Results of the public consultation on SCENIHR's preliminary Opinion on Biological effects of ultraviolet radiation relevant to health with particular reference to sunbeds for cosmetic purposes

A public consultation on this Opinion was open on the website of the Scientific Committees from 22 January to 27 April 2016. Information about the public consultation was broadly communicated to national authorities, international organisations and other stakeholders.

A public hearing was also organised in Luxembourg on 12 April 2016, which saw the participation of 26 organisations. The public hearing aimed to complement the public consultation on the Opinion to gather specific comments, suggestions and explanations or contributions on the scientific basis of the Opinion.

Thirty-five organisations and individuals (providing in total 284 contributions and nearly 1000 comments) participated in the public consultation providing input to different chapters and subchapters of the Opinion. The majority of comments came from sunbed industry representatives and sunbed associations, and several came from public health authorities/institutes and NGOs associations. Because of the multitude of the comments, the answers to them by necessity had to be concise.

Each comment received and reference submitted during this time has been carefully considered by the SCHEER. Where appropriate, the text of the relevant sections of the Opinion was edited or explanations were added in response to relevant comments.

The literature has been updated with relevant publications. The scientific rationale and the Opinion section were clarified and strengthened.

In instances where the SCHEER, after consideration and discussion of the comments, decided to maintain its initial views, the Opinion (or the section concerned) remained unchanged.

Several comments, mainly raised by sunbed industry representatives and sunbed associations, claimed that the Opinion did not pay enough attention to the positive effects of exposure to UVR from sunbeds such as vitamin D synthesis, and overlooked the benefits of vitamin D on a number of health conditions including cancers. In this respect, the SCHEER stated that the Opinion does address vitamin D synthesis following UV exposure, although the relation between vitamin D blood levels and risks of diseases including cancer is not discussed in detail because is outside SCHEER's mandate.

Another frequent comment concerned the choice of scientific studies included in the meta-analyses and reviewed by the SCHEER. A paragraph was added to the relevant section to better explain the criteria and methodology used by the SCHEER to weigh scientific evidence.

Several comments concerned risk management or enforcement of legislation (especially about section 5.3). These comments could not be accommodated in the final text of the Opinion because risk management considerations are outside of the remit of the mandate received by the SCHEER. Other comments concerned the use of sunbeds for medical uses, which is also outside the scope of this Opinion.

The SCHEER thank all contributors for their comments and for the references provided during the public consultation.

The table below shows all comments received on different chapters of the Opinion and SCHEER's response to them. It is also indicated if the comment resulted in a change of the Opinion.

Comments received during the public consultation on the SCENIHR preliminary Opinion on "Biological effects of ultraviolet radiation relevant to health with particular reference to sunbeds for cosmetic purposes"

Comments 1-92

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
1	Baldermann Cornelia, German Federal Office for Radiation Protection, cbaldermann@bfs.de, Germany	1. EXECUTIVE SUMMARY		See comments to chapter "Abstract" Page 11 / line number 18: There is a mistake in the sentence "…a study with irradiation with UVA also showed has shown also the induction of …". Correction could be: "… a study with irradiation with UVA has also shown the induction of … ".	The comment was accepted and the text was changed for clarity.
2	Gilroy Steven, Joint Canadian Tanning Association JCTA, info@TanCanada.org, Canada	1. EXECUTIVE SUMMARY	 Chang_Kuehn_Feb._17_2015_Response_t  Petitti_D_response_to_Wehner_2014_in_I  CDC-Sunburn___Sun_issue_MMWR_May_	Page 10 - line 10 to 20 The accuracy of the Wehner research (2012, 2014) has been called into question through a Rapid Response letter by Chang & Kuehn (Feb. 17, 2015). It reported that crude categorization of ever vs. never exposure results in conflation of different levels of exposure with, presumably, different degrees of risk. Chang & Kuehn went on to say: "We found that prevalence estimates from the majority of these studies were based on highly selected or non-representative populations. These source populations call into question whether the results from these studies can be generalized to the entire populations of the United States, Northern and Western Europe, or Australia. Furthermore, low participation rates and non-randomized sampling methods in many studies likely resulted in biased findings. Publication bias was also evident, with preferential publication of studies reporting a higher prevalence of indoor tanning, further undermining the validity of the meta-analysis results." They reported: "The annual cancer incidence estimates also have inherent uncertainty, although confidence intervals appear not to have been reported by the sources relied upon by Wehner et al. Thus, the reported 95% confidence intervals around	The text regarding the Wehner publications has been amended "ever vs. never" is the most common "denominator" in meta-analyses which put together results from many different studies. Confidence intervals in meta-analyses are "statistical errors". Nevertheless, meta-analyses are the epidemiological "gold standard".

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				the estimated number of skin cancer cases attributable to indoor tanning are not true confidence intervals because they do not incorporate the uncertainty in the relative risk and cancer incidence estimates. Furthermore, as stated earlier, the meta-analysis confidence intervals describe only statistical error; they do not describe the extent of study heterogeneity. In other words, the estimates of attributable skin cancer cases are much more uncertain and unstable than reported and do not provide a valid estimate of the true prevalence (if there is a single prevalence) of indoor tanning in the general population." In addition to the issues outlined by Chang & Kuehn regarding the accuracy of the Wehner research there are further issues. The tanning industry has not been increasing as Wehner states with an absolute increase in past year exposure of 3.4% in adults, 2.1% in university students and 1.7% in adolescents. The American Suntanning Association reported January 7, 2016 that the 10% federal excise tax started in 2010 has devastated the tanning industry in the USA by closing 10,000 businesses with the loss of 100,000 jobs. Studies included by Wehner in their prevalence analysis from the NCI and CDC support this trend. Past year exposure by adults, NCI 2005 – 8%, NCI 2007 – 9%, CDC and NCI 2012 – 5.6%. Based on these national studies tanning by adults has reduced by 38% since 2007. The past year prevalence for adults in United States stated by Wehner of 13% is double the CDC/NCI 2012 study of 5.6%. This would indicate that Wehner's prevalence analysis is severely overstated which would reduce the overall impact greatly. Petitti 2016 reports in PubMed; The meta-analytically derived estimate of the prevalence of ever exposure to indoor tanning for adults in Northern and Western Europe based on the studies identified by Wehner et al. (2014) is meaningless; the estimate of the number of skin cancers attributable to indoor tanning in Northern and Western Europe based on this meaningless estimate is meaningless. According to this report on page 24 – line 1 to 9 the National Youth Risk Behaviour Surveys (Guy 2014) showed a decrease in the use of sunbed for student where states	

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				had restrictions. So this would be another confounder for both Wehner 2012 and 2014. This would back up the NCI and not Wehner numbers.	
3	Gilroy Steven, Joint Canadian Tanning Association JCTA, info@TanCanada.org, Canada	1. EXECUTIVE SUMMARY	 Holick_2011_-_Evaluation_treatment_and  Schwalfenberg_2010_-_Addressing_vitami  Baggerly_2015_-_Sunlight_and_Vitamin_D  Cashman_2016_-_Vitamin_D_deficiency_in  Mason_2010_-_Photoprotection_by_125-(	Page 9 – Line 9 to 12 Solar UV was classified as a Group 1 carcinogen by IARC in 1992. This document states on page 60, line 15 states "There is no difference in the biological effects induced by UV-radiation in respect to their origin, the natural solar UV or artificial UV" Therefore solar UV and the UV emitted from sunbeds is the same and has the same risks from burning exposure or overexposure and the same benefits such as vitamin D production. Page 10 – line 23-24 According to Dr. M. Holick in 2016, the statement above is incorrect. He states the following about the production of vitamin D from UVB; there are 2 things going on simultaneously both 7-dehydrocholesterol and previtamin D are absorbing ultraviolet radiation. The previtamin D3 will photoisomerize to lumisterol and tachysterol. At the same time 7-dehydrocholesterol will be converted to previtamin D and thus the amount of previtamin D3 does not decrease. It is in a photoequilibrium. Therefore, total pre-vitamin D3 levels would not be degraded by excess UV exposure. Page 10 - line 26 to 31 Dermatology groups are concerned about skin cancer and only look at a risk when it comes to skin. Regular use of sunbeds will provide users with summertime values of vitamin D. (Schwalfenberg2010). Usual exposure still leaves a significant amount of the population below IOM guidelines of 50 nmol/L. New research has recently found that 40% of Europeans are below this value (Cashman 2016). Diet plays a minor role in vitamin D levels (Baggerly 2015). That leaves people 2 sources – UV (outside or inside) and supplements. Supplements enter the body through the digestive tract vs through the skin with UV, the skin requires the vitamin D right away for photoprotection from excessive UV light (Mason 2010). In addition, it is possible to reach toxic levels of vitamin D through supplements a point made clearly in	The text of the Opinion is correct. No changes to the Opinion are required in relation to this comment. The comment was accepted and the text on vitamin D has been amended. A full discussion on adequate vitamin D levels is outside the scope of the mandate. The narrow-band doses for immunosuppression by UV-A

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			 UK_-_Consensus_Vitamin_D_position_stat  Baarnhielm_2012_-_Sunlight_is_associete  Cancer_Risk_Factors_in_Ontario_-_Ultravi	the UK Consensus Vitamin D Position Statement (2010). Vitamin D achieved through UV is self-regulating thereby you cannot become toxic through UV exposure (Holick 1981) Page 10 – line 32 to 35 According to the IARC Monograph (100D) of 2012, this is not the case, it states the following on page 87; The major steps of UV-induced immune suppression have been determined but it should be noted that, in many instances, these details were obtained following a single or a few exposures of a rodent model or human subjects to UVR and that the dose chosen was sufficient to cause burning. In addition, the source used to emit UVR frequently contained more than 50% UVB (wavelength 280–315 nm), considerably more than natural sunlight. When someone reviews the research stated in this report you find that the dosage is high, unbalanced and that sunbed lamps were not used to test if they created an immune suppression. Immunosuppression or modulation of the immune system can be beneficial and may have greater benefits for autoimmune diseases at high levels in Northern Europe such as multiple sclerosis (Baarnhielm 2012) Page 10 – 39 to 42 Line 40 – "significantly increased risk" may be an exaggeration in this case. 15% for sunbeds is 4X less than the 60% for solar outdoor UV (Cancer Care Ontario – Cancer Risk Factors in Ontario – Ultraviolet Radiation 2013) and is less than the cancer risk for processed meats. According to IARC in a Q&A document for the press, the question was asked about comparing tobacco and processed meats since both are in Group 1, the answer given was; No, processed meat has been classified in the same category as causes of cancer such as tobacco smoking and asbestos (IARC Group 1, carcinogenic to humans), but this does NOT mean that they are all equally dangerous. The IARC	in humans are mentioned in the Opinion. The relation between latitude, natural outdoor sunlight and disease is outside the scope of the mandate. In the Baarnhielm data on sunbed use there was no adjustment for sunlight/other UV exposure. The text of the Opinion is correct. No changes to the Opinion are required in relation to the comment.

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4	Gilroy Steven, Joint Canadian Tanning Associaion JCTA, info@TanCanada.org, Canada	1. EXECUTIVE SUMMARY	Lindqvist_2014_-_Avoidance_of_sun_expo De_Winter_2001_Roza_Pavel_2001-_Sola Bataille_2013_-_Melanoma_-_Shall_we_mo	Page 10,43/45 Tendency to sunburn, but the number of sunburns and whether Skin Type 1 (always burn and never tan) cases were removed from the data set is not noted. Therefore this would skew the results under 35 (IARC 2006), 59% under 35 (Boniol 2012) and now 35% under age 25 and over age 25, 11% (Colantonio 2014). Page 11,8/11 That statement is untrue. A large cohort study by Lindqvist in 2014 reported that use of sunbeds reduces all-cause mortality risk by 33%. This large cohort study followed 29,518 Swedish women for 20+ years. The study found that women who used sunbeds and sunbathed during summer or on holiday, had a greatly reduced risk for all-cause mortality. The study concluded: The mortality rate amongst avoiders of sun exposure was approximately twofold higher compared with the highest sun exposure group, resulting in excess mortality with a population attributable risk of 3%. The results of this study provide observational evidence that avoiding sun exposure is a risk factor for all-cause mortality. Following sun exposure advice that is very restrictive in countries with low solar intensity might in fact be harmful to women's health. Page 11line16/19 De Winter 2001reports how excessive UV exposure was used in animal studies: In almost all animal experiments documenting the carcinogenic properties of UV radiation, five to seven exposures a week have been applied (Strickland, 1986; Van Weelden et al,1988; Kelfkens et al, 1991; De Gruijl et al, 1993; Wulf et al, 1994). There is no doubt that such frequent irradiations result in the accumulation of cellular injury (Vink et al, 1991) and, consequently, increase the risk of DNA mutations. The question remains whether UV radiation would be such a strong carcinogen if the irradiations were performed at reduced frequency. Page 11 line 27/28 Other cancers such as internal cancers have also shown C→T changes similar to the UV-signature that were not caused by UV (Alexandrov 2013) (Bataille	Tendency to sunburn is closely related to skin type 1. Text on the Lindqvist paper has been added in the chapter on All-cause Mortality. No change in the Executive Summary. The references provided are older and outside of the scope; the Opinion deals with new evidence since the 2006 SCCP report. No change in the Executive Summary.

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				2013) Alexandrov to large of a file to upload	No changes in the text needed
5	Gilroy Steven, Joint Canadian Tanning Association JCTA, info@TanCanada.org, Canada	1. EXECUTIVE SUMMARY	de_Winter_2001_-_Solar-Simulated_Skin_A Mason_2010_-_Photoprotection_by_125-(Mason_2012_-_Sunlight_Vitamin_D_and_S Cui_Fisher_2007_-_Science_Daily_-_Guard	Page 11 – line 21 to 27 There is no mention of research on DNA repair system after the creation of photoprotection from UV exposure. De Winter 2001 using tanning equipment reports: The ultraviolet sensitivity for erythema decreased on average by 75%. The cyclobutane pyrimidine dimer formation was reduced on average by 60%. Further information on the control of sunbeds is also mentioned in the discussion section and should be used. There is no mention in the report that DNA damage is reduced and by this happening the repair system is no longer over tasked. Mason 2010 also reference to photoprotection by 3 responses to UV exposure; The two well known mechanisms of endogenous photoprotection are increased pigmentation and increased cornification [2,3,12]. The increased depth of the stratum corneum attenuates UV penetration (Fig. 1). Melanin, which absorbs UV and thus protects DNA, is produced in greater amounts by melanocytes after UV and is transferred to adjacent keratinocytes, where melanin caps are formed over the nuclei. These processes take hours to days, so that increased cornification and pigmentation protect from the next UV exposure, not the initial one. UV also produces previtamin D which thermally isomerizes into vitamin D [13]. Mason 2012 research states: The photoprotective effects of vitamin D compounds against thymine dimers and apoptosis demonstrated in mouse and human skin, and protection against photoimmune suppression and photocarcinogenesis in mice has led to the proposal that photosynthesis of vitamin D from UVB in skin and its local conversion to the active hormone 1,25(OH)2D3 is an adaptive mechanism for cellular defense against further UV exposures. Mason 2010 also reports; The reduction in DNA damage after UV in the presence of 1,25(OH)2D3 has been reported in keratinocytes [50,145,146,148,151] skin fibroblasts [145]	The text has been amended. Text on protection by a tan has been added. Recent work by Mason's group has been mentioned in the Opinion. The SCHEER considers this comment personal view and hazardous extrapolation from mice to humans. p53 regulates a large number of genes, but tanning (in humans) is also triggered by repair of DNA, and melanocytes (which actually produce melanins) do not use p53 pathway in their response to UV, and p53 mutations are rare in human melanomas, contrary to carcinomas. Detailed analysis of pigment regulation is outside the mandate. No changes to the Opinion are required in relation to the comment.

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				and melanocytes [147]. Thymine dimers increased after UV, reaching a maximum level after 6 hours [50]. In the presence of 1,25(OH)2D3, thymine dimers were reduced 30 minutes after UV exposure. A reduction in thymine dimers with silibinin was also reported one hour after irradiation in Skh:hr1 hairless mice [152]. A reduction of thymine dimers by 1,25(OH)2D3 within this short time frame is inconsistent with improved DNA repair, as the rate of repair by the NER pathway is relatively slow (6-24 h)[66-69]. The increase in thymine dimers after irradiation and their suppression by the vitamin D hormone within 30 minutes leads to a proposal that thymine dimers may be produced by a metabolic processes, which is suppressed by vitamin D compounds, in addition to being produced by direct DNA absorption of UV. Cui 2007 press release states: A protein known as the "master watchman of the genome" for its ability to guard against cancer-causing DNA damage has been found to provide an entirely different level of cancer protection: By prompting the skin to tan in response to ultraviolet light from the sun, it deters the development of melanoma skin cancer, the fastest-increasing form of cancer in the world. In a study in the March 9 issue of the journal Cell, researchers at Dana-Farber Cancer Institute report that the protein, p53, is not only linked to skin tanning, but also may play a role in people's seemingly universal desire to be in the sun — an activity that, by promoting tanning, can reduce one's risk of melanoma. Unable to upload the rest of Cui 2007 2 PDFs are to large of files	
6	Gilroy Steven, Joint Canadian Tanning Association JCTA, info@TanCanada.org, Canada	1. EXECUTIVE SUMMARY	Diffey_2003_-_A_quantitative_estimate_c	Page 11 – line 34 to 38 A study quantifying the impact of sunbed use in the UK on melanoma mortality concluded: "Sunbed use could be regarded as a relatively minor self-imposed detriment to public health compared with other voluntary 'pleasurable' activities associated with significant mortality, such as smoking and drinking alcohol. While cosmetic tanning using sunbeds should be discouraged, prohibition is not warranted especially as exposure to the sun, which cannot be regulated, remains the major	The Opinion is on the health effects of sunbeds per se. Regulation is outside the scope of the mandate. No changes to the Opinion are required in relation to the comment.

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				contributory factor to the risk of melanoma." (Diffey 2003) Page 11 – 38 to 42 The three most recent cohort studies referenced above were not based on the new 0.3 lamps introduced in 2007 and therefore do not represent the risk for the new 0.3 lamps. In addition, the new meta-analysis research reports show that the estimated risk for using a sunbed at a younger age is reducing. For example, the IARC 2006 increased risk for under age 35 was 75%, Boniol 2012 reported the risk of 59% for those under age 35, and Colantonio 2014 the most recent and up to date analysis reported a 35% risk for people under age 25 and an 11% risk for people over age 25. The 76% risk as reported by Cust was based on Australian data and cases which were not using the new 0.3 European lamp and also had high outdoor UV exposure which could confound these numbers. Out of 604 melanoma cases only 137 or 22% "Ever" used a sunbed. The study reported 78% of the cases or 467 cases never used a sunbed. So for 100% of these cases their melanoma was from 'other causes' not a sunbed. But for the young sunbed users, 76% of their melanoma was attributed to sunbeds. This requires further investigation. A UK study using the same questionnaire and method of analysis as the Australian study by Cust et al. (2011) by Elliott (2012) found a non-significant ever-use risk of sunbeds of 6% (OR 1.06, 95% CI 0.83–1.36). In addition, Elliott (2012) reported age at first use of sunbeds showed a small non-significant increased risk for use of 16% (OR 1.16, 95%CI 0.84–1.62). Page 11/12 – lines 44 to 46 & 1,2 Based on the research provided, there is not strong evidence that all UV exposure causes skin cancer. Long term excessive exposure can be	The text of the Opinion is correct. No changes to the Opinion are required in relation to the comment. The Opinion concludes that no safety limit can be set for sunbeds It is not excluded that this reduction is not due to differences in studies included in the meta-analyses The text of the Opinion is correct. No changes to the

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				related to SCC, but not melanoma or BCC. Intermittent and sunburning level are related to CMM and BCC. SCC is also related to sunburning levels. Creating a protective tan increases vitamin D levels and reduces DNA damage by 60% and sunburns by 75%. Vitamin D and a tan protect not against the first exposure, but every exposure thereafter. This added protection allow the repair of DNA without over tasking the repair system. Every time someone loses their photoprotection, the exposure damage of the first exposure exists.	Opinion are required in relation to the comment.
7	Gilroy Steven, Joint Canadian Tanning Association JCTA, info@TanCanada.org, Canada	1. EXECUTIVE SUMMARY	Schwalfenberg_2010_-_Addressing_vitami Cancer_Risk_Factors_in_Ontario_-_Ultravi Holick_2007_-_Vitamin_D_and_Skin_Physic Janz_2013_-_Vitamin_D_blood_levels_of_(	Page 12 – line 5 to 8 Regular sunbed use has been proven to provide 25(OH)D levels of 95 nmol/L which were higher than the levels people achieved who received lots of sun exposure (Schwalfenberg 2010). This is due to the fact that sunbed exposure of UVB is provided to a much higher percentage of the body skin area, up to 100%. Sunbed use has not been endorsed by health agencies who continue to be influenced by the risks of UV such as skin cancer vs the benefits such as vitamin D and other photoproducts. Cancer Care Ontario, in Canada, reported that the melanoma risk for intermittent UV exposure from outdoor solar UV was 61% (IARC 2012) and the risk from UV-emitting Indoor tanning devices was 15% (IARC 2006). To suggest solar outdoor UV exposure for vitamin D production over sunbed use will put the population at a 4X higher risk for melanoma. Holick 2007 recommends: "Exposure to sunlamps that produce UVB radiation is an excellent source for producing vitamin D3 in the skin and is especially efficacious in patients with fat malabsorption syndromes." The Canadian Arm Forces uses sunbed in the arctic bases for vitamin D production – CFS Alert base (see attachment). Some provincial regulations for the indoor tanning in Canada actual have a medical exemption. One province stated the reason was the lack of phototherapy equipment	The text on vitamin D has been amended. A full discussion on adequate vitamin D levels is outside the scope of the mandate.

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
			Cashman_2016_-_Vitamin_D_deficiency_in Holick_2011_-_Evaluation_treatment_and Langlois_2010_-_Vitamin_D_status_of_Ca Baggerly_2015_-_Sunlight_and_Vitamin_D	in the Northern parts of Canada. The reason I note this is that Health Canada and other radiation committee rely on IEC recommendation for harmonization. Vitamin D levels at higher latitudes drop in winter. In Canada, 25% of the population does not meet Health Canada and the Institute of Medicine's vitamin D guidelines of 50 nmol/L in the summer and this rises to 40% in the winter (Janz 2013). In Europe, a recent study has found that 40.4% of the population does not meet a 25(OH)D blood level of 50 nmol/L (Cashman 2016). This proves that the current recommendation of usual exposure of face and hands to UVR from the sun and common diet do NOT provide sufficient vitamin D levels for 40% of the population. It should be noted that other groups recommend higher vitamin D blood levels than Health Canada and the IOM. The Endocrine Society in the USA recommend a 25(OH)D level of 75 nmol/L (Holick 2011). A group of 50 of the top vitamin D scientists, researchers and doctors through GrassrootsHealth recommend that for optimal health everyone maintain a 25(OH)D level of between 100-150 nmol/L. In Canada 90% of the population is below 100 nmol/L (Langlois 2010).	
8	ANSES	1. EXECUTIVE SUMMARY		§ 1- Executive summary, p10, lines 9-20; p25, lines 11-45 and p26, lines 1-33 Comment: The prevalence data are limited to Western Europe. There is no mention of data from central European countries. Because of the European status of SCENIHR, it would be worth mentioning this lack of data and calling for evaluation of prevalence in central European countries, in particular because of the presence of fair skin populations with an equally high risk of death from melanoma as compared to western countries.	No changes to the Opinion are required in relation to the comment. All available data were assessed.

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9	ANSES	1. EXECUTIVE SUMMARY		§ 1- Executive summary, p10, lines 21-37 Comment: There is no mentioning of accidents and side-effects like severe sunburns which sometimes occur after sunbed use. Although there is no systematic study of these events, many epidemiological studies report sunburn occurring with sunbed use and could be considered as a marker of risk, even though hardly quantifiable.	No changes to the Opinion are required in relation to the comment. This issue is discussed in the Opinion.
10	ANSES	1. EXECUTIVE SUMMARY		§ 1- Executive summary, p11, lines 5-6; p42, lines 22-31 Comment: It should be noticed that despite sunbed use were self-reported, studies could show that the increased risk were not due to a particularly old or recent generation of tanning devices. In addition, these sunbeds clearly corresponded to cosmetic use to acquire a tan as the great majority of studies excluded use of UV-emitting devices for medical reasons.	No changes to the Opinion are required in relation to the comment.
11	ANSES	1. EXECUTIVE SUMMARY		§ 1- Executive summary, p11, lines 26-27 Comment: The importance of UVA is clearly identified by the authors who wrote several times "Importantly, UVA has been shown to be at least as much involved as UVB in DNA damage and mutation induction". This may be a bit an overstatement. For the different biological endpoints related to cancer (DNA damage, mutagenesis), UVA is 2 to 3 orders of magnitude less efficient than UVB. It can thus be estimated that the contribution of UVA to the deleterious effects of sunbeds is at the most in the range of 10 to 20%. It could be counter-productive if this kind of sentence were used against the rest of the text that is of very high quality.	Text has been modified for clarity.

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
12	Dr. Richarz Frank, IEC TC61 / MT16 'Biological effects of optical radiation', MT16@richarz-consulting.de, Germany	1. EXECUTIVE SUMMARY	 Sunbed_and_codliver_oil_as_Vitamin_D_s  Colantonio 2014 - The association of inc  IARC Report_VitD.pdf  Melanoma Treatment (PDQ®) - PubMed He  WHO solaruvradfull_18070	page 9 line 4 - 27 It has to be mentioned here that the European Commission is asking for both positively e.g. vitamin D regulation and negatively, e.g. skin and ocular melanoma. page 10 line 22 - 37 "It was the task for SCENIHR to report both sides of the UVR related science. In 2006 WHO has presented a document called ""Global burden of disease from solar ultraviolet radiation"", giving an overview over both sides of the UVR related science and the associated disease burden. It is clearly indicated that there is a personal exposure to UVR relative to skin type with minimal risk. Point B represents optimal UVR exposure: a person with careful titration of correct UVR dose for skin type. The file WHO solaruvradfull_180706 was to big to upload and is send to the SCENIHR office by mail. page 10 line 28 - 30 "- Huge parts of the European population are vitamin D deficient - Sunbed use can increase the vitamin D level, while intake of the recommended supplementation of 200 IU fail to even keep the vitamin D level at summer levels. (Moan 2007) - Sunbeds are a good opportunity especially for the elderly home bound population" page 11 line 44 - page 12 line 8 "The comparison to natural UV radiation is missing and the left side of the WHO graph is being ignored by the SCENIHR authors. WHO states as last sentences of their summary: Notably, a counterfactual of zero UVR exposure would not result in a minimum disease burden, but rather a high disease burden due to diseases of vitamin D deficiency. The file WHO solaruvradfull_180706 was to big to upload and is send to the SCENIHR office by mail." page 11 line 44 - page 12 line 8 "The WHO had indicated in 2006 that there is a point of minimal risk of UV exposure (B). MT16 was hoping to get some information from SCENIHR about this point. The file WHO solaruvradfull_180706 was to big to upload and is send to the SCENIHR office by mail."	The term risk has been replaced by health effects. The Opinion deals with the questions posed by the European Commission. No changes to the Opinion are required in response to the comment. The Opinion states that sunbed use induces vitamin D. However, there is no consensus about the optimal blood levels neither of vitamin D nor on recommendation for optimal vitamin D management. The Opinion deals with the effects from exposure to sunbeds per se. No changes to the summary are required in relation to the comment. Risk management for outdoor UV exposure is outside the mandate. The Opinion concludes that no safe limit for UV irradiance from sunbeds can be established.

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13	Wunsch Alexander, Medical Light Consulting, praxis@alexanderwunsch.de, Germany	1. EXECUTIVE SUMMARY	 1.pdf  2.pdf  3.pdf  4.pdf	P10/22-24: "There is evidence that the fraction of UV-B emitted from sunbeds can induce vitamin D production. However, excess exposure can even be counterproductive due to photodegradation of pre-vitamin D3 in the skin." It is evident that the Opinion is biased as long as the non-cancer health effects focus almost completely on negative aspects. Even the only positive effect mentioned (VD3) is qualified with the truism/platitude that overdosage (excess exposure) can be counter-productive. Modern sunbeds are built and equipped with capable systems to prevent overdosage. P10/32-35: "The role of UVB in immunosuppression is well established, but there is now evidence for an immune suppressive effect by UVA in the wavelength range from 350 – 390 nm. UV light (UVA as well as UVB) has both a local (i.e. in the skin) and a systemic immunosuppressive effect." This is rather an immunomodulatory effect than an immunosuppressive effect. Only subpopulations of the immune cell population react with suppression. Other cell lines remain fully functional. This could also interpreted as an adaptive effect: Under the influence of high UVR levels, the concentration of germs is lower in the environment and in the skin microbiome. Under these circumstances some immune cells can be deactivated. Other immune cell species - e.g. those needed for repair of light induced tissue stress (mast cells, macrophages etc.) - remain unaffected by UVR. (1.pdf) P11/6-8: "With the exception of a negative association for breast cancer in one cohort no association was found between sunbed use in adolescence and/or early adulthood and internal cancer risk." Since breast cancer exhibits a much higher incidence compared to melanoma, it would be intersting to discuss the potentially protective effect of sunbed use - especially with regard to VD3, which has demonstrated to be a potentially protective factor for breast cancer. (2.pdf) In particular, further investivation would be important due to the estrogen dependency of breast cancer and the protective influence of melatonin.(3.pdf, 4.pdf)	The text on vitamin D has been amended. Most publications use the term immunosuppression. No changes to the Opinion are required in relation to the comment. No change in the Executive Summary needed. There is currently no convincing evidence that vitamin D could be a protective factor for breast cancer. In addition, the reference given (2.pdf) refers to bone mineral density.

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
14	Wunsch Alexander, Medical Light Consulting, praxis@alexanderwunsch.de, Germany	1. EXECUTIVE SUMMARY	 1.pdf  2.pdf  3.pdf	P12/5-8: "Because of evidence of the carcinogenic effects of sunbed exposure and of the nature of skin cancer induction (there are no indications for threshold levels of UV-irradiance and –dose), there is no safe limit for UV irradiance from sunbeds." This is contradictory, that there should be no indications for threshold levels, because the cancer induction only did work with neonatal transgenic mice, but not with elder subjects. It has to be clarified that tumor induction in rodent skin only works, when the protective hair layer is removed and a photoadaptation is circumvented. No incremental irradiation strategy is applied in these kinds of experiments, therefore photoadaptation is not possible. Removal of the furry layer resembles the removal of the corneal layer in human skin, which significantly contributes to UV protection. Experiments with the shaved skin of nocturnal species can only result in reductionistic conclusions, but will not yield reliable insights for the conditions in human (=diurnal) skin, which exhibits the most complex anatomical construction in the animal kingdom. (1.pdf) It is commonly accepted that there obviously are safe levels of UV irradiation for certain ethnic groups who are much less susceptible to skin cancer compared to fair-skinned ethnicities. (2.pdf) The whole report has a rassistic bias, since it claims that the European population is mostly fair-skinned. This might have been the case a century ago, but this concept does not hold anymore in the 21st century and in a globalized world. It is reflected from scientific work that people with darker skin complexion have a higher need for sunlight in order to maintain their VD3 levels. Since the sunlight intensity/UVB content in higher latitudes does not suffice in many cases, artificial insolation can help to compensate for the lack of intensity of natural sunlight. (3.pdf)	No change in the Opinion needed. From a mechanistic point of view there is no evidence for a safe threshold limit. Recommendations on outdoor UV exposure and vitamin D levels are outside the scope of this Opinion
15	Manaras Nikos, European Academy of Dermatology and Venereology,	1. EXECUTIVE SUMMARY		**Comments for Public Consultation on Preliminary Opinion on Biological effects of ultraviolet radiation relevant to health with particular reference to sunbeds for cosmetic purposes**	Supportive statement acknowledged by SCHEER. No changes to the Opinion are required in relation to the comment.

