founded, considering	The sentence cited in the comment refers just to alternatives to Hg dental amalgam: it has been made clear now in the text. Regarding the effects of Hg on human health, the literature is updated. Details about the toxicity of alternatives will be found also in the on-going opinion on the direct effects of dental amalgam

				several scientific articles recently presenting new data on genetic susceptibility to metallic Hg among certain individuals. I perfomed a simple google scholar search and found additional articles from later than 2008.	on human health.
Q1.10.	Organisation , Public authority , Flemish Environmental Agency No agreement to disclose personal data	Mostly agree		In Flanders, we do not have an exact mass balance of mercury emissions coming from dental amalgam separators. However, we notice that some types of separators do not successful eliminate small mercury particles out of the waste water. This leads to high Hg concentrations (> 10 mg/l Hg) in the waste water coming from the separator. In that context, we have following questions to the scientific committee: - Does the committee has figures on mercury concentrations (mg/l) in the waste water stream coming directly from the separator, before the stream is mixed with other waste water? - Are there certain types amalgam separators that perform better than others, Is there a type that can be considered as Best Available Technique? - Are the concentrations in table 3 of the SCHER document measured immediately after the separator or in the total effluent (after mixing with domestic waste water or other waste water streams?) We presume that some amalgam separators perform less than theoretically expected. For that reason, we fully support a substitution of amalgam by alternatives without mercury. We intent to do some research on amalgam separators. In that context, extra information from the scientific committee would be very welcome."	According to the information available to SCHER the concentration of Hg in Flanders do not reach the extreme high levels indicated (>10 mg/L). Most probably, the value should be >10 µg/L, which is in agreement with known results. To SCHER there is no information available on the concentration of Hg before the waste water treatment facility, so in the waste stream of the separator. There are different kinds of separators (filtration, sedimentation, ion exchange, centrifugation and a mix of these technologies). However, no information is available to SCHER that compares these technologies or a technology that should be considered as the Best Available Technique (BAT). The measurements indicated in the SCHER document in table 3 concern measurement after the waste water treatment facility (WWTF) before discharge into natural surface water. Therefore, these measurements include all kinds of Hg sources to the WWTF. SCHER does agree with the statement that more information should be welcomed on the efficiency of the different separator techniques. Unfortunately, SCHER is not able to provide this

					information, which is beyond its mandate.
Q1.11.	Organisation , Other, CED - Council of European Dentists , ced@eudental.eu	Mostly disagree	Disagreement with the interpretation of the existing scientific and other data	The draft opinion concludes that the worst case scenario could lead to a risk of secondary poisoning. However, this scenario seems highly unlikely. The worst case scenario figure suggests the release of 460g/dentist/yr, which assuming this is based on 46wks/yr and an average 5 day week would imply emissions of 2g/day. Published studies of mercury release suggest that emissions to waste water are significantly lower. Studies of waste water from dental clinics in Denmark in 1996 reported levels of 270mg per day in the absence of separators which would equate to only 62g/dentist/yr (Arenholt-Bindslev and Larsen, 1996) Similarly analysis of emissions from dentists in Canada in 2002 (Adegbembo and Watson, 2004) were estimated at 170mg/day per dentist in the absence of separators (equivalent to about 51g/dentist per year). Given that there has been a general reduction in the use of amalgam since these studies it seems reasonable to assume that current levels are likely to be even lower. Estimated quantity of mercury in amalgam waste water residue released by dentists into the sewerage system in Ontario, Canada. J Can Dent Assoc. 70 759a-759f.	I As for previous comments, the meaning of "worst" and "best" scenarios must be considered. In both cases they are based on assumptions that are in the higher or lower end of the variability range of different parameters. So, all the individual assumptions are possible. The contemporaneous occurrence of all assumptions (for both "best" and "worst" case) should be considered as not highly probable but not impossible in the EU. No doubt those in most realistically occurring situations, emissions are lower than those estimated in the worst case scenario. The assessment of all site-specific scenarios realistically occurring in the EU is impossible. Therefore, two extreme (but not impossible) cases and an average scenario have been developed. II There is no contradiction between this comment and the conclusions of the opinion. The overall conclusion of the opinion, about the risk for surface water, is that, where good environmental controls are in place, the risk is

				Arenholt-Bindslev, D. and Larsen, A.H. (1996). Mercury levels and discharge in waste water from dental clinics Water, Air, and Soil Pollution 86; 93-99. Fan, P.L., Chang, S.B. and Siew, C. (1992). Environmental hazard evaluation of amalgam scrap. Dent Mater.8: 359-61. Fan, P.L., Arenholt-Bindslev, D., Schmalz, G., Halbach, S. and Berendsen, H. (1997). Environmental issues in dentistry--mercury. FDI Commission. Int Dent J. 47: 105-9. Stone ME. (2004). The effect of amalgam separators on mercury loading to wastewater treatment plants. J Calif Dent Assoc. 32: 593-600.	absent or negligible. Risk is only possible if there is no control of emissions. The SCHER is aware that only a fraction of mercury is available for methylation. However, the amount of this fraction may be highly variable as a function of a number of environmental parameters that cannot be generalised to a European situation. This is the reason for the different scenarios proposed for the methylation rate (from 1% to 0.0001%). The proper methylation rate should be assessed case by case.

				The source for the worst case scenario figure is quoted as Richardson, 2011 but this review paper deals with human exposure to mercury from amalgam fillings rather than emissions from dental clinics. The figure quoted in the previous 2008 opinion was an average of 14g/dentist/yr. It should be noted that the figures for the best case situation where good environmental controls are in place are in line with those reported in published studies (Arenholt-Bindslev and Larsen, 1996; Adegbembo and Watson, 2004). Assessment of the environmental impact of dental amalgam should consider that only a fraction of the mercury present in amalgam waste is likely to be readily released to the environment and thus being potentially available for methylation. Any assessment based on the total amount of recoverable mercury is likely to significantly overstate the potential environmental impact (Fan et al., 1997). The rate at which mercury is released from waste amalgam is typically low even when ground to a fine powder, it is minimally soluble in normal waste water (Arenholt-Bindslev and Larsen, 1996). Experimental tests show only small amounts of mercury are released even after prolonged exposure to acid (Fan et al., 1992). Analysis of the wastewater from dental clinics gives a breakdown into the various forms of mercury waste released (Stone, 2004). The majority (99.6 per cent) of the waste containing mercury consists of mercury bound in the form of amalgam particles. Mercury directly available for conversion into methyl mercury represent less than 0.04 per cent of the total quantity of waste. Adegbembo AO and Watson PA. (2004).	

				Estimated quantity of mercury in amalgam waste water residue released by dentists into the sewerage system in Ontario, Canada. J Can Dent Assoc. 70 759a-759f. Arenholt-Bindslev, D. and Larsen, A.H. (1996). Mercury levels and discharge in waste water from dental clinics Water, Air, and Soil Pollution 86; 93-99. Fan, P.L., Chang, S.B. and Siew, C. (1992). Environmental hazard evaluation of amalgam scrap. Dent Mater.8: 359-61. Fan, P.L., Arenholt-Bindslev, D., Schmalz, G., Halbach, S. and Berendsen, H. (1997). Environmental issues in dentistry--mercury. FDI Commission. Int Dent J. 47: 105-9. Stone ME. (2004). The effect of amalgam separators on mercury loading to wastewater treatment plants. J Calif Dent Assoc. 32: 593-600.	

Q1.12.	Organisation , NGO , Tandvårdsskadeförbundet (The Swedish Association of Dental Mercury Patients) , lidmark@gmail.com	Disagree	Other The Expert Report refers to different types of mass balances which are based on very uncertain numbers and calculations. We strongly question some of them and we believe there is still too much uncertainty to allow an	The SCHER report greatly underestimates mercury in deceased Tandvårdsskadeförbundet/The Swedish Association of Dental Mercury Patients) 2013-11-20 Our investigation of emissions from cremation shows that the number of grams of mercury in a deceased in Sweden is on average 10 to 20 grams. This is three to six times more than the Swedish official figure of 3 grams (Factsheet from the Swedish EPA) and far more than the 1.5 grams which SCHER (2013) and the Bio Intelligent Service Report (2012) count with. . If SCHER´s estimation is right there would in average be just one small amalgam filling in a deceased person and this cannot be true. Different kinds of fillings weighting from 1 gram to 10 grams, meaning that they contains 0.5 to 5 grams of mercury each. Pictures of different kinds of fillings are shown below. Figure 1: Example of small and big amalgam fillings	It is correct that some values estimating the content of deceased persons are greatly varying, especially in Scandinavian countries. Nevertheless the SCHER is of the opinion that the most recent information as presented in the Bio Intelligence Service Report (2012) is a sound source for the assumption of 1.5 g/p as an estimate in the risk assessment

				The three grams of mercury, which is the Swedish official estimate, equals one to three small fillings, as half of the weight is made up of pure mercury. Other countries have made estimates of the same size (see figure 2). Even those estimates are too small in our opinion as well as SCHER´s 1.5 grams per cremated corpus. Figure 2: The average of mercury in deceased in European countries Country Amount of mercury/cremation Sweden 3 Denmark 4 Norway 2-4.9 Switzerland 2.5 Source:Naturvårdsverket, Branschfakta Krematorieverksamhet (2010). Swedish EPA. Factsheet We have understood that the knowledge about the amount of the population´s dental amalgam is not sufficient. Our estimation of mercury and the amount of amalgam fillings and mercury in deceased is based on statistics concerning the presence of amalgam fillings and own teeth in elderly, information from dentists and dentist nurses and the weighing of removed amalgam received from members. The only estimation of filling materials in the Swedish population comes from the ten year old Dental Material Royal Commission´s report Dental Material and Health based on a survey to a statistical sample of the Swedish population. This shows that 73 percent born 1924 to1946 had amalgam in their teeth. In Sweden the percentage may have dropped after amalgam ban in 2009, but no dramatic differences is expected in older people. Figure 3: Proportion of people with amalgam fillings and edentulous Borns 1924-1929 (%) 1930-1946 (%) Edentulous 16 8 Only amalgam 35 39 Amalgam + other fillings 32 40 Other dental filling materials 15 13 No fillings 0 1 Source:	