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
	nikos@eadv.org, Belgium			Joint Contribution by: European Academy of Dermatology and Venereology (EADV) European EUROMELANOMA Campaign European Dermatology Forum (EDF) European Association of Dermato Oncology (EADO) The European Academy of Dermatology and Venereology (EADV), the European EUROMELANOMA campaign, the European Dermatology Forum (EDF) and the European Association of Dermato-Oncology (EADO) have studied the SCENIHR report on the primary biological effects of ultraviolet radiation relevant to health, with particular reference to sunbeds for cosmetic purposes. The goal of this report was to update the scientific and medical evidence to ensure sufficient levels of protection for the health and safety of users. A further objective of this report was to answer the question whether a wavelength for which the total irradiance is negligible and thus minimises the risks of developing skin cancer through the use of sunbeds. The aforementioned stakeholders have carefully read the report's content about the exposure, the cancer and non-cancer health effects, the mechanistic studies and the risk characterisation. We approve the scientific content and the methodology used to make the report. We fully support the report's proposed conclusions: Ultraviolet (UV) radiation is a complete carcinogen, acting both as an initiator, through genotoxicity, and as a promoter, through immunosuppression. Sunbed use increases the risk of skin melanoma, squamous cell carcinoma and, to a lesser extent, basal cell carcinoma, especially when first exposure takes place at a young age. There is moderate evidence that sunbed exposure may also cause ocular melanoma. Early-onset melanomas (melanomas occurring before the	

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
				age of 30) are particularly associated with sunbed use. The potentially beneficial effects of sunbed use are more than outweighed by the many severe adverse effects. There is no need to use sunbeds to boost vitamin D synthesis; and UV overexposure may in fact reduce vitamin D levels. There is no safe limit for sunbed use. Not only is sunbed use carcinogenic, there is no evidence of a threshold for skin cancer induction related to UV-irradiance and UV-dose. On behalf of: The European Academy of Dermatology and Venereology *Prof. Dr. Erwin Tschachler – President* The European Dermatology Forum *Prof. Dr. Lars French – President* The European Association of Dermato- Oncology *Prof. Dr. Claus Garbe - President* The EUROMELANOMA Campaign *Prof. Dr. Veronique del Marmol – Chair* **About EADV** Founded in 1987, EADV is a non-profit association whose vision is to be the premier European Dermato-Venereology Society, with the key aims of improving the quality of patient care, providing continuing medical education (CME) for all Dermato-Venereologists in Europe and advocacy on behalf of the specialty and patients. **About EADO** EADO is an independent non-profit organization dedicated to promote, coordinate and improve clinical and laboratory research activities in the field of skin cancer including primary and secondary prevention, early detection, clinical diagnosis and clinical and experimental research. The EADO community currently counts over 400 eminent members from more than 40 countries, representing a variety of disciplines -- dermatologists, oncologists and clinical as well as basic research scientists interested in the field of Dermato Oncology. **About Euromelanoma**	

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
				Established in 1999, Euromelanoma is a pan-European skin cancer campaign, active in 33 countries. Euromelanoma exists to promote and share information on skin cancer prevention, early diagnosis and treatment and is led by a network of European dermatologists. Euromelanoma's activities are focused on reaching three key audiences; the general public; the scientific community; and European and national policy makers. The membership concept has been broadened to include all areas of Europe and elsewhere, and the development of alliances and affiliations with other organisations. EADV currently represents approximately 5,000 members. **About EDF** Founded in 1997, EDF is a non-profit professional organisation dedicated to improving the healthcare needs of dermatology patients in Europe. EDF's mission is to implement actions aimed at preventing skin diseases and improving the quality of health care for dermatologic & and venereologic patients in Europe. The EDF represents approximately 200 active members consisting of heads of academic departments and key Opinion leaders in dermato-venereology across Europe. **About EADO** EADO is an independent non-profit organization dedicated to promote, coordinate and improve clinical and laboratory research activities in the field of skin cancer including primary and secondary prevention, early detection, clinical diagnosis and clinical and experimental research. The EADO community currently counts over 400 eminent members from more than 40 countries, representing a variety of disciplines -- dermatologists, oncologists and clinical as well as basic research scientists interested in the field of Dermato Oncology. **About Euromelanoma** Established in 1999, Euromelanoma is a pan-European skin cancer campaign, active in 33 countries. Euromelanoma exists to promote and share information on skin cancer prevention, early diagnosis and treatment and is led by a network of European dermatologists. Euromelanoma's	

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				activities are focused on reaching three key audiences; the general public; the scientific community; and European and national policy makers.	
16	Lipman Gary, The Sunbed Association, garylipman.tsa@gmail.com, United Kingdom	1. EXECUTIVE SUMMARY	 EN16489-1_EN.pdf	Page 9, line 13: States 'The health and safety hazards associated with the use of sunbeds'. This should read 'The potential health and safety hazards associated with the use of sunbeds'. The wording, as stated, asserts rather suggests a potential health and safety hazard if abused. Page 9, lines 16-17: Advice by properly trained salon personnel at point of service is paramount over knowledge of consumer. Page 9, lines 20-21: Please identify what market surveillance, when it was carried out and where. Since 1995 all members of The Sunbed Association (TSA) in the UK agree to abide by our Code of Practice that, amongst other things, includes well informed staff, trained and certified by TSA. Moreover, salon staff across Europe can now receive accredited Tanning Salon training to the EN16489 Standard. TSA has harmonised its existing training to meet with EN16489 and received appropriate accreditation. Page 9, lines 23-25: Can the committee please identify 'other skin-related diseases associated with the use of sunbeds' and provide research in support. The Sunbed Association is not aware of any such skin related diseases. Indeed, many Doctors refer patients with skin conditions such as psoriasis and eczema to professional sunbed salons. Page 9, lines 28-29: This is correct. As such, the committee must limit evidence and research that only relates to UV tanning devices for cosmetic purposes in a professional tanning salon and not conflate data from UV devices used for medical purposes (as referenced in my comments for Page 5, lines 27-31) and also home use sunbeds and sunlamps. Page 10, lines 6-8: Since 1995 all members of The Sunbed Association (TSA) in the UK agree to abide by our Code of Practice that, amongst other things, includes well informed staff, trained and certified by TSA. TSA's Code of Practice exceeds all legislative and regulatory requirements alongside all other best practice procedures.	No change in the Opinion is needed. Terms of reference were to "reassess the safety risks associated with the use of sunbeds" and not the potential risks. This is risk management issue. No changes to the Opinion are required in relation to the comment. This is risk management issue. No changes to the Opinion are required in relation to the comment. The text of the Opinion has been amended. The Opinion is focusing on the effects from sunbed use per se, not on effects from medical treatments. No changes to the Opinion are required in relation to the comment. This is a risk management issue. No changes to the Opinion are required in relation to the comment.

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
				Moreover, salon staff across Europe can now receive accredited Tanning Salon training to the EN16489 Standard. TSA has harmonised its existing training to meet with EN16489 and received appropriate accreditation. contd/...	
17	Yared Wendy, Association of European Cancer Leagues, director@europeancancerleagues.org, Belgium	1. EXECUTIVE SUMMARY		**Brussels, 26th April 2016** **Public consultation on the SCENIHR Preliminary Opinion on Biological effects of ultraviolet radiation relevant to health with particular reference to sunbeds for cosmetic purposes** **Consultation response from the Association of European Cancer Leagues (ECL)** The Association of European Cancer Leagues (ECL) would like to express its full endorsement of the findings and conclusions of the SCENIHR Preliminary Opinion on Biological effects of ultraviolet radiation relevant to health with particular reference to sunbeds for cosmetic purposes. The important causal link between sunbed use and skin cancer are fully recognised in this report, concluding that "there is no safe limit for UV irradiance from sunbeds", in line with ECL's position. ECL centres its cancer prevention activities on the 4th Revision of the European Code against Cancer (www.cancercode.eu), a joint initiative of the World Health	No changes to the Opinion are required in relation to the comment. Statement acknowledged by the SCHEER.

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
				Organization's International Agency for Research on Cancer (IARC) and the European Commission. The message in the Code against Cancer which is dedicated to UV exposure advises to "avoid too much sun, especially for children. Use sun protection. Do not use sunbeds". In line with the SCENIHR Opinion, IARC also notes that the use of sunbeds exposes the individual to unnecessary excess UV and should be avoided at all times. ECL would also like to support the fact that only sunbed use for cosmetic purposes are included in the scope of this scientific Opinion. In conclusion, ECL fully supports the findings of the SCENIHR Preliminary Opinion on Biological effects of ultraviolet radiation relevant to health, with particular reference to sunbeds for cosmetic purposes, in particular the link to increased skin cancer incidence. ECL would like to see this scientific Opinion used in the future as an evidence base for legislation or policy. It is important that these conclusions can already be used to inform consumers, in particular those under 30, of cancer and other health risks associated with sunbed use. **About the Association of European Cancer Leagues (ECL)** ECL is a membership-based umbrella organisation based in Brussels and active on EU wide cancer control. ECL members are cancer organisations at national and regional level in the wider Europe region. ECL member leagues have a combined income of over 700 million Euro (US$1,209,000,000), over 6,000 staff members and more than half a million volunteers in their fight against cancer. The vision of Association of European Cancer Leagues (ECL) is for a Europe Free of Cancers. The role of ECL is to	

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
				facilitate the collaboration between cancer leagues throughout Europe and to influence EU and pan-European policies. The mission of the Association of European Cancer Leagues is to influence and improve cancer control and cancer care in Europe through collaboration between its members in their fight against cancer, and to influence EU and pan-European policies.	
18	Boonen Brigitta, Belgian Cancer Foundation-Stichting tegen Kanker - Fondation contre le Cancer, bboonen@cancer.be, Belgium	1. EXECUTIVE SUMMARY		Public consultation on the SCENIHR Preliminary Opinion on Biological effects of ultraviolet radiation relevant to health with particular reference to sunbeds for cosmetic purposes Consultation response from the Belgian Cancer Foundation The Belgian Cancer Foundation would like to express its full endorsement of the findings and conclusions of the SCENIHR Preliminary Opinion on Biological effects of ultraviolet radiation relevant to health with particular reference to sunbeds for cosmetic purposes. The important causal link between sunbed use and skin cancer are fully recognised in this report, concluding that "there is no safe limit for UV irradiance from sunbeds", in line with ECL's position. The Belgian Cancer Foundation centres its cancer prevention activities (amongst many other) on the 4th Revision of the European Code against Cancer (www.cancercode.eu), a joint initiative of the World Health Organization's International Agency for Research on Cancer (IARC) and the European Commission. The message in the Code against Cancer which is dedicated to UV exposure advises to "avoid too much sun, especially for children. Use sun protection. Do not use sunbeds". In line with the SCENIHR Opinion, IARC also notes that the use of sunbeds exposes the individual to unnecessary excess UV and should	No changes to the Opinion are required in relation to the comment. Statement acknowledged by the SCHEER.

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
				be avoided at all times. ECL would also like to support the fact that only sunbed use for cosmetic purposes are included in the scope of this scientific Opinion. In conclusion, The Belgian Cancer Foundation fully supports the findings of the SCENIHR Preliminary Opinion on Biological effects of ultraviolet radiation relevant to health, with particular reference to sunbeds for cosmetic purposes, in particular the link to increased skin cancer incidence. The Belgian Cancer Foundation would like to see this scientific Opinion used in the future as an evidence base for legislation or policy. It is important that these conclusions can already be used to inform consumers, in particular those under 30, of cancer and other health risks associated with sunbed use.	
19	de Gruijl Frank, representing none, degruijl@planet.nl, Netherlands	1. EXECUTIVE SUMMARY		1.1 - pg 9, lines 9 – 12, Surprising, for someone acquainted with the 1992-report on "Solar and Ultraviolet Radiation", IARC monograph 5. Following criteria from this earlier Monograph sunbed use should be classified as carcinogenic to humans (sufficient evidence, Group 1), and UV as probably carcinogenic to humans (limited evidence, Group 2A). IARC has now apparently finally fallen in line and consents that UV, either from the sun or sunbeds, is indeed carcinogenic: nothing special about sunbed. Apparently, only a change of mind on the part of IARC on how to evaluate the scientific data. Pg 9, lines 13 – 17, note that all the circumstances in sun parlors are conductive to well controlled UV exposure, very much in contrast to exposure to solar UV radiation. This document does not appear to consider this as an opportunity in limiting UV exposures, extending to those from the sun. To frame the data to aim for an opportunistic one-sided restriction on sunbed exposures may be counter productive in curbing skin cancer risk (especially if tanners compensate by further uncontrolled sun exposures). Pg 9, lines 22 -24, the concerns about sunbeds - over sun	The assessment of literature published before 2006 is outside of the scope of the Opinion. Statement acknowledged by the SCHEER. This is a risk management issue. Advice on outdoor sun exposure is outside the mandate. No changes to the Opinion are required in relation to the comment.

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
				exposures - is to a large extend attributable to epidemiologists who restricted themselves to study skin cancer risk from sunbed use, based on a set exposure criteria very different from earlier ones established in studying skin cancer risks from sun exposure. Ie, all these studies lack fitting comparisons to risks from sun exposures. (unfortunately, public campaigns and political lobbies tend to suffer more and more from the same disbalance) 1.2 - Pg 9, line 40, LVD? Low Voltage Directive? (define LVD in line 33) Pg 10, line 8, shouldn't these restriction be extended to sun exposure? Could sun parlors channel these messages to people who want to tan, and discourage uncontrolled/unprotected sunbathing? 1.3 - Pg 10, line 19: absolute increases in %%? Pg 10, line 19: when and where, same population? Increase over 1, 5, 10 or 20 years, accurary? (significant?). And as remarked with the Abstract: a very selective representation of increasing sunbed use; Telegraph.co.uk 28 june 2013, Kathy Young reports on a study of Simple Business: "The study, based on 750,000 quote requests, revealed a steep decline in tanning salons of 29 per cent since 2012, suggesting that the dangers associated with sunbeds have finally hit home." (http://www.simplybusiness.co.uk/about-us/press-releases/tanning-salons/) (see also Boyle et al, Br J Dermatol 2010;163:1269-75). Also, reports on already low sunbed use in Australia declining, and among female students in the US: "From 2009 to 2013, tanning decreased among female students (from 25.4 percent to 20.2 percent), .. " (Gery P. Guy, et al. Trends in Indoor Tanning Among US High School Students, 2009-2013. JAMA Dermatology, 2014; DOI: 10.1001/jamadermatol.2014.4677)	The Opinion carefully assessed, in line with the mandate, the studies on skin cancer risk attributable to exposure from sunbeds per se. The abbreviation, LVD, is now included and explained in the annex. These are risk management issues. No changes to the Opinion are required in relation to the comment. Text is clear. No changes to the Opinion are required in relation to the comment. Details are given in the main text. No changes to the Opinion are required in relation to the comment.

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20	de Gruijl Frank, representing none, degruijl@planet.nl, Netherlands	1. EXECUTIVE SUMMARY		1.4 - Pg 10, line 23, this is a chemical "in a tube" result. Has never been established in human studies and therefore speculative. As sunbeds with a trace of UVB have clear net effect in raising vitamin D/carcidiol levels Pg 10, line 26, this has actually never been empirically established, it is derived from experiments with artificial UV sources (first by the Holick group with people in bathing suits exposed to 1 MED from Westinghouse sunlamps, assuming direct proportionality to skin area and dose, leading to "Holick's rule: ¼ MED to ¼ of the body surface yielding 1000 IU). Pg 10, line 26, ½ h? not in winter in NW Europe, or comparable latitudes. Pg 10, lines 30 -31, here again the lack of expertise on UV-vitD shows: under heavy overcast UV(B) (UV-index < 2 or 3) will be insufficient to induce appreciable amounts of vitamin D, and the Western diet is know to be inadequate in vitamin D. In Summer the sun generates ample vitamin D, but not in Winter when vitamin D statuses on average fall below minimal desirable levels (calcidiol < 50 nmol/l). Pg 10, line 35, there is alos experimental evidence that UVA can counteract UVB immunosuppression 1.5 - Pg 10, line 40, " risk of" not "from cutaneous melanoma" Pg 10, line 44, certainly not "all studies" are adjusted for all mentioned factors, and certainly variably and not always appropriately – proper criticism would be in order here Pg 10, line 45, is "suggests" sufficient ground for this official document to consider seriously a possibly increased melanoma risk? Pg 11, line 4, a study cited shows no increase in risk of BCC at all, and a later one a modest increase in risk comparable to melanoma (note, however, that absolute risk of the latter is considerably lower, and therefore the added risk for BCC consirably greater) 1.6 - Pg 11, lines 18 – 19, note that the HGF mice tend to develop melanoma spontaneously and that UV accelerates development (ie strongly shortens the latency). Pg 11, line 21, here the document is not consistent because	Text of the Opinion was changed. Measurements are cited in the text. No changes to the Opinion are required in relation to the comment. No changes to the Opinion are required in relation to the comment. The text on sun exposure, latitude and season in relation to vitamin D has been amended. No change in the Executive Summary required. The text of the opinion was changed. Text of the Opinion was changed. No changes to the Opinion are required in relation to the comment. No changes to the Opinion are required in relation to the

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
				elsewhere it is recognized that UVA also induces cyclobutane pyrimidine dimers, not necessarily oxidative DNA damage (which is also very efficiently caused by UVB). Pg 11, line 25, UVA signature mutations? All the aforementioned experiments show cyclobutane pyrimidine dimer-associated mutations (earlier thought to be UVB specific) or oxidation-related mutations (e.g. typically G to T or T to G). Pg 11, lines 26 -27, misleading as UVB is several orders of magnitude more efficient in inducing mutations than UVA (shown by various mutation action spectra) to the extent that UVB will dominate over UVA in sunlight. This difference in efficacy between UVA and UVB, particularly in inducing cyclobutane pyrimidine dimers and related mutations, is confirmed by cited Ikehata. Recent studies employing NGS and "genomic landscaping" of mutations in melanoma, BCC and SCC show a predominance of UV(B) signature mutations (action spectrum for the causative cyclobutane pyrimidine dimers in the skin peaks strongly in UVB to be continued	comment. The text was changed. No changes to the Opinion are required in relation to the comment. Text changed for clarity. No changes to the Opinion are required in relation to the comment.
21	de Gruijl Frank, representing none, degruijl@planet.nl, Netherlands	1. EXECUTIVE SUMMARY		1.7 - Pg 11, lines 34 -35, it is not "far from negligible"; at the 5% level it is in fact really marginal and probably practically undetectable in the noise of statistics on melanoma incidences. Also, note that many case-control studies have been done in age-restricted cohorts (often < 60 yrs) while melanoma incidence increase strongly with ages over 60 years. Pg 11, lines 37- 38, no evidence what so ever that sunbeds may actually increase mortality from melanoma, on the contrary, UV/sun-related melanoma appear to have a better prognosis than melanoma in general. Pg 11, line 39, it does not "seem modest" it is "modest" and likely to be over estimated because of inadequate correction for sunbathing which sunbed users are bound to subject to, too. Pg 11, line 39, highest RR at young age - with very low absolute risks - and dropping with increasing age. Still that strongly increased when the young users are over 60 years? Most studies do not provide this information.	The text was modified for clarity. The text was modified for clarity. The text was modified for clarity. The text was modified for clarity.

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
				Pg 11, line 42, "may be very high"? is this an unreliable/uncertain fraction? Should it then be mentioned at all? Especially considering that the melanoma incidence below 3 years of age is exceedingly low, and mortality negligible on a population scale. 1.8 - Pg 11, line 45, UV a promoter only by immunosuppression? UV is known to induce growth stimuli (e.g. epidermal hyperplasia), affect fibroblasts etc! On the other hand, the induction of large amounts mutations by UV is suspected to increase the immunogenicity of the skin tumors. Pg 11, line 45, "strong evidence"? Many scientists would beg to differ, e.g. read Colantonio et al (J Am Acad Dermatol 2014 May;70(5):847-57) who classify all studies underlying metastudies on skin cancer risk from sunbeds as "poor to mediocre" in quality based . Pg 12, line 1, why "to lesser extent" when relative risks are comparable to those of melanoma, and an absolute risk, and therefore added risk, that is appreciably larger than for melanoma. Pg 12, line 3, it is debatable whether sunbeds indeed increase the risk of skin cancer appreciably; it is marginally at most for melanoma and basal cell carcinoma, and possibly most substantial for squamous cell carcinomas, especially in added absolute risk; but all these estimated increases in risk are still suspected to suffer from insufficient (impossible full) correction for sunbathing habits among sunbed users. The melanoma risk under the age of 30 years is very low and an fraction attributable to sunbed is use is even lower – with vanishingly low mortality rates at these ages the problem is negligible compared to really high incidences of melanoma in elderly men. Pg 12, line 11 -12, there may be no safe limit for sunbed use, as there is for sun exposure- which impact on a population scale is likely to be an order of magnitude higher – but it would appear marginal, especially where melanoma risk is concerned. The problem should be put in proper context, both compared to sun exposure and the high incidence of melanoma in elderly men!	The text was modified for clarity. The SCHEER disagrees. No changes to the Opinion are required in relation to the comment. No changes to the Opinion are required in relation to the comment. No changes to the Opinion are required in relation to the comment. No changes to the Opinion are required in relation to the comment. No changes to the Opinion are required in relation to the comment.

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22	Lipman Gary, The Sunbed Association, garylipman.tsa@gmail.com, United Kingdom	1. EXECUTIVE SUMMARY	 Vit_D_Synthesis_in_relation_to_latitude__  Vitamin_D_toxicity.pdf	Page 2 of comments for Executive Summary: Page 10, lines 23-24: It is incorrect to state that excess exposure using sunbeds leads to photo degradation of pre-vitamin D3 in the skin. Overexposure, leading to burning, from all UV, not just sunbeds must be avoided. Page 10, lines 24-26: Exposing the face and hands a few minutes to half an hour, as stated omits the fact that this calculation is based upon daily exposure all year round. In Northern Europe it is not possible for the body to synthesise Vitamin D between October and April. Page 10, line 26: Can the SCENIHR please define 'widespread consensus' and provide empirical evidence in support of these Opinions. Page 10, line 30: The level of what constitutes Vitamin D sufficiency varies greatly not only between health departments in different countries, but also individual experts. Vitamin D naturally synthesized by the body as a result of exposure to UV is absorbed better and can be stored by the body. Vitamin D from dietary supplements can also cause toxicity whereas naturally produced Vitamin D cannot. As stated in the title, while this paragraph should focus on health effects, it actually questions the "necessity" of sunbeds to enhance Vit D levels. There is also widespread evidence that dietary supplements are not necessary and present some risks. SCENIHR should refrain from suggesting alternatives Page 10, lines 36-37: This is not a health issue, this is a cosmetic issue and beyond the remit of the SCENIHR Page 10, lines 43-45/ Page 11 line 1: Can the SCENIHR	The text was modified for clarity. The text was modified for clarity. No need to change the Executive Summary. This has already been clarified in the main text. The text was modified for clarity. No changes to the Opinion are required in relation to the comment. The SCHEER considers the acceleration of the aging of the skin to be a health issue. No changes to the Opinion are required in relation to the

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
				please identify which analyses they are referring to. If they are referring to the previously mentioned meta- analyses, I believe we have demonstrated earlier that all these papers used the same flawed data source and the results were flawed as a result.	comment. The analyses are presented in the main text.
23	Lipman Gary, The Sunbed Association, garylipman.tsa@gmail.com, United Kingdom	1. EXECUTIVE SUMMARY	 Highlighted_Leeds_Report_-_Intl_Journal_  Boniol_et_al-2013-International_Journal_c  Elliott_et_al-2013_Response_to_Boniol-Ir  EJC_Multicentre_epidemiological_study_o  Grant-IARC-sunbed-epub.pdf  Meta_Analyses_Data_Source.pdf	Page 3 of Executive Summary comments: Page 10, lines 39-45: It is too simplistic to isolate sunbeds and say they are dangerous. It is an unproven direct causal link. The cause of melanoma is a mixed and complex subject. It is misleading to state that meta-analyses provide definitive evidence of risk. Risk expressed as a relative risk may be perceived to be larger than the same risk presented as both an absolute risk reduction or as a number needed-to-treat. The authors have presented studies that, at first glance, appear to corroborate each other. Sadly, all the studies present an incorrect conclusion, as they all use the same flawed data source. A meta-analysis can be a powerful statistical tool, but it cannot compensate for poorly designed or carried out studies. In other words, to borrow a phrase from computer science, garbage in, garbage out. The studies in the meta-analyses provided were by no means all garbage, but they were not perfect either as their conclusions are misleading. The research provided by the authors of the report and the research authors themselves assert these papers as evidence of a link between sunbed use and melanoma. That would be acceptable if they only used sunbeds in their research. By including UV devices for medical use and home devices in the data source used in the meta-analysis, the resultant extrapolation is skewed and therefore flawed. Where sunbeds alone have been tested (Luxembourg Health Institute published in the European Journal of Cancer 41 (2005) 2141–2149 and International Journal of Cancer published research from Faye Elliott, Section of Epidemiology and Biostatistics, Leeds Cancer Research UK Centre, Leeds Institute of Molecular Medicine and Cancer Genetics (10.1002/ijc.26347)) no such link was found. When Messrs Autier and Boniol questionned the study, the authors robustly defended their study,	No changes to the Opinion are required in relation to the comment. The analyses are presented in the main text.

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
				questions and conclusions, which said 'In summary we have found no evidence of sunbed use as a risk factor for melanoma in the UK ...'. Independent scientific analysis of the IARC data source irrefutably clarifies that any increased risk is associated with medical use UV equipment - at a staggering 96% - and to a much lesser degree home use equipment but NOT with professional sunbeds. Meta-analyses carry the weight of all of the studies that they summarise. This credence makes it imperative that meta-analysis can be trusted to be an impartial tool and makes the validity of meta-analytic summary a far more important issue than measurement error. Their data can often be skewed by some weighted data and thereby obscures the result. As such, in my Opinion, meta-analyses are a crude blunt tool that can and do lose important detail. contd/...	
24	Lipman Gary, The Sunbed Association, garylipman.tsa@gmail.com, United Kingdom	1. EXECUTIVE SUMMARY	 Grant-IARC-sunbed-epub.pdf  Papas__Grant_summary_of_IARC_report_  suntan_poster_4-final-Montreal.pdf  Papas_2011_Abstract_3rd_North_America	Page 4 of comments on Executive Summary: Page 10, lines 39-45: In 2009 Dermato-Endocrinology published A Critique of the International Agency for Research on Cancer's meta-analyses of the association of sunbed use with risk of cutaneous malignant melanoma (1:6, 1-7;). The conclusion was 'This meta-analysis of the association of CMM risk with respect to sunbed use by the IARC does not support the evidence that sunbed use is a risk factor for CMM when the confounding factors of skin phenotype and latitude are considered. The IARC study only claims association, not causality, and the criteria for causality do not appear to be satisfied'. Research was published at the North American Congress of Epidemiology in Montreal, Canada in June 2011 showing 'Differential Risk of Malignant Melanoma by Sunbed Exposure Type' by Mia A. Papas, PhD, Anne H. Chappelle, PhD, William B. Grant, PhD. The conclusion stated 'When professional sunbed usage is considered independent of home and medical exposures there is no association with melanoma'. The IARC report failed to disclose is that the data from the studies they examined also showed: 1. There was no statistical connection between indoor tanning usage and melanoma for people with skin types dark enough to tan. (Grant WB, "Critique of IARC Meta-Analysis of the	No changes to the Opinion are required in relation to the comment. The analyses are presented in the main text.

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
			UK_case_study_-_Veronique_Bataille_-.pd	Association of Sunbed Use with the Risk of Melanoma. Dermato-Endocrinology 1:6, 1-7; Nov./Dec. 2009) The only connection was with people with "Skin Type I" (fair/sensitive skin) who use home tanning units for therapeutic reasons, but crucially, are screened from tanning in professional sunbed salons. 2. Closer analysis of data from the IARC report -- when separated by unsupervised home usage of UV equipment verses usage in professional sunbed facilities and medical usage of medical UV equipment in hospitals and clinics -- reveals that no statistically significant increase in relative risk* (6 percent) was attributable to commercial tanning facility usage, while larger increases (40 percent and 96 percent) were attributable to home and medical usage of UV equipment. By removing skin type 1, the relative risk is insignificant. The often quoted '75% (or 59% (Boniol)) increase' is an amalgamation of all the studies and therefore should never have been attributed solely to professional sunbeds. It must be reiterated that only vulnerable groups (for example those with sensitive skin who burn easily and rarely tan, so called skin type 1) have a relative risk of 6%. This group are screened out by professional tanning salons. Moreover, US studies are irrelevant when addressing usage in Europe. The method of usage in the US is very different to Europe. In a paper published by Veronique Bataille et al 'Exposure to the sun and sunbeds and the risk of cutaneous melanoma in the UK: a case-control study' (European Journal of Cancer 40 (2004) 429-435); 'This case–control study of melanoma did not find that exposure to natural or artificial ultraviolet radiation was significantly associated with an increased melanoma risk in the population overall'.	
25	Rodrigues & Araujo-Soares Angela & Vera, Newcastle University, angela.rodrigues@newcastle.ac.uk, United Kingdom	1. EXECUTIVE SUMMARY		General comment: This report synthesises relevant information about the links between UV exposure and several impacts on the skin, including cancer. In the introduction and at the end of the document, more emphasis should be placed on recommendations emerging from the evidence collected in this document. Recommendations for different stakeholders (i.e. healthcare professionals, policymakers, public health specialists,	These recommendations deal with risk management, which is not in the remit of the SCHEER.

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
				researchers) would help shape policy and practice and highlighting this in this document would facilitate the translation of current knowledge into practice/implementation. If no concrete ban is recommended (as we believe it should) in this report on sunbeds emitting UV levels equivalent to UV index of 12, then clear recommendations for research should be made. These recommendations could be targeting behavioural scientists, public health experts, dermatological experts, as well as biomechanics engineering scientists.	
26	Williams Sarah, Cancer Research UK, sarah.williams2@cancer.org.uk, United Kingdom	1. EXECUTIVE SUMMARY	 Dennis_et_al.zip	Cancer Research UK welcome the publication of the Opinion on sunbeds by SCENIHR. Sunbeds are an established cause of skin cancer, and it is important that people considering using these devices for cosmetic purposes have access to clear and consistent information about the health risks. It is important that the public are informed that even sunbeds that meet EU standards can pose health risks to users. We would encourage you to be cautious in discussing age of initiation in relation to risk. It is important that older people do not mistakenly interpret these statements around risk as indicating they can use sunbeds safely. We also note evidence (Dennis et al 2008, attached) on sunlight exposure which suggests that sunburn at any age increases the risk of melanoma.	The text was modified for clarity.

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
27	Khazova Marina, Public Health England, marina.khazova@phe.gov.uk, United Kingdom	1. EXECUTIVE SUMMARY		PHE fully supports the position that the use of sunbeds for cosmetic purposes should be discouraged, with effective enforcement of the ban on under-18 use, strict control on tanning duration and promotion of information on the health risks of sunbed use. Such an integrated approach on safe equipment, safe use and information should reduce the risk of detrimental impact of sunbed use on public health. The SCENIHR Opinion on health effects of sunbed use is important; it should be based on an objective and comprehensive analysis of scientific evidence. We feel that the selection of evidence in the review was confirmation biased, sometimes lacks objectivity and the data not supporting pre-emptive conclusions are given insufficient consideration. There is a lack of clarity about the fundamental difference between irradiance and radiant dose, i.e. irradiance x time. Despite stating that it is the dose and not dose rate which may cause harmful effects, the majority of the analysis refers to irradiance, i.e. dose rate. Emphasis on restriction of dose rate to 0.3 W/m2 (equivalent of UVI 12) without consideration of the duration of exposure is misleading.	The text was modified for clarity.
28	Khazova Marina, Public Health England, marina.khazova@phe.gov.uk, Sweden	1. EXECUTIVE SUMMARY		p10, lines 9-20. WHO in "Global burden of disease from solar ultraviolet radiation" (2006) gave a clear indication that there is an increased burden of disease due to insufficient exposure to UVR and that there is an optimum of exposure with maximum benefit and minimal risk. This SCENIHR report is imbalanced and biased towards detrimental impact of UVR exposure. The report should include the effect of UVR on cardiovascular health; in particular, on nitric oxide release. See, for example: 1. D Liu, BO Fernadez, A Hamilton, N N Lang, J MC HGallaher, DE Newby, M Feelisch and R Weller. UVA irradiation of human skin vasodilates arterial vasculature and lowers blood pressure independently of nitric oxide synthase.	Guidance on outdoor UV exposure is outside the scope of the Opinion. Text on blood pressure has been added. The text on vitamin D has been amended A full discussion on defining adequate vitamin D levels is

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
				Journal of Investigative Dermatology, v134, 1839-1846, 2014 2. R Weller. Sunlight has cardiovascular benefits independently of Vitamin D. Blood Purif 2016, 41, 130-134. 3. A Juzeniene and J Moan. Beneficial effects of UV radiation other than via vitamin D production. Dermatoendocrinol. 2012 Apr 1; 4(2): 109–117. Possible protective effects of chronic low level of UVR exposure or the role of intermittent high dose UV radiation exposure in melanoma induction should also be discussed. p10, lines 23-24. Photodegradation of VitD was never confirmed in human studies carried out since 1989. Below is a small selection of recent studies that showed an increase of Vitamin D after repeated exposure without evidence of any photodegradation, including a publication by A Webb: 1. M.Bodekær, B.Petersen, E.Thieden, P.A.Philipsen, J.Heydenreich, P.Olsen and H.C.Wulf. UVR exposure and vitamin D in a rural population. A study of outdoor working farmers, their spouses and children. Photochem. Photobiol. Sci., 2014, 13, 1598-1606 2. M Gröbner, J Gröbner and G Hülsen. Quantifying UV exposure, vitamin D status and their relationship in a group of high school students in an alpine environment. Photochem. Photobiol. Sci., 2015,14, 352-357 3. M D Farrar, A R Webb, R Kift, M T Durkin, D A, A H, J L Berry and L E Rhodes. Efficacy of a dose range of simulated sunlight exposures in raising vitamin D status in South Asian adults: implications for targeted guidance on sun exposure. Am J Clin Nutr, 2013, vol. 97, no. 6, 1210-1216 4. E Thieden, H L. Jørgensen, N R Jørgensen, P A Philipsen, H C Wulf Sunbed Radiation Provokes Cutaneous Vitamin D Synthesis in Humans—A Randomized Controlled Trial. Photochemistry and Photobiology, V 84, no 6, 2008, 1487–1492 5. McKenzie R, Liley B, Johnston P, Scragg R, Stewart A, Reeder AI, Allen MW. Small doses from artificial UV sources elucidate the photo-production of vitamin D. Photochem Photobiol Sci. 2013 12(9):1726-37. 6. R McKenzie et al. Sunburn versus vitamin D induced by UV from solaria and sunlight in New Zealand. Weather and Climate, 32(1), 52-64, 2012 p10, lines 32-37. Erythema weighting used throughout this	outside the scope of the Opinion. The Opinion has a focus on sunbeds per se. Text has been added mentioning research on health benefits from sunbeds.

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				draft report for the assessment of risk from sunbeds masks the contribution of UVA due to very low spectral weighting (6.8 10-4 at 350nm and 1.7 10-4 at 390nm) p12, lines 5-8. This sentence is a direct contradiction with the 2006 WHO Global burden of disease from solar ultraviolet radiation" 2006 which showed that there is an increased burden of disease due to insufficient exposure to UVR and there is an optimum of exposure with maximum benefit and minimal risk. The overall conclusion, based on complete dismissal of health benefits from UVR exposure, seems to lack balance.	
29	Gilroy Steven, Joint Canadian Tanning Association JCTA, info@TanCanada.org, Canada	2. BACKGROUND		2. BACKGROUND – Page 13 – line 1 Page 13 -line 4 to 7 The reference to Group 1, carcinogenic to humans, should be clarified since the IARC Monograph of 2012 (100D) states this to the reader of the Monograph on page 1 - The term 'carcinogenic risk' in the IARC Monographs series is taken to mean that an agent is capable of causing cancer. The Monographs evaluate cancer hazards, despite the historical presence of the word 'risks' in the title. The IARC Monograph states the agent could be a cancer causing, not that it is. This is a very important piece of information not clarified in this document. Colantonio 2014 also states the limitation of the research used by the IARC Monograph, since the same research was used by Colantonio, except 2. Colantonio did not use MacKie 1989 – Women and Veierod 2003. MacKie was reviewed and discarded and Veierod 2003 was replaced by Veierod 2010. Colantonio states the following about the research papers reviewed: The quality of evidence contributing to review results ranges from poor to mediocre." Colantonio was the first research paper to identify the quality of the research done on sunbeds. If this report is reviewed by lawmakers, they should know the quality of the research which is being presented in the full report. The word "(definite)" seem to have been added by the writer of this report and is not what IARC states a Group 1 actually is. According to IARC a Group 1 is "Carcinogenic to humans" which means it's capable of causing cancer and not definite. This document reports "There is no difference in the biological (and general health) effects induced by UV radiation in respect to their origin,	Line 4-7: On page 90 in IARCs Monograph 100D, in § 5 "Evaluation", the Agency clearly states that "Use of UV emitting devices IS carcinogenic to humans (Group 1). No changes to the Opinion are required in relation to the comment. The paper of Colantonio 2014 was considered; No changes to the Opinion are required in relation to the comment. The word "definite" has been used to clarify that IARC in 2012 now states that UVR from UV emitting devices IS carcinogenic to humans (Group 1). No changes to the Opinion are required in relation to the

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				the natural solar UV or artificial UV from e.g. tanning devices. UV-radiation (UVA, UVB, UVC) from the sun or from tanning devices has been classified by IARC (2009) as carcinogenic to humans (class 1, IARC). (Page 60, *. Opinion, Line 15-18).” The sun and solar UV has been included in IARC Group 1 since 1992. UV from sun or sunbeds is the same and has the same risks and the same benefits.	comment.
30	No personal data provided	2. BACKGROUND		§ 2- Background, p14, lines 34-39 Comment: Most regulations provide a technical framework for artificial tanning equipment control, set limit values for artificial UV irradiance from equipment and prohibit its use by those less than 18 years of age. However, the high UV doses allowed, the lenient restrictions on use, especially for sensitive persons, and the lack of resources available to the units in charge of inspection, make it impossible to reduce the number of health events associated with the use of sunbeds. Moreover, the fact that it is the service personnel in tanning studios who are assigned of information and prevention measures is not efficient. Thus, it becomes necessary to find new ways of implementing an effective public health policy.	The comment deals with risk management which is outside the scope of the SCHEER.
31	Dr. Richarz Frank, IEC TC61 / MT16 'Biological effects of optical radiation', MT16@richarz-consulting.de, Germany	2. BACKGROUND		page 13 line 40 to page 14 line 1- 4 This surveillance was performed while a good number of member states had not yet enforced the NEW requirements of the 2007 EN standard. Therefore the degree of compliance varied a lot between the member states.	The SCHEER disagrees with the comment. No changes to the Opinion are required in relation to the comment.
32	Petri Aspasia, Greek Atomic Energy	2. BACKGROUND		page 13, line 4: I believe the correct year is 2009.	The SCHEER agrees with the comment.

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
	Commission (EEAE), aspasia.petri@eeae.gr, Greece				The text of the Opinion was changed for clarity.
33	de Gruijl Frank, representing none, degruijl@planet.nl, Netherlands	2. BACKGROUND	Winterdip_tan_vitD_colds_PPS.pdf	2. Background - pg 13, line 11 -12, vitamin D only from sunlight, not from sunbeds? Substantial vitamin D induction by sunbeds has been amply shown by several studies with volunteers (e.g., de Gruijl FR, Pavel S. Photochem Photobiol Sci. 2012 Dec;11(12):1848-54). Pg 13, line 37 - 39, why not have staff instruct patrons to do the same with exposures to the sun? Commonly, a more dominant source of UV (risk) than sunbeds - Pg 14, lines 5-10, as is the case here, considering risk from sunbeds notoriously without proper reference to sun exposures	Text on vitamin D induction by sunbeds has been added in the main text. This is a risk management issue. No changes to the Opinion are required in relation to the comment.
34	Dr. Richarz Frank, IEC TC61 / MT16 'Biological effects of optical radiation', MT16@richarz-consulting.de, Germany	4. APPROACH TO THE DEVELOPMENT OF THIS OPINION	sccp_o_031b.pdf Papas_Poster_June_2011_Montreal.pdf	page 16 line 14 "SCCP had clearly indicated that presence of freckles is no independent risk factor to recommend not to use a sunbed. The risk factors are: (i) skin photo-types I and skin photo-type II and the presence of freckles (ii) atypical and/or multiple moles (iii) a family history of melanoma" page 16 line 26 - 29 The IARC numbers are estimates from studies around the world. These especially include a high number of studies from countries with high portions of people with a emigrational background (especially in the USA and in Australia), who have not been adopted to the environment and the high natural UV output of their living area. page 16 line 26 - 29 The report misses to indicate which studies adjust for sun exposure and which don't. Some studies misses the question whether sunbed users are getting themselves exposed to natural sunlight with a higher rate than the controls. Haluza 2016 showed that	Text of the Opinion is correct. No changes to the Opinion are required in relation to the comment. IARC was cited correctly. No changes to the Opinion are required in relation to the comment. IARC was cited correctly.

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
				tanning bed users are showing a 2 times higher prevalence to sun exposure than the rest of the population. Therefore a relative risk of 1.15 shows a protection against melanoma if the dose related risk increase is correct. page 16 line 26 - 29 Ezzedine 2007 showed indoor tanners are also regular sunbathers and moreover have more behavioral risk factors for cancer, such as smoking. page 16 line 26 - 29 "2-3% of the European population are treated by UV therapy for skin diseases like psoriasis. These additional exposure path was not extracted by none of the cited studies. Furthermore Papas 2011 showed a separation of the meta studies used in the IARC report into home units, professional sunbed use and medical equipment use with the by far highest OR at medical equipment." page 16 line 26 - 29 Colantino 2014 has given corrected values with focus on Europe. He found a small association for melanoma between "ever" versus "never" indoor tanning of (RR, 1.1, 95%; CI, 0.98-1.24) and if first exposure took place at a young age of (RR=1.35, 95% CI 0.99, 1.84). Scientific paper is to big to upload and will be submitted by mail to the SCENIHR office. page 16 line 41 - 46 The ECs questions were related to "all" instead of "a" health effect. It was not the question to purely investigate on adverse health effects.	No changes to the Opinion are required in relation to the comment.

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
35	Lipman Gary, The Sunbed Association, garylipman.tsa@gmail.com, United Kingdom	4. APPROACH TO THE DEVELOPMENT OF THIS OPINION	 EJC_Multicentre_epidemiological_study_o  Highlighted_Leeds_Report_-_Intl_Journal_  Boniol_et_al-2013-International_Journal_c  Elliott_et_al-2013_Response_to_Boniol-Ir	Page 16, lines 18-19: Recognising latency period, that can be 20-30 years, I therefore must ask the SCENIHR how they can rely on research results often used for relating sunbed use and melanoma. Page 16, lines 31-32: It seems that the SCENIHR have chosen to ignore the two significant studies – one from the Luxembourg Health Institute and one from the Leeds Cancer Research Institute - that sought to prove a causal relationship between sunbed use and melanoma, and neither of them could. The Luxembourg research states 'In conclusion, sunbed and sun exposure were not found to be significant risk factors for melanoma in this case–control study performed in five European countries'. Jean- Francois Dore and Marie-Christine Chignol, members of the SCENIHR, were two of the authors of this research, so are entirely familiar with its conclusion as a result. The conclusion of the Leeds report states: 'In summary, we have found no evidence for sunbed use as a risk factor for melanoma'.	Text of the Opinion is correct. The studies were carefully evaluated. No change in the Opinion is needed.
36	de Gruijl Frank, representing none, degruijl@planet.nl, Netherlands	4. APPROACH TO THE DEVELOPMENT OF THIS OPINION		4.2 - pg 16, line 24 -25, correction for confounders was variable among studies especially where sun exposure is concerned; questionable whether adequate proxies of (sun) exposure was used, especially where melanoma and basal cell carcinomas are concerned. Proper analyses of covariances were not dealt with in any of the studies, while sunbed users are most likely to be sunbathers, where remembrance of sunbed exposures is probably far more reliable than of sun exposures. Hence, using weak epidemiological studies as input will necessarily result in weak meta-analyses. 4.3 - pg 16, line 37, risks? Apparently, not only risk of skin cancer: experimental studies in human and in cell cultures would probably concern DNA damage and mutations (risk?), not easily equated to genuine skin cancer risk. It is advisable to use the term "risk" for genuine risk and not for a variety of (adverse) biological endpoints. - pg 17, line 46, please	IARC was cited correctly. No changes to the Opinion are required in relation to the comment.

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
				specify "shape of the effect"; is "nature/severity of the effect" meant? - pg 17, line 20, "coherent evidence"? Meaning "consistent evidence"? And "from human studies .." I assume. - pg 17, line 21, "in absence of conflicting evidence from other lines of evidence"? terrible sentence, "other lines of evidence" or other kinds of studies? And are mere observational humans studies that are consistent sufficient? (overemphasis on epidermiology?). No supportive evidence from other studies required?	Text was changed for clarity.
37	SFRP - Société française de radioprotection - section Rayonnements non ionisants, section.rni.sfrp@gmail.com, France	5. TECHNICAL BACKGROUND		Comments on the SCENIHR document « Biological effects of UVR relevant… particular reference to sunbeds for cosmetic purposes », J.P. CESARINI (on behalf of Section Rayonnements non ionisants SFRP / Non ionizing radiation section SFRP) In general le document is perfectly written, extremely complete to evaluate the risks presented by artificial UVR use for cosmetic purposes. I have very few critics concerning the test. 1) In the chapter 5. TECHNICAL BACKGROUND, there is a number of inexact assessments and the authors seem to be confused using different terms. In sunbeds, two types of mercury lamps exist: the low-pressure mercury fluorescent tubes and the high-pressure mercury tubes with specific filters to produce the required spectrum. The spectrum of the first type is obtained by variations of the powder composition inside the discharge tube. The spectrum of the second type is obtained by the composition of the glass filter. Both types may be used separately or in combination in some sunbeds. It is important that the distinction has to be made since risks of accidents are not identical. For the low-pressure tubes, aging of the lamp (300 hours) contributes to a decrease of the emission and, as a consequence, either inefficacity or prolonging the time of exposure. For the high-	Informative comment. The text has been changed for clarity.

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
				pressure tube, the major risk is a broken filter since very high temperature is generated by the discharge. A broken filter lets unfiltered emission to pass through (UVA, B and C). 2) This is a general comment. There are several publications, particularly in England concerning the frequency of accidents occurring during the practice of artificial UV tanning. In the years 1990, more than 20% of users have suffered of severe erythema, burning and eye discomfort. I did not find reference to this important paper which can be easily found by the authors.	
38	Khazova Marina, Public Health England, marina.khazova@phe.gov.uk, United Kingdom	5. TECHNICAL BACKGROUND		Section 5.1 Page 19, lines 9-11. The most common definition is that published by the International Commission on Illumination (CIE), which defines UVC from 280 nm to 100 nm. CIE also represents the UV zones as UV-A, UV-B and UV-C (ILV: International Lighting Vocabulary. Standard CIE S 017/E:2011). Section 5.2 p19, lines 18-21 and 32-35. This technical information is incorrect for solar UVR; see World Meteorological Organization GAW publications 125 and 164: 125 Instruments to measure solar ultraviolet radiation Part 1: Spectral instruments; 164 Instruments to measure solar ultraviolet radiation Part 2: Broadband instruments measuring erythemally weighted solar irradiance. p19, line 26. Wiener's law should be Wien's law. p19, lines 37-40. Incorrect statement. Spectral irradiance is NOT spectrally flat in UVA and it varies by more than an order of magnitude from 315 nm to 400nm. p19, lines 45-46. Incorrect statement. The primary emission of low pressure sunbed lamps is from mercury, with a few very strong peaks in UVC and UVB, where the quantum efficiency to excite phosphor is much higher than from UVA emission.	The text has been changed accordingly. The text about solar UVR measurements has been changed accordingly. The text has been corrected. No change in the text is required. No change in the text is required.

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
				p20, lines 1-6 and 11-17. Very unclear sentences, needs re-wording. p20, Figure 2 and caption to Fig.2. The reference to 2003 data from ssk.de web-site is no available any longer; reference is not in References; it is not clear at all what is presented on this graph and what it is supposed to illustrate. UVC-emitting lamps are not compliant with EN 60335-2-27:2013 standard. There is a need to include data for the lamps in modern and non-medical sunbeds. p21, Table 2. This Table is not identical to Table BB.3 of the EN 60335-2-27:2013 standard. Section 5.3 p.21, lines 12-23. Interpretation of technical "regulations" (EN 60335-2-27:2013 standard) mixes up requirements of superseded and corrected earlier versions of this standard. p22, lines 10-21. Comparison of emission limits of the equipment required by the EN standard don't make the important distinction between erythema spectral weighting used in the standard and S(λ) spectral weighting of the ICNIRP exposure limits (they are not identical); it is not erythema that is considered as biological end-point in the ICNIRP limits. Furthermore, Directive 2004/25/EC is applicable to occupational exposures only; members of the public are not covered by this Directive and the corresponding national legislation. p.25, lines 7-8. Incorrect statement: high pressure Xe lamps are used in the overwhelming majority of sunbeds, at least – as face lamps.	No change in the text is required. The reference exists in the footnote. The correct URL has been inserted in the text. Data from manufacturers are not available in the public domain, therefore the data cited are used as an example. The table has been modified. Nowhere in the text is it written that limits are identical. The note about occupational exposure has been added in the text for clarity. The text has been changed for clarity.

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
39	Baldermann Cornelia, German federal Office for radiation Protection, cbaldermann@bfs.de, Germany	5.1 Physical characteristics of UVR		Page 18 / line number 11 – 14 / Figure 1: There are several, overlapping and not clearly defined subdivisions for the UV range. In most of them UV-C includes the wavelength range between 100nm and 280nm, and not a range of 200 nm to 280 nm as shown in Figure 1. Mostly vacuum UV is understood as part of UV-C. The origin of the figure is the website of a magazine for nails professionals. It is recommended to use a figure which has a scientific background, e.g. the wavelength ranges of UV-C, UV-B and UV-A as shown in the "International Lightning Vocabulary" of the International Commission on Illumination CIE (CIE 1987). Page 19 / line number 2-11: The most common definitions divide the UV spectrum into: UVA (400 nm – 315 nm), UVB (315 nm – 280 nm), UVC (280 nm – 100 nm). It is recommended to use this subdivision of the UV range.	The text has been changed for clarity. The text has been changed for clarity.
40	Lipman Gary, The Sunbed Association, garylipman.tsa@gmail.com, United Kingdom	5.1 Physical characteristics of UVR		Page 19, line 5: As such, the committee must limit evidence and research that only relates to UV tanning devices for cosmetic purposes in a professional tanning salon and not include home use sunbeds.	The SCHEER disagrees. No change in the text is required.

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
41	Baldermann Cornelia, German Federal Office for Radiation Protection, cbaldermann@bfs.de, Germany	5.2 UVR spectra		Page 20 / line number 7 - 8: "In general, the UVR spectra of artificial sources differ considerably from natural sunlight, in particular with considerable higher irradiance in the UV range." should be corrected to: "In general, the UVR spectra of artificial sources differ considerably from natural sunlight, in particular with considerable higher irradiance in the UVA range." Page 20 / line number 11 – page 21 / line number 2: In figure 2, the described emission lines (line number 15 – 17) are not visible. It should be pointed out if these emission lines are typical for mercury fluorescent lamps independent of that what is shown in figure 2. In figure 2 there are German phrases which should be translated into English. Page 21 / line number 3 - 4: In footnote 7, version EN 60335-2-27:2010 is mentioned. But the described specification is also given in EN 60335-2-27:2009 and EN 60335-2-27:2013. Page 21 / line number 6 - 9: Table 2 shows the UV Type classes, their wavelength, UVR effective irradiance, and spectral characteristic. Regarding UV type 4, the wavelength range 250 nm to 320 nm and the UVR effective irradiance are not shown. In the standard EN 60335-2-27:2013, the spectral characteristic is not shown. The mentioned spectral characteristic of UV type 3 and 4 are not understandable. In UV Type 3 there is an equal part of UVB and UVA. In which context can be said that UVA and UVB are limited? There is also to mention, that by using the table from this standard UV type 3 devices are defined as less than 150 mW/m² and not less than or equal 150 mW/m² for UVA and UVB. In this standard it is also specified for UV Type 4 the UVR effective irradiance as more than or equal 150 mW/m2 in UVB range and less than 150 mW/m2 in UVA range. Page 22 / line number 7: EN 60335-2-27:2013 sets out that the UV emitting appliances are not allowed to exceed a maximal erythemal irradiation of 0.3 W/m2, not 0.7 W/m2 (700 mW/m2). The value "700 mW/m2" can be found in the consolidated version of the international standard IEC 60335-2-27 Ed 5.2 2015-04. Page 22 / line number 8: A dash lacks in front of the sentence "a totally effective shortwave irradiance for Wavelengths 200-280nm not exceeding 3 mW/m².".	The text of the Opinion was corrected. The information is given in English in the caption to Figure 1. The text of the Opinion has been amended. The text of the Opinion has been amended. The text of the Opinion has been corrected.

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
42	Imre Krisztian, Lighttech Lamp Technology LTD., imrek@lighttech.hu, Hungary	5.2 UVR spectra	 1.pptx	I'd like to comment on line number 15. The modern low pressure tanning lamps which been developed since 2007 do not emit UVC radiation. The special combination of the glass and the applied phosphor make sure that no any UVC radiation can come through. Furthermore in the equipment special filter glasses and acrylics provide even more safe environment for the persons.	This part of the Opinion refers to UV lamps technology in general. No changes to the Opinion are required in relation to the comment.
43	Imre Krisztian, Lighttech Lamp Technology Ltd, imrek@lighttech.hu, Hungary	5.2 UVR spectra	 2.pptx	Line number 43. The report states that the sunbeds and sunlamps have not evolved from the 1990s. I definitely disagree with this statement. The manufacturers developed new lamps and new sunbeds after 2007 in order to meet the 0.3W/m2 legislation in Europe. New lamp types been implemented with limited UVB output. Furthermore all the sunbed manufacturers developed newer filters, acrylics and other components over the years. The author might meant that no UV LED were developed and the industry still using the fluorescent lamp technology but let me point out that the UV LEDs are still very expensive, inefficient and have short life compared to the LEDs which used in general lighting as widespread. So the traditional fluorescent technology will stay as long as the LED chip industry will not come up new solutions for the above mentioned problems.	Text of the Opinion is correct. No changes to the Opinion are required in relation to the comment.
44	Dr. Richarz Frank, IEC TC61 / MT16 'Biological effects of optical radiation', mt16@richarz-consulting.de, Germany	5.2 UVR spectra	 EN60335-2-27_2013_e.pdf	page 20 figure 2 "SSK 2003 is not in the reference list There is no such publication on the SSK.de website" page 21 line 2 The origin of this data is unclear and a sunbed with this spectrum is not legal in a sunbed in Europe. SCENIHR should give a better explanation of this figure. page 21 line 6 - 9 "Table 2 shows wrong relation signs and miss two information: UV type 4 250 - 320 nm ≥150 Total effective irradiance should not exceed 0,3 W/m2 Better	The text has been changed.

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
				copy the table BB.3 from the standard"	
45	Lipman Gary, The Sunbed Association, garylipman.tsa@gmail.com, United Kingdom	5.2 UVR spectra		Page 19, lines 30-31: The sentence 'However, this may not be justified in artificial UV sources' is not justified and asserts that there is a possibility that UVC is emitted from sunbeds. This is wholly untrue and I ask the SCENIHR to either substantiate this stance or remove the sentence. Page 19, lines 42-43: It is incorrect to state that professional sunbeds have not changed since the 1990s. Advances in technology have improved the overall safety of the devices and lamp technology has evolved according to the latest medical advice. Indeed, the most significant change was made in July 2007 when all sunbeds supplied new or traded second-hand in Europe, had to comply with EN 60335-2-27 which requires all sunbeds to have a maximum UV emission level of 0.3W/m2. Page 20, line 7: A photon is a photon and there is no difference between sunshine that reaches the earth's surface and the output of a sunbed. There is no such thing as artificial UV to the skin as the reaction is the same. Page 21, line 2: The words 'UVC is present' are not justified and asserts that there is a possibility that UVC is emitted from sunbeds. This is wholly untrue and I ask the SCENIHR to either substantiate this stance or remove these words. Page 21, line 18: The words 'UVC radiation' are not justified and asserts that there is a possibility that UVC is emitted from sunbeds. This is wholly untrue and I ask the SCENIHR to either substantiate this stance or remove these words.	The text of the Opinion is correct. No changes to the Opinion are required in relation to the comment.
46	Nilsen Lill Tove, Norwegian Radiation Protection Authority, Lill.Tove.Nilsen@nrpa.no, Norway	5.2 UVR spectra		Page 20, line 20-22: The figure text is unclear regarding which figures and/or spectra that show UV type 1 and 2 and which show UV type 3 and 4, respectively.	No changes to the Opinion are required in relation to the comment.

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
47	de Gruijl Frank, representing none, degruijl@planet.nl, Netherlands	5.2 UVR spectra		pg 19, line 18 -19. A monochromator is normally not considered to be "a filter", but an optical device that employs a dispersive element (grating or prism) to separate and select wavelengths from an incident spectrum. An optical filter is a device that selectively transmits a certain wavelength range, e,g, using a sheet of glass with absorbing dyes for a broad range or with an interference coating for a narrow range. (These devices are, of course, not only used for measurements but also for irradiation with specific wavelengths). pg 19, lines 20 – 21, these are rather abstract descriptions (what is the intended audience?) perhaps give examples: thermopile, pyroeletric detectors detecting heat/temperature increase from radiation absorption or high-voltage phototubes, diodes converting radiation (photons) to electrical current. pg 19, line 26; "At solar"? pg 19, line 30: UVC is not detectable at the Earth's surface (in fact the most sensitive radiospectrometers detect nothing - but noise - below 290 nm). pg 19, line 31: "justified"? or "may not be true for .." pg 19, lines 32; "multifrequency imaging detectors"? What are those? Monochromators equipped with diode array detectors of CCDs? No real "imaging" involved pg 19, lines 34 – 36; awkward description ("impact of needed spectral filters") of the problem of measuring the steep cut-off of the solar spectrum in the UVB range; there is, however, no real problem in measuring UVA, as stated in line 38 ("less critical"? really "much easier"). The steep roll-off of the solar spectrum in the UVB range is difficult to measure properly (narrow bandwidth/high wavelength resolution/ required in order not to lessen the steepness, and extra filtering to block leakage/higher harmonics/ from high power at higher wavelengths)	The text has been changed. The text has been changed. The text of the Opinion is correct. No change in the text is required. Text of the Opinion is correct. No changes to the Opinion are required in relation to the comment. The text has been changed. The text has been changed for clarity. Text of the Opinion is correct. No change in the Opinion is needed. No change in the text is needed. The text was changed for clarity.

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
				pg 19, 38 – 39: ".. because of a higher radiant power and more gradual increase in power over this wavelength range" – the spectrum is not "flat" over this wavelength range (although it may almost look like that on a logarithmic scale). pg 19, line 43: this is not true UVA/UVB ratios changed. pg 20, line 1: not quite correct, modern sunlamps are more UVA enriched than midday Summer Sun to achieve a more effective tanning. pg 20, line 16, emission line at 302 nm not worth mentioning? pg 20, line 22, strike out "almost" pg 21, line 2: "worst case" of what? "left corner"? top or bottom? "the figure"? Figure 2?	No change in the text is needed. Text of the Opinion has been corrected for clarity.
48	No personal data provided	5.3 Regulations and standards		page 22 line number 12 "... persons are excluded, the guidelines of ICNIRP11 and the Directive 2004/25/EC specify ...: 1. the footnote no. 11 is not shown at the bottom of the page 2. the correct numbering of the Directive should probably be 2006/25/EC, and not 2004/25/EC	Text of the Opinion corrected. Text of the Opinion corrected.

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
49	Zeyen Thierry, European Glaucoma Society Foundation, thierry.zeyen@telenet.be, Belgium	5.3 Regulations and standards	 NorthernIrelandSunbedsBill.pdf	line 36 Many countries have followed the example of France and begin to bring in the mandatory wear of protective eyewear. However the European Glaucoma Society Foundation believes that mandatory provision of protective eyewear with no specifications as to what is suitable or protective makes the mandatory provision meaningless. The term is very broad and it is open for interpretation. Standards in this area may be needed including what structures can realistically monitor compliance with the eyewear usage. Some countries like Northern Ireland have opted for to prescribe standards for such eyewear through subordinate legislation rather than on their main Bill; the reason being that as eyewear design changes standards may require updating in parallel. We attach reference. However basic structural requirements e.g. 'eyewear with side protection' can be added to the mandatory clauses. A better approach would be to identify and promote good practices across the European Union and the precise specifications which are proven to give the best protection for the eyes of the sun bed users.	No change in the text is needed.
50	Gilroy Steven, Joint Canadian Tanning Association JCTAin, info@TanCanada.org, Canada	5.3 Regulations and standards	 Baggerly_2015_-_Sunlight_and_Vitamin_D  Lindqvist_2014_-_Avoidance_of_sun_expo	In Canada, the following are the provincial and territory restrictions for minors: Newfoundland/Labrador - under 19 Prince Edward Island – under 18 New Brunswick – under 19 Nova Scotia – under 19 Quebec – under 18 Ontario – under 18 – provisions for a medical exemption Manitoba – under 18 – medical exemption Saskatchewan – under 18 – medical exemption Alberta – pending under 18 – medical exemption British Columbia – under 18 – medical exemption Northwest Territories – under 19 Yukon – no regulations Nunavut – no regulations Page 24 – Line 16 This document reports "There is no difference in the biological (and general health) effects induced by UV radiation in respect to their origin, the natural solar UV or artificial UV from e.g. tanning devices.	No change in the text is needed.

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
				UV-radiation (UVA, UVB, UVC) from the sun or from tanning devices has been classified by IARC (2009) as carcinogenic to humans (class 1, IARC). (Page 60, *. Opinion, Line 15-18).” The sun and solar UV has been included in IARC Group 1 since 1992. UV from sun or sunbeds is the same and has the same risks and the same benefits. Baggerly 2015 stated: Increased sun exposure based on latitude, has been associated with protection from several different types of cancer, type 1 diabetes, multiple sclerosis and other diseases. Lindqvist 2014 found that the use of sunbeds reduces all-cause mortality risk by 33%. This large cohort study followed 29,518 Swedish women for 20+ years. The study found that women who used sunbeds and sunbathed during summer or on holiday, had a greatly reduced risk for all-cause mortality. The study concluded: The mortality rate amongst avoiders of sun exposure was approximately twofold higher compared with the highest sun exposure group, resulting in excess mortality with a population attributable risk of 3%. The results of this study provide observational evidence that avoiding sun exposure is a risk factor for all-cause mortality. Following sun exposure advice that is very restrictive in countries with low solar intensity might in fact be harmful to women’s health.	These issues were dealt with in the main text.
51	No personal data provided	5.3 Regulations and standards		§ 5.3- Regulations and standards, Regulation of sunbed use, p22, lines 37-38 Comment: It is written “This decree was reinforced in 2013 (Decree n°38 2013-1261 of 27 December 2013)”. You could complete with examples: the maximum annual dose shall not exceed 10 kJ/m² (previously 15 kJ/m²) and the initial inspection of tanning equipment must now be carried out before making it available to the public (previously there was only a technical control every 2 years).	No change in the Opinion is needed.

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
52	No personal data provided	5.3 Regulations and standards		§ 5.3- Regulations and standards, Regulation of sunbed use, p22 Comment: Medical Device (MD) are defined in the Council Directive 93/42/EEC of 14 June 1993 (medical devices are used to diagnose, prevent, monitor, treat, etc.). Products can also be medical devices if a medical claim is being made by the manufacturer for the device, although these products are usually not. If potentially beneficial effects of sunbed use are mentioned by the industry (cf. discussion on vitamin D §7), then, such devices should be considered as medical devices (Class IIa). Therefore, they should respect the specific regulation and be submitted to authorization. Clinical trials should be done also in order to support a reasonable assurance of safety and effectiveness for the marketing application… The Council Directive also stipulates that medical devices emitting radiations should be designed and manufactured in such a way that radiation exposures must be kept as low as reasonably acceptable for the intended purpose. Therefore, if tanning booths were considered equipment to overcome the deficit of vitamin D, they should not be equipped with UVA lamps and should only deliver UVB doses much weaker than now, just right for production of vitamin D. This would most likely lead to devices that would not induce a tan to users.	Informative comment. No change in the Opinion is needed. The SCHEER disagrees with the comment.

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
53	No personal data provided	5.3 Regulations and standards		§ 5.3- Efficacy of sunbed regulations, p22, lines 37-38 Comment: There are some indications that restrictions in sunbed use may succeed in reducing prevalence of use and, eventually, associated risks. On the contrary, restrictions in sunbed use are not totally efficient. For example, despite a legal ban, minors have used sunbeds: 3.5 % of minors (15-17 years old) in France in 2010 [Baromètre cancer 2010] and 8.7 % of minors (14-17 years old) in Germany in 2012 [Diehl et al., 2013]. Moreover, compared to adults, minors are more likely to use unsupervised sunbeds (in fitness center, swimming pool/sauna) and are less frequently advised by service personnel [Diehl et al., 2013]. References: Diehl et al. (2013). Use of sunbeds by minors despite a legal regulation: extent, characteristics, and reasons. J Public Health. Beck F, Gautier A (dir.). Baromètre cancer 2010. Saint-Denis : Inpes, 2011.	Informative comment. No change in the Opinion is needed.

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
54	Dr. Richarz Frank, IEC TC61 / MT16 'Biological effects of optical radiation', mt16@richarz-consulting.de, Germany	5.3 Regulations and standards	 11-Autier-UVA-sunbeds-sunscreens-melan	page 22 line 4 - 7 The content of these lines is not part of EN 60335-2-27 and needs to be deleted. It is content from IEC 60335-2-27 which got a common modification by the European Standardization body CENELEC. These lines are therefore in contradiction to the content of the European version. page 22 lines 30-34 "Natural sunlight in Europe contains between 0 and 4% UVB depending on the date of the year, time of the day and especially latitude. Regulations such as in France have led to sunbeds which are in the lower range of the UVB percentage, since higher (more noonish, more vitamin D producing) UVB percentage was forbidden by law." page 24 line 11 The absolute numbers of the increase in Iceland are too very small. Therefore the probability of the contribution of sunbeds to the increase of melanoma should be assessed. page 24 line 11 It should be mentioned that the studies in Iceland gave evidence of two types of melanoma. (Autier 2011) One with high incidence rate and maybe UVR related, but non-aggressive and a second one, more age related and more aggressive. This would explain the stable mortality of melanoma while the incidences are exponentially increasing.	The text has been modified for clarity. Informative comment. No change in the Opinion is needed. Informative comment. No change in the Opinion is needed. Informative comment. No change in the Opinion is needed.

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
55	Lipman Gary, The Sunbed Association, garylipman.tsa@gmail.com, United Kingdom	5.3 Regulations and standards		Page 23, lines 39-40: The SCENIHR report states 'There are some indications that restrictions in sunbed use may succeed in reducing prevalence and use and eventually associated risks'. I have searched for such indications to no avail. Can the SCENIHR please provide the source of such indications. Moreover, the ban on professional tanning salons in Australia has made the situation far worse. As a result of the ban, the professional sunbeds were purchased by home users. In such circumstances there are no professionally trained members of staff to ensure best practice. Indeed, some members of the public are operating a tanning business from their home. This is the unintended consequence of a ban on sunbed salons. Page 24, lines 1-4: As the vast majority of the European industry only allows customers aged 18 and over to use sunbeds, this information is irrelevant.	The text is correct. The references are provided in the text. No change in the Opinion is needed. No change in the Opinion is needed.

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
56	Lipman Gary, The Sunbed Association, garylipman.tsa@gmail.com, United Kingdom	5.3 Regulations and standards	 APPGoS_Sunbed_Inquiry_Report_2014-Fir	Page 2 of submission for this section: Page 23, line 25: The Sunbed Association (TSA) was a contributor to the APPGOS (2014) enquiry. We demonstrated the procrastination by Government and NGOs in implementing support for compliance that can only be considered deliberate indifference Local Authorities have existing powers to implement, and Government has a responsibility to direct them to do so. Compliance has been very successful in many European countries where the regulatory bodies have worked closely with the local sunbed association. In the Netherlands for example, the authorities and anti-cancer advocates work hand in hand with their sunbed association and as a result, nearly 100% of salons there are fully compliant without the need for regulations. It has been through education and lobbying from sunbed suppliers, that salons have successfully embraced the European Standard on emission levels. The Chairman of the APPGOS remarked in his summary of the day that the APPGOS must support TSA in its efforts as our Code of Practice and training impressed and reassured the committee.	No change in the Opinion is needed.
57	Petri Aspasia, Greek Atomic Energy Commission (EEAE), aspasia.petri@eaae.gr, Greece	5.3 Regulations and standards		page 22, line 7: 300 mW/m2	The text has been modified for clarity.