				Dental material och Hälsa, SOU 2003:53, Annex 3 page 310 (complementary question) Of those born in 1930 to 1946, 79 percent had amalgam and only eight percent had missing teeth or no repairs. The proportion of older people with their own teeth will increase considerably in coming years and the same happens in other European countries. The 73 percent of people over 67 years who have amalgam fillings have amalgam crowns of the molars and also several other teeth repaired with amalgam according to the consulted dentists and dental nurses. Our conclusion from the interviews are that a normal person with amalgam have 2-4 crowns or big molar fillings, 2-8 medium sized fillings and 2-4 small fillings. An amalgam crown of a molar has a weight of 9 to 10 grams, a big molar filling around 8 grams and smaller filling weight from a little less than one gram and upwards. Half of the amalgam filling consists of pure mercury. Below we make calculations for two groups according to the interviews with dentists and dental nurses; one with few amalgam fillings and the other one with more. We find that an average person above the age of 67 in Sweden who has dental amalgam according to our calculations above has at least 15 grams mercury in the teeth and some have as much as 30 grams (see figure 5). Figure 4: Amount of mercury in older people with amalgam Small proportion amalgam Lar	

Q1.13.	Organisation NGO, World Alliance for Mercury Free Dentistry No agreement to disclose personal data	Mostly disagree	Relevant scientific and other information missing from the analysis	Les estimations les plus pessimistes (worst scenario) doivent être prises en compte dans le calcul de l'imprégnation des poissons. En effet : 1). Une partie de la population (en particulier les forts consommateurs de régions côtières, et parmi eux des femmes enceintes et des enfants) dépasse la TWI [INRA AFSA 2006] ; or, il est indispensable de protéger l'ensemble de la population. 2). Les expositions aux différentes espèces de mercure se cumulent. Or le « pire scénario » sévit dans les pays où la situation est la plus critique quant à l'exposition au mercure dentaire, comme en France et en Pologne (consommateurs à eux deux de la moitié du mercure dentaire, première source d'exposition) [Bio Intelligence Service 2012]. Si elle se veut protectrice pour tous, l'évaluation des risques doit reposer sur les données les plus inquiétantes et non sur les valeurs « moyennes ».	See Q1- 5
Q1.14.	Organisation Other, German Dental Association (BZÄK) and National Association of Statutory Health Insurance Dentists (KZBV)	Mostly disagree	Relevant scientific and other information missing from the analysis	The draft opinion concludes that the worst case scenario could lead to a risk of secondary poisoning. The figures for the worst scenario (460g Hg/dentist per year, Richardson, 2011) and average cases (160g/dentist/yr, BIOSIS report) look very high. Studies on waste/waste water from dental clinics reported levels of 57g/dentist/yr (Arenholt-Bindslev and Larsen, 1996) and 51g/dentist/yr (Adegbembo and Watson, 2004). Given that there has been a general reduction in the use of amalgam since these studies were performed it seems reasonable to assume that current levels are likely to be even lower. The unrealistic figures should be corrected. Adegbembo AO and Watson PA. (2004). Estimated	See answer Q1 - 11

	No agreement to disclose personal data			quantity of mercury in amalgam waste water residue released by dentists into the sewerage system in Ontario, Canada. J Can Dent Assoc 70: 759-759f. Arenholt-Bindslev D and Larsen AH (1996). Mercury levels and discharge in waste water from dental clinics. Water, Air, and Soil Pollution 86: 93-99. Biointelligence Service (2012). Study on the potential for reducing mercury pollution from dental amalgam and batteries. Final Report prepared for the European Commission – DG ENV. 242 pp. Richardson G. M., Wilson R.. Allard D Purtill C. Douma S., Gravière J. (2011). Mercury exposure and risks from dental amalgam in the US population, post-2000. Science of The Total Environment, 409, 4257-4268.	
Q1.15.	Organisation NGO, Non Au Mercure Dentaire No agreement to disclose personal data	Mostly disagree	Disagreement with the interpretation of the existing scientific and other data	Les estimations les plus pessimistes (worst scenario) doivent être prises en compte dans le calcul de l'imprégnation des poissons. En effet : 1) Une partie de la population (en particulier les forts consommateurs de régions côtières, et parmi eux des femmes enceintes et des enfants) dépasse la TWI* ; or, il est indispensable de protéger l'ensemble de la population. 2) Les expositions aux différentes espèces de mercure se cumulent. Or le « pire scénario » sévit dans les pays où la situation est le plus critique quant à l'exposition au mercure dentaire, comme en France et en Pologne (consommateurs à eux deux de la moitié du mercure dentaire, première source d'exposition**). Si elle se veut protectrice pour tous, l'évaluation des risques doit reposer sur les données les plus inquiétantes et non sur les valeurs « moyennes ». * INRA, AFSSA. Etude des Consommations ALimentaires	See Q1 5

				de produits de la mer et Imprégnation aux éléments traces, PolluantS et Oméga 3. 2006. ** BIOIS 2012	
Q1.16.	Organisation Other, ONCD - ORDRE FRANCAIS DES CHIRURGIENS-DENTISTES/FRENCH DENTAL COUNCIL , cedric.grolleau@oncd.org	Agree		There is indeed a risk caused by the mercury associated as component to dental amalgam. This restorative material is actually implicated in mercury release and production of amalgam vapors and debris. The removal of old restorative fillings, when necessary (in case of a real allergy, only established on a patch test basis), may contaminate the air nearby the dental chair. As shown by many data and published articles, up to now no harmful effects were detectable or reported on dental surgeons and nurses. Since many years, this was taken into account by the French sanitary authorities and included in good practices as shown by the following items : a) Only encapsulated forms of dental amalgam are allowed to be put in the market ; b) Amalgam separators are used for each dental unit to avoid contamination by amalgam residual debris; c) Water filters contribute to retain small mercury-rich particles. The reduction of amalgam fillings is mostly related to esthetic appreciation by dentists and their patients, rather than by adverse effects established on a medical basis.	Organisation is in agreement with the SCHER preliminary opinion. No reaction needed

Q1.17.	Organisation Business, EUREAU , carla.chiaretti@eureau.org	Disagree	Other Disagreement with the interpretation of the existing scientific and other data AND Relevant scientific and other information missing from the analysis	1. Underestimated Hg releases from daily erosion of amalgam fillings in the teeth of the population to the wastewater treatment plants The daily erosion of mercury from amalgam fillings are not estimated at all. The losses of Hg to the wastewaters of Stockholm from more than one million inhabitants due the daily erosion of existing amalgam dental fillings in teeth and related losses, is by far the main source of Hg to waste water treatment plants. The daily erosion from amalgam teeth is 60-80% of the total emission from dental care in Sweden. EUREAU is uncertain if this investigation has been done in other cities or member states, but nevertheless the investigation is most probably valid for many more European cities than Stockholm. More than 90% of mercury in the urban waste water in Stockholm originates from amalgam. Sources: Stockholm Water Company 2003. -Mercury Sources - an estimation from the Stockholm Water Company (2003) -Arch Environ Health. 2002 Jul-Aug;57(4):366-70. Mercury in saliva and the risk of exceeding limits for sewage in relation to exposure to amalgam fillings. Leistevuo J, Leistevuo T, Helenius H, Pyy L, Huovinen P, Tenovuo J. National Public Health Institute, Antimicrobial Research Laboratory, Turku, Finland. -Skare I. Mass Balance and Systemic Uptake of Mercury Released from Dental Amalgam Fillings. Water, Air Soil Pollut. 80(1-4):59-67 (1995) -Study on the potential for reducing mercury pollution from dental amalgam and batteries, Final report European Commission – DG ENV 11 July 2012, (figure 12, page 153, erosion of Hg from amalgam fillings)	I The erosion of mercury from amalgam fillings is not considered in the three scenarios of surface water emissions. It is estimated in the BioIS report as about 20% of the total emissions to urban WWTP on an European average. However, this component is included in the measured values in WWTP effluents and may be an explanation of the higher value of measured concentrations in comparison to calculated in the best case scenario. Some considerations about the issue of humans with dental filling as source of mercury/ methyl-mercury have been included in the text of paragraph 3.2.2.4. 2) SCHER does not claim any scientific basis for its estimation that the discharge of Hg may be lowered with a factor of 50 and it may be considered an optimistic view. It is just an estimation based on a potential increase of the use of separators by European Union dentists. If, however, this estimation would not reveal correct in the coming years it only makes the estimation of the best case less probable. This would not change the results of the risk assessment as no risk was identified in that scenario. 3) The 2011 OSPAR Report indicates air emissions from cremations in the order of 2.8 t Hg/year for the 25 Member States for which

				2. Overestimated control technology reductions of dental mercury release pathways. From the European perspective, only 14 member states require installation of amalgam separators, according to BIOIS (p.158). Assumptions on percent of clinics and removal capability is overstated. The estimate that 75% of dental offices have installed, properly operate/maintain separators is highly questionable given range of uncertainties. For example, Member States' data in Annex H shows that in some cases amalgam separators are confused with chair side traps.Without maintenance, studies show that performance and effectiveness of separators is questionable. The amalgam separators are not maintained as expected (see ref Lagerkvist). Therefore, Hg releases are much greater to water from the use of dental amalgam than stated in the SCHER opinion. Extract from the opinion: “Based on future developments, especially in the percentage separators, the concentration in surface water is expected to reduce by about a factor of 50.” An expected reduction of the Hg concentration in surface water “by about a factor of 50” after installation of more amalgam separators has no scientific evidence what so ever. Firstly, it is not possible to reduce the Hg content of surface waters to any larger degree with amalgam separators but rather the output of amalgam from dental clinics. Secondly, a factor 50 is an extremely large reduction, which could only be achieved by much more sophisticated methods than amalgam separators. Such a large reduction would demand filtering the surface water with micro pore filters or interventions to	data is available or could be estimated. This value is in very good agreement with the value of 3 t Hg/year used in the opinion. Also considering other data sources, the values used in the opinion seem not underestimated.