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
58	Nilsen Lill Tove, Norwegian Radiation Protection Authority, Lill.Tove.Nilsen@nrpa.no, Norway	5.3 Regulations and standards		Page 22, line 7: Line 7 should be deleted, as it is not correct that the EN 60335-2-27:2013 gives a limitation of 700 mW/m² for the wavelengths 250-400 nm for commercial use. The limit of 300 mW/m² is the valid upper limit. Only the international sunbed standard IEC 60335-2-27: 2012 gives the limit of 700 mW/m² for commercial use. It is not allowed to copy and distribute the whole or parts of the European standard, EN 60335 2-27. It is therefore not attached.	The text has been changed for clarity.
59	Nilsen Lill Tove, Norwegian Radiation Protection Authority, Lill.Tove.Nilsen@nrpa.no, Norway	5.3 Regulations and standards	 Nilsen2008_PP_Trends_UVirradTanningDe  NorwegianRadiationProtectionRegulations.	Page 22, line 30: France was not the first country to publish a decree to control the commercial use of tanning devices, but probably the first to require mandatory attendance. Taken from Nilsen et al. Trends in UV Irradiance of tanning Devices in Norway: 1982-2005. Photochem Photobiol, 2008, 84:1100-1108, with comments: Norway and Sweden were among the first countries to implement national regulations for indoor tanning devices, i.e., in 1982 and 1983, respectively. In Norway, all models were required to have an approval from the Norwegian Radiation Protection Authority (NRPA) before being sold, used or advertised in Norway. The approval was based on UV measurements from accepted laboratories. In addition, the regulations included requirements for user instructions and labeling. The Norwegian and Swedish regulation authorities agreed upon radiation limits, being around 4 and 2–2.5 times the UVA and ACGIH-weighted UVB values, respectively, for typical clear sky summer sun irradiances at noon at 60oN. These limits were approximately the same as the requirements for UV type 3 sunbeds, and the Nordic radiation protection authorities were active when the sunbed classification system were formed and then published in 1987 (Gunnar Saxebøl, NRPA, Director Department for Radiation Protection and Nuclear Safety). The Norwegian, Swedish and Finnish regulations allowed only UV type 3 sunbeds for cosmetic purposes. The Norwegian regulations were reinforced in 2004 and 2010 (Regulations on Radiation Protection and Use of Radiation, FOR-2010-29-1380:	The text has been changed accordingly.

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
				http://www.nrpa.no/dav/a3e3933033.pdf)	
60	Nilsen Lill Tove, Norwegian Radiation Protection Authority, Lill.Tove.Nilsen@nrpa.no, Norway	5.3 Regulations and standards		Page 23, line 3-11: Regarding national legislation, the Member States should have followed the European Standard 60335-2-27 on the 300mW/m² limit. The Norwegian regulations regarding Radiation Protection and use of Radiation have specifically included this standard, and thereby made it mandatory. In addition to not following the radiation limit as given by the SCCP Opinion, many member States do not restrict sunbed use for people with known risk factors for skin cancer (skin phototypes I and II and the presence of freckles, atypical and/or multiple moles, a family history of melanoma).	Informative comment. No change in the Opinion is needed.
61	Nilsen Lill Tove, Norwegian Radiation Protection Authority, Lill.Tove.Nilsen@nrpa.no, Norway	5.3 Regulations and standards	 Nilsen2016_Ultraviolet_exposure_from_in	Page 23, line 25: Poor compliance is shown for several countries in a recent systematic review regarding measurements of tanning beds by Nilsen et al. (UV exposure from indoor tanning devices: A systematic review. Br J Dermatol. 2016 Jan 7. doi: 10.1111/bjd.14388). It could also be mentioned that the epidemiological studies "measure" the effects on skin cancers from a market of both compliant and non-compliant sunbeds and sun-studios.	The reference has been included in the Opinion.
62	de Gruijl Frank, representing none, degruijl@planet.nl, Netherlands	5.3 Regulations and standards		pg 22, line 1, "CIE erythema action spectrum", presumably pg 22, line 6, "useable in the household"? meaning: "intended for home application"? pg 22, line 10: strike out "time >weight< weighted average(TWA)" as units below do not correspond with a time-averaged exposure (which comes down to an exposure rate) pg 22, line 24, which of course is really futile as people exposed themselves regularly to higher doses in their leisure time - they won't take notice of any instruction to stop doing this. Such a recommendation for the general	The text has been corrected. The text has been corrected. No change in the Opinion is needed. This is outside the scope of SCHEER. No change in the Opinion is needed.

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
				population should be put in context! pg 23, line 2, how useful is this considering free sunbathing by youngsters? Is success measured? Or is there compensatory behavior? Again: what about the context? Any information available? pg 23, lines 30 – 37, it is rather striking that these countries banning solaria have high levels of ambient UV radiation to which tanners will have unlimited easy access. Moreover, solaria use was low in Australia anyway. In this context the measure would appear symbolic and futile, scientifically illogical. Any information on the (scientific) rational? pg 23 line 41, significant change? pg 23 line 45, how serious then is this observation? Should it be here in a document intended to be authorative? pg 24, line 4, "system access"? meaning? pg 24, line 6 -8, this is a somewhat strange conclusion! Legislation should be complied with and therefore effective. If it would not be, the legislation would be completely futile, useless - no compliance would just signify failure and administrative incompetence (not knowing what works and what does not). pg 24, lines 10 – 15, here the authors overstep the power of the observational, ecological data from Iceland. They impose causality between heath campaigns, melanoma incidences, and a decrease in solaria; scientifically unwarranted, especially without a word of caution. Moreover, it is a rather dubious view: increased melanoma incidence (in young women on extremities) is "switch on and especially off" almost immediately in parallel to number of sun tanning studios. Ie no lasting effect, where one would expect a lasting effect of a cancer-causing agent.	This is outside the scope of SCHEER. No change in the Opinion is needed. This is outside the scope of SCHEER. No change in the Opinion is needed. This is a matter of view. No change in the Opinion is needed. It is a publication from the peer-reviewed literature. No change in the text is required.

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
				Therefore, these are not likely to be genuine malignant melanoma (activated nevi? or more physical awareness among sunbed users). Moreover, no effect on mortality was discernible. Considering full context and being more careful and critical about the implications of these data is called for! pg 24, line 16, what is the substantiation of this view of ANSES that sunbeds have no beneficial effects? Quoting it without comment raises the impression that the authors subscribe to this dubious view. Like the sun, sunbeds - at least through raising vitamin D levels – contribute to beneficial health effects. And if a slight increase in melanoma risk associated with sunbeds is to be considered of a causal nature, one would expect a similar conclusion about beneficial health effects associated with sun/sunbed exposures. pg 24, lines 19 – 22, again without comments from the authors, the impression is raised that these recommendations are sound and fully justified. Proper context is required here: how important would such measures be in the light of free sunbathing and sun holidays? Aside from the fact that it would be a poorly justified form of paternalism over citizens who choose to tan by using a sunbed instead or in addition to sun bathing - where the latter is probably more risk-bearing, certainly on a population scale.	The text was changed for clarity The authors' report is cited here. No change in the text is required. We do not see any causality implied. The authors themselves reported that sunbeds "likely played an important role in affecting the melanoma incidence trends" which justifies the wording in the Opinion. No change is required in the text. This is a risk management issue which is not in the scope of SCHEER. No change in the Opinion is needed. This is outside the scope of SCHEER. No change in the Opinion is needed.

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
63	Lipman Gary, The Sunbed Association, garylipman.tsa@gmail.com, United Kingdom	5.3 Regulations and standards	 APPGoS_Sunbed_Inquiry_Report_2014-Fir	This submission replaces previous 2 separate submissions for 5.3 Regulations and Standards from Gary Lipman. The other 2 recalled were submitted on Monday 25th April. Page 23, line 25: The Sunbed Association (TSA) was a contributor to the All Party Parliamentry Group On Skin (APPGOS) (2014) enquiry. We demonstrated the procrastination by Government and NGOs in implementing support for compliance that can only be considered deliberate indifference Local Authorities have existing powers to implement, and Government has a responsibility to direct them to do so. Compliance has been very successful in many European countries where the regulatory bodies have worked closely with the local sunbed association. In the Netherlands for example, the authorities and anti-cancer advocates work hand in hand with their sunbed association and as a result, a high proportion of salons there are fully compliant without the need for regulations. It has been through education and lobbying from sunbed suppliers, that salons have successfully embraced the European Standard on emission levels. The Chairman of the APPGOS remarked in his summary of the day that the APPGOS must support TSA in its efforts as our Code of Practice and training impressed and reassured the committee. Page 23, lines 39-40: The SCENIHR report states 'There are some indications that restrictions in sunbed use may succeed in reducing prevalence and use and eventually associated risks'. I have searched for such indications to no avail. Can the SCENIHR please provide the source of such indications. Moreover, the ban on professional tanning salons in Australia has made the situation far worse. As a result of the ban, the professional sunbeds were purchased by home users. In such circumstances there are no professionally trained members of staff to ensure best practice. Indeed, some members of the public are operating a tanning business from their home. This is the unintended consequence of a ban on sunbed salons. Page 24, lines 1-4: As the vast majority of the European industry only allows customers aged 18 and over to use sunbeds, this information is irrelevant.	Informative comment. No change in the Opinion is needed.

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
64	Olofsson Katarina, Swedish National Electrical Safety Board/Swedish Radiation Safety Authority, katarina.olofsson@elsakerhetsverket.se, Sweden	5.3 Regulations and standards		Please be informed that the preliminary SCENIHR-document contains an error concerning the EN-standard 60335-2-27:2013. The SCENIHR-document incorrectly states that the maximum erythemal irradiance of commercial sunbeds is 700 mW/m2 (0,7 W/m2) - and not 0,3 W/m2 as is the correct common Cenelec-modification from the IEC. The EN-limit 0,3 W/m2 (= "tropical sun", UV-index 12) was recommended by the SCCP. In the SCENIHR-document, section 5.3, on page 21-22 "Regulations and standards" you find the following text passage (lines 22-23, 1-9). (The line containing erroneous information is here marked in bold): "The voluntary harmonised standard EN 60335-2-27:2013 sets out requirements for the safety of sunbeds, including limits for ultraviolet radiation emission. Appliances shall have effective irradiances (weighted with the erythema action spectrum) limited as follows: • a total effective irradiance not exceeding 300 mW/m² • the total wavelength-band related effective irradiance not exceeding − 150 mW/m² for wavelengths 250-320nm and 320-400nm, respectively if useable in the household or − 700 mW/m² for wavelengths 250-400nm if for commercial use a total effective short-wave irradiance for wavelengths 200-280nm not exceeding 3 mW/m²." To make the cited text passage correctly refer to the EN60335-2-27:2013, simply delete the line starting with the 2nd dash (SCENIHR-document, page 22, line 7) and also delete the "or" at the end of the previous line.	The text of the Opinion has been amended.
65	Lorenz Christina, KBL AG, clorenz@kbl.de, Germany	6. EXPOSURE FROM SUNBEDS: Prevalence of sunbed use	 Facts_Sunbed_Industry_Summary_April_2	page 25 line 38 - 45 The numbers presented are biased by the studies performed in the USA. In Europe a decrease of sunbed prevalence can be shown.	The text of the Opinion has been changed for clarity.

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
66	Lorenz Christina, KBL AG, clorenz@kbl.de, Germany	6. EXPOSURE FROM SUNBEDS: Prevalence of sunbed use	Wehner_2012_-_Indoor_tanning_and_nor 2014_Wehner.pdf	page 25 line 38 - 45 The numbers presented are biased by the studies performed in the USA. In Europe a decrease of sunbed prevalence can be shown. Especially to be seen in figure 7 of Wehner 2014.	Text has been changed for clarity. The decline seen in Figure 7 is mostly from Denmark. This is mentioned in the paragraph 'prevalence of sunbed use'.
67	Gilroy Steven, Joint Canadian Tanning Association JCTA, info@TanCanada.org, Canada	6. EXPOSURE FROM SUNBEDS: Prevalence of sunbed use	Chang_Kuehn_Feb._17_2015_Response_t CDC-Sunburn___Sun_issue_MMWR_May_ Petitti_D_response_to_Wehner_2014_in_I	Page 25 – line 20/21 The accuracy of the Wehner research (2012, 2014) has been called into question through a Rapid Response letter by Chang & Kuehn (Feb. 17, 2015). It reported that crude categorization of ever vs. never exposure results in conflation of different levels of exposure with, presumably, different degrees of risk. Chang & Kuehn went on to say: We found that prevalence estimates from the majority of these studies were based on highly selected or non-representative populations. These source populations call into question whether the results from these studies can be generalized to the entire populations of the United States, Northern and Western Europe, or Australia. Furthermore, low participation rates and non-randomized sampling methods in many studies likely resulted in biased findings. Publication bias was also evident, with preferential publication of studies reporting a higher prevalence of indoor tanning, further undermining the validity of the meta-analysis results. They reported: The annual cancer incidence estimates also have inherent uncertainty, although confidence intervals appear not to have been reported by the sources relied upon by Wehner et al. Thus, the reported 95% confidence intervals around the estimated number of skin cancer cases attributable to indoor tanning are not true confidence intervals because they do not incorporate the uncertainty in the relative risk and cancer incidence estimates. Furthermore, as stated earlier, the meta-analysis confidence intervals describe only statistical error; they do not describe the extent of study	The comment has been considered and the text in the Opinion has been amended for clarity.

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
				heterogeneity. In other words, the estimates of attributable skin cancer cases are much more uncertain and unstable than reported and do not provide a valid estimate of the true prevalence (if there is a single prevalence) of indoor tanning in the general population. In addition to the issues outlined by Chang & Kuehn regarding the accuracy of the Wehner research there are further issues. The tanning industry has not been increasing as Wehner states with an absolute increase in past year exposure of 3.4% in adults, 2.1% in university students and 1.7% in adolescents. The American Suntanning Association reported January 7, 2016 that the 10% federal excise tax started in 2010 has devastated the tanning industry in the USA by closing 10,000 businesses with the loss of 100,000 jobs. Studies included by Wehner in their prevalence analysis from the NCI and CDC support this trend. Past year exposure by adults, NCI 2005 – 8%, NCI 2007 – 9%, CDC and NCI 2012 – 5.6%. Based on these national studies tanning by adults has reduced by 38% since 2007. The past year prevalence for adults in United States stated by Wehner of 13% is double the CDC/NCI 2012 study of 5.6%. This would indicate that Wehner's prevalence analysis is severely overstated which would reduce the overall impact greatly. Petitti 2016 reports in PubMed The meta-analytically derived estimate of the prevalence of ever exposure to indoor tanning for adults in Northern and Western Europe based on the studies identified by Wehner et al. (2014) is meaningless; the estimate of the number of skin cancers attributable to indoor tanning in Northern and Western Europe based on this meaningless estimate is meaningless. According to this report on page 24 – line 1 to 9 the National Youth Risk Behaviour Surveys (Guy 2014) showed a decrease in the use of sunbed for student where states had restrictions. So this would be another confounder for both Wehner 2012 and 2014. This would back up the NCI and not Wehner numbers.	

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
68	Gilroy Steven, Joint Canadian Tanning Association JCTA, info@TanCanada.org, Canada	6. EXPOSURE FROM SUNBEDS: Prevalence of sunbed use	 CDC-Sunburn___Sun_issue_MMWR_May_  Diffey_2015_-_Suntanning_with_sunscre	Page 25 – line 41 to 45 According to a CDC /NCI report 2010; Nationwide, 5.6% of adults reported indoor tanning in the past 12 months (Table 1). Compared with the overall adult population, a higher prevalence of indoor tanning was found among persons aged 18–21 years (12.3%), 22–25 years (12.3%), and 26–29 years (9.3%); According to NCI report in 2007 adult use was 0.09 (0.08-0.09) or 9%. That would be a decrease of 38% in adults using tanning equipment. According to the American tanning industry the salon locations went from 20,000 to 14,000 location in the same time as reported by Wehner 2014. This would match up with the data from NCI but not with Wehner 2014. This seem to indicate that the data used in this report from Wehner 2014, would be suspect on whether it was valid or not. According to this report on page 24 – line 1 to 9 the National Youth Risk Behaviour Surveys (Guy 2014) showed a decrease in the use of sunbed for student where states had restrictions. So this would be another confounder for both Wehner 2012 and 2014. This would back up the NCI and not Wehner numbers. 6.2 UV exposure from sunbeds - Trends in UV irradiance Page 26 – line 34 Page 26 – 37 to 42 The numbers quoted above are reference from IARC 2006a and re-referenced in IARC 2012. A better comparison to artificial tanning would be phototherapy or an outdoor worker. - A typical dose in a single course of UVB phototherapy can be in the range of 200–300 times the MED - For example, it has been estimated that indoor workers in mid-latitudes (40–60°N) receive an annual exposure dose of solar UVR to the face of about 40–160 times the MED, depending on their level of outdoor activities, whereas the annual solar exposure dose for outdoor workers is typically around 250 times the MED. A new study by Diffey (2015) found that: "a 2-week sunbathing vacation that avoids sunburn on sunscreen-protected skin can result in a higher cumulative UV exposure, and by implication a greater health risk, than a 10-session sunbed course."	The comment has been considered and the respective changes in the Opinion have been made. This comment is outside of the scope of the paragraph *UV exposure from sunbeds - Trends in UV irradiance.*

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
69	Lipman Gary, The Sunbed Association, garylipman.tsa@gmail.com, United Kingdom	6. EXPOSURE FROM SUNBEDS: Prevalence of sunbed use	 EN16489-1_EN.pdf	Page 26, lines 4-7: Professional sunbed salon operators refuse consumers with Skin Type 1 (sensitive skin) from using a sunbed. Typically they are advised to use fake tan. Training schemes explicitly identify skin types according to the Fitzpatrick scale and the absolute requirement to refuse those with sensitive skin who burn easily and rarely tan. It seems that SCENIHR were not aware when compiling this Opinion that an accredited pan European Standard for Professional Indoor UV Exposure services was launched. This is EN16489. A review of this accredited tanning salon training will confirm the high standards that learners need to achieve to become certified.	The comment refers to risk management, which is out of the scope of the SCHEER. No changes to the Opinion are needed.
70	Nilsen Lill Tove, Norwegian Radiation Protection Authority, Lill.Tove.Nilsen@nrpa.no, Norway	6. EXPOSURE FROM SUNBEDS: Prevalence of sunbed use		Page 26, line 28-33: It is unclear what is meant by the first sentence regarding 1.4% past year exposure. For whom is this exposure valid? It is also unclear what the Danish campaign has to do with an efficacy of an under-18 ban. There is no under-18 ban in Denmark. However, a campaign to achieve such a ban may have resulted in reduced number of sunbeds available. Please, clarify.	The comment has been considered and the respective changes in the Opinion have been made.
71	Reimers Jens-Uwe, JK-Holding GmbH, jens-uwe.reimers@de.jk-group.net, Germany	6. EXPOSURE FROM SUNBEDS: Prevalence of sunbed use		page 25 line 38 - 45 The numbers presented are biased by the studies performed in the USA. In Europe a decrease of sunbed prevalence can be shown. Especially to be seen in figure 7 of Wehner 2014.	The text of the Opinion has been changed for clarity.
72	Marx Henrik, DSF - Danish Sunbed Federation, marx@remarx.dk, Denmark	6. EXPOSURE FROM SUNBEDS: Prevalence of sunbed use	 Danskernes_solarievaner_2015.pdf	6.1 Prevalence of sunbed use - line 19-22: The SCENIHR preliminary Opinion states, with reference to a report written by employees of the Danish Cancer Society, that "In Denmark, not only the prevalence of sunbed use in children is noticeable (Krarup et al., 2011), but also the age at first use may be very young: up to 13% of ever sunbed users having started sunbed exposure before the age of 13, and up to 75% between the ages of 13 to 15 (Koster et al., 2011)." COMMENT: The preliminary report is misleading on the points regarding the prevalence of sunbed use in Denmark. - The survey was made in 2008, not 2011 as it appears in the report. (Published in 2011). - The Danish	The comment has been considered and the respective changes in the Opinion have been made.

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
				Cancer Society has published similar surveys in 2009, 2010, 2011, 2012, 2013, 2014 and 2015 showing a constant decrease trend in the prevalence of subbed use by all age categories. - SCENIHR chose the oldest survey with the highest prevalence of sunbed use by children. - The report was made by the Danish Cancer Society funded by TrygFonden and the largest cosmetic retailer in Denmark (MATAS). - Authors: A.F. Krarup (analysis & evaluation consultant), Brian Køster (Ph.d. student), Camilla Thorgaard (public advocacy consultant), Anja Philip (campaign manager) and Inge Haunstrup Clemmensen (MD Ph.d.) were all employed by the Danish Cancer Society at the time. -The authors have chosen to reveal their funding from TrygFonden, but not their partnership with the cosmetic industry in Denmark (MATAS). MATAS was paying the Danish Cancer Society to help them promote cosmetics, and the funding was directly linked to the actual sales numbers: https://www.matas.dk/kb - More recent surveys* from 2015 and also made by the Danish Cancer Society shows that the prevalence of sunbed use has declined substantially to15% among adolescents between 15-19 years of age. (A 57% decline since 2007) - The Danish Cancer Society has not reported sunbed use among children below the age of 15 years since 2012, supposedly because the number was close to zero (0,6% age 5-11). - 3% of the respondents* 15 to 64 years of age where under the age of 13 the first time they used a sunbed. - In the 2012 survey, 30% of the respondents under the age of 14 did not know what a sunbed was. - It shall be noted that a respondent is labeled a "sunbed user" by the Danish Cancer Society if they have used a sunbed once within a 12 month period. *Reference: "Danskernes solarievaner 2015" Solkampagnen | Kræftens Bekæmpelse og TrygFonden (Report published by the Danish Cancer Society and TrygFonden, January 2016)	

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
73	de Gruijl Frank, representing none, degruijl@planet.nl, Netherlands	6. EXPOSURE FROM SUNBEDS: Prevalence of sunbed use		6.1 - pg 25, line 34, concerning women/men ratio in sunbed use: again putting this in context, it is interesting to note that for the US in 2016 it is expected that: "About 76,380 new melanomas will be diagnosed (about 46,870 in men and 29,510 in women). About 10,130 people are expected to die of melanoma (about 6,750 men and 3,380 women)." `(http://www.cancer.org)" Illustrating that the gender difference in sunbed use is a far cry from the actual gender difference in melanoma risk and mortality. Further indicating that sunbed use had no substantial bearing on melanoma incidences and mortality. pg 25, line 40, "including all time periods"? not very informative. how far back and including 2007-2012? pg 25, line 44, "increases" (absolute in %?) compared with? The primary analysis? Meaning what/when? Significant increases? pg 26, line 2, "higher' than what? pg 26, line 15, "safety" compared to risk from sun exposure? pg 26, lines 28 – 29, "may be rather effective"? Isn't this trivial? Shouldn't it be effective, if it is a real ban? If it is not successful, the legislation is simply a failure. What does the 1.4% mean? (last year sunbed use among youth<18 years? If so, a pretty poor ban).	The SCHEER disagrees. No change in the Opinion is needed. No change in the Opinion is needed. The text of the Opinion was changed for clarity. No change in the Opinion is needed. No change in the Opinion needed. Text was changed for clarity
74	Van de Linde Dignus, Vdl Hapro bv, D.van.de.linde@vdlhapro.com, Netherlands	6. EXPOSURE FROM SUNBEDS: Prevalence of sunbed use		Line 10, home use of sunbeds. The scenihr report expresses concern about the uncontrolled use and duration of use. Fact1: home sunbeds carry very clear, complete and correct instructions for use. They also carry all precribed warnings from the standard. Fact 2 a typical home use sunbed is always in Uv type 3, with a max of 0,15 W/m2 weighted erythema both in Uva and uvb. Fact 3: a typical home use sunbed carries low pressure lamps without internal reflector. Weighted erythemal emission of a typical home	SCHEER disagrees because these comments relate to manufacturers specifications. No changes to the Opinion are needed.

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				use sunbed is 0,12 W/m2 uva and 0,12 w/m2 uvb far under the maximum allowed by the standard. Fact 4 home use sunbeds are delivered in uv typ 3 classification and stay in uv type 3. There is no tendency at home users to change original lamps for stronger lamps bringing the bed out of uv type 3. Fact 5. a home use sunbed has a timer that can not exceed 30 minutes it can not exceed the allowed maximum dose. Fact 6. we have not been reported or have found any reports on incidents in the past 15 years on sunburn or overexposure on a homeuse sunbed. Why does Scenihr expresses its concern about uncontrolled use. Which artcicles that people have at home do not carry a risk of uncontrolled use or with other words when instructions are not followed. Must we ask the European commission to police at home the uncontrolled use or consumption of chips, cola, beer, hamburgers, french fries, mayonaise, candy, hair dryers, electrical swas etc. Or should we ask the european commission to be concerned about drilling machines when they are not used according manufacturer instructions. Where does the scenihr committee see the need for a concern on home sunbeds. When the instructions are followed correctly, a home sunbed is a safe product to use. As it is for more than thousand products that I have at home. Should we not give the consumer some freedom and responsibility to use a product in a right way. A home use sunbed is very appreciated by people in mid age and older, living in smaller villages where no tanning salons are available. Use is very much appreciated especially in winter times when the warmth of a sunbed is relaxing and the uv light gives people a pleasant feeling of joy in the dark days of winter. And again no incidents of overexposure or sunburn are known.	The carcinogenicity of UV from sunbeds puts this in a different perspective.
75	Van de Linde Dignus, Vdl hapro bv, D.van.de.linde@vdlhapro.com, Netherlands	6. EXPOSURE FROM SUNBEDS: Prevalence of sunbed use		The numbers presented are biased by the studies performed in the USA. In Europe a decrease of sunbed prevalence can be shown and is clear fact. Especially to be seen in fig 7 of Wehner 2014	See response to comment 66.

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
76	Levy Joseph, American Suntanning Association, joe@smarttan.com, United States	6. EXPOSURE FROM SUNBEDS: Prevalence of sunbed use	 Petitti_-_Wehner_Review_.pdf	Dr. Diana Petitti, a former vice chair of the U.S. Preventative Services Task Force and a champion of women's health issues, has reviewed the Wehner et al reports that are used in the SCENIHR report as a basis to establish the prevalence of sunbed use and the risk from sunbed use. Dr. Wehner's review (attached) believes this paper to be so incapable of producing conclusions that she calls its conclusions "meaningless." She states, "The meta-analytically derived estimates of prevalence of ever-exposure to indoor tanning for adults in Northern and Western Europe is meaningless" and "The estimate of the number of skin cancers attributable to indoor tanning in Northern and Western Europe based on this estimate is meaningless." As supplied in my power point presentation to the SCENIHR committee, the massive 8-fold variation in reported skin cancer incidence from country to country in Europe (WHO data supplied) -- with no corresponding significant difference in mortality data from country to country -- make definite conclusions about environmental risk factors impossible, as the default explanation for such a range has to first be differences in reporting and detection rather than differences in actual disease. Because none of the input studies used in Wehner et al are capable by design of differentiating non-burning UV exposure from exposure that results in a burn, this analysis cannot be used as a sound basis for any policy.	The text of the Opinion has been changed for clarity. See answers to comments 67 and 68.
77	Bocionek Peter, JW Holding GmbH (R & D), peter.bocionek@jw-holding.de, Germany	6.2 UV exposure from sunbeds - Trends in UV irradiance		page 28, line 11 - 16: Irradiance regulation for sunbeds is based on UVI=12, so any comparison with Oslo summer sun (UVI=5) does not show any scientific value. page 29, line 13 - 31: Two statements are missing here: 1. The relevant biological issue is the biologically effective UVR dose and not the dose rate/irradiance 2. Compliance can only be achieved by joint actions between all stakeholders and controls by market surveillance authorities (like speed limits).	SCHEER disagrees with the comment. No changes to the Opinion are required in relation to the comment. Statements were already in the text of the Opinion. No changes to the Opinion are required in relation to the comment.

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
78	Baldermann Cornelia, German Federal Office for Radiation Protection, cbaldermann@bfs.de, Germany	6.2 UV exposure from sunbeds - Trends in UV irradiance		Page 28 / line number 31 – 33: The sentences ""While according to the European standard, erythemal-effective irradiance should not exceed 0.3 W/m². The values measured ranged between 0.10 and 1.32 W/m² with a mean of 0.56 ± 0.21 W/m².” should be combined to one sentence: „While according to the European standard, erythemal-effective irradiance should not exceed 0.3 W/m², the values measured ranged between 0.10 and 1.32 W/m² with a mean of 0.56 ± 0.21 W/m².” Page 29 / line number 23 - 31: In this passage it is noticeable that for the same thing (sunbed) different terms are used like “Sunbed UV emitters”, „tanning appliance“, „machines“, “tanning machines”. It would be advisable to choose a consistent naming like “UV emitting appliances” or “UV emitting devices” for technical matters and “sunbed” in colloquial context.	No changes to the Opinion are required in relation to the comment. The text was harmonised.
79	Lorenz Christina, KBL AG, clorenz@kbl.de, Germany	6.2 UV exposure from sunbeds - Trends in UV irradiance		page 27 line 6 - page 28 line 41 "The EU member states took different approaches to make existing sunbeds in the market compliant with the new irradiance limits. The Netherlands authorities made clear the new standards are to be applied to existing sunbeds as well, took a joint action with the industry and consumer organisations and changed the complete market in 1 year. Germany introduced a law, which transfered the requirements of the standard to requirements in the tanning salons and enforced it in November 2012 (6,5 years after the SCCP Opinion) controls are not known yet All other member states stay vague about the enforcement of the SCCP 2006 Opinion and the changed standard EN 60335-2-27:2007 Its like setting a general speed limit, but not controlling it. The compliance will be low."	This is a risk management issue. No changes to the Opinion are required in relation to the comment.

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
80	Pedersen Ronny, Norwegian Tanning Association, ronny@mida.no, Norway	6.2 UV exposure from sunbeds - Trends in UV irradiance	Schematic_diagram_of_the_relation_betw	page 27 line 27 There were very few sunbeds available on the Norwegian marked in the early -80s. From 1992 the UV-type 3 regulations were mandatory. This is the main reason why the UV-A output increased in Norwegian tanning devices and beyond the control of the industry.	No changes to the Opinion are required in relation to the comment.
81	Pedersen Ronny, Norwegian Tanning Association, ronny@mida.no, Norway	6.2 UV exposure from sunbeds - Trends in UV irradiance	From_the_book_Sunlight__Vitamin_D_and_	page 28 line 18 It is inaccurate to state that solaria UVR have become less similar to the outdoor sun. From the book Sunlight, Vitamin D and Skin Cancer- Chapter UV-radiation and health- Optimal time for sun Exposure on page 4 measurements of mid-summer sun in Oslo is compared to UV-type 3 solarium and the spectrum is equal at around pm. 4.30(measurements done by Professor Johan Moan)	The text of the Opinion was changed for clarity.
82	Dr. Richarz Frank, IEC TC61 / MT16 'Biological effects of optical radiation', MT16@richarz-consulting.de, Germany	6.2 UV exposure from sunbeds - Trends in UV irradiance	iec60335-2-27_ed5.0_en.pdf 10_-_Diffey_-_A_model_to_calculate_sun_	page 26 line 40 "The annual dose for outdoor workers in Europe of about 600MED should be mentioned here as well. 600MED is based on two references: 1. WHO showed outdoor workers will receive about 30% of the ambient UVR per year 2. Diffey 2007 showed the ambient, cloud corrected UVR in Denmark to be 1.800 MED. The file WHO solaruvradfull_180706 was to big to upload and is send to the SCENIHR office by mail." page 27 line 3 - 5 It should be mentioned that EN 60335-2-27:2013 includes additional dose requirements for specific exposures, exposures during a tanning course and for annual exposure in annex DD. page 27 line 6 - page 28 line 41 If irradiance is not prominently introducing a harmful effect, why is non-compliance with the irradiance limits a problem? page 28 line 11 - 16 "Irradiance regulation is based on UVI=12, so any comparison with Oslo summer sun (UVI=5) does not show any scientific value.	This is outside of the scope of the mandate. The Opinion correctly cites the standard. No changes to the Opinion are required in relation to the comment. The standard is limiting the irradiance, therefore for the same exposure time non-compliance is a problem. No changes to the Opinion are required in relation to the comment.

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
				Comparison should be made to the standard values, which are purely erythemal weighted values. There are no specific UVB or UVA limits in the standard that could be ""considerably exceeded"". UVI in Oslo summer is 5, which corresponds to an erythemal weighted irradiance of 0,125W/m2. A 26 times higher value would result in an erythemal weighted irradiance of 3,25 W/m2! SCENIHR should distinguish more carefully between erythemal weighted irradiance and unweighted irradiance in the whole document!" page 28 line42 - page 29 line 11 The irradiance limit in Australia was set to 0,9W/m2 erythemal weighted. Additionally as indicated on page 27 line 3-5 irradiance is not the problem! page 29 line 8 - 11 These are unweighted values and cannot be compared to any of the values before. page 29 line 15 - 20 the numbers for students are only based on US studies and not comparable for Europe page 29 line 21 - 22 The prevalence is not increasing in Europe as is shown in figure 7 of Wehner 2014 page 29 line 13 - 31 "The relevant biological issue is the biologically effective UVR dose and not the dose rate/irradiance " page 30 Table 3 is meaningless for Europe since it is dominated by USA studies. Figure 7 in the same reference (Wehner 2014) shows a decrease of prevalence in Europe.	This is a personal view. No changes to the Opinion are required in relation to the comment. It is the UVA irradiance that has been found to be 26 times higher (Nilsen et al.). SCENIHR (and Nilsen et al distinguish carefully between erythemal weighted and unweighted irradiances Text of the Opinion was checked and changed where necessary. Text was modified for clarity.