				cause the Hg bond to colloids and organic matter to precipitate. Thirdly, SCHER do not at all consider that Hg precipitated in waste water tubes from historic uses of dental amalgam will act as a source of Hg slowly being released into the water with time due to bacterial activity and intermittent occasions of extreme flushing events in the waste water tubes, re-suspending settled Hg. Sources: - Lagerkvist, RAB. 2012. Stockholm Vatten, Sweden. Personal communication.	
				3. Underestimated average amount of mercury in people and Hg releases to air. Underestimates Hg releases from cremation. In light of the available evidence and research reports (2011 OSPAR report).The estimation is not a reasonable interpretation of available information	

Q1.18.	Organisation Trade union, European Trade Union Confederation www.etuc.org No agreement to disclose personal data	Agree		Les commentaires de la Confédération européenne des syndicats concernent l'exposition au mercure des travailleurs dans le secteur de dentisterie references for question 2: (1/2) Bibliographie Ahlbom A, Norell S, Rodvall Y. et al Dentists, dental nurses, and brain tumours. BMJ (Clin Res Ed) 1986. 292662. Arnetz BB, Hörte LG, Hedberg A, Malker H. Suicide among Swedish dentists. A ten-year follow-up study. Scand J Soc Med. 1987;15(4):243-6. Aydin N, Karaoglanoglu S, Yigit A, Keles MS, Kirpinar I, Seven N. Neuropsychological effects of low mercury exposure in dental staff in Erzurum, Turkey. Int Dent J. 2003 Apr;53(2):85-91. Bittner ACJ, Echeverria D, Woods JS: Behavioral effects of low-level exposure to Hg0 among dental professional: a cross-study evaluation of psychomotor effects. Neuortoxicol Teratol 1998, 17:161-168. Canto-Pereira LH, Lago M, Costa MF, Rodrigues AR, Saito CA, Silveira LC, Ventura DF. Visual impairment on dentists related to occupational mercury exposure. Environ Toxicol Pharmacol. 2005 May;19(3):517-22. Colson DG. A safe protocol for amalgam removal. J Environ Public Health. 2012;2012:517391. de Oliveira MT, Pereira JR, Ghizoni JS, Bittencourt ST, Molina GO. Effects from exposure to dental amalgam on systemic mercury levels in patients and dental school students. Photomed Laser Surg. 2010 Oct;28 Suppl 2:S111-4. Echeverria D, Woods JS, Heyer NJ, Rohlman D, Farin FM, Li T, Garabedian CE. The association between a genetic polymorphism of coproporphyrinogen oxidase, dental mercury exposure and neurobehavioral response in humans. Neurotoxicol Teratol. 2006 Jan-Feb;28(1):39-48. Echeverria D,	No reaction needed

				Woods JS, Heyer NJ, Rohlman DS, Farin FM, Bittner AC Jr, Li T, Garabedian C. Chronic low-level mercury exposure, BDNF polymorphism, and associations with cognitive and motor function. Neurotoxicol Teratol. 2005 Nov-Dec;27(6):781-96. Echeverria D, Heyer NJ, Martin MD, Naleway CA, Woods JS, Bittner AC Jr. Behavioral effects of low-level exposure to elemental Hg among dentists. Neurotoxicol Teratol. 1995 Mar-Apr;17(2):161-8. Eriksson M, Hardell L, Malker H. et al Increased cancer incidence in physicians, dentists, and health care workers. Oncol Rep 1998. 51413–1418.1418. Figà-Talamanca I. Occupational risk factors and reproductive health of women. Occup Med (Lond). 2006 Dec;56(8):521-31. Gonzalez-Ramirez D, Maiorino RM, Zuniga-Charles M: Sodium 2,3-dimercaptopropane-1-sulfonate challenge test for mercury in humans: II. Urinary mercury, porphyrins and neurobehavioral changes of dental workers in Monterrey, Mexico. J Pharmacol Exp Ther 1995 , 272:264-274. Heyer NJ, Echeverria D, Bittner AJ, Farin FM, Garabedian CC, Woods JS: Chronic low-level mercury exposure, BDNF polymorphism, and associations with self-reported symptoms and mood. Toxicol Sci 2004 , 81:354-363. Heyer NJ, Echeverria D, Farin FM, Woods JS. The association between serotonin transporter gene promoter polymorphism (5-HTTLPR), self-reported symptoms, and dental mercury exposure. J Toxicol Environ Health A. 2008;71(19):1318-26. Hilt B, Svendsen K, Syversen T, Aas O, Qvenild T, Sletvold H, Melø I. Occurrence of cognitive symptoms in dental assistants with previous occupational exposure to	

				metallic mercury. Neurotoxicology. 2009 Nov;30(6):1202-6. Jones L, Bunnell J, Stillman J. A 30-year follow-up of residual effects on New Zealand School Dental Nurses, from occupational mercury exposure. Hum Exp Toxicol. 2007 Apr;26(4):367-74. Karahalil B, Rahravi H, Ertas N. Examination of urinary mercury levels in dentists in Turkey. Hum Exp Toxicol. 2005 Aug;24(8):383-8. Kasraei Sh, Mortazavi H, Vahedi M, Bakianian Vaziri P, Assary M. Blood Mercury Level and Its Determinants among Dental Practitioners in Hamadan, Iran. J Dent (Tehran). 2010 Spring;7(2):55-63. Langworth S, Sällsten G, Barregård L, Cynkier I, Lind ML, Söderman E. Exposure to mercury vapor and impact on health in the dental profession in Sweden. J Dent Res. 1997 Jul;76(7):1397	

Q.19.	Individual, Ioannis Anastasiou, dentalan@gmail.com	Mostly disagree	Other I believe that mercury is not free in amalgam and it is not contaminating the environment. Caution must be taken at the places were amalgam is manufactured and not in every day praxis	Sorry no data	No reaction needed
Q1.20.	Organisation Public authority, Chemicals and Emerging Technolo Department for Environment, Food and Rural Affairs No agreement to disclose personal data	Agree		Hg releases from crematoria need to be considered more, not least in view of the abatement systems that have been put in place (for example within the UK) in recent years.	No reaction needed

SUBMISSIONS					SCHER'S COMMENTS
No.	**Name of individual/ organisation**	**Do you agree with the observations made by the Scientific Committees?**	**Nature of disagreement**	**The evidence (s) with the reference(s)**	**SCHER's response**
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?					
Q2.1.	Organisation NGO, Health Care Without Harm , No agreement to disclose personal data	Uncertain		n/a	No reaction needed
Q2.2.	Individual, No agreement to disclose personal	Mostly agree		Lars D. Hylander, Anders Lindvall, Lars Gahnberg(2006) High mercury emissions from dental clinics despite amalgam separators Science of The Total Environment, Volume 362, Issues 1–3, 1 June 2006, Pages 74-84 S. Kontogianni, A. Xirogiannopoulou, A. Karagiannidis(2008) Investigating solid waste production	No reaction needed

	data			and associated management practices in private dental units Waste Management, Volume 28, Issue 8, 2008, Pages 1441-1448	
Q2.3.	Individual No agreement to disclose personal data	Disagree	Relevant scientific and other information missing from the analysis	Dentists apply a highly toxic mixture (amalgam). Health risks from mercury emission into the environment is secondary in this context. Even more important are the direct effects of emissions right from the mouth into the body and following storage in the organism. The additional exposure through the environment only leads to summation effects. So if one renounces amalgam in the mouth, one massively reduces the health risks at all.	The terms of reference for this opinion are quite clear: review and update, if appropriate, the scientific opinion adopted in May 2008 on "The environmental risks and indirect health effects of mercury in dental amalgam ". The working group agrees that human health effects due to environmental exposure only sum up to the direct exposure to amalgam.

Q2.4.	Organisation NGO , Elena Lymberidi-Settimo on behalf of the European Environmental Bureau, the World Alliance for Mercury Free Dentistry and the Mercury Policy Project , elena.lymberidi@eeb.org	Disagree	Other 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	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/	There are no doubts about the toxicological hazard created by Hg and MeHg. The opinion was asked to evaluate the contribution of Hg coming from the use of mercury in dental amalgam to the risk associated to environmental exposure. Since it has been estimated that the contribution of dental amalgam to environmental exposure is only a minor fraction of the total human exposure, other sources should be under a strict control. Regarding the effects due to the direct exposure due to dental filing, this is included into the mandate of another SCENIHR opinion. Point 2 In the report of Bio Intelligence Service (2012) a minimum required efficiency of 95% is mentioned due to adequate maintenance. In the new version of the EXCEL-sheets an efficiency is assumed for the average case of 70% and for the best case of 95%. The new results, however, do not change the risk conclusions

			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	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.	

			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.		

Q2.5.	Organisation NGO, World Alliance for Mercury Free Dentistry No agreement to disclose personal data	Mostly disagree	Relevant scientific and other information missing from the analysis	The SCHER report ignores the many publications that have shown insufficient protection afforded by the current TWI. The TWI must protect the most vulnerable organisms. - This is first of the embryo, fetus and child, the developing nervous system is extremely sensitive to the effects of mercury, even at very low doses. Some studies have demonstrated an inverse relationship between the concentration of mercury in cord and psychomotor development, verbal and performance IQ of young children [Lederman 2008], and between the concentration of mercury in maternal erythrocytes and performance of vocabulary as well as visuomotor abilities of the child [Oken 2008], in moderately intensive fish populations. - Second, a significant proportion of the population is particularly vulnerable to very low levels of mercury exposure because of its genetic susceptibility and thus its inability to eliminate mercury [Wang 2012, Goodrich 2011, Schläwicke 2008, Godfrey 2003, Heyer 2004, Heyer 2008, Heyer 2009, Echeverria 2010, Lee 2010, Woods 2012] . In addition, assessments used to determine the toxicological reference values do not take into account the multi-shot (mixture effects): yet it is shown that mercury toxicity is greatly enhanced by the lead [Schubert 1978] , the hydroxide aluminum or antibiotics [Haley 2005]. It also demonstrated that the capacity of urinary mercury disposal to reduce as exposure [DeRouen 2006; Mutter 2011]. Finally, the European people do not undergo comparable mercury exposure: the French and the Poles are on average much more exposed to dental mercury, while the Spanish, French (still more people in Guyana)	First of all, it should be clear that the opinion was aimed to evaluate the contribution of Hg from dental amalgam to the environmental burden (and the related risk), not the effects due to total environmental exposure to Hg and MeHg. The issue of vulnerable people, although mentioned in the several citations included in the text has been now expanded, with some very recent references. The higher susceptibility in children was already addressed, but the concept has been stressed. By the way in the derivation of the Health based value used in the opinion, EFSA already considered these factors: indeed, data were obtained from human studies in children, to which assessment factors were applied, to account for possible kinetic variability among individuals due to genetic polymorphisms. The absence of a threshold for the Hg-induced effects has not been scientifically proven. The evaluation of the mixture effects was not included in the questions from the Commission. Finally SCHER cannot conclude that mercury in dental amalgam should be banned: this is a risk management measure and is out of our mandate.

				and all coastal residents are more exposed to methylmercury in fish. It would be unacceptable to consider an average exposure, which would leave millions of Europeans exposed beyond the TWI. Given the foregoing, and having established that mercury (metal- and organic form) is a neurotoxic, immunotoxic and endocrine disruptor, it is impossible to determine a threshold below which adverse effects would be excluded [WHO 2005] : the current TWI is not sufficiently protective. This indisputable fact should be mentioned by the SCHER must conclude that all unnecessary uses of mercury should be banned as soon as possible. THUS, IT IS THE "WORST CASE SCENARIO" TO BE CHOSEN BY EXPERTS TO PROTECT THE EUROPEAN POPULATION.	

Q2.6.	Individual, Florian Schulze (CAT-Berlin) , florianschulze@hotmail.com	Mostly disagree	Disagreement with the interpretation of the existing scientific and other data	The use of mercury must be considered not only against the background of it's elevated toxicity in the methylated form but also in interaction with other toxic elements like lead or cadmium. The inter-individual ability to eliminate methylmercury from the body, and the genetic predisposition to effects of mercury have another effect on the risk of mercury-induced disease,too.(WHO2010) Recent studies about low-level intoxications with mercury proof long-term developmental delays (loss of IQ) in unborn and young children. Other toxic effects include alteration of sensory functions, motor coordination, memory and attention. Mercury has been linked to diseases like myocardial infarction, heart rate variability, blood pressure, attention-deficit/hyperactivity disorder, amyotrophic lateral sclerosis, autism and Parkinson's disease.[1-9] These serious health effects should be taken into consideration regarding the ongoing increase of Hg and MeHg levels in the environment and fish. Mercury is a chemical of global concern owing to its long-range atmospheric transport, its persistence in the environment once anthropogenically introduced, its ability to bioaccumulate in ecosystems and its significant negative effects on human health.(Minamata Convention) It is never removed from the environment; it is just moved to other locations and eventually buried under soils and sediments. Due to anthropogenical impact the mercury level in surface water has tripled during the past century and the MeHg concentration in historical archives, such as marine bird feathers, increased of a factor of 4 for the North Atlantic during	See answer to the previous comment (Q2-5) for the human effects part. Concerning the environment the SCHER is of the opinion that these additional references provide interesting information but are not useful for the current risk assessment at the local scale.

				that time, supporting the assertion of a first order relationship between the pools of available inorganic Hg and MeHg formed in the upper ocean.[10,11] It has been predicted that the concentration of Hg in North Pacific intermediate waters will double by the year 2050, relative to 1995, assuming actual atmospheric Hg deposition rates[12] and according to a recent study, warmer sea surface temperatures could result in greater bioaccumulation of MeHg in fish, and consequently, increased human exposure. [13] The Report quotes a recent study about mercury concentration in hair from mother and children which are generally below the EFSA derived TWI but not below the limit derived by US EPA. Another study (Table 4) exclusively analyses the estimated transformation of the mercury-emission of dentists into the environment to MeHg in fish and shows that in a worst case scenario the limits by the US EPA and EU could be exceeded. This demonstrates that the contemporary exposure of MeHg is already elevated and that there is a close relation between the emission of Hg and the exposure to MeHg by the consumption of fish even if the dental emission is only a relatively small contribution to the total anthropogenic emission. From my point of view these alarming circumstances and their in fact existing health effects should not only lead to a more conservative threshold (WFD) but to protect the human health and the environment from anthropogenic emissions and releases of mercury and mercury compounds by an unconditionally phase out of dental amalgam. PS: References are attached in a mail to SANCO-SCHER-PUBLIC-	

				CONSULTATIONS@ec.europa.eu.	

Q2.7.	Organisation Business, Eight dental societies, all for MERCURY-FREE dentistry: Accademia Internazionale di Odontoiatria Biologica, British Society of Mercury-Free Dentists, Deutscher Berufsverband der Umweltmediziner, Deutsche Gesellschaft für Umwelt-Zahnmedizin, European Academy for Environmental Medicine	Mostly disagree	Relevant scientific and other information missing from the analysis	All dentist members of our eight associations -- from Germany, Italy, Spain, Sweden, and the United Kingdom -- practice mercury-free dentistry. We support, and refer you to, the submission by European Environmental Bureau/World Alliance for Mercury-Free Dentistry/Mercury Policy Project, a comprehensive and thoroughly research report on how the SCHER report should be improved. Our contribution is in response to your question 9.	No reaction needed

	e.V. , International Academy of Oral Medicine & Toxicology--Europe, IAOMT-Sweden, MERCURIADOS (Dental Section) , charlie@toxicteeth.org				

Q2.8.	Organisation Public authority, Swedish Chemicals Agency No agreement to disclose personal data	Disagree	Other Disagreement with the interpretation of the existing scientific and other data Relevant scientific and other information missing from the analysis	The wording of the conclusion is so vague that the reader may make and use its own conclusion. The worst case scenario for surface water seems not to be an extreme worst case as presented in the report, but rather a realistic worst case, since it is based on measured values. In addition, the methylation rates used in the calculations for secondary poisoning cannot be regarded as being worst case. It is not transparent where from the rates used have been derived. The worst case percentage (1%) is a low estimate. There are several reports of much higher rates of methylation measured in the environment (Watras 1994) (cf.). A realistic worst case scenario should consider compartments with high methylation rates. Only the exposure of Hg from dental amalgam has been considered in the risk assessment. This approach underestimates the exposure and consequently the risk to the environment. The risk assessment should be based on an exposure from all sources. The contribution from dental amalgam can be expressed as a percentage of the total Hg-exposure. In the assessment of secondary poisoning it is clearly demonstrated that, even at the low methylation rates used in the assessment, risk to the environment has been concluded. This is not expressed clearly in the motive to question no. 1 in the consultation. Since MeHg bioaccumulates, the most important endpoint is secondary poisoning, i.e. effects on organisms higher in the food chain. Hence, mercury used in dental amalgam constitutes a risk of mercury to the environment, even without taking other sources of Hg into account. In	The following citation from the SCHER opinion is far from vague "The SCHER concludes that a risk of secondary poisoning due to methylation cannot be excluded. These risks depend on the methylation rate of inorganic mercury which may differ with exposure conditions." In addition, the conclusion of the commenter is correct stating that the worst case scenario seems not to be an extreme worst case. It has not been the intention of the SCHER to develop an extreme worst case scenario but a realistic worst case scenario. Further, it should be considered that the remit of the SCHER mandate did not allow taking into account all sources of Hg but only the source dental amalgam. For the environmental compartments air and soil the SCHER concludes that insufficient data are available to establish a sound scientific risk assessment for the local scale. The level of methylation has been taken from the previous SCHER opinion (2008), based on Stone et al. (2003) and was considered a reasonable value. The maximum value used in the bioaccumulation section was a factor of 5 higher.

				Sweden, heavy restrictions have been set on fish for human consumption due to diffuse mercury contamination of the environment. It has been estimated that the atmospheric deposition in Sweden must decrease by 80%, in order to decrease the concentration in fish to levels below the maximum content of MeHg for fish, set by WHO/FAO (Sundblad, 2012; UNEP, 2002). Since leaking from existing dental amalgam fillings is now the major source of mercury emissions in municipal waste water in Sweden, see previous question for references, this contribution is needed for the assessment in this section too. References to Question 2 (The full references are sent by email) Watras 1994 Sundblad 2012 UNEP 2002	

Q2.9.	Individual No agreement to disclose personal data	Mostly agree		From the SCHER-rapport s. 14.“Based on future developments, especially in the percentage separators, the concentration in surface water is expected to reduce by about a factor of 50.” If I understand the statement correctly, the authors claim that by installing amalgam separators, the Hg concentration will decrease in receiving surface waters by a factor 50, more than an order of magnitude. I asked myself: how is this possible with separators just recovering 95% and not extremely large losses of Hg from dental clinics. Another problem is that the authors did not address the contribution of Hg from wearing of fillings in the mouth of people. In my opinion, yes, with separators, the current and future loading (mass per a period time) to surface waters is reduced in the present. However, the surface waters also have a historical load that they are carrying - this load has presumably not been remitted. The concentration of the surface water is then mainly a function of the historical loading. To reduce the concentration by a factor og fifty you'd have to dilute the historically loaded surface water with a factor fifty with water that is 100% free of Hg - requiring 100% efficiency. This is not the case with the best available seperator technology. Given the dynamics of the hydrological systems, just removing Hg with seperators has thus a very limited impact on present Hg concentration in surface water. This positive effect in fact might even be balanced with the fact that the mercury captured might be processed and sold perhaps even to a place with little control, where it will be (intentionally or unintentionally) eventually	See the answer to Q.1 -6 and Q2 -3. Concerning the comment on the separators there is first of all a misunderstanding. The SCHER is of the opinion that the discharge of Hg due to amalgam fillings would be reduced by about a factor of 50, not the total of all possible Hg emission to surface water. The new text makes this distinction very clear.

				reintroduced into the environment. In short, unless the authors can produce a mass balance equation to quantify their claim, then I would suggest that they must re-examine the above statement.	