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
83	Wunsch Alexander, Medical Light Consulting, praxis@alexanderwunsch.de, Germany	6.2 UV exposure from sunbeds - Trends in UV irradiance		P26/40-42: "However, there are large variations in UV output of different machines and the UV spectrum emitted by tanning machines has evolved in recent years." This statement, not bolstered by references, is contradictory to the statements found on page 19, lines 42-43: "Most modern sunbeds have not changed much from the original devices".	The reference list was updated. The text of the Opinion was changed for clarity.
84	Lipman Gary, The Sunbed Association, garylipman.tsa@gmail.com, United Kingdom	6.2 UV exposure from sunbeds - Trends in UV irradiance	 EN16489-1_EN.pdf	Page 26, line 36: It is incorrect to state that UV index 12 is equivalent to midday tropical sun. UV index 12 is equivalent to midday Mediterranean sun. Since 1 April 2009, all sunbeds supplied new or traded second-hand, must comply with EN 60335-2-27 which requires all sunbeds to have a maximum UV emission level of 0.3W/m2. The SCENIHR report clearly states that 'the value for Mediterranean midday sun is 0.43W/m2' (Page 28, line 37). As such to give the impression that sunbeds in Europe emit an output equal to midday tropical sun is misleading. Page 26, lines 36-38: Those from vulnerable groups, such as those with sensitive skin will be screened out in a modern professional tanning salon Page 27, lines 3-5: The aforementioned accredited Professional indoor UV exposure services training Standard EN 16489 ensures that salon staff are able to assess skin type, screen out contraindications and ensure that consumers are given the correct session time appropriate for their skin type. Page 27, lines 20-24: It should be noted by the SCENIHR that unstaffed salons represent an extremely small part of the market. The vast majority of tanning salons employ staff. Page 27, lines 37-40: Can the SCENIHR disclose when the second inspection was carried out. It is important to identify	The text of the Opinion was changed for clarity. SCHEER disagrees with the comment. Different weighting factors have been clearly indicated. The text of the Opinion was changed for clarity. Text of the Opinion is correct. No changes to the Opinion are required in relation to the comment. Text of the Opinion is correct. No changes to the Opinion are required in relation to the comment.

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
				how close this was to implementation of the change in output Standard in 2009 to 0.3W/m2. An implementation period of three years is normal, post introduction of a change to a Standard before local compliance is enforced and this needs to be taken into consideration in order to provide context. Page 28, lines 1-5: It should be noted that unattended, so called unstaffed salons are not the 'norm' across Europe and indeed, are banned in some countries. The vast majority of professional tanning salons have well trained staff in attendance at all open times. Page 28, lines 29-41: This is disingenuous in the extreme. Since 1 April 2009, all sunbeds supplied new or traded second-hand, must comply with EN 60335-2-27 which requires all sunbeds to have a maximum UV emission level of 0.3W/m2. TSA lobbied Government and NGOs to extend this to existing sunbeds in the market. We received no such support. The Sunbed Association (TSA) has been working with its members, non-members and the enforcement departments within local authorities since that time to inform about the change in UV emission levels, advise how to become compliant and ensure compliance. Sunbeds have been required to have a maximum UV output since 2009. New laws/regulations typically have a three year implementation time. Therefore, as the research quoted was carried out between October 2010 and February 2013, the results reflect an early snapshot of a transition time. If the study was undertaken today the results would be dramatically different. Page 28, lines 42/ Page 29, lines 1-11: It is not appropriate to quote measurements taken from sunbeds outside of Europe. Since 1st April 2009, all sunbeds supplied new or traded second-hand in Europe , must comply with EN 60335-2-27 which requires all sunbeds to have a maximum UV emission level of 0.3W/m2. In Australia the output was restricted to of 0.9W/m2, three times the European limit.	The text of the Opinion was changed for clarity. No changes to the Opinion are required in relation to the comment. The comment is not supported by scientific evidence. SCHEER disagrees. The text of the Opinion is correct. No changes needed. Text of the Opinion is correct. No change in the text needed. Different weighting factors have been clearly indicated.

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
				Page 29, line 27: It is incorrect to state that UV index 12 is equivalent to midday tropical sun. UV index 12 is equivalent to midday Mediterranean sun. Since 1 April 2009, all sunbeds supplied new or traded second-hand, must comply with EN 60335-2-27 which requires all sunbeds to have a maximum UV emission level of 0.3W/m2. The SCENIHR report clearly states that 'the value for Mediterranean midday sun is 0.43W/m2' (Page 28, line 37). As such to give the impression that sunbeds in Europe emit an output equal to midday tropical sun is misleading.	The text of the Opinion was changed for clarity.
85	Nilsen Lill Tove, Norwegian Radiation Protection Authority, Lill.Tove.Nilsen@nrpa.no, Norway	6.2 UV exposure from sunbeds - Trends in UV irradiance	 Nilsen2016_Ultraviolet_exposure_from_in	Page 26, line 43 to page 27, line 2: A systematic review regarding measurements of tanning beds worldwide is recently been published by Nilsen et al. (UV exposure from indoor tanning devices: A systematic review. Br J Dermatol. 2016 Jan 7. doi: 10.1111/bjd.14388). It shows the exposure compared to national regulations and international recommendations as well as compared to that of natural sun. This review looked at 18 studies, thirteen from Europe, two from Australia and three from USA, and that involved measurements of 2895 sunbeds. Data on the tanning devices' erythema weighted UV irradiances, UV index, compliance with any legal irradiance limits, wavelength distribution (how much is UVA and how much is UVB) and how they compare to natural sun, were extracted. Erythema-weighted UV from modern tanning devices was high and generally higher than from natural sun, and with large variations between devices. The mean UVB irradiances of the reviewed studies were between 0.1 and 2.3 times that from natural sun at Crete or Melbourne, whereas mean UVA irradiances were 1.7 to 12 times higher, except in one older Australian study from 1986. European studies comparing sunbed measurements to the legally allowed irradiance limits found low compliance, meaning most sunbeds gave out more UV than is permitted. UVA was generally much higher than from natural sun and with increasing amounts over time in Europe.	Text has been expanded to add the new research and the reference list was updated.

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
86	Nilsen Lill Tove, Norwegian Radiation Protection Authority, Lill.Tove.Nilsen@nrpa.no, Norway	6.2 UV exposure from sunbeds - Trends in UV irradiance		Page 27, line 3-5: It is stated that it is the dose and not dose rate that prominently introduce harmful effects. If this is the case, then it makes no sense to limit the dose rate, as 0.3 W/m². However, on page 36, lines 36-39, you refer to a higher melanoma likelihood for users of high-speed/high-intensity devices and high pressure devices. This may indicate that also the dose-rate may play a role. Therefore, you may rephrase and change wording on page 27, line 3 from "it is not the dose rate" to a more open phrase.	The text of the Opinion was changed for clarity.
87	Nilsen Lill Tove, Norwegian Radiation Protection Authority, Lill.Tove.Nilsen@nrpa.no, Norway	6.2 UV exposure from sunbeds - Trends in UV irradiance		Page 29, line 3-11: UV irradiances in this section are given as erythema-weighted and unweighted UVB and UVA irradiances without specifying which refers to each of them. Also the UVI should be explained. Specifying erythema-weighted or unweighted numbers lacks throughout the report.	The text of the Opinion was changed for clarity.

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
88	Reimers Jens-Uwe, JK-Holding GmbH, jens-uwe.reimers@de.jk-group.net, Germany	6.2 UV exposure from sunbeds - Trends in UV irradiance		page 27 line 6 - page 28 line 41 "The EU member states took different approaches to make existing sunbeds in the market compliant with the new irradiance limits. The Netherlands authorities made clear the new standards are to be applied to existing sunbeds as well, took a joint action with the industry and consumer organisations and changed the complete market in 1 year. Germany introduced a law, which transfered the requirements of the standard to requirements in the tanning salons and enforced it in November 2012 (6,5 years after the SCCP Opinion) controls are not known yet All other member states stay vague about the enforcement of the SCCP 2006 Opinion and the changed standard EN 60335-2-27:2007 Its like setting a general speed limit, but not controlling it. The compliance will be low."	This is a risk management issue. No changes to the Opinion are required in relation to the comment.
89	de Gruijl Frank, representing none, degruijl@planet.nl, Netherlands	6.2 UV exposure from sunbeds - Trends in UV irradiance	Miller_SA_BJD2008.pdf	pg 26, line 36, UV index 12: Brisbane & Sidney tropical? peak values > 20 in tropics peak values > 12 in subtropics. (https://www.niwa.co.nz/sites/niwa.co.nz/files/import/attachments/Liley_2.pdf) pg 26, line 40: better estimates of annual doses: annual personal UV exposure actually measured median of 166 SED (standard erythema dose), 95% range: 37-551 SED, for children, indoor workers, golfers etc. in Denmark (Thieden et al. J Invest Dermatol. 2004 Dec;123(6):1147-50.) Indoor workers 132 SED (17 - 841 SED), excl holidays, Thieden et al, Arch Dermatol 2004. pg 27, line 4, evidently an important remark, one that points out that limiting the irradiance from sunbeds is of secondary importance (lowering the irradiance will lengthen the exposure and reduce the chance of severe overexposure).	The text of the Opinion was changed for clarity. No change in the Opinion is needed. Page 27, line 4: the text of the Opinion was changed for clarity.

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
				pg 27, line 33, "short wave" meaning UVB? -pg 28, line 13, but as stated earlier, not exposure rate but exposure is decisive for skin reaction/risk pg 28, line 18, how high was UVA output in 2008 in comparison to earlier mentioned 112 mw/m2 in 1993 – 2005? pg 28, line 19, "less similar to natural sun" that is midday summer sun. Ratio UVA/UVB of sun at low elevation increases. Longer exposure time required with low standing sun than with sunbed pg 29, lines 7, 8, 10 W/m2 or mW/m2 (CIE erythema weighted)? Summary pg 29, line 14, "higher" than what? pg 29, line 25, "may lead to reduced risks" but no data available on such an effect of reduced sunbed use. shown on risk of skin cancer pg 29, line 30, "higher UVA irradiance" for more effective tanning. More rapidly achieving a certain level of tanning with lower accumulated total erythemal dose (in SEDs), when comparing a 98%UVA/2%UVB source to a 95%UVA/5%UVB sun-like source (Miller S et al. Br J Dermatol 2008, 159:921-93)	No changes in the Opinion are needed. No changes in the Opinion are needed. No changes in the Opinion are needed. Page 29, line 7,8, 10: It is already stated that these are erythemically weighted irradiances in W/m². Page 29, line 14: No change in the Opinion is required. Text of the Opinion has been changed for clarity. No change in the Opinion is required.
90	Van de linde Dignus, Vdl hapro bv, D.van.de.linde@vdlhapro.com, Netherlands	6.2 UV exposure from sunbeds - Trends in UV irradiance		It's frustrating to see how many countries did not make any legislation to make the new harmonized standard an obligation. It's also frustrating to see that in far most of the countries with legislation there is very poor or none cotrol of the legislation. The eu member states took different approaches to make existing sunbeds in the market compliant with the new irradiance limits. The dutch authorities made clear the new standards are to be applied to existing sunbeds as well , took a joint action with the	This comment relates to risk management, which is outside the scope of this Opinion.

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
				industry and consumer organisations and changed the complete market in one year. Germany introduced a law, which transfered the requirements of the standard to requirments in the tanning salons and enforced it in November 2012. (6,5 years after sccp publication of Opinion) . Controls are not known. All other member states stay vague about the enforcement of the SCCP 2016 Opinion and the changed standard En 60335-2-27-2007. It,s like setting a general speed and not controlling it. The industry has done what it could. All manufacturers have implemented the 0,3 W/m2 immediately when the new standard became valid. Besides the manufacturers created a unit passport to facilitate controls and enforcement. The passport shows the exact uv emitters indicating the xy codes. The industry also sharply introduced the xy codes when they became in force by the standard. Main problem is the availability of stronger lamps in the free market that are changed into to sunbeds. That's why controls and enforcement are so needed. We need sunbeds that comply to the standard. The manufacturers call on the Eu commission to work together with the industry and facilitate better and stronger enforcement for optimum consumer safety.	
91	Van de Linde Dignus, Vdl Hapro, D.van.de.linde@vdlhapro.com, Netherlands	6.2 UV exposure from sunbeds - Trends in UV irradiance		Page 29 There is no increase in sunbeds use at all. Industry figures show a clear and strong decrease since 2009 up till now 2016. The number of studios have decreased, the number of lamp sales decreased dramatically which proves strongly that less sunbed hours are being run in Europe. The indication of increased prevelance is totally wrong and not based on facts.	No change in the Opinion is needed.

No	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Response
92	Khazova Marina, Public Health England, marina.khazova@phe.gov.uk, United Kingdom	6.2 UV exposure from sunbeds - Trends in UV irradiance		p 26, lines 35-42 and rest of section. There is a fundamental difference between irradiance and radiant dose, i.e. irradiance x time. Despite stating that it is the dose and not dose rate which may cause harmful effects, the majority of the analysis refers to irradiance, i.e. dose rate. Emphasis on restriction of dose rate to 0.3 W/m2 (equivalent of UVI 12) without consideration of the duration of exposure is misleading. Example given in Section 6.2 compares doses of indoor workers with hypothetical sunbed exposure of 20-30 MEDs (>20-30 sessions a year), without consideration of > 50-60 SEDs received in a few days of holiday in Spain published by Petersen et al in 2015. Typical UVR dose from sunbeds reported by H Oliver in 2006 and Khazova et al in 2015 from field survey studies are much lower than exposures during sunbathing holidays (H E Oliver. The Impacts of optical radiation in the environment on skin: hazards, measurement, regulation and protection. A Thesis submitted for the degree of Doctor of Engineering, Brunel University, 2006. M Khazova, J B. O'Hagan and S Robertson. Survey of UV Emissions from Sunbeds in the UK. Photochemistry and Photobiology. v 91, no 3, 545–552, 2015) p27-29. The latest data on emission from sunbeds are published in: L.T.N. Nilsen, M. Hannevik and M.B. Veierød. Ultraviolet exposure from indoor tanning devices: a systematic review. British Journal of Dermatology, DOI: 10.1111/bjd.14388 p27. There are a number of editorial issues on this page: line gaps between lines 15 and 17; the reference should be superscript on line 19; and on line 22 "sunbed need" should be "sunbeds need".	The text has been changed for clarity. The text of the Opinion has been amended. The text has been changed for clarity. The text of the Opinion has been corrected.

Results of the public consultation on the preliminary opinion on biological effects of ultraviolet radiation relevant to health with particular reference to sunbeds for cosmetic purposes

Comments 93-203

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
93.	Zeyen Thierry, European Glaucoma Society Foundation, thierry.zeyen@telenet.be, Belgium	7. HEALTH EFFECTS:	MacularDegeneration Refs.pdf	lines 5-7 The European Glaucoma Society Foundation would like to draw the attention of the Scientific Committee that the risk of developing macular degeneration is missing in this section and throughout the document despite the severity of the disease as it leads to irreversible visual impairment. The risk of macular degeneration is particularly high for the people over 40 years of age. We urge the Scientific Committee to add the risk on macular degeneration in this Opinion paper due to the risk of permanent blindness and to explore ways by which how such serious health risk can be communicated and brought to the attention of the sunbed users. We include scientific evidence for such risk.	The SCHEER agrees with the comment. A new section regarding eyes has been included in the Opinion.
94.	Zeyen Thierry, European Glaucoma Society Foundation, thierry.zeyen@telenet.be, Belgium	7. HEALTH EFFECTS:	_UV_macular_degeneration_2.pdf risk_factor_AMD_3.pdf	Lines 5-7: Age related macular degeneration (AMD) must be included in this reference to eye damage because of the irreversibility in visual impairment. One of the references suggests that the controversiality around AMD and UV link is a methodological issue that must not be overlooked as it is significantly linked with GDP per capita with implications for health equity.	The SCHEER agrees with the comment. A new section regarding eyes has been included in the Opinion.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
95.	Zeyen Thierry, European Glaucoma Society Foundation, thierry.zeyen@telenet.be, Belgium	7. HEALTH EFFECTS:		Lines 14 - 26: A sentence has to be added in this summery of non-cancerous effects regarding the visual impairment linked with UV in analogy to the other health non-cancerous effects as the evidence is strong with implications for GDP and health equity. The EGS has provided a number of references throughout the paper. The public has to be aware that exposure to UV light may cause a range of eye conditions and it may trigger the early onset of diseases normally linked with ageing such as cataract and age related macular degeneration (AMD) with irreversible loss of vision in the case of AMD.	The SCHEER agrees with the comment. A new section regarding eyes has been included in the Opinion.
96.	Baldermann Cornelia, German Federal Office for Radiation Protection, cbaldermann@bfs.de, Germany	7. HEALTH EFFECTS:		Page 31 / line number 8: The term „non-malignant skin cancer" should be corrected to „non-melanoma skin cancer".	The SCHEER agrees with the comment. The text has been corrected.
97.	Vuerich Michela, ANEC, the European consumer voice in standardisation, anec@anec.eu, Belgium	7. HEALTH EFFECTS:	 ANEC-SERV-2016-G-015.pdf		Supportive statement acknowledged by the SCHEER.
98.	Gilroy Steven, Joint Canadian Tanning Association, info@TanCanada.org, Canada	7. HEALTH EFFECTS:	 UK_-_Consensus_Vitamin_D_position_stat	7. HEALTH EFFECTS Page 31 – line 1 Page 31 – line 4 to 6 It's interesting that in the Abstract, Executive Summary, Opinion sections the writer uses words like definite and a further example; Page11 - line43 to 45 1.8 Overall Conclusion The SCENIHR concludes that UV is a complete carcinogen, acting as both an initiator, through genotoxicity, and a promoter, through immunosuppression. When you read the Background information you see something very different – "excessive exposure" and "causally related". The whole tone of the report changes instead of an absolute, there is types of exposure and a casual risk of skin cancer that the European	No changes in the Opinion are needed. No changes in the Opinion are needed.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				Commission should be concerned about. These excessive exposure amount can be controlled. De Winter 2001 states this; An analogous situation applies when people daily expose their skin on sunny beaches and the skin does not get enough opportunity to rest. From the viewpoint of DNA repair kinetics this is a hazardous way of tanning. Indoor tanning is not safer than the sun but the use of timers and the possibility of easily regulating the exposure frequency could make it safer than the attitude of millions of people who want to get a tan during the first days of their sunny holidays. Page 31 – line 7 A large meta-analysis of melanoma risk factors (IARC 2012 Monograph) found that chronic UV exposure (defined as continuous regular UV exposure) had a 5% reduced risk of melanoma. 7.1 Non-cancer health effects Page 31 – line 23 7.1.1 Vitamin D Page 31 – line 24 Page 31 - line 29-32 Additionally, the UK Consensus Vitamin D Position Statement (2010) supported by British Association of Dermatologists, Cancer Research UK, Diabetes UK, the Multiple Sclerosis Society, the National Heart Forum, the National Osteoporosis Society and the Primary Care Dermatology Society stated "Enjoying the sun safely, while taking care not to burn, can help to provide the benefits of vitamin D without unduly raising the risk of skin cancer." Therefore, if UV from sun or sunbed is the same, based on this statement endorsed by BAD, people who do not burn using a sunbed would not unduly increase their risk of skin cancer. Page 31 - line 32-35 Higher vitamin D levels have been associated with significantly lower all-cause mortality. Schottker 2014 was a meta-analysis from eight cohort studies from Europe and the United States on vitamin D and mortality. It showed that the lowest quintile of 25(OH)D	Chronic (outdoor) exposure to UV is not the subject of this Opinion. Advice on sunbathing is outside the mandate of this Opinion. Biological effects can still appear at doses that are below doses causing burning. No changes to the Opinion are needed.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				concentration compared to the top was associated with a 57% increased risk of all-cause mortality, a 41% increased risk of cardiovascular mortality and a 70% increase in cancer mortality for those subjects with a history of cancer. Chowdhury 2014 in a large systematic review and meta-analysis of observational cohort (73 studies 849,412 participants) and randomized intervention studies (22 studies 30,716 participants) found that lower vitamin D levels were at a 35% higher risk for all-cause mortality. Using population prevalence estimates of vitamin D, Chowdhury found that 9.4% of all deaths in Europe and 12.8% of those in the United States could be attributed to vitamin D deficiency. Page 31- line 35-37 This "notion" by Autier has been vigorously refuted by correspondence published in the Lancet (2014) from vitamin D scientists such as Giovannucci, Holick, Grant, Feelisch, Weller, Garland, Gorham, Mohr and others. The primary influencer of 25(OH)D blood levels is the generation of vitamin D or lack thereof through UV exposure. Schottker 2014 , Chowdhury 2014 and Lancet 2014 to large of a file to upload	All-cause mortality is reviewed in paragraph "All-cause mortality". A discussion on appropriate vitamin D levels in blood is outside the mandate. The SCHEER is aware of the debate, which partially focuses on the effects of supplementation. The SCHEER is of the Opinion that based on the studies thus far, this hypothesis cannot be ignored. In the text the word "consequence" has been changed to "association".
99.	Gilroy Steven, Joint Canadian Tanning Association JCTA, info@TanCanada.org, Canada	7. HEALTH EFFECTS:	 Holick_2007_-_Vitamin_D_and_Skin_Physic  Cashman_2016_-_Vitamin_D_deficiency_in	Summary – page 34 – line 14 Page 34 - line 15-20 According to Dr. Holick (2007) "Exposure to sunlamps that produce UVB radiation is an excellent source for producing vitamin D3 in the skin and is especially efficacious in patients with fat malabsorption syndromes." Usual exposure to UVR from the sun (even on cloudy days) and a normal diet are NOT sufficient to achieve a sufficient vitamin D level of 20 ng/ml (50 nmol/L) per Cashman (2016). Dietary sources are not strong sources of vitamin D. Supplements can reach toxic levels whereby UV exposure self regulates vitamin D production and does not reach toxic levels.	The Opinion clearly states that vitamin D levels in the blood can be raised by sunbed exposure. A full discussion on diet, supplements and treatment of medical conditions is outside the mandate. No changes in the Opinion are needed.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
100.	Dr. Richarz Frank, IEC TC61 / MT16 'Biological effects of optical radiation', MT16@richarz-consulting.de, Germany	7. HEALTH EFFECTS:		page 31 line 22 The WHO has already shown that there are two sides of UV related burdens: too much and too little UVR. SCENIHR only focus on the "too much" effects and falls back behind 2006 knowledge. The file WHO solaruvradfull_180706 was to big to upload and is send to the SCENIHR office by mail.	The effects of "too little" UV radiation is not an issue related to sunbeds use for cosmetic purposes. No changes in the Opinion are needed.
101.	Wunsch Alexander, Medical Light Consulting, praxis@alexanderwunsch.de, Germany	7. HEALTH EFFECTS:		P31/8: Non-malignant skin cancer is a contradiction, since all cancers are malignant by definition. The correct term should read: non-melanoma skin cancers, NMSC.	The SCHEER agrees with the comment. The typo has been corrected.
102.	Lipman Gary, The Sunbed Association, garylipman.tsa@gmail.com, United Kingdom	7. HEALTH EFFECTS:		Page 31, line 4-5: This is a cosmetic issue and not a health concern and therefore outside the remit of the SCENIHR. Nevertheless, it is clear that it is accepted that it is excessive or chronic exposure that can lead to health concerns, not exposure per se. Page 31, line 10: Once developed, it is true to say that melanoma can be fast growing. However, the latency period of between 20-30 years needs consideration in order to provide context. Page 31, line 14: Metatastic spread of SCC (a lesion as opposed to a cancer easily capable of metastasis) is less likely and thankfully rare in comparison. Unlike melanoma, SCC can be successfully excised.	Premature skin aging is seen as a health issue by SCHEER. As shown by the Iceland study, sunbed use acts as a promoter, shortening latency. No changes in the Opinion are needed.
103.	de Gruijl Frank, representing none, degruijl@planet.nl, Netherlands	7. HEALTH EFFECTS:		- pg 31, line 10, too strong; even with Breslow thickness >1 mm the 5-yr survival rate is not zero! (most melanoma are thin with 5 yr survival > 95%).	The text of the Opinion was amended
104.	Khazova Marina, Public Health England, marina.khazova@phe.gov.uk, United	7. HEALTH EFFECTS:		Section 7.1.1 Vitamin D p32, lines 18-22. The scope of this SCENIHR report is biological effects of UVR, not advice on diet or supplementation; this sort of sufficiently supported statement should be avoided and deleted. Section 7.2.1 Human health effects p34, lines 15-26. The report needs to include the effect of UVR on cardiovascular health; in particular, on nitric oxide release.	The SCHEER agrees with the comment. The text has been changed accordingly.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				p35, lines 14-19 and p36-37, lines 40-47 and 1-2, respectively. This is unacceptable comment and it should be deleted. Citation of referenced sources and comments on differences of interpretation in those sources are the appropriate way for SCENIHR to handle such situations.	The text on diet or supplements has been modified. Text discussing blood pressure has been added.
				p43, lines 28-34 and footnote 14. Exposure of 23 SEDs to neonatal mice would likely require hospitalisation of Caucasians due to severe burns. Relevance to humans in realistic situations?	The SCHEER agrees with the comment. The text has been changed accordingly.
				Section 7.3 Experimental Animal studies p49, lines 34-41. What is the relevance of this study?	The text of the Opinion has been modified.
				p53, lines 32-25. Experiments on embryo kidney cells cannot be directly translated to skin exposure: UVC doesn't penetrate beyond dead upper layer of the skin.	The text of the Opinion has been modified.
				Section 7.5 Risk characterisation p58, lines33-40. There is no reference to Tierney et al 2015 included in the listing: P. Tierney, F.R. de Gruijl, S. Ibbotson and H. Moseley. Predicted increased risk of squamous cell carcinoma induction associated with sunbed exposure habits. British Journal of Dermatology, v 173, no 1, 201–208, 2015. Modelling of cancer risk due to sunbeds used as evidence in this paper is based on absolutely unrealistic assumptions: >83 sunbeds sessions/year or even 151 sessions/year, or 3 session every week (302 SEDs).	No change in the Opinion needed. The reference list was updated.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
105.	Zeyen Thierry, European Glaucoma Society Foundation, thierry.zeyen@telenet.be, Belgium	7.1 Non-cancer health effects: Vitamin D	risk_factor_AMD_3.pdf _UV_macular_degeneration_2.pdf	lines 23-24: Please note that the document states 7.1 Non-cancer health effects and 7.1.1. Vitamin D. The table of contents provided however for comments does not have this distinction. Our comment is a general one referring to the 7.1 Non cancer health effects. A separate section on visual impairment MUST be added under the heading 7.1 Non cancer health effects out of responsibility to increase awareness among the public regarding eye damage related with UV and in particular the irreversible visual impairment caused by associated with age related macular degeneration (AMD). Most eye conditions caused by UV can be repaired. However aside the fact that conditions are painful and treatment is costly, eye conditions normally related to ageing, such as cortical cataract and AMD, occur earlier under UV exposure. Again we would like to stress that the controversiality around AMD and UV link is a methodological issue that must not be overlooked as it is significantly linked with GDP per capita with implications for health equity.	Numbering was corrected. Please see the answers to comments 93-95.
106.	Autier Philippe, International Prevention Research Institute, philippe.autier@i-pri.org, France	7.1 Non-cancer health effects: Vitamin D	PhAutier_Comments_SCENIHR_UV.docx		The SCHEER acknowledges the constructive comments in the separate document and has adapted the text where needed. A full discussion on vitamin D levels and vitamin D supplementation is outside the scope of the mandate.
107.	Bocionek Peter, JW Holding GmbH (R & D), peter.bocionek@jw-holding.de, Germany	7.1 Non-cancer health effects: Vitamin D		page 32, line 18: The given statement is wrong. During the months from October to March there is no possibility to produce vitamin D by exposure to solar radiation in Middle and North Europe. Due to the absorption in the atmosphere no vitamin D effective UV radiation hits the earth's surface.	The text on vitamin D has been amended.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
108.	Baldermann Cornelia, German Federal Office for Radiation Protection, cbaldermann@bfs.de, Germany	7.1 Non-cancer health effects: Vitamin D		Page 31 / line number 42 - 43: The physiologically active form of vitamin D is 1,25-dihydroxy-vitamin D. Therefore the sentence "Further conversion into the physiologically active 25-hydroxy- and 25-dihydroxy-vitamin D occurs in the liver and kidney." should be replaced by the following sentence: "Further conversion into 25-hydroxy-vitamin D and the physiologically active 1,25-dihydroxy-vitamin D occurs in the liver and kidney." Page 32 / line number 10 – 12: The fact that a continuous increase in UV exposure does not lead to a continuing increase in the vitamin D blood serum level is not referable solely to exposure to artificial UV radiation in sunbeds, but applies to both natural and artificial UV radiation. It is suggested to insert the passage "However, tThe increase of UV-induced vitamin D production is limited. After reaching a plateau it will not increase; on the contrary: high UV doses can lead to degradation of vitamin D and reduce the vitamin D level (Holick 1981, Webb 1989)." as a single standing passage after line number 3 on page 32 and to complement it with the reference "Gilchrest, B.A., Sun exposure and vitamin D sufficiency. Am J Clin Nutr, 2008. 88(2): p. 570S-577S". Thus, the passage will be: "However, the increase of UV-induced vitamin D production is limited: after reaching a plateau it will not increase (Gilchrest 2008). On the contrary, high UV doses can lead to degradation of vitamin D and reduce the vitamin D level (Holick 1981, Webb 1989)." Page 32 / line number 18 – 20: There is a still ongoing discussion about the intake of appropriate vitamin D concentrations in the absence of endogenous vitamin D synthesis to achieve an optimal vitamin D level in blood serum. The German Nutrition Society (DGE) for example indicates that in the absence of endogenous	The SCHEER agrees with the comment. The text has been changed accordingly. The SCHEER agrees with the comment. The text has been changed accordingly. A discussion on appropriate vitamin D blood levels and vitamin D intake is outside the mandate.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				vitamin D synthesis an intake of 20 micrograms (800 IU) per day is appropriate (see.: ÖGE, S.u.D., Referenzwerte für die Nährstoffzufuhr. Vol. 1. Aufl., 5. überarb. Nachdruck (20. August 2013). 2013, Bonn: Umschau Buchverlag; https://www.dge.de/wissenschaft/referenzwerte/vitamin-d). Therefore, and because supplementation of vitamin D is not the issue of this Opinion, the naming of quantities is not effective. It should be just emphasized that supplementation increases the vitamin D level in blood serum effectively.	No changes in the Opinion are needed.
109.	Gilroy Steven, Joint Canadian Tanning Association JCTA, info@TanCanada.org, Canada	7.1 Non-cancer health effects: Vitamin D	 Holick_2011_-_Evaluation_treatment_and  Luxwolda_2012_-_Traditionally_living_pop  Baggerly_2015_-_Sunlight_and_Vitamin_D	Page 31 - line 38-40 The Institute of Medicine (IOM) (2010) recommends that people maintain a vitamin D level of at least 20 ng/ml (50 nmol/L). This is what is followed by Health Canada. It should be noted that other groups recommend higher vitamin D blood levels than Health Canada and the IOM. The Endocrine Society in the USA recommend a 25(OH)D level of 30ng/ml (75 nmol/L) (Holick 2011). A group of 50 of the top vitamin D scientists, researchers and doctors through GrassrootsHealth recommend that for optimal health everyone maintain a 25(OH)D level of between 40-60 ng/ml (100-150 nmol/L). In Canada 90% of the population is below 40 ng/ml (100 nmol/L) (Langlois 2010). It should be noted that African nationals living under ancestral conditions exhibit vitamin D status in the middle of this range of 46 ng/ml (115 nmol/L) (Luxwolda 2012). According to the lab testing in Canada the optimum blood levels should be between 75nmol/L to 150nmol/L Page 32 - Line 1-3 Recent research	A discussion on appropriate vitamin D blood levels and vitamin D intake is outside the mandate. No changes in the Opinion are needed.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
			Langlois_2010_-_Vitamin_D_status_of_Car Cashman_2016_-_Vitamin_D_deficiency_in Holick_2007_-_Vitamin_D_and_Skin_Physic Mason_2012_-_Sunlight_Vitamin_D_and_S	from Europe have found that 40.4% of the population does not meet a 25(OH)D blood level of 20 ng/ml (50 nmol/L) (Cashman 2016). This shows that people who are following the current health organizations recommendations to avoid sun exposure at midday and use sun protection strategies is having a devastating effect on vitamin D levels. Page 32 - line 4-6 Few foods naturally contain or are fortified with vitamin D. In Europe, where very few foods are fortified with vitamin D, children and adults would appear to be at especially high risk (Holick 2007). This statement is not true according to the NIH website on vitamin D - https://ods.od.nih.gov/factsheets/VitaminD-HealthProfessional/, it clearly states in the Introduction; Vitamin D is a fat-soluble vitamin that is naturally present in very few foods, added to others, and available as a dietary supplement. It is also produced endogenously when ultraviolet rays from sunlight strike the skin and trigger vitamin D synthesis.In the section under sources it states the following: Very few foods in nature contain vitamin D. The flesh of fatty fish (such as salmon, tuna, and mackerel) and fish liver oils are among the best sources [1,11]. Small amounts of vitamin D are found in beef liver, cheese, and egg yolks. Vitamin D in these foods is primarily in the form of vitamin D3 and its metabolite 25(OH)D3 [12]. Some mushrooms provide vitamin D2 in variable amounts [13,14]. Mushrooms with enhanced levels of vitamin D2 from being exposed to ultraviolet light under controlled conditions are also available. There are a number of relevant research paper missing. Mason2012, this is a full review of vitamin D and Skin cancer. This paper identifies the protective effects of vitamin D and how vitamin D is probably the first line of defense against skin	Please see the answer above.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				cancer, where melanin production and cornification is second and third. Mason 2012 state; The photoprotective effects of vitamin D compounds against thymine dimers and apoptosis demonstrated in mouse and human skin, and protection against photoimmune suppression and photocarcinogenesis in mice has led to the proposal that photosynthesis of vitamin D from UVB in skin and its local conversion to the active hormone 1,25(OH)2D3 is an adaptive mechanism for cellular defense against further UV exposures. Research from Vitamin D researchers state that 80 to 90% of vitamin D is produced from sunlight and not food (Yang 2011 - IARC 2008 Vitamin D and Cancer). Also vitamin D produced by UVB through the skin is controlled and will not go to toxic levels, where supplements can achieve toxic levels (IARC 2008 Vitamin D and Cancer).	The protective effect (from a paper by Mason's group) is now mentioned in the text.
110.	Gilroy Steven, Joint Canadian Tanning Association, info@TanCanada.org, Canada	7.1 Non-cancer health effects: Vitamin D	Holick_2011_-_Evaluation_treatment_and UK_-_Consensus_Vitamin_D_position_stat Schwalfenberg_2010_-_Addressing_vitami	Page 32 - line 9-12 According to Dr. M. Holick (Feb 2016): there are 2 things going on simultaneously both 7-dehydrocholesterol and previtamin D are absorbing ultraviolet radiation. The previtamin D3 will photoisomerize to lumisterol and tachysterol. At the same time 7-dehydrocholesterol will be converted to previtamin D and thus the amount of previtamin D3 does not decrease. It is in a photoequilibrium. Page 32 – line 13 to 17 Other sources can take a person to toxic levels, UV can't. According to Dr. M. Holick (Feb 2016): there are 2 things going on simultaneously both 7-dehydrocholesterol and previtamin D are absorbing ultraviolet radiation. The previtamin D3 will photoisomerize to lumisterol and tachysterol. At the same time 7-dehydrocholesterol will be converted to previtamin D and thus the amount of previtamin D3 does not decrease. It is in a photoequilibrium. Page 32 – line 22-26 This document reports "There is no difference in the biological (and general	The SCHEER agrees with the comment. The text has been changed accordingly.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				health) effects induced by UV radiation in respect to their origin, the natural solar UV or artificial UV from e.g. tanning devices. UV-radiation (UVA, UVB, UVC) from the sun or from tanning devices has been classified by IARC (2009) as carcinogenic to humans (class 1, IARC). (Page 60, *. Opinion, Line 15-18)." The sun and solar UV has been included in IARC Group 1 since 1992. UV from sun or sunbeds is the same and has the same risks and the same benefits, expect a sunbed can be controlled. The UK Consensus Vitamin D Position Statement (2010) endorsed by British Association of Dermatologists, Cancer Research UK, Diabetes UK, the Multiple Sclerosis Society, the National Heart Forum, the National Osteoporosis Society and the Primary Care Dermatology Society stated "Enjoying the sun safely, while taking care not to burn, can help to provide the benefits of vitamin D without unduly raising the risk of skin cancer."Therefore, if UV from sun or sunbed is the same, based on this statement endorsed by BAD, people who do not burn using a sunbed would not unduly increase their risk of skin cancer. The bottom line is that sunbeds are an effective producer and source of vitamin D (Schwalfenberg 2010). Melanoma skin cancer risks from intermittent outdoor UV exposure is 61% (IARC Monograph 2012) whereby melanoma risk from indoor sunbed exposure is 16% (Colantonio 2014). Therefore sunbeds provide a 4X lower risk than outdoor exposure and should be embraced and recommended.	Advice on sunbathing is outside the mandate of this Opinion. The Opinion states that sunbeds can raise blood levels of vitamin D.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
111.	ANSES	7.1 Non-cancer health effects: Vitamin D		§ 7. Health effects, p34, lines 17-18 Comment: It should be noticed that there is also no consensus on whether increasing vitamin D level would be a desirable health intervention and there is no scientific evidence to support such an intervention. And even, if some interventions could be desirable for improving one's health in particular populations, these populations are not yet clearly identified nor the level below which such intervention would bring a health benefit.	The SCHEER agrees with the comment.
112.	Grant William, Sunlight, Nutrition and Health Research Center, wbgrant@infionline.net, United States	7.1 Non-cancer health effects: Vitamin D		p. 31, line 23. The title should be "Non-skin cancer health benefits"	It is not certain that immunosuppression is a health benefit.
113.	Grant William, Sunlight, Nutrition and Health Research Center, wbgrant@infionline.net, United States	7.1 Non-cancer health effects: Vitamin D	 112-Pan_can_Wolpin .pdf	p. 31, lines 29-35. For pancreatic cancer, a a pooled analysis of nested case–control studies with 451 cases and 1,167 controls from five cohorts through 2008 found a significant inverse correlation between 25(OH)D concentration and incidence of pancreatic cancer [Wolpin, 2012]. Wolpin BM, Ng K, Bao Y, Kraft P, Stampfer MJ, Michaud DS, Ma J, Buring JE, Sesso H, Lee IM, Rifai N, Cochrane BB, Wactawaski-Wende J, Chlebowski RT, Willett WC, Manson JE, Giovannucci EL, Fuchs CS. Plasma 25-hydroxyvitamin D and risk of pancreatic cancer. Cancer Epidemiol Biomarkers Prev. 2012;21(1):82-91.	Discussion of relations between vitamin D blood levels and risk of cancer is outside the mandate. No changes to the Opinion are required in relation to the comment.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
114.	Grant William, Sunlight, Nutrition and Health Research Center, wbgrant@infionline.net, United States	7.1 Non-cancer health effects: Vitamin D	 Grant_Breast_cancer _case-control_Antica	p. 31, lines 29-35. If the criterion for vitamin D reducing risk of cancer is support from observational studies finding consistent inverse associations between vitamin D status and incidence and/or mortality rates, then there is strong evidence that vitamin D does reduce the risk of many types of cancer. The references listed in lines 31-32 all had biases in terms of who did the reviews, which papers they included, and how they assessed the findings. A better approach is to find the best paper(s) for each type of cancer. For breast cancer, 11 case-control studies from seven countries find the same inverse correlation between 25-hydroxyvitamin D [25(OH)D] and incidence [Grant, 2015]. The reason that prospective studies with follow-up timed longer than three years do not find significant inverse correlations is that 25(OH)D concentrations vary with season and time and breast cancer develops very rapidly, supported by the recommendations to have mammographic screening annually. Grant WB. 25-Hydroxyvitamin D and breast cancer, colorectal cancer, and colorectal adenomas: case–control versus nested case–control studies, Anticancer Res. 2015;35(2):1153-60.	A full discussion on the relation between vitamin D and cancer is outside the scope of this mandate.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
115.	Grant William, Sunlight, Nutrition and Health Research Center, wbgrant@infionline.net, United States	7.1 Non-cancer health effects: Vitamin D	Moukayed_Grant_vit_D_cancer_Nutrients.	p. 31, lines 29-35. In addition, results from other types of studies such as ecological studies and clinical trials. For example, geographical ecological studies in single mid-latitude countries are in substantial agreement that solar UVB doses are inversely correlated with incidence and/or mortality rates of about 15 types of cancer, and most of these studies accounted for other cancer risk-modifying factors [Moukayed, 2013]. The only mechanism proposed to explain these findings is vitamin D production from solar UVB exposure. Moukayed M, Grant WB. Molecular link between vitamin D and cancer prevention. Nutrients. 2013;5(10):3993-4021.	A full discussion on the relation between vitamin D and cancer is outside the scope of this mandate.
116.	Grant William, Sunlight, Nutrition and Health Research Center, wbgrant@infionline.net, United States	7.1 Non-cancer health effects: Vitamin D	49-Bolland_WHI_2011.pdf 64-UV_lymphoma_Boffetta.pdf	p. 31, lines 29-35. A reanalysis of a major clinical trial with supplements of 400 IU/d vitamin D plus 1500 mg/d calcium in the U.S. found that women who had not taken vitamin D or calcium prior to enrolling taking vitamin D plus calcium significantly decreased the risk of total, breast, and invasive breast cancers by 14-20% and nonsignificantly reduced the risk of colorectal cancer by 17% [Bolland, 2011]. Bolland MJ, Grey A, Gamble GD, Reid IR. Calcium and vitamin D supplements and health outcomes: a reanalysis of the Women's Health Initiative (WHI) limited-access data set. Am J Clin Nutr. 2011 Oct;94(4):1144-9. "A multicentre case–control study during 1998–2004 in France, Germany, Ireland, Italy and Spain, comprising 1518 cases of NHL, 268 cases of Hodgkin lymphoma, 242 cases of multiple myeloma and 2124 population or hospital controls found The risk of Hodgkin and NHL was increased for increasing skin sensitivity to the sun [odds ratio (OR) for no suntan vs very brown 2.35, 95% CI 0.94–5.87 and 1.39, 95% CI 1.03–1.87, respectively]. The risk of diffuse large B-cell	A full discussion on the relation between vitamin D and cancer is outside the scope of this mandate. The Opinion is about evidence for health effects from sunbeds per se. A discussion on outdoor (sun) exposure is outside the scope of the mandate. The Boffetta study is reviewed in the IARC monograph, which is mentioned in the chapter on internal cancers.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				lymphoma was reduced for increasing adult personal (OR for highest vs lowest quartile of exposure in free days 0.62, 95% CI 0.44–0.87) and for occupational exposure to UV radiation (OR for highest vs lowest exposure tertile 0.63, 95% CI 0.37–1.04)..... A protective effect was observed for use of sun lamps for diffuse large B-cell lymphoma (OR for 25þ times vs never 0.63, 95% CI 0.38–1.03)." Boffetta P, van der Hel O, Kricker A, Nieters A, de Sanjosé S, Maynadié M, Cocco PL, Staines A, Becker N, Font R, Mannetje A', Goumas C, Brennan P. Exposure to ultraviolet radiation and risk of malignant lymphoma and multiple myeloma--a multicentre European case-control study. Int J Epidemiol. 2008 Oct;37(5):1080-94.	
117.	Grant William, Sunlight, Nutrition and Health Research Center, wbgrant@infionline.net, United States	7.1 Non-cancer health effects: Vitamin D	 64-McDonnell_et_al._25OHD_cancer_incic	A pooled analysis of cancer incidence for 2304 women, of whom 58 developed cancer during a mean observational period of 3.9 years found a very significant inverse correlation between either baseline or mean 25(OH)D concentration and all-cancer incidence. Women with 25(OH)D concentrations _40 ng/ml had a 67% lower risk of cancer than women with concentrations <20 ng/ml (HR = 0.33, 95% CI = 0.12–0.90). [McDonnell, 2016].	Please see above: a full discussion on vitamin D levels and disease is outside the scope of the Opinion.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
118.	Grant William, Sunlight, Nutrition and Health Research Center, wbgrant@infionline.net, United States	7.1 Non-cancer health effects: Vitamin D	Cannell__Grant__Holick_Vit_D_inflammatio Grant_EJCN.pdf Pludowski_Warsaw_vitamin_D_AR_2013.	p. 31, lines 35-37. The statement regarding low vitamin D status is a consequence of inflammatory disease was an assumption, not a fact. From Autier, 2014, p. 12: "Many prospective studies have shown associations between low 25(OH)D concentrations and a wide range of acute and chronic health disorders. However, an equally similar number of randomised trials have not confirmed that raising of 25(OH)D concentrations can modify the occurrence or clinical course of these disorders. Hence, associations between 25(OH)D and health disorders reported by investigators of observational studies are not causal. Low 25(OH)D could be the result of inflammatory processes involved in the occurrence and progression of disease." In response to that paper, a review of clinical trials of vitamin D and biomarkers of inflammation was conducted. It was found that for baseline 25(OH)D concentration < 20 ng/mL, there was a 50% chance that a beneficial effect would be found; however, for higher baseline concentrations, the probability dropped to 26% [Cannell, 2015]. Cannell JJ, Grant WB, Holick MF. Vitamin D and inflammation. Dermatoendocrinol. 2015 Jan 29;6(1):e983401. p. 31, lines 38-40 The best estimate of the health effects of vitamin D indicate that the optimal level of 25-hydroxyvitamin D is above 30-40 ng/mL: Grant WB. An estimate of the global reduction in mortality rates through doubling vitamin D levels. Eur J Clin Nutr. 2011 September;65(9):1016-26. McDonnell SL, Baggerly C, French CB, Baggerly LL, Garland CF, Gorham ED, Lappe JM, Heaney RP. Serum 25-Hydroxyvitamin D Concentrations ≥40 ng/ml Are Associated with >65% Lower Cancer Risk: Pooled Analysis of Randomized Trial and Prospective Cohort Study. PLoS One. 2016 Apr 6;11(4):e0152441 Pludowski P, Holick MF, Pilz S, Wagner CL, Hollis BW, Grant WB, Shoenfeld Y, Lerchbaum E, Llewellyn DJ, Kienreich K, Soni M. Vitamin D effects on musculoskeletal health,	The SCHEER agrees with the comment. The text has been changed accordingly. A discussion on vitamin D levels and vitamin D supplementation in relation to disease is outside the scope of the mandate.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				immunity, autoimmunity, cardiovascular disease, cancer, fertility, pregnancy, dementia and mortality- a review of recent evidence. Autoimmun Rev. 2013 Aug;12(10):976-89.	
119.	Grant William, Sunlight, Nutrition and Health Research Center, wbgrant@infionline.net, United States	7.1 Non-cancer health effects: Vitamin D	 211-Tanning_vit_D_colds_de_Gruijl.pdf  34-Sunbeds_vit_D_Orlova_Moan.pdf  64-25OHD_half-life_Jones.pdf  411-Hypponen_25OHD_season.pdf	p. 32, lines 7-9. See, also additional papers showing that sunbeds used in Europe produce vitamin D: de Gruijl FR, Pavel S. The effects of a mid-winter 8-week course of sub-sunburn sunbed exposures on tanning, vitamin Dstatus and colds. Photochem Photobiol Sci. 2012 Dec;11(12):1848-54 Orlova T, Moan J, Lagunova Z, Aksnes L, Terenetskaya I, Juzeniene A. Increase in serum 25-hydroxyvitamin-D3 in humans after sunbed exposures compared to previtamin D3 synthesis in vitro. J Photochem Photobiol B. 2013 May 5;122:32-6. p. 32, lines 10-12. The reason for the plateau is primarily related to the amount of vitamin D produced and destruction by enzymes. Destruction by UV is a minor effect. Plasma 25(OH)D half-life is likely to be determined by the metabolism of 25(OH)D to downstream metabolites and by its catabolism, driven primarily by the activities of the enzymes CYP27B1 (producing 1,25(OH)2D) and CYP24A1 (catabolising 25(OH)D and further downstream metabolites) [6] Jones KS, Assar S, Vanderschueren D, Bouillon R, Prentice A,	The Opinion states that sunbeds can enhance vitamin D levels in the blood. The text has been modified. The SCHEER agrees with the comment. The text has been changed accordingly. The line with the word degradation