Q2.10.	Organisation Public authority, Flemish Environmental Agency No agreement to disclose personal data	Mostly agree		No extra comment	The Organisation is in agreement with the SCHER opinion. No reaction needed
Q2.11.	Organisation Other, CED - Council of European Dentists , ced@eudental.eu	Disagree	Relevant scientific and other information missing from the analysis	The particulate nature of amalgam waste entering the wastewater system has a direct impact on the capture of the mercury waste from wastewater. Amalgam waste entering drains consists of a wide range of particle sizes (Letzel et al., 1997; Drummond et al., 2001). However, the density of the particles means that amalgam separators can effectively remove a significant fraction of even the smallest particles. (Drummond et al., 2003). Even in the absence of separators the relatively large particles containing a significant quantity of mercury are likely to be retained in simple chair-side traps even and vacuum filters (Jokstad and Fan, 2006). The draft opinion cites a methylation rate of potentially as high as 0.2% based (Stone et al., 2003). A more recent publication from the same author reports a methylation rate of 0.013 per cent in dental waste water containing amalgam in a more typical clinical situation (Stone, 2004). Conversion to methyl mercury is likely to be highly dependent on the oxidation conditions in the	According to the SCHER, the additionally presented information is in support of the current risk assessment. The particle size indicated is well suited for a separation by filtration or centrifugation. Also a capture rate of Hg in a WWTP of 80% seems a reasonable estimate and is not far from the estimated 90% in the SCHER opinion.

				waste and the presence of bacteria (Zhao, et al., 2008; Zhao, et al., 2012). However, the mercury available for this conversion is only a small fraction of the total mercury present in the waste. As stated above in section 4 the majority of mercury waste in wastewater will be in the form of amalgam particles which are relatively insoluble. The concentration of mercury in wastewater will be significantly reduced by passage through a wastewater treatment plant (WWTP). Some particles will be retained in influent grit traps whilst more will be trapped in sewage sludge. Capture rates for mercury at WWTP are reported to be as high as 80 per cent (Fan et al., 1997). In the UK where amalgam separators are required by law the discharge levels of mercury from over 90 per cent of waste water treatment plants is below the freshwater EQS (Gardner et al., 2012). Clearly amalgam waste only represents one potential source of amalgam with industrial and atmospheric deposition also contributing to total mercury levels. Drummond, J.L., Hathorn, R.M., Cailas, M.D. and Karuhn, R. (2001).	

				Particle size analysis of amalgam powder and handpiece generated specimens. Dent Mater. 17: 322-32. Drummond, J.L., Liu, Y., Wu, T.Y. and Cailas, M.D. (2003). Particle versus mercury removal efficiency of amalgam separators. J Dent. 31: 51-8. Gardner, M., Jones, V., Comber, S., Scrimshaw, M.D., Coello-Garcia, T., Cartmell, E., Lester, J. and Ellor, B. (2013). Performance of UK wastewater treatment works with respect to trace contaminants. Sci Tot Envir 456-457 ; 359–369. Fan, P.L., Arenholt-Bindslev, D., Schmalz, G., Halbach, S. and Berendsen, H. (1997). Environmental issues in dentistry--mercury. FDI Commission. Int Dent J. 47: 105-9. Jokstad, A. and Fan, P.L. (2006). Amalgam waste management. Int Dent J. 56: 147-53. Letzel, H., de Boer, F.A. and van 't Hof, M.A. (1997). An estimation of the size distribution of amalgam particles in dental treatment waste. J Dent Res. 76: 780-8. Gardner, M., Comber, S., Scrimshaw, M.D., Cartmell, E., Lester, J.and Ellor, B. (2012). The significance of hazardous chemicals in wastewater treatment works effluents. Sci Total Environ.437:363-72. Stone ME, Cohen ME, Liang L, Pang P. (2003). Determination of methyl mercury in dental-unit wastewater. Dent Mater. 19: 675-9. Stone ME. (2004). The effect of amalgam separators on mercury loading to wastewater treatment plants. J Calif Dent Assoc. 32: 593-600. Zhao, X, Rockne, K.J., Drummond, J.L., Hurley, R.K., Shade, C.W and Hudson, R.J. (2008). Characterization of methyl mercury in dental wastewater and correlation with sulfate-reducing bacterial DNA. Environ Sci Technol. 42: 2780-6. Zhao, X., Rockne, K.J. and Drummond, J.L. (2012). Aeration	

				prevents methyl mercury production in dental wastewater. J Environ Sci Health A Tox Hazard Subst Environ Eng. 47: 598-604.	
Q2. **12.**	Organisation NGO, Tandvårdsskadeförbundet (The Swedish Association of Dental Mercury Patients) , lidmark@gmail.com	Disagree	Relevant scientific and other information missing from the analysis	A true analysis of how mercury affects health should take into account other mercury sources as persons own fillings, mercury from food, mercury from coal mining and combustion of coal etc. as well as variations in people´s genetic susceptibility to mercury. Nothing of this has been done in the new SCHER report and therefore we question the quality. We refer in this section to comments made by the EEB.	See answers to Q1.6. and Q2.3

Q2.13.	Organisation NGO, World Alliance for Mercury Free Dentistry No agreement to disclose personal data	Mostly disagree	Relevant scientific and other information missing from the analysis	Le rapport du SCHER ne tient pas compte des nombreuses publications qui ont montré l'insuffisante protection offerte par la TWI actuelle. La TWI doit protéger les organismes les plus vulnérables. - Il s'agit en premier lieu de l'embryon, du fœtus et de l'enfant, dont le système nerveux en développement est extrêmement sensible aux effets du mercure, même à très faibles doses. Des études ont ainsi mis en évidence une relation inverse entre la concentration en mercure du cordon et le développement psychomoteur, les performances verbales et le quotient intellectuel du jeune enfant [Lederman 2008], ainsi qu'entre la concentration en mercure des hématies maternelles et les performances de vocabulaire ainsi que les capacités visuomotrices de l'enfant [Oken 2008], dans des populations modérément consommatrices de poissons. - Deuxièmement, une proportion non négligeable de la population est particulièrement vulnérable à de très faibles niveaux d'exposition au mercure du fait de sa susceptibilité génétique et donc de sa difficulté à éliminer le mercure [Wang 2012, Goodrich 2011, Harari 2012, Schläwicke 2008, Godfrey 2003, Heyer 2004, Echeverria 2005, Heyer 2008, Heyer 2009, Echeverria 2010, Jacob-Ferreira 2010, Lee 2010, Jacob-Ferreira 2011, Woods 2012, de Marco 2012]. Par ailleurs, les évaluations qui servent à déterminer les valeurs toxicologiques de référence ne prennent pas en considération les multi-expositions : il est pourtant démontré que la toxicité du mercure est considérablement augmentée par celle du plomb [Schubert 1978], de l'hydroxyde d'aluminium ou des	See answer to Q2.5

				antibiotiques [Haley 2005]. Il aussi été démontré que les capacités d'évacuation urinaire du mercure diminuent au fur et à mesure de l'exposition [DeRouen 2006 ; Mutter 2011]. Enfin, les populations européennes ne subissent pas des expositions mercurielles comparables : les Français et les Polonais sont en moyenne beaucoup plus exposés au mercure dentaire, alors que les Espagnols, les Français (encore davantage les habitants de la Guyane) et tous les habitants côtiers sont plus exposés au méthylmercure des poissons. Il serait inacceptable de tenir compte d'une moyenne d'exposition, qui laisserait des millions d'Européens exposés au-delà de la TWI. Compte tenu de ce qui précède, et étant établi que le mercure (sous forme métallique et organique) est un neurotoxique, un immunotoxique et un perturbateur endocrinien, il s'avère impossible de déterminer un seuil en deçà duquel des effets nocifs seraient exclus [WHO 2005] : la TWI actuelle n'est donc pas suffisamment protectrice. Ce fait indiscutable devrait être mentionné par le SCHER qui doit conclure que tous les usages évitables du mercure doivent être prohibés au plus vite. AINSI, C'EST BIEN LE « PIRE SCENARIO » QUI DOIT ETRE CHOISI PAR LES EXPERTS POUR PROTEGER LA POPULATION EUROPEENNE.	

Q2.14.	Organisation Other, German Dental Association (BZÄK) and National Association of Statutory Health Insurance Dentists (KZBV) No agreement to disclose personal data	Disagree	Disagreement with the interpretation of the existing scientific and other data	The risk of adverse effects from mercury increases by the conversion of inorganic mercury into organic mercury compounds. According to studies by Stone (Stone, 2004) on dental amalgam waste, the majority of the mercury (99.6 per cent) in amalgam waste is tightly bound to other metals in the form of amalgam particles. Thus, the mercury available for a methylation is only a small fraction of the total mercury present in the waste. This fact is not considered in this risk assessment. This part in the draft report must therefore be verified and corrected. Stone ME. (2004). The effect of amalgam separators on mercury loading to wastewater treatment plants. J Calif Dent Assoc 32: 593-600.	To the opinion of the SCHER the effect considered in the comment has been taken into account by the different methylation rates assumed. Of course, the risk assessment could be further refined and all specific sources and routes of exposure be considered but in effect it would not change the conclusions established in the current opinion.