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				Schoenmakers I. Predictors of 25(OH)D half-life and plasma 25(OH)D concentration in The Gambia and the UK. Osteoporos Int. 2015 Mar;26(3):1137-46. p. 32, lines 18-21. The recommendations given hers for UV exposure and oral intake are too low to achieve 30-40 ng/mL, especially in winter. Hyppönen E, Power C. Hypovitaminosis D in British adults at age 45 y: nationwide cohort study of dietary and lifestyle predictors. Am J Clin Nutr. 2007 Mar;85(3):860-8.	has been removed. The SCHEER agrees with the comment. The text has been changed accordingly. The recommendation about dose has been removed.
120.	Grant William, Sunlight, Nutrition and Health Research Center, wbgrant@infionline.net, United States	7.1 Non-cancer health effects: Vitamin D	 64-Mult_sclerosis_UV__vitamin_D_Lucas.d	p. 33, lines 11-16. There are vitamin D-dependent and independent benefits of UV exposure on risk of multiple sclerosis: Lucas RM, Byrne SN, Correale J, Ilschner S, Hart PH. Ultraviolet radiation, vitamin D and multiple sclerosis. Neurodegener Dis Manag. 2015 Oct;5(5):413-24.	Text on evidence for UV from sunbeds on multiple sclerosis is inserted in the chapter on non-cancer health effects.
121.	Dr. Richarz Frank, IEC TC61 / MT16 'Biological effects of optical radiation', MT16@richarz-consulting.de, Germany	7.1 Non-cancer health effects: Vitamin D	 Grant__Garland__Holick_UV_vit_D_econor  J._Nutr.-2005-Calvo-310-6.pdf  Sonnenspektrum_CIE.pdf	page 31 line 31 "IARC 2008 conclusions should be added: - No health effect with Vitamin D supplementation. -Vitamin D could be more influential on cancer progression and thus for cancer mortality rather than cancer incidence." The file IARC 2008 is too big for an upload and therefore submitted per e-mail. page 31 line 39 WHO states <20ng/ml as deficient and 30 ng/ml as optimal page 31 line 45 NIH propose a daily production or intake of vitamin D of 400 IU = 10µg, Grant 2005 and others propose a daily production or intake of 1000 IU = 25 µg and the very recent draft scientific Opinion of the European Food Safety Authority recommends a daily intake of 600 IU = 15µg. page 32 line 3 "Even the title of Rhodes study says "",but not the proposed	A full discussion on appropriate vitamin D blood levels and vitamin D intake is outside the mandate.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
			Ausgewa_hlte_Frage n_und_Antworten_zu Recommended_sum mer_sunlight_exposu	optimal"" The very same authors published in the same year 2010: ""The role of sunlight exposure in determining the Vitamin D status of the UK white adult population"" with the conclusion: ""Late summer Vitamin D levels are to low to retain sufficient during winter time. The majority becomes insufficient during winter < 20 ng/ml"" " page 32 line 6 It should be mentioned that beside intake of higher amounts of fish liver oil a normal diet is not able to provide sufficient Vitamin D. It has either be produced in the normal natural process in the human skin by UVR or needs to be taken by supplements. (Calvo 2005) page 32 line 7 The UVB content of sunbeds lays around 1-2%, a typical summer afternoon value in Middle Europe. Therefore the UVB content in sunbeds do not differ from natural UVR. Values of UVB do not exceed 3,5% UVB at noon on June 21st with clear sky and 220 DU. (CIE 151:2003) page 32 line 12 Natural production of Vitamin D will regulate the Vitamin D level accordingly. Only oral supplements > 100µg/day have been shown to lead to an oversupply of Vitamin D and kidney diseases. (BfR 2014) page 32 line 18 Due to the longer pathway through the atmosphere in winter time natural UVR doesn't contain any UVB in Scandinavia from October to April. Without UVB there will be no Vitamin D production in this time and due to the lowered UVR exposure to indoor workers in general the Vitamin D level at the end of summer is mostly not sufficient to stay healthy during the winter. (Webb 2010)	

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
122.	Dr. Richarz Frank, IEC TC61 / MT16 'Biological effects of optical radiation', MT16@richarz-consulting.de, Germany	7.1 Non-cancer health effects: Vitamin D	 Recommended_summer_sunlight_exposu  The_role_of_sunlight_exposure_in_determ	Summary page 34 line 15 - 26 "UVR is the NATURAL way to achieve sufficient or optimal vitamin D levels. Unfortunately modern life habits do not allow 'natural' behavior of most of the European population with a natural exposure from spring to fall in achieving a healthy vitamin D level. Exposing of face and hands do not provide sufficient Vitamin D in wide parts of Europe over the year. End summer levels of indoor workers are too low to keep the population on a sufficient level over the winter. (Webb2010) Usual exposure to UVR of the sun and a normal diet is NOT sufficient to achieve sufficient Vitamin D levels"	A full discussion on appropriate vitamin D blood levels and vitamin D intake is outside the mandate.
123.	Wunsch Alexander, Medical Light Consulting, praxis@alexanderwunsch.de, Germany	7.1 Non-cancer health effects: Vitamin D	 1.pdf  2.pdf	P31/23: Chapter regarding Vitamin D is numbered 7.1.1 in the Opinion, but the chapter number does not appear on the web page for response to the Opinion, therefore no correct referral to this topic is possible. Pagination is wrong, which might lead to rejection of comments of this essential topic due to the automatized process. In addition to that, pagination (page number) of page 31 in the Opinion is also missing! 7.1.1 Vitamin D 31/34-35: "These analyses confirm the association with colon cancer, whereas the association with other types of cancer is as yet unclear." The association with other types of cancer might be not finally confirmed, but has to be discussed in greater detail than found in the Opinion. P31/43-45 + P32/1: Studies in Lille, France (Lat 50.28 N) have shown that in June, for phototype II skin 20-30 minutes of exposure of the face and hands to sunlight are sufficient to produce 1,000 international units vitamin D (Colette Brogniez, personal communication). Interestingly, such important claims are based on "personal communication". Again, the message to the public is: Expose face and hands to sunlight in order to maintain a sufficient vitamin D level. According to	The SCHEER agrees with the comment. The text has been changed accordingly. A full discussion on vitamin D and cancer is outside the mandate of the Opinion. Advice on outdoor natural sun exposure is outside the mandate of the Opinion. A discussion on food contamination by toxic chemicals

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				recent recommendations the message should read instead: Protect the sun terraces (face and hands) whenever you can and use large areas of the skin normally shielded from sunlight for cutaneous vitamin D synthesis instead. The larger the skin area and the higher the solar elevation angle, the shorter the exposure time necessary for sufficient effects. (1.pdf) 32/4-6: A major source of vitamin D can be dietary intake: fish and fish liver oils contain ample amounts of it and to a lesser extent vitamin D is present in beef liver, cheese and egg yolk (NIH 2014). The recommendation to replace sunlight exposure with fish and fish liver oil is a Janus-faced issue due to the mercury contamination leading to long term deposition of this highly toxic heavy metal in the organism. The dietary recommendations are useless for vegan population. The recommendation might also be misleading due to the unhealthy amounts of liver (hormones and toxins), cheese (fat) and egg yolk, which would be necessary to reach the desired levels. In addition, the content of any compound is subject to considerable variations in natural products which makes reliable planning difficult. (2.pdf) 32/18: A few minutes outdoors around the middle of the day is sufficient. Again, the public is encouraged to expose the predilection sites for NMSC to the sunlight.	is outside the mandate of the Opinion.
124.	Lipman Gary, The Sunbed Association, garylipman.tsa@gmail.com , United Kingdom	7.1 Non-cancer health effects: Vitamin D		Page 34, lines 15-20: This hypothesis requires a particular intensity of sunshine exposure daily throughout the year to maintain adequate Vitamin D sufficiency. It defies medical science, logic and common sense to state that humans in Europe can synthesise Vitamin D on cloudy days. I rather suspect this hypothesis emanates from sub-tropical areas of Australia. Australia and New Zealand have the highest ambient UV levels in the world. Page 34, lines 21-22: It is accepted by the SCENIHR that it is excessive or over exposure to sunshine that causes health concerns, not	The SCHEER agrees with the comment. The text has been changed accordingly.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				exposure per se. It is therefore disingenuous to state that UV light (UVA as well as UVB) has an immunosuppressive effect on the skin and also a systemic immunosuppressive effect. Context is important when statements like these are made. Page 34, lines 23-24: This is a cosmetic issue and not a health concern and therefore, in my Opinion, outside the remit of the SCENIHR. Nevertheless, it is clear that it is accepted that it is excessive or chronic exposure that can lead to health concerns, not exposure per se. Page 34, lines 25-26: Humans are not addicted to UV exposure. We are attracted to UV exposure. It is entirely natural because most living things are supposed to get regular UV exposure to be healthy. This is nature's design. To say anyone is addicted to UV is like saying they are addicted to air, food or water. We are naturally attracted to these things because we need them.	The Opinion states that these effects are dose-dependent. The word addictive has been removed, whereas this issue is discussed in the preceding paragraph.
125.	Lipman Gary, The Sunbed Association, garylipman.tsa@gmail.com , United Kingdom	7.1 Non-cancer health effects: Vitamin D	 Vit_D_Synthesis_in_relation_to_latitude__  EN16489-1_EN.pdf	Second page of points for this section. Other submission is for summary section of 7.1 Page 32, lines 1-3: Whilst this may well be correct, citing a sunny day in June ignores the fact that, this hypophysis requires such exposure daily throughout the year to maintain adequate Vitamin D sufficiency and even on a sunny day between October and May in the Northern hemisphere, the sun is not strong enough for the skin to synthesise Vitamin D. Page 32, lines 4-6: A typical sunbed session can generate 10,000 IU Vitamin D. It is true that diet can help the body obtain Vitamin D sufficiency. However, the volume of fish, fish liver oils, beef liver, cheese and egg yolk that a person would need to eat is too substantial for most people. SCEHIHR ignores the fact that many people are vegetarian, vegan and some have intolerance to dairy products.	The text on vitamin D has been amended. The text of the Opinion has been amended.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				Page 32, lines 10-12: High UV doses refers to antiquated sunbeds, medical UV devices and or over exposure in general. Since July 2007, all sunbeds supplied new or traded second-hand in Europe , must comply with EN 60335-2-27 which requires all sunbeds to have a maximum UV emission level of 0.3W/m2. In professional tanning salons an appropriate session time will be provided to a screened client to help ensure that they do not exceed the recommended dosage. Client details will be registered and usage will be recorded to prevent excessive use. Salon staff across Europe can now receive accredited Professional indoor UV exposure services training to the EN16489 Standard. Page 32, lines 15-17 The use of the word 'excessive' indicates chronic use and over exposure. This is far more likely in the natural sunshine as, statistically speaking, more people over expose themselves to UV in sunshine than on a sunbed. In professional tanning salons an appropriate session time will be provided to the screened client to help ensure that they do not exceed the recommended dosage. Client details will be registered and usage will be recorded to prevent excessive use. Salon staff across Europe can now receive accredited Professional indoor UV exposure services training to the EN16489 Standard. The volume of fish, fish liver oils, beef liver, cheese and egg yolk that a person would need to eat is too substantial for most people. SCENIHR ignores the fact that many people are vegetarian, vegan and some have intolerance to dairy products. contd/...	The text of the Opinion has been amended. Lines are removed.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
126.	Lipman Gary, The Sunbed Association, garylipman.tsa@gmail.com, United Kingdom	7.1 Non-cancer health effects: Vitamin D	Moan_Grant_sunbeds_as_UV_Sources_wit 1211_de_Gruijl_effects_of_a_mid_winter_ 211-UVB_vit_D_Engelsen__1_.pdf	Contd/... this is 2nd page of comments for this section (total 3 pages) Page 32, lines 22-26 The British Association of Dermatologists (BAD) have chosen to ignore the research papers that confirm that sunbed use can synthesise Vitamin D. In my Opinion, the BAD decision not to recommend sunbeds to enhance Vitamin D is borne from political ideology and ignores compelling research proving the efficacy of Vitamin D synthesis from sunbeds.	Other public organisations also do not recommend sunbed use for vitamin D.
127.	Nilsen Lill Tove, Norwegian Radiation Protection Authority, Lill.Tove.Nilsen@nrpa.no, Norway	7.1 Non-cancer health effects: Vitamin D	Bogh2010_Vitamin_D_depends_on_baselin Bogh2011_BJD_surfacearea_vitD_UVBdos Bogh2012_BJD_suberythemal_UVBdose_v	Page 31, line 43-45 and page 32, line 1-3: With reference to the study in Lille, it should be included how many subjects that were included, as well as the variations among the subjects. Furthermore, it should be specified if the 20-30 minutes exposure refers to a single exposure. It is known that the vitamin D content in the blood levels off after several UV exposures, and that the increase in vitamin D varies among individuals and depends very much on the baseline. This is shown by Rhodes et al., as you already refer to, and also by Bogh et al. (J Investigative Dermatol 2010: 130: 546-553 and Br J Dermatol 2011: 164: 163-169). Page 32, line 7-12: Bogh et al. also show vitamin D levels after sunbed exposure (J Investigative Dermatol 2010: 130: 546-553, Br J Dermatol 2011: 164: 163-169 and Br J Dermatol 2012: 166: 430-433)	No change in the Opinion is needed. The text has been modified to make it clear that vitamin D is levelling off. The Bogh studies (not with sunbeds) confirm that small amounts of artificial UVB raise vitamin D levels.
128.	de Gruijl Frank, representing none, degruijl@planet.nl,	7.1 Non-cancer health effects: Vitamin D		7.1.1 - p32, line 1, "personal communication" not suited for an authorative document like this. inadequate info to assess methodology/reliability:	

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
	Netherlands			remove pg 32, line 5, MUCH less vitamin D in other foods than fish pg 32, line 12, never shown in vivo, sun/sunbeds yield net gain in vitamin D pg 32, lines 13 -15, completely unsubstantiated speculative statement – should be removed pg 32, line 16, Levin 2005, this is a review without original data to support this statement; this review goes back to the older data which did not show that degradation is an important factor with sunbeds, use of which does result in substantial increases in UV levels. (optimal spectra for tanning and vitamin D are, however, likely to differ, especially where UVA is concerned, and UV lamps can be designed to match these purposes) pg 32, line 17, "other adequate sources available" is a misleading statement as the Western diet is recognized to be notoriously inadequate in vitamin D by various official bodies and institutes; sun exposure is an essential source of vitamin D for the Western population and determines the seasonality in vitamin D status. (Moreover, recent research on alterative metabolites of vitamin D, from CYP11A1, could imply differences in UV induced vitamin D metabolites/effects from those by oral vitamin D; Slominski et al. Steroids. 2015;103:72-88) pg 32, line 18, "a few minutes" in sunny in Australia, but not in NW Europe if only hands and face are exposed, and certainly not if it is not an exposure around noon. pg 32, lines 25 -26, this is the case because the evidence for a beneficial UV effect over a vitamin D effect is weak/insufficient 7.1.2 - pg 32, line 39 –	Up to a plateau, because equilibrium ensues. The text has been changed. The SCHEER disagrees with the comment. The text of the Opinion was changed accordingly. Other sources are sunlight as well as diet or supplements. Many public health authorities recommend easily available oral supplementation. The text of the Opinion has been amended for clarity.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				41, there is also proof that UVA counters UVB immunosuppression in mice by IL12 production (Reeve VE, et al. Photochem Photobiol. 2006;82:406-11) - pg 33, line 7, UVA at high dosages could antagonize immunosuppression at lower dosages, as it does counteract UVB-induced immunosuppression. - pg 33, line 8-10, whereas UVB (and vitD) is known to upregulate expression of antimicrobial peptides! 7.1.4 Mood and behaviour -pg 34, lines 5-6, UV releases endorphins in mice: Fell GL, et al, Cell. 2014;157:1527-34 Summary - pg 34, line 18, with heavy overcast UV-index falls below 3, like in Winter when no vitamin D is formed in the skin by UV. - pg 34, line 20, special vitamin D sources are available (amply?), mainly fatty fish or pills. But who is aware of that? The normal Western diet is inadequate. Other food is simply not adequate if not strongly fortified. Only realistic option is vitD supplementation in winter to attain summer levels of vitD - pg 34, lines 21-22, but UVA loses its immunosuppressive effects at high dosages and counteracts UVB induced immunosuppression	This is reflected upon in the Opinion. This is reflected upon in the Opinion.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
129.	Gilroy Steven, Joint Canadian Tanning Association JCTA, info@TanCanada.org, Canada	7.1.2 Immunosuppression	Freedman_2000_-_Mortality_from.pdf Van_der_Mei_2003_-_Past_exposure_to_s Baarnhielm_2012_-_Sunlight_is_associete Bjornevik_2014_-_Sun_exposure_and_mul Islam_2007_-_Childhood_sun_exposure_ir Becklund_2011_-_UV_radiation_suppresse	Page 33 Line 11-16 In addition, immunosuppression may have health benefits particularly for modulating the immune system. There is compelling evidence that suggests that higher levels of sun exposure are associated with decreased risk and disease activity in autoimmune diseases like MS, probably through both vitamin D and non-vitamin D pathways (Lucas 2015). Occupational studies have found that outdoor work in an area of high sunlight could reduce the risk of MS mortality by 76% (Freedman 2000). Higher sun exposure during childhood and early adolescence is associated with a 69% reduced risk of MS (Van der Mei 2003). A study from Sweden reported that subjects with low UVR exposure had a 2X increased risk of MS (Baarnhielm 2012). Frequent sunscreen use between birth and the age of 6 was associated with a 44% increased risk of MS in Norway (Bjornevik 2014). A study of twins found that the risk of MS was 60% lower for the twin who spent more time suntanning (Islam 2007).Studies have indicated that UVR is likely suppressing MS independent of vitamin D production and that vitamin D supplementation alone may not replace the ability of sunlight to reduce MS susceptibility (Becklund 2011). Lucas 2015 to large to upload	There are indeed several studies that examine the association between (outdoor) sun exposure and disease. It is far from resolved whether the studies are dealing with UV exposure or other factors. A transposition of these studies to artificial UV exposure is as yet far-fetched, although artificial UV is used to treat several inflammatory skin diseases.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
130.	Wunsch Alexander, Medical Light Consulting, praxis@alexanderwunsch.de, Germany	7.1.2 Immunosuppression	 1.pdf	P32/35-41: "One of the mechanisms is via the immunologically important T lymphocytic cells: besides the reduced activation of effector and memory T cells, UV irradiation also activates the regulatory T and B cells (Schwarz 2008, Halliday 2012). Exposure to UV upregulates several other factors involved in immunosuppression, e.g.. TNF and the cytokines IL-10 and IL-33; this may explain that the suppressive effects of UV on skin immune status occur in the UVB as well as in the UVA range whereby the mechanisms may be different for UVA and UVB (Halliday 2012)." The effect of UV is not immunosuppressive, but immunomodulative: Some cell lines are suppressed, others are stimulated, which can be taken from the phrases cited above. Such reaction forms suggest that there is an underlying reason for the reaction of the organism. Adaptation to a stimulus and not mechanistic damage-only reaction. (1.pdf)	Most authors use the term immunosuppressive, as clearly demonstrated by the experimental effect on contact allergic reactions.
131.	de Gruijl Frank, representing none, degruijl@planet.nl, Netherlands	7.1.2 Immunosuppression		pg 32, line 39 – 41, there is also proof that UVA counters UVB immunosuppression in mice by IL12 production (Reeve VE, et al. Photochem Photobiol. 2006;82:406-11) pg 33, line 7, UVA at high dosages could antagonize immunosuppression at lower dosages, as it does counteract UVB-induced immunosuppression. pg 33, line 8-10, whereas UVB (and vitD) is known to upregulate expression of antimicrobial peptides!	The reference list was updated The text of the Opinion was changed.
132.	Dr. Richarz Frank, IEC TC61 / MT16 'Biological effects of optical radiation', MT16@richarz-consulting.de, Germany	7.1.3 Skin aging		page 33 line 39 Freckling appears with artificial UVR exactly the same as with natural UVR.	To avoid confusion, the word 'typical' has been removed.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
133.	Lipman Gary, The Sunbed Association, garylipman.tsa@gmail.com , United Kingdom	7.1.3 Skin aging		Page 33, lines 22-33: It is accepted by the SCENIHR that it is excessive or over exposure to sunshine that can cause skin-aging. It can, of course be argued that excessive use or intake of anything can lead to health concerns. However, this is a cosmetic issue and not a health concern and therefore, in my Opinion, outside the remit of the SCENIHR. Nevertheless, it is clear that it is accepted that it is excessive or chronic exposure that can lead to health concerns, not exposure per se.	UV exposure has an additive aging effect on the skin, and it is indeed a matter of dose.
134.	Lasse Ylianttila, STUK, lasse.ylianttila@stuk.fi, Finland	7.1.4 Mood and behavior	 1-s2.0-S1011134415300245-main.pdf	page 34, 7-13, I would like to bring to your attention a new (2016) paper, where raised beta-endorphin was was found after UVB exposure.	Text of the Opinion was changed for clarity. The reference list was updated.
135.	Dr. Richarz Frank, IEC TC61 / MT16 'Biological effects of optical radiation', MT16@richarz-consulting.de, Germany	7.1.4 Mood and behavior	 Gambichler_2002.pdf	page 33 line 45 Lam 1992 has only added UVA to this 'light therapy' not UV in total. UVB might have additional effects. page 34 line 1 Wrong citation probably due to copy and paste text from Feldman 2004. Correct citation is Broadstock 1992. page 34 line 6 but obviously psychological benefits are existing (Gambichler 2002)	Studies on additional UVB benefits could not be identified. The text of the Opinion was corrected. The Gambichler study was not cited because it was not a DBPC trial and could only hypothesise the attribution of well-being to having a tan.
136.	Lipman Gary, The Sunbed Association, garylipman.tsa@gmail.com , United Kingdom	7.1.4 Mood and behavior		Page 33, lines 43-46/ Page 34, lines 1-6: Humans are not addicted to UV exposure. We are attracted to UV exposure. It is entirely natural because most living things are supposed to get regular UV exposure to be healthy. This is nature's design. To say anyone is addicted to UV is like saying they are addicted to air, food or water. We are naturally attracted to these things because we need them.	These lines refer to a peculiar subgroup.