Q2.15.	Organisation NGO, Non Au Mercure Dentaire No agreement to disclose personal data	Mostly disagree	Relevant scientific and other information missing from the analysis	Le SCHER ne tient pas compte d'un problème de santé publique majeur, en partie induit par la pollution d'origine dentaire : la résistance bactérienne aux antibiotiques. L'OMS (mai 2013) rappelle que les résistances aux antimicrobiens augmentent la morbidité comme la mortalité et qu'elles élèvent en conséquence le coût des dépenses de santé. On observe aujourd'hui une augmentation extrêmement préoccupante de ces résistances : 3,7 % des nouveaux cas de tuberculose sont multirésistants ; de nombreuses infections nosocomiales sont provoquées par des bactéries hautement résistantes telles que S. aureus résistant à la méthicilline ou des bactéries Gram négatives communes (P. aeruginosa, A. baumanii) multirésistantes. En France, l'Inserm estime que le cas le plus préoccupant, en ville comme à l'hôpital, est celui des entérobactéries productrices de bêta-lactamases à spectre étendu (E. coli ou K. pneumoniae).	The SCHER recognized that the problem indicated here may be of serious concern as it indicates the possibility of increased resistance of bacteria to dental amalgam. However, to the opinion of the SCHER it has no relation to the emission of dental amalgam to the environment and subsequently to potential effects to humans and/or the environment. Therefore, the SCHER considers this comment irrelevant for the problem at hand as it is outside the current remit of the SCHER. See also Q2.5

				Le mercure est identifié depuis plus de 50 ans comme un vecteur de l'antibiorésistance et l'on compte aujourd'hui de nombreuses références dans Medline sur ce sujet. On a commencé à s'intéresser dans les années 1960 à la résistance de S. aureus à la fois à certains antibiotiques et au mercure, en milieu hospitalier [Dyke 1967, Rosendal 1981]. Cette résistance multiple a bientôt été rencontrée dans d'autres milieux et pour d'autres espèces de bactéries : E. coli [Grewal 1999], Citrobacter [Nakahara 1984], K. pneumoniae [Nakahara 1978], S. typhimurium [Makino 1981] et d'autres espèces encore [Ferreira da Silva 2007, Cabarello-Flores 2012, Resende 2012]. Assez vite, on a avancé puis confirmé l'hypothèse selon laquelle c'est l'utilisation du mercure qui induit l'antibiorésistance [Hall 1970, Joly 1975, Poiata 2000]. Selon le rapport BIOIS (2012), en Europe, le mercure dentaire contamine chaque année : Ø l'air (3,5 tonnes issues des cabinets dentaires + 2 tonnes issues des bouches des porteurs + 6 tonnes issues des boues d'épuration + 4,5 tonnes de déchets + 3 tonnes venant des crémations = 19 tonnes) Ø l'eau (1 tonne issue des usines de traitement des eaux usées + 1 tonne provenant des boues d'épuration + 1 tonne de déchets = 3 tonnes) Ø le sol et les eaux souterraines (8 tonnes provenant des boues d'épuration + 4 tonnes venant des enterrements + 8,5 tonnes de déchets = 20,5 tonnes) Or l'induction de l'antibiorésistance dans l'environnement par la pollution au mercure a été clairement mise en évidence [Timoney 1978, Rasmussen 1998, McArthur 2000, Ball 2007]. Deux récentes études viennent souligner l'urgence de cette problématique :	

				1) Meredith et al. [2012] ont montré que la bioaccumulation de mercure dans les poissons (telle que celle induite par le mercure dentaire selon l'expertise du SCHER) peut conduire à une accumulation de bactéries résistantes au mercure et aux antibiotiques, même en l'absence de source d'émission de mercure ponctuelle. 2) Même si la part d'antibiorésistance induite par le mercure est inquantifiable, il faut se garder d'imaginer que le phénomène resterait marginal. Skurmik et al. [2010] ont comparé une population française métropolitaine (exposée aux antibiotiques et sans exposition importante au mercure) à une population amérindienne de Guyane française (peu exposée aux antibiotiques, très exposée au mercure) : c'est la flore bactérienne des Amérindiens qui contient le plus d'e. coli résistantes aux antibiotiques. L'amalgame dentaire pourrait également induire une résistance aux antibiotiques dans la flore intestinale du porteur ; de solides travaux soutiennent cette hypothèse [Summers 1993, Edlund 1996, Wireman 1997, Ready 2007]. Il s'agit là encore d'un problème de santé publique en raison de la dissémination de ces bactéries résistantes via les eaux usées. On dispose donc aujourd'hui d'éléments concordants pour affirmer que le mercure dentaire constitue un danger, facilement éliminable, du point de vue de la résistance aux antibiotiques – problème de santé publique éminemment préoccupant.	

Q2.16.	Organisation Other , ONCD - ORDRE FRANCAIS DES CHIRURGIENS-DENTISTES/FRENCH DENTAL COUNCIL , cedric.grolleau@oncd.org	Mostly disagree	Relevant scientific and other information missing from the analysis	Since 150 years, only a limited number of allergic reactions were detected in patients' oral mucosa. All the medical attempts to identify severe illness due to mercury-containing fillings have no serious biological and medical basis. In contrast, allegations are quite numerous, but were shown to be mostly psychosocial diseases without any medical support. Severe adverse effects are only detected in some workers employed by industry using mercury, but none were due to dental fillings of human teeth. Up to now, nephrologists refuted the effects on kidney, and it was the same for most of the incriminated general diseases. No conclusion could be drawn and at worst, these points are still open for discussion. In general, it was concluded that the indirect exposure of humans to methylmercury is far below tolerable limits. On waster water treatment, see also answer to question 1 on the use of water filters.	The comments seem not to be in real disagreement with the opinion.
Q2.17.	Organisation Business EUREAU , carla.chiaretti@eureau.org	Uncertain		---	No reaction needed

Q2.18.	Organisation, Trade union, European Trade Union Confederation www.etuc.org No agreement to disclose personal data	Agree		Le rapport du SCHER ignore une problématique de santé publique directement liée au mercure dentaire : l'intoxication des dentistes et de leurs assistantes. Des autopsies ont révélé des niveaux de mercure très augmentés dans l'hypophyse, le cortex occipital et le cortex rénal de personnels dentaires [Nylander 1989]. On observe des niveaux de mercure augmentés dans le sang des dentistes [Tezel 2001, Kasraei 2010] et dans leurs urines – ces dernières constituant le meilleur indicateur de l'exposition à court terme au mercure inorganique [Lehto 1989, Steinberg 1995, Karahalil 2005, de Oliveira 2010]. Les niveaux de mercure urinaire sont encore plus élevés chez les assistant-e-s dentaires [Nilsson 1986]. Même si, pour une majorité de professionnels, on trouve des niveaux de mercure urinaire relativement bas, on observe qu'ils sont pour quelques individus à des niveaux comparables à ceux pour lesquels on a rapporté des effets sur les reins et le système nerveux central [Skare 1990]. En outre, certains travaux ont mis en évidence chez ces travailleurs des symptômes imputables au mercure, mais qui ne sont pas corrélés aux niveaux de mercure mesurés dans les urines [Ritchie 2004]. En effet ceux-ci ne rendent pas compte du mercure accumulé dans l'organisme. Un test de mobilisation avec le chélateur de référence (DMPS) est un bien meilleur indicateur de la charge corporelle en mercure ainsi que des problèmes rénaux et cognitifs qui lui sont liés, chez les dentistes comme chez les assistant-e-s [Gonzalez-Ramirez 1995]. Ce test révèle une concentration de mercure urinaire multipliée par 10 pour les dentistes – alors qu'elle n'est multipliée en	Comment outside the scope of the opinion

				moyenne que par 5,9 pour les porteurs d'amalgames et par 5,3 pour des témoins sans amalgames [Molin 1991]. Là aussi, l'augmentation de l'excrétion du mercure urinaire est plus grande encore chez les assistant-e-s dentaires [Zander 1992].	

				Le risque d'absorption du mercure par les professionnels ne tient pas seulement au nombre d'obturations nouvelles pour lesquelles ils utilisent des amalgames, mais aussi aux conditions dans lesquelles ils travaillent sur les amalgames préexistants : une majorité de professionnels ne prennent malheureusement pas de protections suffisantes [Colson 2012, Warwick 2013]. D'autre part, des études sur des professionnels de la dentisterie ont montré qu'à exposition comparable, des facteurs génétiques peuvent augmenter les effets du mercure sur la sphère cognitive, l'humeur et le comportement [Heyer 2008, Echeverria 2006, Echeverria 2005, Heyer 2004, Echeverria 1995] Plusieurs travaux ont montré que l'exposition au mercure des dentistes est associée à une augmentation de la prévalence de nombreux symptômes [Neghab 2011, Ritchie 2002]. En particulier, de nombreuses études concordantes relèvent des troubles sensoriels, cognitifs, neurologiques et psychosomatiques chez les dentistes [Schach 2003, Ritchie 1995, Langworth 1997, Ngim 1992, Uzzell 1986, Shapiro 1982, Bittner 1998, Aydin 2003, Canto-Pereira 2005], et plus encore chez les assistantes dentaires [Moen 2008 , Hilt 2009]. Des publications observent une proportion de suicides augmentée chez les dentistes hommes [Arnetz 1987, Meltzer 2008, Petersen 2008], d'autres constatent des problèmes rénaux augmentés chez les dentistes [Verschoor 1988, Samir 2011], et certains risques de cancers sont augmentés chez les dentistes [Simning 2007], notamment les cancers du cerveau [Navas 2002, Navas 2002, Ahlbom 1986], du système reproducteur	