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137.	de Gruijl Frank, representing none, degruijl@planet.nl, Netherlands	7.1.4 Mood and behavior		7.1.4 Mood and behaviour -pg 34, lines 5-6, UV releases endorphins in mice: Fell GL, et al, Cell. 2014;157:1527-34 Summary - pg 34, line 18, with heavy overcast UV-index falls below 3, like in Winter when no vitamin D is formed in the skin by UV. pg 34, line 20, special vitamin D sources are available (amply?), mainly fatty fish or pills. But who is aware of that? The normal Western diet is inadequate. Other food is simply not adequate if not strongly fortified. Only realisitic option is vit D supplementation in winter to attain summer levels of vit D pg 34, lines 21-22, but UVA loses its immunosuppressive effects at high dosages and counteracts UVB induced immunosuppression	Endorphin release also in cells taken from human subjects. Statement on cloudy days has been removed. A full discussion about the need for vitamin D supplementation is outside the mandate of the Opinion. Losing this effect at higher doses is discussed in the Opinion. Counteraction is only shown in mice. The reference list was updated.
138.	Bocionek Peter, JW Holding GmbH (R & D), peter.bocionek@jw-holding.de, Germany	7.2.1.1 Meta-analyses and systematic reviews		page 34, line 38 - 43 Only four of the 19 single studies of the meta-analysis show positive results, i.e. the relative risks and the corresponding 95% confidence intervals are above 1.0. However, the dichotomization of the exposure is very differently defined at two studies. The remaining 16 studies show deviating results, i.e. 1.0 is within the 95% confidence interval. Since at six studies the calculated relative risk is negative, the meta-analysis results in an overall relative risk of 1.15 merely, in which "1" is contained in the corresponding 95% confidence interval (1.00 – 1.31). From the biometric point of view, the melanoma risk couldn't be proved as a consequence of the use of UV appliances for tanning purposes. The prospective description of the cohort study of Veierød et al. (2003) is doubtful due to the retrospective share of 40 years, particularly since the problem specifications are also unclear at the interview. At this study there is	The SCHEER agrees with the comment that meta-analyses are challenging to carry out. An introductory paragraph has been added concerning meta-analysis.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				a considerable discrepancy which indicates a miscalculation at the decisive relative risk. A relative risk of 2.58 (adjusted) is taken into the meta-analysis while a value of 1.63 (not adjusted) is being the result from the given frequencies. In the rule however, the deviations are less than 10% between adjusted and not adjusted relative risks or odds ratios. Furthermore and unlike to the six other studies this one-armed study has to be classified as not suitable for the meta-analysis from the biometric standpoint. Moreover, it should be taken into account that the damaging contribution of intended or unintentional UV exposure by natural sun radiation is only heavily delimitable and assessable from the additional effects of artificial UV exposure.	
139.	Bocionek Peter, JW Holding GmbH (R & D), peter.bocionek@jw-holding.de, Germany	7.2.1.1 Meta-analyses and systematic reviews		page 35, line 4 - 7 The seven single studies of the meta-analysis don't satisfy always the biometric requirements. Clear weaknesses cannot be overlooked at the definition of the target parameters. Often the primary target sizes aren't defined obviously and in addition, the necessary care at the separation between primary and secondary target parameters is also missing. Consequently, numerous risk calculations (up to almost 50) are carried out with the same data set. This leads to a multiple test problem at all studies as a consequence because the specified level of significance (usually 5%) will be exceeded widely. Since no adequate α-adjustment was performed, the probability of overestimations increases considerably. This means that the calculated odds ratios don't offer a confirmatory interpretation possibility but they have descriptive character only. The study of Westerdahl et al. (2000) contains a miscalculation at an odds ratio which is relevant for the meta-analysis. The value for the first use of indoor tanning equipment at the age < 35 years mentioned in the original paper is 2.0, whereas an odds ratio of 1,5 is arising from the given frequencies. Further discrepancies at the	Please read the response to comment 138.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				calculations give reason for doubts which will be strengthened by differing group sizes and missing values. The authors of the IARC study select in most cases for the meta-analysis odds ratios as high as possible – if not even the highest – what doesn't correspond to scientific objectivity free of doubt. The mentioned calculation errors in the single studies are relevant calculations for the meta-analysis. In both cases the miscalculations were overlooked by the authors of the IARC study. Furthermore, the data of the study of Westerdahl et al. (2000) were mixed up. The values which are listed in the meta-analysis don't belong to the corresponding age group of the original paper. The new calculation of the odds ratio for the complete population of the study of Walther et al. (1980) carried out by the authors of the IARC study is inadmissible from the biometric view. This odds ratio is neither part of the publication nor aim of the study. The methodical defects of the IARC meta-analysis found out from the biometric view give clear reason to doubt the results and the scientific value of this study. Therefore, the explanatory power is negligible.	
140.	Steven Gilroy, Joint Canadian Tanning Association JCTA, info@TanCanada.org, Canada	7.2.1.1 Meta-analyses and systematic reviews	 Papas_2011_Abstract_3rd_North_America  Papas_Poster_June_2011_Montreal.pdf  Grant_2009_IARC_sunbed_DE_epub.pdf	Page 35 – Line 31-44 Colantonio 2014 also re-examined the melanoma risk of age at first sunbed use. Colantonio found that for first use age 25 the risk was 11% (OR 1.11, 95% CI 0.86-1.42). This is substantially less risk for younger age than what was reported by IARC 2006 and Boniol 2012. Nowhere in this section or anywhere else in the report does it talk about the limitation of the research used by all 4 meta-analyses. Colantonio (2014) states the following about the research papers reviewed for the meta-analysis which were also included in IARC 2006 and Boniol 2012: The quality of evidence contributing to review results ranges from poor to mediocre. Colantonio continue on to explain the problem with the research: This low-medium quality is likely a result of the case control study design that was used in almost half of	Studies have been carefully evaluated. The SCHEER disagrees with the comment. No changes to the Opinion are required in relation to the comment. The SCHEER disagrees with this comment. Text was changed for clarity. A new introductory paragraph has been added to section 'Human health effects'.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				the studies especially those with enrollment occurring before the year 2000. A case control design can estimate the magnitude of association of tanning bed use and melanoma because the disease has a long induction period; however, it is vulnerable to bias particularly selection, recall, and interview bias. In particular, observational studies can produce misleading results regarding the association of tanning bed use and melanoma as the exposure to tanning beds could not be allocated randomly or use blinding. Bias was potentially present in all included studies and several studies possibly had large amounts of bias. The case-control design is also limited in establishing a temporal relationship between tanning bed exposure and development of melanoma. More recent studies with enrollment occurring since the year 2000 have begun to use prospective cohorts and nested case-control designs that reduce the likelihood of bias and should improve the overall quality of evidence. No evidence of publication bias was observed from a funnel plot analysis in the overall estimate of association or by geographic region (Supplemental Fig 8). There have been 5 prior systematic reviews of a possible association between indoor tanning and malignant melanoma. Comparison of data extracted by them demonstrates an alarming tendency for data extracted for one review to be copied by subsequent reviewers without reference to the original article, precluding checking for errors. For example, the International Agency for Research on Cancer (IARC) Working Group published an influential review in 2007 that appeared to have typographical errors in the number of controls reported for MacKie et al in 1989 (180 instead of 280) and Adam et al in 1981 (207 instead of 507). These errors were replicated in 2 subsequent reviews. Further information in the research paper should be review by SCHENIHR. Colantonio was the first research paper to identify	

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				the quality of the research done on sunbeds to date and nowhere in this report does it highlight limitation of research showing increase risk. Additionally, Papas 2011 reviewed the 2006 IARC data and showed that location of the equipment was an independent risk factor, the increase risk for commercial equipment was 6%, home units at 40% and phototherapy at a 96% for an average increase of 15%. All risks included people with Skin Type 1 (always burn, never tan). According to Dr W Grant, when you remove Skin Type 1 from the data set, there is a statistically insignificant risk (Grant 2009). These risks would also hold true for the two newer meta-analyses by Boniol (2012) and Colantonio (2014).	
141.	Gilroy Steven, Joint Canadian Tanning Association JCTA, info@TanCanada.org, Canada	7.2.1.1 Meta-analyses and systematic reviews	 Diffey_2003_-_A_quantitative_estimate_c  Papas_Poster_June_2011_Montreal.pdf  Grant_2009_IARC_sunbed_DE_epub.pdf	Summary – Melanoma Page 35/36 – line 45 to 48 & line 1 to 4 The most recent meta-analysis with the greatest number of studies (Colantonio 2014) reported an increased melanoma risk for ever use of sunbeds of 16% and first exposure before the age of 25 at 35%, but also concluded the increase risk for over 25 was 11%. This has not increased since the last SCCP report which was based on an ever lifetime risk of 25% and first exposure as a young adult risk of 69% (Gallagher 2005). Therefore the risk has not increased in the past 10 years and in fact the risk of first exposure as a young adult has decreased. This risk must be viewed in context of other accepted Group 1 risks such as consuming processed meats which is based on a cancer risk of 18%. Diffey 2003 concluding statement still rings true: "Sunbed use could be regarded as a relatively minor self-imposed detriment to public health compared with other voluntary 'pleasurable' activities associated with significant mortality, such as smoking and drinking alcohol. While cosmetic tanning using sunbeds should be discouraged, prohibition is not warranted especially as exposure to the sun, which cannot be regulated, remains the major contributory factor to the risk of melanoma." Nowhere in this section or	Studies have been carefully evaluated. The SCHEER disagrees with the comment. No changes to the Opinion are required in relation to the comment.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				anywhere else in the report does it talk about the limitation of the research used by all 4 meta-analyses. Colantonio (2014) states the following about the research papers reviewed for the meta-analysis which were also included in IARC 2006 and Boniol 2012: The quality of evidence contributing to review results ranges from poor to mediocre. Colantonio continue on to explain the problem with the research: This low-medium quality is likely a result of the case control study design that was used in almost half of the studies especially those with enrollment occurring before the year 2000. A case control design can estimate the magnitude of association of tanning bed use and melanoma because the disease has a long induction period; however, it is vulnerable to bias particularly selection, recall, and interview bias. In particular, observational studies can produce misleading results regarding the association of tanning bed use and melanoma as the exposure to tanning beds could not be allocated randomly or use blinding. Bias was potentially present in all included studies and several studies possibly had large amounts of bias. The case-control design is also limited in establishing a temporal relationship between tanning bed exposure and development of melanoma. More recent studies with enrollment occurring since the year 2000 have begun to use prospective cohorts and nested case-control designs that reduce the likelihood of bias and should improve the overall quality of evidence. No evidence of publication bias was observed from a funnel plot analysis in the overall estimate of association or by geographic region (Supplemental Fig 8). Further information in the research paper should be review by SCHENIHR. Additionally, Papas 2011 reviewed the 2006 IARC data and showed that location of the equipment was an independent risk factor, the increase risk for commercial equipment was 6%, home units at 40% and phototherapy at a 96% for an average increase of	

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				15%. All risks included people with Skin Type 1 (always burn, never tan). According to Dr W Grant, when you remove Skin Type 1 from the data set, there is a statistically insignificant risk (Grant 2009). These risks would also hold true for the 2 newer meta-analyses by Boniol (2012) and Colantonio (2014).	
142.	Grant William, Sunlight, Nutrition and Health Research Center, wbgrant@infionline.net, United States	7.2.1.1 Meta-analyses and systematic reviews	64-Sunbeds__vitamin_D__health_Moan.p	p. 34, line 37. Studies of melanoma risk with respect to sunbed use should be restricted to those from Europe since different lamp intensities, UVB to UVA ratio and populations are involved. Figure 1 in Moan [2012] can be used to see the relative risk findings. The highest risks were found in the U.S. and Australia. Moan J, Baturaite Z, Juzeniene A, Porojnicu AC. Vitamin D, sun, sunbeds and health. Public Health Nutr. 2012 Apr;15(4):711-5.	Results for Europe presented where available in the publications (Colantonio). Additional information included from Boniol et al regarding analyses by latitude.
143.	Dr. Richarz Frank, IEC TC61 / MT16 'Biological effects of optical radiation', MT16@richarz-consulting.de, Germany	7.2.1.1 Meta-analyses and systematic reviews		page 35 line 46 - page 36 line 4 "The IARC2005 report was not analyzed by SCENIHR on its relevance for European populations. Using the data from the IARC reports the European population is under much lower risk than presented here. Show Osterlind 0.73, Zanetti 0.9 and 2x Westerdahl 1.3 and 1.2 sums up to RR1.05 (95%CI 0,67-1,6)"	See the response to comment no. 142.
144.	Nilsen Lill Tove, Norwegian Radiation Protection Authority, Lill.Tove.Nilsen@nrpa.no, Norway	7.2.1.1 Meta-analyses and systematic reviews		Page 35, line 40: It is unclear what is meant by "... exposure less than or equal to 1 year…". Is it exposure within 1 year, or exposure within the last year?	The text of the Opinion was changed for clarity.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
145.	de Gruijl Frank, representing, degruijl@planet.nl, Netherlands	7.2.1.1 Meta-analyses and systematic reviews		7.2.1.1 Meta-analyses and systematic reviews pg 35, line 29, for RR starting age < 35, meta-analysis mostly including studies that found an overall significant effect (1 exception); i.e., an inherent bias. Pg 35, Lines 38 – 44, ORs independent of age? Summary - Pg 35, line 46, of course, being largely based on the same studies: but are the studies consistent? A fair percentage with no effects and some with large effects - pg 36, lines 2 - 4, parallel years of sunbathing?	See the response to comment no. 138.
146.	Bocionek Peter, JW Holding GmbH (R & D), peter.bocionek@jw-holding.de, Germany	7.2.1.2 Case-control studies		page 38, line 37 - page 39, line 5: Clough-Gorr reported 89% use before 1980. At that time the use of so-called alpin sun (equipped with high-pressure mercury lamps) was popular. These sunlamps emit a considerable amount of UVC and UVB radiation, which is not comparable with current sunbeds.	The text of Opinion was changed for clarity.
147.	Lorenz Christina, KBL AG, clorenz@kbl.de, Germany	7.2.1.2 Case-control studies		page 37 line 22 - 34 More than 10 sunbeds sessions was associated in the study by Cust 2011 with 5-times higher risk for those with under median lifetime sunexposure. But 10 sunbeds sessions do not change the risk for those with over median lifetime sun exposure. Showing again it is the overall dose not the source of UVR what makes the effect.	The text of Opinion was changed for clarity.
148.	Gilroy Steven, Joint Canadian Tanning Association JCTA, info@TanCanada.org, Canada	7.2.1.2 Case-control studies	 Mia_Papas_lazovich_review.pdf	Studies published since 2006 Page 36 – Line 10 Page 36 – Line 11 to 15 A review by Papas on the research done by Lazovich has shown a number of problems; This study is subject to several limitations that would lead to caution in the interpretation of the measures of association found for indoor tanning use and melanoma. The results of the study by Lazovich may be due to possible bias and confounders present in the study, therefore caution is warranted. Two types of bias, selection and recall are discussed in detail in the response. In addition, limitations in exposure	Text on case-control study design was added. Papas paper is grey literature and is not in the public domain.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				classification and analytic strategy are presented. Page 36 – Line 23-24 Lazovich 2010 reported that cases with high outdoor sun exposure had a 15% reduced risk of melanoma. This suggests that higher outdoor UV exposure is not a risk for melanoma. This is supported by IARC 2012. As stated in this report, outdoor UV and the UV from sunbeds are identical (page 60, Line 15-18) The mechanism has not been found that would explain how sunbeds are an independent risk of melanoma without burning exposure. Page 37 – line 22 to 26 and 35 to 37& 39 to 42 The key difference in the 2 research paper seems to be the ambient UV index in each country and sunlight exposure, possibly sunburning and excessive exposure from outdoors. This seemed to be confirmed in a meeting that took place in Dec 2014 with the UK tanning association TSA, JCTA, Australian representative from the industry and New South Wales (NSW) Government and the Chief Medical Officer of NSW. The Chief Medical Officer from New South Wales stated the only reason for banning the industry in Australia was because of the high ambient UV index they have year round and the public didn't need any further exposure. It seems the government was only banning the industry because they couldn't ban outside exposure. Page 38 – line 1to 3 Cust – 604 cases and 479 controls – 20.7% difference Elliott – 959 cases and 513 controls with 174 sibling = 687 controls – 28.4% After review of Elliott paper the difference was only 28.4. Cust was 20.7% difference between case and controls. If the problem exists in the 1 piece of research than the problem would also exist in Cust as well. Page 38 – line 14 to 18 It should be noted that the research paper was completed in 2006, but the research is from patients before 2000 and dates back as far as 1976. This research would not be relatable to new lamps now being used (as stated in the research paper). There was no Fitzpatrick Skin typing done, so it's unknown whether Skin Type 1 (always burn,	

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				never tan) would have been the substantial risk factor (IARC 2006 Effects of natural and artificial UV radiation on human skin). IARC 2006 states; There is a considerable range of susceptibility of the human skin to the carcinogenic effects of UV radiation, and in humans, there is an estimated 1000-fold variability in DNA repair capacity after UV exposure. Also the research could not give a reason for the different regions having different risks for skin cancer. Also there is no mention about who was controlling the equipment, whether a trained and certified operator or the client. No mention of the type of education the person using the equipment had. Stated in the research was limitation of self-reported assessment on pigmentation phenotypes and exposure which may lead to misclassification. All could be confounder to the research.	

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
149.	Gilroy Steven, Joint Canadian Tanning Association JCTA, info@TanCanada.org, Canada	7.2.1.2 Case-control studies		Summary of case-control studies -Page 39 – 6 What is not mentioned in the Summary is, adjustment for removal of Skin Type1 (always burn and never tan) and how many times someone sunburned in their lifetime. Paragraph 2 should be removed, if not, Cust should be noted about controls and cases. Fear (2011) is research from a group in 1991 to 1992, the recall bias would be high. These results would not reflect the lamps being used today in Europe. Page 39 - line 7-9 This document selectively failed to review and discuss a number of more recent studies that were used by Boniol 2012 and Colantonio 2014 in their respective meta-analysis that showed that indoor tanning has minimal risk for melanoma: Clough-Gorr2008 (USA) ever use OR 1.14 (95% CI 0.80-1.61) Fears 2011 (USA) ever use OR 0.93 (95% CI 0.75-1.15) Zivkovic 2012 (Croatia) ever use OR 0.12 (95% CI 0.01-0.99) 7.2.1.3 Cohort studies – Page 39 – line 21 Summary of cohort studies - Page 40 – line 29 Page 40 - line 30-31 In summary, it should be noted; the three most recent cohort studies where done before an under 18 restriction took place in European countries.	The SCHEER disagrees with the comment. The SCHEER disagrees with the comment. Clough-Gorr 2008, Fears 2011 are analysed. As far as Zivkovic 2012 is concerned, the text of the Opinion was amended. The SCHEER disagrees. Sweden's is the oldest regulation.
150.	Dr. Richarz Frank, IEC TC61 / MT16 'Biological effects of optical radiation', MT16@richarz-consulting.de, Germany	7.2.1.2 Case-control studies		page 36 line 11 - 39 "It is not clear in the text, whether studies are used which adjust for additional sun exposure or not and we miss a discussion on the weaknesses in some studies. Confounders are showing high Odd ratios and needed to be corrected before calculating the effects of indoor-tanning. (OR: moles=13,8; red hair 3,53; fair skin 3,63; sunburns 2,56; burn from indoor 2,6; sunscreen use high 1,31 and medium 1,34) We also miss information on which studies are based on some kind of dosimetry regarding the sunbeds. Unfortunately only very few have performed measurements of the sunbeds in use,	See the answer to comment 148. Text was changed in the Summary to note lack of data on type of sunbeds and quantitative measurements of radiation.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				that could give some information of average exposure, and they should discuss this weakness of some studies." page 37 line 22 - 34 More than 10 sunbeds sessions was associated in the study by Cust 2011 with 5-times higher risk for those with under median lifetime sun exposure. But 10 sunbeds sessions do not change the risk for those with over median lifetime sun exposure. Showing again it is the overall dose not the source of UVR what makes the effect. page 38 line 11 - 20 This US study is not relevant in Europe. Especially the outdoor behavior of the cases and controls was not used to adjusted the risk ratios. page 38 line 21 - 36 Fears 2011 used data from 1991-1992 collected in the USA, when people have been predominately exposed to old fashioned sunlamps with known to be different spectra. page 38 line 37 - page 39 line 5 Clough-Gorr reported 89% use before 1980. Again a time with old fashioned sunlamps, not comparable with current sunbeds.	
151.	Wunsch Alexander, Medical Light Consulting, praxis@alexanderwunsch.de, Germany	7.2.1.2 Case-control studies	 1.pdf  2.pdf  3.pdf	P36/19-22: "Adjustment was made for potential confounders including age, gender, eye and skin colour, freckles and moles, annual income, education, family history of melanoma, lifetime sun exposure (routine, leisure activities outdoors, during work) and sunscreen use." Important confounders such as MCR1 receptor genetics, hormonal birth control, endocrine disruptors in cosmetics etc. were not taken into account. In many studies these factors have not been assessed. Estrogen plays a role in melanomagenesis, which is not mentioned throughout the whole Opinion. This should be taken into account, especially with respect to the fact that female gender contributes to the melanoma cases to higher rates in many studies and analyses. The influence of estrogen is also important for the evaluation of studies like the Nurses Health Study, where the population under examination is of female gender only. (1.pdf, 2.pdf, 3.pdf) P36/24-27: "There was a significant	See the answer to comment 148. No changes to the Opinion are required in response to the comment.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				increasing dose-response relationship with increasing number of sessions per year: ≤10 OR= 1.34(95%CI 1.00-1.81); 11-24 OR=1.80 (95%CI 1.30-2.49); 25-100 OR=1.68 (95%CI 1.25-2.26); >100 OR=2.72 (95%CI 2.04-3.63) (p-trend 0.0002)." If these numbers are correct, it should be questioned why there is no linear dose-response relationship: The OR for 25-100 sessions is lower than for 11-24 and > 100, respectively!	
152.	Wunsch Alexander, Medical Light Consulting, praxis@alexanderwunsch.de, Germany	7.2.1.2 Case-control studies	1.pdf 2.pdf 3.pdf 4.pdf 5.pdf 6.pdf	P36/19-22: "Adjustment was made for potential confounders including age, gender, eye and skin colour, freckles and moles, annual income, education, family history of melanoma, lifetime sun exposure (routine, leisure activities outdoors, during work) and sunscreen use." Important confounders such as MCR1 receptor genetics, MC1R receptor variants, BRAF or N-RAS mutations, TP53 protein expression level, other oncogenes (e.g. CDK4, CCND1), endocrine disruptors in cosmetics etc. were not taken into account. In many studies these factors have not been assessed. (1.pdf - 12.pdf	See comment 151.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
			7.pdf 8.pdf 9.pdf 10.pdf 11.pdf 12.pdf		
153.	Lipman Gary, The Sunbed Association, garylipman.tsa@gmail.com , United Kingdom	7.2.1.2 Case-control studies	EJC_Exposure_to_the_sun_and_sunbeds_	Page 37, lines 3-9: This section deals with reported burns, apparently sustained on a sunbed. Clearly, a burn indicates excessive exposure. Can the SCENIHR identify if these burns were sustained on a sunbed in a professional tanning salon, or unsupervised home use on a sunbed or using a sunlamp. It is generally accepted that excessive use leading to burning must be avoided, whether in sunshine, or on a sunbed.	No changes to the Opinion are required in response to the comment. Data unavailable to answer the comment.

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			 Highlighted_Leeds_Report_-_Intl_Journal_  Boniol_et_al-2013-International_Journal_c  Elliott_et_al-2013_Response_to_Boniol-Ir  EN16489-1_EN.pdf	In professional tanning salons an appropriate session time will be provided to the screened client to help ensure that they do not exceed the recommended dosage. Client details will be registered and usage will be recorded to prevent excessive use. Salon staff across Europe can now receive accredited Professional indoor UV exposure services training to the EN16489 Standard. Page 37, lines 22-34 It is not appropriate to quote measurements taken from sunbeds outside of Europe. Since 1st April 2007, all sunbeds supplied new or traded second- hand in Europe , must comply with EN 60335-2-27 which requires all sunbeds to have a maximum UV emission level of 0.3W/m2. In Australia the output was restricted to of 0.9W/m2, three times the European limit. Moreover, Australia has the highest ambient UV in the world. As it is not possible to prove direct causation was isolated as attributable to a sunbed to the exclusion of sunlight and the fact that professional sunbeds outside the EU have a far higher output, only European studies, based upon the Standard since 2007 (output of 0.3W/m2) should only considered for the purposes of objectivity. Page 37, lines 35-46: This is an outrageous and indeed disingenuous interpretation of the Leeds Cancer Research Institute (Elliott et al 2012) - that sought to prove a causal relationship between sunbed use and melanoma and found no association. The conclusion of the report states: 'In summary, we have found no evidence for sunbed use as a risk factor for melanoma'. Page 38, Lines 1-4 The designs were the same as the Australian study (page 37, line 22).	No changes to the Opinion are required in response to the comment about manufacturing standards and salon practices. The Elliott paper and the comments on the design are reported in the Opinion.
154.	Reimers Jens-Uwe, JK-Holding GmbH, jens-uwe.reimers@de.jk-group.net, Germany	7.2.1.2 Case-control studies		page 37 line 22 - 34 More than 10 sunbeds sessions was associated in the study by Cust 2011 with 5-times higher risk for those with under median lifetime sun exposure. But 10 sunbeds sessions do not change the risk for those with over	See the answer to question 147.

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				median lifetime sun exposure. Showing again it is the overall dose not the source of UVR what makes the effect.	
155.	Nilsen Lill Tove, Norwegian Radiation Protection Authority, Lill.Tove.Nilsen@nrpa.no, Norway	7.2.1.2 Case-control studies		Page 36, line 8: Section 8.2.2.1 does not exist. Page 36, line 18: You say: "Participants who reported indoor-tanning-related burns were excluded." However, in line 29-32 on the same page you state that cases were more likely than controls to report having experienced painful burns from indoor tanning. Furthermore, on page 37, line 3-9 you refer to the same dataset, and there you have excluded those who had reported burns from indoor tanning. You have to check it out and rewrite line 18 on page 36 to get it correct. Page 36, lines 36-39: You refer to a higher melanoma likelihood for users of high-speed/high-intensity devices and high pressure devices. This may indicate that also the dose-rate may play a role in melanoma induction. You should also include whether or not the doses were similar for the high-intensity and conventional devices. Page 37, line 10-15: You say that Boniol have suggested that sunbeds have an effect on melanoma independently from the effect of sunburns. Assuming a multiplicative instead of an additive effect is mentioned as the reason for possible misinterpretation of sunbeds being protective. This argument seems to be very important, but it is not easy to understand for non-epidemiologists. We would like to see some more explanation in this section. Can this be the case in other publications you refer to in the Opinion? If so, and if you have the knowledge, it would be nice if you discuss such uncertainties when presenting the studies. Page 38, line 11-20: It is not clear to us whether the US Nurses' Health Study has been adjusted for sun exposure or not. It is important that you include whether or not each of the studies you refer to are adjusted for sun exposure and discuss both strengths and weaknesses. The Opinion with conclusions is important for all working with	Text corrected and expanded. The reference list was updated.

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				sunbeds, and if the quality is good, it will be important in forming future regulations and information campaigns.	
156.	de Gruijl Frank, representing none, degruijl@planet.nl, Netherlands	7.2.1.2 Case-control studies		7.2.1.2 Case-control studies - pg 36, lines 18 -19, people with indoor tanning burns were not excluded in the first study. - pg 36, line 22, very high sunbed use in comparison to other studies - pg 36, line 27, Risk increased with years of sunbed use, but remarkably not with first sunbed use before the age of 35 yrs! No comment on this point? - pg 36, line 30, but people with indoor tanning burns were excluded according to lines 18-19? - pg 36, line 43, multivariate analysis is not adequate if variates (e.g. sunbed use and sunbathing) are highly correlated; no proper analysis of covariance was presented, as in all studies before. In later interview, Lazovich mentioned possible remaining difficulties with confounding - pg 37, line 7, not sunburn severity, but number of times - pg 37, line 30, small absolute risk - pg 37, lines 33 – 34, covariance with sun exoposure/sun bathing? - pg 38, lines 1-2, not the first UK study without effect; and Autier himself participated in a study without effect and produced a followup to 'explain away' this lack of effect (bias in answers from informed patients) - pg 38, lines 35 – 36, no risk from sunbed use in males: pretty striking; - protective effect? (eg from hours outdoors?). No comment here? - pg 38, line 42, relative risk of starting before age of 20y smaller than that of ever use? (not significantly probably, pointing out to marginal differences in relative risks) - pg 38, line 45, significant trend? Summary of case control studies - pg 39, line 10, not all adjusted or adjusted similarly, and possibly inadequately, eg total sun exposure known not to be relevant to melanoma risk - pg 39, lines 15 -16, "imbalance between cases and controls", but does it result in a reduced risk compared to control, ie were the latter older? - pg 39, " similar behaviours"	See responses to comments above, including 148 and 155.

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				which should be either risk bearing or controlled for - not a good argument - pg 39, lines 18 – 20, likely to be related to the intensity of the sun bathing behaviour too	
157.	Gilroy Steven, Joint Canadian Tanning Association JCTA, info@TanCanada.org, Canada	7.2.1.3 Cohort studies	de_Winter_2001_-_Solar-Simulated_Skin_A	7.3.1.3 Cohort studies – page 47 – line 39 Page 48 - line 22-25 Summary The key finding of Zhang 2012, the well-conducted US nurses' cohort study showed a minor BCC risk of 15% and SCC risk of 15%. 35 7.3.2 Experimental animal studies – Page 48 – line 35 Summary Page 49/50 Line 42 to 47 & 1,2 What is missing from this summary is the dosage use to create tumors, this should be noted. According to De Winter 2001: In almost all animal experiments documenting the carcinogenic properties of UV radiation, five to seven exposures a week have been applied (Strickland, 1986; Van Weelden et al,1988; Kelfkens et al, 1991; De Gruijl et al, 1993; Wulf et al, 1994). There is no doubt that such frequent irradiations result in the accumulation of cellular injury (Vink et al, 1991) and, consequently, increase the risk of DNA mutations. The question remains whether UV radiation would be such a strong carcinogen if the irradiations were performed at reduced frequency. A Key point missed in this summary and noted in this section was SCC showed a wavelength dependencies that was similar to the action spectra for human erythema.	No changes to the Opinion are required in response to the comment. Some parts of this comment refer to section 7.3.1.3. The section on experimental animal studies and its summary were reorganised to include a figure from the SCCP Report showing action spectra for human erythema and SCC. Discussion of modalities of UV induction of skin cancers in mice is outside the mandate.
158.	Pedersen Ronny, Norwegian Tanning Association, ronny@mida.no, Norway	7.2.1.3 Cohort studies	Yang_L__Veierod_MB__Loef_M__et_al._F	page 39 line 29-45 "We had limited power to examine the association between the use of solarium during adolescence and melanoma risk because only 2 % of the women in the study reported having such exposure. " The above is a follow-up study from 1991–1992 through 1999, and the women participating were born between 1943 and 1957 (page 2). That means that the women where 18 year between 1961 and 1975.	Text of the Opinion was changed.