				(sein ou testicule) [Eriksson 1998, Rix 1996] et de la peau [Linet 1995, Vagero 1990]. Les assistantes dentaires et les femmes dentistes risquent des troubles de la reproduction [Jones 2007, Rowland 1994, Lindbohm 2007] et l'on sait que l'exposition professionnelle au mercure augmente significativement les risques d'hypertension pour la femme enceinte ainsi que de petit poids à la naissance, de malformations de l'enfant, d'anomalies du tube neural et de bébés mort nés [Pan 2007, Figà-Talamanca 2	
Q2.19.	Individual, Ioannis Anastasiou dentalan@gmail.com	Agree		Sorry, no data	No reaction needed

Q2.20.	Organisation, Public authority, Chemicals and Emerging Technolo Department for Environment, Food and Rural Affairs No agreement to disclose personal data	Agree		The contribution of dental amalgam needs to be quantified more, as it may be proportionally very small (perhaps <1%?); further details of the extent of the major contributions should be included.	No reaction needed

SUBMISSIONS					SCHER'S COMMENTS
No.	**Name of individual/ organisation**	**Do you agree with the observations made by the Scientific Committees?**	**Nature of disagreement**	**The evidence (s) with the reference(s)**	**SCHER's response**
Question 3: Comparison of environmental risk from the use of mercury in dental amalgam and the use of alternatives without mercury					
Q3.1.	Organisation NGO, Health Care Without Harm No agreement to disclose personal data	Disagree	Relevant scientific and other information missing from the analysis	Mercury in Dental Amalgam and Resin-Based Alternatives: A Comparative Health Risk Evaluation Health Care Research Collaborative Authors: Serap Erdal, Ph.D. in collab. with Peter Orris, M.D., M.P.H. June 13, 2012. 68 pages. http://www.noharm.org/lib/downloads/other/Mercury_in_Dental_Amalgam.pdf	The Erdal report has been one of the major sources of information on alternative products. Though very valuable, this information is not sufficient for a complete quantitative risk assessment of alternative products. The general feeling of a possible low level of risk cannot be supported by sound scientific evidence and many knowledge gaps need to be covered.
Q3.2.	Individual No agreement to disclose personal data	Agree		Amjad Shraim, Awadh Alsuhaimi, Jalal Thamer Al-Thakafy (2011)Dental clinics: A point pollution source, not only of mercury but also of other amalgam constituents Chemosphere, Volume 84, Issue 8, August 2011, Pages 1133-1139	No reaction needed

Q3.3.	Individual No agreement to disclose personal data	Agree		Because of the hormone-like effects of Bis-GMA-containing materials further research is needed.	See the answer to Q1.4 bullet VI
Q3.4.	Organisation NGO , Elena Lymberidi-Settimo on behalf of the European Environmental Bureau, the World Alliance for Mercury Free Dentistry and the Mercury Policy Project , elena.lymberidi@eeb.org	Disagree	Disagreement with the interpretation of the existing scientific and other data	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	SCHER agrees that for BPA environmental exposure is much lower when compared to the one form food and beverage or thermal paper. This information has been added into the text. However, dental materials are fabricated not only from bisphenol A glycidyl methacrylate (Bis-GMA) but also bisphenol A dimethacrylate (Bis-DMA).For dental materials, the leakage is limited to resins composed of Bis-DMA (bisphenol A dimethylacrylate) which has an ester linkage that can be hydrolysed to BPA, whereas the ether linkage in Bis-GMA (bisphenol A glycidyl methacrylate) was found to be stable. Measurements have shown that the release of BPA mainly occurs during the few hours directly after application while the BPA level is back to pre-treatment levels at 24 hours. Exposure to BPA released from dental materials is below the recently established t-TDI, also considering that the peak of release is limited to few hours after application. For further details on human health effects see the opinion on 'The safety of the use of bisphenol A in medical devices' for which a public consultation has been launched. BPA

				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,	deriving from dental material can be of limited value for the environment, but potential problems to human health should be considered, when looking at alternatives, and this should be mentioned. The Erdal paper is already cited , but the conclusions are not supported by SCHER.

				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	
Q3.5.	Organisation NGO, World Alliance for Mercury Free Dentistry No	Mostly disagree	Relevant scientific and other information missing from the analysis	Bisphenol A (BPA) is this only danger that has been identified in alternative dental materials. However, the environmental footprint of this substance remains much lower than the one of mercury because BPA is neither biopersistent nor bioaccumulative. Several resins and all glass ionomer cements do not contain BPA. Even though scientific datas confirming their safety are scarce, the use of these materials should be preferred to	See the answer to the Q.3.4

	agreement to disclose personal data			the use of materials for which hazards have been clearly demonstrated.	
Q3.6.	Individual, Florian Schulze (CAT-Berlin) florianschulze@hotmail.com	Uncertain		no comment	No reaction needed
Q3.7.	Organisation Business , Eight dental societies, all for MERCURY-FREE dentistry: Accademia Internazionale di Odontoiatria Biologica, British Society of Mercury-Free Dentists,	Mostly disagree	Relevant scientific and other information missing from the analysis	Responsible dentists and dental manufacturers have long expected and been prepared for regulations to end amalgam use (see note 1, below). Lobbyists for the Council of European Dentists are entitled to speak for themselves -- but they no longer represent the views or the outlook of the majority of practicing European dentists. We practicing dentists do. As dental societies representing practicing dentists, we ask that you also consider: • Based on our years of experience, we have found that there is no need for dental amalgam in Europe. Mercury-free alternatives are proven effective – and even superior – for all clinical situations (see note 2, below). • No reason, no public benefit whatsoever, exists to keep amalgam. Not only is it no longer needed, but it is a primitive material which leads to cracked teeth; it is inimical to modern dentistry's focus on minimally-invasive dentistry. • Amalgam separators address but one pathway of dental mercury into the	The comment suggests a management decision. This outside the scope of the opinion

	Deutscher Berufsverband der Umweltmediziner, Deutsche Gesellschaft für Umwelt-Zahnmedizin, European Academy for Environmental Medicine e.V., International Academy of Oral Medicine & Toxicology--Europe, IAOMT-Sweden, MERCURIADOS (Dental Section) charlie@toxicteeth.org			environment. They in way solve the problem of dental mercury pollution, and not just because separators do not catch all mercury. Most mercury walks out of the office, in the patients, and from there enters the environment via multiple pathways: air, soil, and water. From there, it can convert to methylmercury. The solution is not to catch dental waste; the solution is source control -- phase out this 19th-century product. • There is no advantage to amalgam, but its patent disadvantages -- massive pollution into Europe's air, water, land, and dental offices -- make urgent its demise. By ending amalgam use, we significantly reduce mercury in the environment and people's exposure to methylmercury while at the same time delivering higher quality dental care with 21st century mercury-free materials. ------- Note 1: European Dental Materials Conference, The Demise of Amalgam Use and Development of Enhanced Materials to Advance Novel Dentistry, Birmingham (29-30 August 2013), http://www.europeandentalmaterials.com/Programme / Note 2: N.J.M. Opdam, E	

Q3.8.	Organisation Public authority, Swedish Chemicals Agency No agreement to disclose personal data	Disagree	Other Disagreement with the interpretation of the existing scientific and other data Relevant scientific and other information missing from the analysis	For mercury, only releases of dental mercury from dental clinics have been considered in the risk assessment. However, for the substitutes SCHER concludes that a risk assessment for the relevant compartments and life cycle assessment covering all kind of aspects is required. We do not understand the logic of these requirements. Environmental toxicity data for the alternatives are scarce, but as far as we know none of the substances in composite materials is on any list for priority substances. Bisphenol A is a controversial substance. However it is readily degradable in both the human body and in the environment. Therefore it will not have the same long lasting effects as dental amalgam when used as a dental restorative material. Published studies show that the time frame when the use of bisphenol A may lead to a risk seems to be significantly lower compared to the use of mercury in dental amalgam. No significant emissions have been detected from fillings from the day after the placement. Salivary BPA concentration levels peaked over a 3 hour period following sealant placement and returned to baseline levels within 24 hours. (Zimmerman-Downs, 2010).	See answer to Q.3.4

				On the contrary, mercury is listed as a priority hazardous substance e.g. within the water Framework Directive and is also restricted for several uses in Reach. Mercury is also one of few chemicals that have been acknowledged as a substance of global environmental concern, based on the comprehensive scientific evidence in the Global Mercury Assessment Report (UNEP 2002; UNEP 2013) This recently resulted in action at global level, through the adoption of the Minamata Convention that shows a clear political will of phasing out as far as possible the use of this substance of global concern. The Convention was newly signed by nearly 100 countries. This recognition at global level of the risks associated to the use of mercury should be addressed in risks assessments at regional or local level. Environmental toxicity data for alternatives are reported by SCHER, table 5, and is thus apparently available even if the quality of the data was discussed in the draft opinion. For comparison we suggest that relevant parameters on mercury should be added to Table 5. The large difference in density between dental amalgam and alternative plastic fillings leads to e.g. a 10-fold higher consumption for one filling or waste volume for mercury compared to methacrylate polymers, if expressed in weight. This could also be applied to possible emissions although there are also other parameters to take into account for assessment of emissions. Considering the lack of monitoring data for the environmental impact from the substitutes, one need to consider if the non-availability means that there is no exposure of importance to take into account or if the substances are	

				there but not measured yet. Information on biodegradability indicates that even if we were to start a measurement program, we would probably not find any amounts of importance in e.g. wastewater. Table 5 in the Draft SCHER opinion would preferably be supplemented with data on degradability. Some random samples show that information about degradability is available in the substance registration data published at ECHAs webpage and that most of the substitutes seem to be readily degradable substances. We did not find it appropriate to extract this (publicly available) information for inclusion in the public consultation as the COM (through ECHA) is the owner of this database. In our view, the well-intended but possibly misguided recommendation for more research on alternative methods may be used by dental amalgam proponents to allow for indefinite further use of dental amalgam, contrary to policies and actions already adopted by Sweden and some other EU member states. References to Question 3 (The full references are sent by email) UNEP 2002 UNEP 2013 Zimmerman-Downs 2010	
Q3.9.	Individual No agreement to disclose	Mostly agree		Again. Do conclude with more research is necessary strays from what I think the whole pupose of such a study is, to enable decision making. But I am not an expert here and defer to expertise from colleagues to	No reaction needed

	personal data			address this point. I am leary of researchers recommending more research (i.e. more funding in their field) rather than concrete policy actions or at least a stringent evaluation based on the recautionary principle.	
Q3.10.	Organisation Public authority, Flemish Environmental Agency No agreement to disclose personal data	Agree		No extra comment	No reaction needed
Q3.11.	Organisation Other, CED - Council of European Dentists , ced@eudental.eu	Agree		Additional references will be sent in attachement to the following mailbox: SANCO-SCHER-PUBLIC-CONSULTATIONS@ec.europa.eu.	No reaction needed

Q3.12.	Organisation NGO, Tandvårdsskadeförbundet (The Swedish Association of Dental Mercury Patients) , lidmark@gmail.com	Disagree	Relevant scientific and other information missing from the analysis	It seems like the SCHER report have not answered the question. In our view mercury is an extremely toxic substance for both environment and health. Almost nothing is comparable. However we are also worried about the use of bisfenol A and metals other than mercury in dental care. Also in this section we refer to the comments made by EEB	See answer to Q.3.4
Q3.13.	Organisation NGO World Alliance for Mercury Free Dentistry No agreement to disclose personal data	Mostly disagree	Relevant scientific and other information missing from the analysis	Le seul danger qui ait été identifié dans les matériaux dentaires alternatifs est le bisphénol A (BPA). Son empreinte environnementale est toutefois nettement moindre que celle du mercure puisque le BPA n'est ni biopersistant, ni bioaccumulable. Plusieurs résines et l'ensemble des ciments verres ionomères ne contiennent pas de BPA. Même si les données scientifiques manquent pour affirmer leur innocuité, leur usage doit être préféré à celui de matériaux dont les dangers ont été clairement identifiés.	See answer to Q.3.4

Q3.14.	Organisation Other, German Dental Association (BZÄK) and National Association of Statutory Health Insurance Dentists (KZBV) No agreement to disclose personal data	Agree		Our organizations agree with with the conclusions of SCHER and the Council of European Dentists (CED). 1. The scientific community is not yet fully able to demonstrate the relative emerging risks of the use of alternative materials; 2. Evidence about the toxicology of the alternative materials is a work in progress The profession should urge manufacturers to fully declare the chemical composition of the alternative materials; 3. The environmental data regarding the use of alternative materials is lacking and the profession should urge the decision-makers to know more; 4. More research on alternative materials is highly recommended.	No reaction needed
Q3.15.	Organisation NGO, Non Au Mercure Dentaire No agreement to disclose personal data	Mostly agree		Le seul danger qui ait été identifié dans les matériaux dentaires alternatifs est le bisphénol A (BPA). Son empreinte environnementale est toutefois nettement moindre que celle du mercure puisque le BPA n'est ni biopersistant, ni bioaccumulable. Plusieurs résines et l'ensemble des ciments verres ionomères ne contiennent pas de BPA. Même si les données scientifiques manquent pour affirmer leur innocuité, leur usage doit être préféré à celui de matériaux dont les dangers ont été clairement identifiés.	See answer to Q.3.4

Q3.16.	Organisation Other, ONCD - ORDRE FRANCAIS DES CHIRURGIENS-DENTISTES/FRENCH DENTAL COUNCIL , cedric.grolleau@oncd.org	Mostly agree		No risk has been demonstrated for the use of mercury in dental amalgam. In contrast, it is very surprising to see that there is only one reference in the SCHER 2013 document concerning non-adverse effects of alternative material. All the many scientific publications related to the risks induced by resin-containing cements are simply omitted. The reference to a paper published in a document that is not indexed in a peer-reviewed journal (Erdal S.2012) is not acceptable. Many solid articles establish the reverse. Although resins were improved during the last 20 years, the occurrence of allergic reactions (more severe than those induced by mercury-containing fillings) and cell cytotoxicity (apoptotic reactions induced on the pulp and gingiva) are well documented. It is also clear that the next evolution of resin-containing restorative material will not involve Bisphenol A release. But, for the moment there is still cytotoxicity and genotoxicity. This is certainly the reason why the conclusions of the experts are : « Therefore it may not be possible to confirm on the basis of scientific evidence that all alternative tooth filling material are safe». And this is certainly the reason why the Minamata Convention -presented in the 7-11 October 2013 conference- suggests a phase-down of mercury-containing restorative materials, as opposed to a phase-out or a ban ; this is more reasonable, at least from a clinal point of view. There is, indeed, still a need for promoting research and development of quality mercury-free materials for dental restoration before deciding to ban a dental material that has proven its qualities for most of the patients. Of course, prevention	No reaction needed

				should be our first aim in order to minimize the need for dental restorations. It seems premature to suppress in dental schools the training on the use of mercury-containing materials. This is the case for a limited number of dental schools with European countries. Access to mercury-containing dental restorative materials should be maintained for the coming years, at least for public health reasons.	
Q3.17.	Organisation Business, EUREAU, carla.chiaretti@eureau.org	Disagree	Other Disagreement with the interpretation of the existing scientific and other data AND Relevant scientific and other information missing from the analysis	"Environmental toxicity data for the alternatives are scarce, but as far as we know none of the substances in composite material are on any list for priority substances, or have been subject to any alerts from waste water organisations. On the contrary, mercury is listed as a priority hazardous substance e.g. within the Water Framework Directive. Mercury is also one of few chemicals that have been acknowledged as a global environmental problem, based on the comprehensive scientific evidence presented in the Global Mercury Assessment Report (UNEP 2002)" Sources: Consultation	Comments are outside the scope of the mandate. No reaction needed

				on SCHER preliminary report on “The environmental risk and indirect health effects of mercury in dental amalgam”. Response from Swedish Chemicals Agency (2008)	

Q3.18.	Organisation Trade union, European Trade Union Confederation www.etuc.org No agreement to disclose personal data	Mostly agree		references for question 2 (2/2) Moen B, Hollund B, Riise T. Neurological symptoms among dental assistants: a cross-sectional study. J Occup Med Toxicol. 2008 May 18;3:10. Molin M, Schütz A, Skerfving S, Sällsten G. Mobilized mercury in subjects with varying exposure to elemental mercury vapour. Int Arch Occup Environ Health. 1991;63(3):187-92. Navas-Acien A, Pollan M, Gustavsson P. et al Occupation, exposure to chemicals and risk of gliomas and meningiomas in Sweden. Am J Ind Med 2002. 42214–227.227. Navas-Acien A, Pollan M, Gustavsson P. et al Interactive effect of chemical substances and occupational electromagnetic field exposure on the risk of gliomas and meningiomas in Swedish men. Cancer Epidemiol Biomarkers Prev 2002. 111678–1683.1683. Neghab M, Choobineh A, Hassan Zadeh J, Ghaderi E. Symptoms of intoxication in dentists associated with exposure to low levels of mercury. Ind Health. 2011;49(2):249-54. Ngim CH, Foo SC, Boey KW, Jeyaratnam J. Chronic neurobehavioural effects of elemental mercury in dentists. Br J Ind Med. 1992 Nov;49(11):782-90. Nilsson B, Nilsson B. Mercury in dental practice. II. Urinary mercury excretion in dental personnel. Swed Dent J. 1986;10(6):221-32. Nylander M, Friberg L, Eggleston D, Björkman L. Mercury accumulation in tissues from dental staff and controls in relation to exposure. Swed Dent J. 1989;13(6):235-43. Pan J, Song H, Pan XC. Reproductive effects of occupational exposure to mercury on female workers in China: a meta-analysis. Zhonghua Liu Xing Bing Xue Za Zhi. 2007 Dec;28(12):1215-8. Petersen MR, Burnett CA. The suicide mortality of working physicians and dentists.	No reaction needed

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				The effect of occupational exposure to mercury vapour on the fertility of female dental assistants. Occup Environ Med. 1994 Jan;51(1):28-34. Samir AM, Aref WM. Impact of occupational exposure to elemental mercury on some antioxidative enzymes among dental staff. Toxicol Ind Health. 2011 Oct;27(9):779-86. Schach V, Jahanbakht S, Livardjani F, Flesch F, Jaeger A, Haikel Y. Le risque mercuriel dans les cabinets dentaires : histoire ancienne ou futur proche ? INRS, 2003. Shapiro IM, Cornblath DR, Sumner AJ, Uzzell B, Spitz LK, Ship II, Bloch P. Neurophysiological and neuropsychological function in mercury-exposed dentists. Lancet. 1982 May 22;1(8282):1147-50. Simning A, van Wijngaarden E. Literature review of cancer mortality and incidence among dentists. Occup Environ Med. 2007 Jul;64(7):432-8. Skare I, Bergström T, Engqvist A, Weiner JA. Mercury exposure of different origins among dentists and dental nurses. Scand J Work Environ Health. 1990 Oct;16(5):340-7. Steinberg D, Grauer F, Niv Y, Perlyte M, Kopolovic K. Mercury levels among dental personnel in Israel: a preliminary study. Isr J Med Sci. 1995 Jul;31(7):428-32. Tezel H, Ertas OS, Ozata F, Erakin C, Kayali A: Blood mercury levels of dental students and dentists at a dental school. Br Dent J 2001 , 191:449-452. Uzzell BP, Oler J. Chronic low-level mercury exposure and neuropsychological functioning. J Clin Exp Neurop	
Q3.19.	Individual, Ioannis Anastasiou,	Agree		Sorry no data	No reaction needed

	dentalan@gmail.com				
Q3.20.	Organisation Public authority, Chemicals and Emerging Technolo Department for Environment Food and Rural Affairs No agreement to disclose personal data	Agree		Fully agree that more research on alternative materials is needed.	No reaction needed