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				And 10 years of age in 1953 and 1967 (study calculates from 10 and above). This is long before tanning devices were common in Norway and Sweden, and therefore it can not be argued that use of a tanning device before the age of 18 year are associated with an increased risk of melanomas. The SCENIHR Opinion also selectively choose which data from the study to claim. On page 5 of the Veierod et.al 2003,2010, on page 5, it says; "Use of solarium at ages 30-39 and 40-49 years also appeared to be associated with a risk, although not a statistically significantly increased risk of melanoma" For the SCENIHR Opinion to just «cut away» that part from the context is after our Opinion misleading and not accurate. This is especially negative since both IARC and SCENIHR Opinion supports their conclusions widely on this report. The above information is also made available to the Norwegian Government in a public hearing in 2011 by Professor Johan Moan at the Radiumhospital in Oslo; https://www.regjeringen.no/contentassets/9ebf89b077594753b7dbad3766b498b2/radiumhospitalet.pdf Also in SCCP Opinion 2006, referred to in SCENIHR page 16 line 17; «They note that UVR tanning devices were not in widespread use before the 1990s…….»	

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159.	Dr. Richarz Frank, IEC TC61 / MT16 'Biological effects of optical radiation', MT16@richarz-consulting.de, Germany	7.2.1.3 Cohort studies		page 39 line 29 - 45 "SCENIHR conceals other data from the same study: The RR for a 4 weeks/year southern vacation in the age of 10-19 years is 1.87 (95%CI 1.35-2.58) The RR for >2 sunburns/year age 10-19 is 1.92 (95%CI 1.34-2.74) Which provides higher risk than using a sunbed once a month for 30 years (RR 1.55)" page 40 line 27 - 28 "Sunbed use and frequent sunbathing are connected in all populations. Therefore it is necessary to differentiate between both behaviors prior to associating a risk to sunbeds in all studies. Nielsen et.al. have done this and showed a reduced risk. This evaluation of the strength of the confounders should be performed on all studies used to draw conclusions of."	Risk reported has been adjusted for sun exposure and sunburn. No change needed. Nielsen et al. reported (data not shown) that when adjusting also for frequent sunbathing events, the risk associated with the highest degree of sunbed use was reduced, but still doubled compared to baseline risk. No change needed.
160.	Dr. Richarz Frank, IEC TC61 / MT16 'Biological effects of optical radiation', MT16@richarz-consulting.de, Germany	7.2.1.3 Cohort studies		page 48 line 11 The sunlamp used before 1982/83 contained even a significant portion of UVC, not only UVB. And there were already high UVA units on the market. All not comparable with modern sunbeds. page 48 line 15 - 21 Older women, who had exposed themself to the older equipment did show an increase in SCC. Younger women, who had exposed themselves to the newer equipment w/o UVC did not show a significant increase in SCC. page 48 line 23 - 25 The US population consists from migrants into an environment where they are not adopted to. Therefore US studies cannot be used to draw conclusions for the European population. Results based on the use of old UVC rich sunlamps cannot give a base for an Opinion on current sunbeds. page 48 line 26 - 34 All studies referenced in this chapter are from the USA or Brasil or draw conclusions based on old UV equipment with different spectra than modern sunbeds. Therefore no transfer to European population and current sunbeds is justified.	This comment belongs to section 7.3.1.3. Text of the Opinion was changed.

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161.	No personal data provided	7.2.1.3 Cohort studies	1.pdf 2.pdf 3.pdf 4.pdf 5.pdf	P39/22-27: "Cohort studies are known to be less susceptible to biases than case-control studies and bring a higher level of evidence. The SCCP report (2006) reviewed a cohort that followed more than 100,000 Norwegian and Swedish women for an average of 8 years and identified use of sunbeds as a risk factor for melanoma, more especially when exposure took place at a younger age (Veierod et al., 2003). A new analysis of the Norwegian-Swedish cohort and two new cohorts are described below." These cohort studies followed only women. The influence of estrogen is a host factor in this group. The role of hormonal birth control on melanoma is not taken into account. The impact of hormone intake on younger and elder women is not taken into account, either. (1.pdf, 2.pdf, 3.pdf) None of the cohort studies cited in the Opinion is adjusted for estrogen as a risk factor due to the study population: Veierod et al. 2003, 2010: 106,379 Norwegian and Swedish women Zhang et al. 2012: Nurses Health Study II, 73,494 female nurses Nielsen et al. 2012: 40,000 Swedish women	See the answer to comment 151. Text of the Opinion regarding the cohort study design added to beginning of section 7.3.1.2.
162.	Dr. Richarz Frank, IEC TC61 / MT16 'Biological effects of optical radiation', MT16@richarz-consulting.de, Germany	7.2.1.4 Other designs	11-Autier-UVA-sunbeds-sunscreens-melan	page 41 line 12 - 16 "This is a wrong citation, turning the statement of the reference to the opposite. Rafnsson clearly states in the results: ""... Younger age groups had more sunny vacations than the older age groups..."" And in the conclusion: ""Young people have more often used sunbeds and taken sunny vacations than the older, indicating a changed behavior in the population.""" page 41 line 23 Berwick (2010) is not in the reference list page 40 line 36 -page 41 line 27 "SCENIHR ignores one of the main conclusions in Hery's discussion:	The SCHEER disagrees. The citation is correct. The comment is a misunderstanding of the Rafnsson article. Icelanders aged 50 and up are more likely to have travelled abroad 11 times or more during their lifetimes than their younger compatriots. However, the text has been modified for greater clarity. The list of references was updated.

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				""Likewise, because there is no efficient treatment for metastatic melanoma, the absence of change in melanoma death rates after 1974 in Iceland suggests that most of the epidemic was due to a non–life-threatening form of melanoma.""" page 41 line 28 - 31 "The data by Hery and Alberg have not been checked for other possible reasons, especially for differences in the diagnostics. One MD (out of only 13 dermatologists in Iceland) is able to change this statistic significantly. The Iceland population consists of only 320.000 people. The absolute number of cases is 3 male cases in 1975 to 30 male cases in 2003. This could be the result of one MD using a different diagnostic and indicator for naming a colored mole an melanoma lesion. NIH states: ""It can be hard to tell the difference between a colored mole and an early melanoma lesion."""" The NIH Melanoma treatment statement is too big for upload and will be submitted by e-mail. page 41 line 32 - 46 1072 excisions (which might be already counted as melanoma incidence) cause only 2 'real' melanomas. Another hint, that incidence increase is due to higher excision and not to a real increase. page 42 line 22 - 31 "The summary, as the chapter itself, misses to discuss two important hypothesizes for the increase of melanoma: The uncertainty of whether the diagnosis level has changed and the consequences of different types of melanoma as indicated in the Hery studies and repeated by Autier 2011."	A sentence has been added in the text. The SCHEER disagrees. Data on invasive melanoma incidence were provided by the Icelandic Cancer Registry, which includes histologically confirmed cases. No modification in cancer registration modalities has occurred that can explain changes in incidence, and a screening effect is not likely to be specific to the female trunk. No change in text needed. The SCHEER disagrees. This is a personal view. The Schmitt et al. study is not about incidence (a case can only be considered as an incident only if histologically confirmed), but about effectiveness of screening. No change needed. The SCHEER disagrees. Histological diagnostic criteria have not changed, and the possibility that a non-life-threatening form of melanoma might have contributed to the increase in incidence in Iceland was considered. No change needed.

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163.	de Gruijl Frank, representing none, degruijl@planet.nl, Netherlands	7.2.1.4 Other designs		7.2.1.4 Other designs - pg 40, line 48, no effect what so ever on mortality - pg 41, line 26-27, UVA? There is still 50% UVB contribution to the sunburn dose from sunbeds. - pg 41, line 17 – 22, as noted before, it is a rather dubious view on the data: increased melanoma incidence (in young women on extremities) is "switch on and especially off" almost immediately in parallel to number of sun tanning studios. Ie no lasting effect, where one would expect a lasting effect of a cancer-causing agent. Therefore, these are not likely to be genuine malignant melanoma (activated nevi?). Moreover, no effect on mortality was discernible. - pg 41, Alberg 2011 may have noted that but not a hint of the argument is given here, and therefore the Here study remains a weak ecological study with an overstretched interpretation, and suspiciously rapid fall in melanoma incidence with disappearance of sun studios - pg 42, line 11, not "Risk" but relative risk. (OR>=RR) Overall Summary of the epidemiological literature on melanoma risk and sunbed use - pg 42, line 26, not "risk" but relative risk. - pg 42, line 29, adjustments are variable (not consistent) and for sun exposure probably not correct (poor or irrelevant proxy). - pg 42, line 29, "suggests" ground enough to be credible? Or still insufficient evidence?	See answer to comment 162.
164.	Baldermann Cornelia, German Federal Office for Radiation Protection, cbaldermann@bfs.de, Germany	7.2.2.1 Experimental animal studies		Page 43, / line number 34: "UVA14" should be corrected to "UVA".	Text of the Opinion was corrected.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
165.	Gilroy Steven, Joint Canadian Tanning Association JCTA, info@TanCanada.org, Canada	7.2.2.1 Experimental animal studies	Cui_2007_Melanoma_and_Tanning_benef Cui_Fisher_2007_-_Science_Daily_-_Guard De_Winter_2001_Roza_Pavel_2001-_Sola Mason_2012_-_Sunlight_Vitamin_D_and_S	7.2.2 Mechanistic studies – Page 42 – 32 Missing in this section is anything to do with photoprotection. Cui 2007 states the following: UV-induced pigmentation (suntanning) requires induction ofa-melanocyte-stimulating hormone (a-MSH) secretion by keratinocytes. a-MSHand other bioactive peptides are cleavage products of pro-opiomelanocortin (POMC). Here we provide biochemical and genetic evidence demonstrating that UV induction of POMC/MSH in skin is directly controlled by p53. Whereas p53 potently stimulates the POMC promoter in response to UV, the absence of p53, as in knockout mice, is associated with absence of the UV-tanning response. The same pathway produces b-endorphin, another POMC derivative, which potentially contributes to sun-seeking behaviors. Furthermore, several instances of UV-independent pathologic pigmentation are shown to involve p53 "mimicking" the tanning response. p53 thus functions as a sensor/effector for UV pigmentation, which is a nearly constant environmental exposure. Moreover, this pathway is activated in numerous conditions of pathologic pigmentation and thus mimics the tanning response. The summary also does not talk about the dosage that is required by most of the research papers. This would far exceed the gradual exposure level in sunbeds. De Winter 2001 states the following: High frequency UV exposures (e.g., daily exposures during sunny holidays) do not leave much time for repair of indicted damage. This factor may logically play an important role in UV carcinogenesis. In almost all animal experiments documenting the carcinogenic properties of UV radiation, five to seven exposures a week have been applied (Strickland, 1986; Van Weelden et al, 1988; Kelfkens et al, 1991; De Gruijl et al, 1993; Wulf et al, 1994). There is no doubt that such frequent irradiations result in the accumulation of cellular injury (Vinket al, 1991) and, consequently, increase the risk of DNA mutations. The question	No change in the Opinion is needed.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				remains whether UV radiation would be such a strong carcinogen if the irradiations were performed at reduced frequency. De Winter 2001 using tanning equipment reports: The ultraviolet sensitivity for erythema decreased on average by 75%. The cyclobutane pyrimidine dimer formation was reduced on average by 60%. In their discussion section it states: An analogous situation applies when people daily expose their skin on sunny beaches and the skin does not get enough opportunity to rest. From the viewpoint of DNA repair kinetics this is a hazardous way of tanning. Indoor tanning is not safer than the sun but the use of timers and the possibility of easily regulating the exposure frequency could make it safer than the attitude of millions of people who want to get a tan during the first days of their sunny holidays. There is no mention in the report that DNA damage is reduced and by this happening the repair system is no longer over tasked. There also no mention of Mason 2012, Mason states in section 4.1. Vitamin D Compounds in the Prevention of Skin Cancer: Results from in vitro Investigations and Animal and Human Studies; The photoprotective effects of vitamin D compounds against thymine dimers and apoptosis demonstrated in mouse and human skin, and protection against photoimmune suppression and photocarcinogenesis in mice has led to the proposal that photosynthesis of vitamin D from UVB in skin and its local conversion to the active hormone 1,25(OH)2D3 is an adaptive mechanism for cellular defense against further UV exposures. I suggest that all of these research papers should have been included in this section. What seems to be reported on is only a dermatology Opinion and not an Opinion from a photobiologist view point. Cui 2007 could not be uploaded, to large of file	

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
166.	ANSES	7.2.2.1 Experimental animal studies		§ 7. Health effects, p44 Comment: On page 44 on the mechanisms underlying melanoma, it could be added that several in vitro studies have shown that melanocytes are more sensitive than keratinocytes to UVA in terms of induction of oxidative DNA damage and reduced DNA repair capacities (Wang et al. Proc. Natl. Acad. Sci. U. S. A., 2010, 107, 12180; Mouret et al. Photochem. Photobiol. Sci. 2012 11, 155–162). These results reinforce the conclusions made on the basis of animal studies of a melanin-driven oxidative pathway in melanoma.	Text of the Opinion was changed.
167.	ANSES	7.2.2.1 Experimental animal studies		§ 7. Health effects, p42-44 Comment: Other animal models are used for the melanoma: pigs, dogs and horses.	No change in the Opinion is needed.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
168.	ANSES	7.2.2.1 Experimental animal studies		§ 7. Health effects, p42, line 33 – Experimental animal studies Comment: In the discussion of the mechanisms leading to non-melanoma skin cancers, the authors mostly describe UVA as an agent that induces oxidative DNA damage. This is true but a growing number of studies show that UVA also leads to the formation of cyclobutane pyrimidine dimers (Kielbassa et al., Carcinogenesis 1997; Perdiz et al. J. Biol. Chem. 2000; Douki et al. Biochemistry 2003; Mouret et al. Proc. Natl. Acad. Sci. USA 2006) and in larger amounts than oxidative damage. This observation is not only interesting from a photochemical point of view but also in terms of biological consequences. Indeed, cyclobutane pyrimidine dimers have been shown to be responsible for mutagenesis of UVB both in vitro and in vivo (You et al. J. Biol. Chem. 2001; Jans et al. Curr. Biol. 2005). Accordingly, the mutagenic signature of UVA in primary cell culture is very similar to that of UVB (Kappes et al. J. Invest. Dermatol. 2006, Ikehata et al. J. Invest. Dermatol. 2008). These recent results contrast with the early data cited by the report which were obtained in Chinese hamster ovary cells (Sage et al. Proc. Natl. Acad. Sci. USA 1996). The mutagenic effects of UVA are thus expected to be more important than previously believed.	No changes in the Opinion needed.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
169.	ANSES	7.2.2.1 Experimental animal studies		§ 7. Health effects, p42, line 38 Comment: On the mechanistic aspects, it may be added that UVA has been reported to decrease DNA repair capacities. Cyclobutane pyrimidine dimers are repaired more slowly in skin and in cultured cells when they are produced by UVA than by UVB (Courdavault et al. DNA repair 2005; Mouret et al. Proc. Natl. Acad. Sci. USA 2006). Moreover, exposure to a preliminary UVA dose decreases the repair rate of dimers in UVB irradiated keratinocytes (Courdavault et al. DNA repair 2005). A possible explanation could be the oxidation of repair protein (Montaner et al. EMBO Rep. 2007; Guven et al. J Invest Dermatol 2015). One can thus envision a double effect of UV radiation with UVB producing most of the DNA damage and UVA hampering their repair.	The text was changed for clarity. The reference list was updated.
170.	Grant William, Sunlight, Nutrition and Health Research Center, wbgrant@infionline.net, United States	7.2.2.1 Experimental animal studies	64-Skin_cancer_vit_D_part_II_Tang__Bik Moukayed_Grant_vit_D_cancer_Nutrients.	p. 44, lines 17-19. UV cannot be considered a "complete carcinogen" since it also has actions that reduce risk of melanoma and non-melanoma skin cancer. Complete implies that there are no redeeming factors. 1,25-dihydroxyvitamin D (1,25D) is produced in the skin. Bikle DD, Halloran BP, Riviere JE. Production of 1,25 dihydroxyvitamin D3 by perfused pig skin. J Invest Dermatol. 1994 May;102(5):796-8. 1,25D reduces risk of cancer. Moukayed M, Grant WB. Molecular link between vitamin D and cancer prevention. Nutrients. 2013;5(10):3993-4021.	The SCHEER disagrees with the comment. No change in the Opinion is needed.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
171.	Grant William, Sunlight, Nutrition and Health Research Center, wbgrant@infionline.net, United States	7.2.2.1 Experimental animal studies	64-Skin_cancer_vit_D_part_II_Tang__Bik 64-Melanoma_prognosis_sun_exposure_C	p. 44, lines 17-19. UV cannot be considered a "complete carcinogen" since it also has actions that reduce risk of melanoma and non-melanoma skin cancer. Complete implies that there are no redeeming factors. 1,25-dihydroxyvitamin D (1,25D) is produced in the skin. Bikle DD, Halloran BP, Riviere JE. Production of 1,25 dihydroxyvitamin D3 by perfused pig skin. J Invest Dermatol. 1994 May;102(5):796-8. 1,25D reduces risk of cancer. Moukayed M, Grant WB. Molecular link between vitamin D and cancer prevention. Nutrients. 2013;5(10):3993-4021. Case Id: 161976e9-2cfc-4a94-840f-ea796c6fdf24 likely including skin cancer Tang JY, Fu T, Lau C, Oh DH, Bikle DD, Asgari MM. Vitamin D in cutaneous carcinogenesis: part II. J Am Acad Dermatol. 2012 Nov;67(5):817.e1-11; quiz 827-8. Sun exposure is associated with favorable cutaneous melanoma prognostic factors. Gandini S, Montella M, Ayala F, Benedetto L, Rossi CR, Vecchiato A, Corradin MT, DE Giorgi V, Queirolo P, Zannetti G, Giudice G, Borroni G, Forcignanò R, Peris K, Tosti G, Testori A, Trevisan G, Spagnolo F, Ascierto PA; CLINICAL NATIONAL MELANOMA REGISTRY GROUP. Sun exposure and melanoma prognostic factors. Oncol Lett. 2016 Apr;11(4):2706-2714	The SCHEER disagrees with the comment. No change in the Opinion is needed.
172.	Dr. Richarz Frank, IEC TC61 / MT16 'Biological effects of optical radiation', MT16@richarz-consulting.de, Germany	7.2.2.1 Experimental animal studies	11-Autier-UVA-sunbeds-sunscreens-melan	page 42 line 44 Schartl 1997 is not in the reference list page 43 line 2 Setlow 1993 is not in the reference list page 43 line 6 Robinson 2000 is not in the reference list page 44 line 26 - 35 Missing reference to Autier 2011, who indicated two types of melanoma. UV related, early incidence, non-aggressive and not UV related, at older age, very aggressive.	The reference list has been updated. No change in the Opinion is needed.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
173.	Nilsen Lill Tove, Norwegian Radiation Protection Authority, Lill.Tove.Nilsen@nrpa.no, Norway	7.2.2.1 Experimental animal studies		Page 43, line 41: Shall it be eumelanin, or just melanin? It is not clear from the original publication if it is so. They conclude with "melanin", not specifying "eumelanin". The melanin used in the original paper consists of > 90% eume¬lanin, and you might be absolutely right. It would be good if you specified. It is important for the understanding of the processes, as fair skin types contain more phaeomelanin. It is also interesting in relation to tanning accelerator creams often sold in the tanning studios. Would use of such products influence DNA damage in the skin?	The text has been amended for clarity.
174.	de Gruijl Frank, representing none, degruijl@planet.nl, Netherlands	7.2.2.1 Experimental animal studies		7.2.2.1 Experimental animal studies - pg 43, line 2, experiments suffered from variable background making especially UVA data inaccurate; Mitchell et al Proc Natl Acad Sci U S A. 2010;107:9329-34 in a better more powerful follow up focused on UVA and could not find any effect from UVA comparable to Setlow's (who always confirmed the weakness of his experiment, and immediately suggesting to give him money to improve up on his earlier results) pg 43, lines 7 -10, melanocytes not in epidermis but probably at dermal side of dermal-epidermal junction like in SCF transgenic mice pg 43, lines 21 – 22, these mice develop melanoma 'spontaneously', UV accelerates their development. p43, line 41, eumelanin is a phenotype known to lower the risk of melanoma in humans; while sunlight carries abundant UVA. (Pheomelanin is related to higher melanoma risks, and known to be less protective. It releases oxygen radicals uo on UV overexposure. Most skins make both eu- and pheomelanin, albeit in different ratios; could the black mice used in these experiments have had a significant fraction of pheomelanin?) pg 44, lines 14- 16, this Opinion of Hocker and	The text has been amended for clarity. The reference list was updated No changes are needed. No changes are needed. No changes are needed.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				Tsao, 2007, needs to be updated in the light of the genome landscape of melanoma (and the other types of skin cancers): tens of thousands of mutations dominated by UV types, including many potential drivers. (Hodis E, et al. A landscape of driver mutations in melanoma. Cell. 2012 Jul 20;150(2):251-63; Zhang T et al. The genomic landscape of cutaneous melanoma. Pigment Cell Melanoma Res. 2016 May;29(3):266-83.) pg 44, lines 22 – 24, what is the purpose of this sentence? What is it driving at? Summary pg 44, line 31, "eumelanin" or possibly pheomelanin	No changes in the Opinion are needed. The text was adapted for clarity. No changes in the Opinion are needed.
175.	Gilroy Steven, Joint Canadian Tanning Association JCTA, info@TanCanada.org, Canada	7.3 Non–melanoma skin cancer	 Chang_Kuehn_Feb._17_2015_Response_t  Autier_2013_-_Comment_Response_-_Vi	7.3.1.1 Meta-analysis and systematic reviews – Page 45 – line 4 Page 45 Line 10-14 The 3 studies used by IARC were; Aubry 1985 (OR 13.4), Bajdik 1996 (OR1.4), and Karagas 2002 (OR 2.5). Aubry is an outlier and does not represent modern sunbed equipment and this report should not have used this research. Page 45 – line 29 to 32 In a Rapid Response in the BMJ by Chang & Kuehn (Feb. 17, 2015) on Wehner 2014, : One problem lies with the use of meta-analytic methods to combine heterogeneous observational data into a single summary estimate. Appreciable heterogeneity was observed across studies included in these meta-analyses, as indicated by I2 values of 36.8%, 47.1%, and 56% for the associations between indoor tanning and basal cell carcinoma, squamous cell carcinoma, and melanoma, respectively [1, 2], and 96.5%, 99.9%, 99.9%*, and 99.9% for the prevalence of ever indoor tanning among adults in the United States, Northern and Western Europe, Australia, and all areas combined, respectively [3]. For example, the estimated prevalence of ever indoor tanning ranged from 19% to 74% in the United States, and	A cross reference was made to the introduction on meta-analysis. A paragraph has been added to include comments on Wehner 2014 by Chang and by Petiti. A paragraph on the use of meta-analytic methods has been added.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				from 11% to 64% in Northern and Western Europe. Further, crude categorization of ever vs. never exposure results in conflation of different levels of exposure with, presumably, different degrees of risk. In the presence of such substantial heterogeneity, a single summary estimate may not be scientifically meaningful [4, 5]. A random-effects summary estimate provides an average of results across studies, but that estimate may not reflect the actual result in any study population and may not be applicable to any real population. Using a random-effects model does not overcome study heterogeneity or circumvent the need to explore potential sources of such heterogeneity. Moreover, using the 95% confidence interval around a random-effects point estimate, as was done with the estimates of indoor tanning prevalence to calculate a range in the number of attributable cases of skin cancer [3], does not take account of study heterogeneity. As stated in the Cochrane Handbook [4]: "The confidence interval from a random-effects meta-analysis describes uncertainty in the location of the mean of systematically different effects in the different studies. It does not describe the degree of heterogeneity among studies as may be commonly believed." When you review Wehner 2012 and 2014 you find that in a 2 year spanned there is a 234% (8.2% / 19.2%) increase in attributable risk in the USA SCC and 251% (3.7% / 9.3%) attributable risk for BCC. This seems to indicate a real problem with data collection on both pieces of research. When you look at the attributable risk for Australia for BCC and SCC in Australia you wonder why those risks are so low. This seems to be a confounder not looked at in either 2012 or 2014. Interesting to note in any research paper used in this report with a negative to indoor tanning (increase risk), no rebuttal has been found or	Wehner 2012 and Wehner 2014 cannot be compared, the first focusing on attributable risk, and the latter on prevalence of exposure. No change needed. No changes to the Opinion are required in response to the

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				reported. But when a positive outcome is reported (limited risk) there is a rebuttal, example Elliott 2012 and Autier 2013 The meta-analysis from Wehner also included Aubry 1985 (OR 13.4) which is not representative of modern sunbed use and appears to be an outlier.	comment.
176.	de Gruijl Frank, , degruijl@planet.nl, Netherlands	7.3.1.1 Meta-analysis and systematic reviews		7.3.1.1 Meta-analysis and systematic reviews - pg 45, line 13, proper analysis of correlation between sunbed and sunbathing to exclude leakage of sunbathing risk into estimated sunbed risk? - pg 45, lines 15 – 16, non-significant results qualify? - pg 45, lines 27 – 28, note that the relative risk of BCC is comparable to that of melanoma, but the absolute risk would be much greater! - pg 45, lines 41 – 42, location SCCs still mainly on face and hands? BCCs located where? Summary - pg 46, line 4, sunbed use and sun bathing covariance analyses? Likely to be impossible to disentangle	No changes to the Opinion are required in response to the comment.
177.	Gilroy Steven, Joint Canadian Tanning Association JCTA, info@TanCanada.org, Canada	7.3.1.2 Case control studies		7.3.1.2 Case control studies – Page 46 – 10 to 27 Both Han 2006 and Ferrucci 2014 do not remove Skin Type 1 (always burn, never tan), do not state anything about the location of the equipment other than to say it was a commercial location. There are confounders for the type of location, who was controlling the equipment. Whether operator was trained and certified. Was the client instructed on the operation of the equipment. Ferrucci 2014 state: A pooled analysis cited by the indoor tanning industry on tanning salon use being harmless in relation to skin cancer relied on data from study populations composed of older individuals and is outdated given the rapidly changing pattern of indoor tanning in the United States." According to this statement, Ferrucci seem to say that all research done by IARC, Boniol and Colantonio is outdated and should not be used, but this report uses them. Han 2006 did not reach statistical significance: SCC - CI 0.93–2.24; BCC - CI 0.87, 2.03). Also Ferrucci 2014 numbers for control and	Lack of data on type of sunbeds and quantitative measurements of radiation was noted in the summary.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				case seem to be small to rely on this research. Page 47 – line 1 to 3& 13 to 15 When you review the Karagas's Table 1 - 656 (99.8% of cases) cases had a mild burn or painful or blistering sunburn. The paper states; Sunburns are among the strongest risk factors for BCC, how can you create a risk for sunbeds when sunburning was not removed from the data set. Also the research states that skin type was not a confounder, did they mean Fitzpatrick Skin type or something else. No data was given in the paper over what Fitzpatrick Skin Type each case and control was. This would be very important to know since Skin Type 1 should not use a sunbed. According to IARC 2006 there is a 1000-fold increase risk if you are a Skin Type 1 compared to a Skin Type 6 for skin cancer. Exposure was collected from before 1975, 1975 to 86 and 86 onward to 2001 and reporting of BCC was in 1993 to 1995/1997 to 2000/2001 to 2002. Is this not to short time period to blame any risk on sunbed use since the industry really did not get started until after the mid 80's. The time period is only 10 to 15 years. Also reported in the paper was that 4 studies have been done and only 1 had similar results. The 2 studies from Europe did not find clear evidence of an association with indoor tanning and BCC at any age.38–41. In addition, not relevant for the new 0.3 lamps or from a time period of 18 ban in Europe 31 Summary of case-control studies – Page 47 – line 31 Page 47 – line 32 – 38 Burning exposure plays a key role in BCC and it is hard to remove this confounding factor from the study results. In addition, none of the studies pertain to the new 0.3 lamp and reflect the current bans on younger than age 18. This should be noted in the summary	
178.	de Gruijl Frank, representing, degruijl@planet.nl, Netherlands	7.3.1.2 Case control studies		7.3.1.2 Case control studies - pg 47, line 10, significant trend in ORs or comparable ORs? – pg 47, lines 26-29, no association with any form of sun exposure? Hispanic genetic background of	No change in the Opinion is needed. No change in the Opinion is

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				influence? Summary case control studies pg 47, line 34, proper to mentioning? It is non-significant. Citing only ns results in line with a genuinely increased risk? pg 47, lines 36 – 37, why selecting highest %% here? Only valid for early onset BCC (age <40 or 50 yrs) when absolute risk is still small.	needed. No change in the Opinion is needed. No change in the Opinion is needed.
179.	Bocionek Peter, JW Holding GmbH (R & D), peter.bocionek@jw-holding.de, Germany	7.3.1.3 Cohort studies		page 48, line 11: The mercury arc lamps (high-pressure mercury lmps) used before 1982/83 contained also a significant portion of UVC, not only UVB. page 48, line 15 - 21: Older women, who had exposed themself to the old UVC rich sunlamps did show an increase in SCC. Younger women, who had exposed themselfs to the newer equipment w/o UVC did not show a significant increase in SCC.	The text was changed for clarity No change in the Opinion is needed.
180.	de Gruijl Frank, representing none, degruijl@planet.nl, Netherlands	7.3.1.3 Cohort studies		7.3.1.3 Cohort studies - pg 48, lines 3-5, no real trend discernible, more like an overall elevated increase - pg 48, lines 14-15, few before age of 20? generally most frequent use is found in young women Overall Summary of the Epidemiological Literature on the association of NMSC and sunbed use. - pg 48, lines 30 – 31, BCC overall comparable to melanoma in RR. Early onset BCC like early sunbed use with melanoma indicates higher relative risk, but at ages with the lowest absolute risk - pg 48, lines 33 -34, comparable to RR of melanoma, but in added absolute risk BCC would come out considerably higher	Text of the Opinion was changed for clarity.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
181.	Baldermann Cornelia, German Federal Office for Radiation Protection, cbaldermann@bfs.de, Germany	7.3.2 Experimental animal studies		Page 48 / line number 39: In this passage no figure is included. The named figure 2 can be found on page 20, and shows the UVR spectra of different UVR lamps. The announced figure should be included to clarify what has been said in the text. As shown in ABBREVIATIONS AND GLOSSARY OF TERMS the abbreviation "SCC" cannot be used for skin cancer in general. This should be corrected in ABBREVIATIONS AND GLOSSARY OF TERMS.	The SCHEER agrees with the comment. The text of the Opinion was adapted. Regarding the use of the abbreviation SCC, this refers to squamous cell carcinoma and not to skin cancer in general.
182.	ANSES	7.3.2 Experimental animal studies		§ 7. Health effects, p 48, lines 41-43 Comment: The authors propose that, in animal studies, erythema can be used as a surrogate for cancer. This comparison may not be really relevant. Indeed, the two phenomena correspond to very different biological responses. In addition erythema is a short term process with a clear threshold, while cancer is a long term effect triggered by initial events (genotoxicity and mutagenesis) that do not exhibit a threshold response.	The SCHEER agrees with the comment. The text of the Opinion was adapted.
183.	Dr. Richarz Frank, IEC TC61 / MT16 'Biological effects of optical radiation', MT16@richarz-consulting.de, Germany	7.3.2 Experimental animal studies		page 48 line 37 Kligman and Sayre 1991 reference is missing page 48 line 38 CIE 1998 reference is missing page 48 line 39 figure 2 is missing page 48 line 40 CIE 1998 reference is missing page 48 line 40 CIE 2000 reference is missing page 48 line 45 Studies should not be called "recent", when only reference is given to studies from Tong 1997 and 1998, Trempus 1998 page 49 line 25 Burns 2004 reference is missing page 49 line 26 Davidson 2004 reference is missing	The word "recent" has been removed from the text. The reference list was updated.
184.	Nilsen Lill Tove, Norwegian Radiation Protection Authority, Lill.Tove.Nilsen@nrpa.no, Norway	7.3.2 Experimental animal studies		Page 48, line 39: It is referred to Figure 2, but that cannot be the case. Figure 2 is on page 20 in this Opinion. Is the figure missing?	The SCHEER agrees with the comment. The text of the Opinion was adapted.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
185.	Baldermann Cornelia, German Federal Office for Radiation Protection, cbaldermann@bfs.de, Germany	7.3.3 Mechanistic studies: Susceptibility		This chapter is part of section "7.3. Non-melanoma skin cancer", but discusses mechanistic effects of UV radiation, especially also of melanoma. The same applies to section "7.3.3.1 Susceptibility", and there especially page 55, where melanoma and basal cell carcinoma (non-melanoma skin cancer) are discussed. Figure 3 which is not dedicated to a special text passage exclusively refers to BCC (a type of NMSC), and not to melanoma. It is recommended to sort the chapters "Mechanistic studies" in sections 7.3 and 7.2, and chapter "Susceptibility" in section 7.3 logically.	The text of the Opinion was changed for clarity.
186.	Gilroy Steven, Joint Canadian Tanning Association JCTA, info@TanCanada.org, Canada	7.3.3 Mechanistic studies: Susceptibility	 De_Winter_2001_Roza_Pavel_2001-_Sola  Mason_2012_-_Sunlight_Vitamin_D_and_S  Cui_2007_Melanoma_and_Tanning_benef  Cui_Fisher_2007_-_Science_Daily_-_Guard	7.3.3 Mechanistic studies – Page 50 – line 3 Page 50 – line 18 to 29 According to De Winter 2001: As expected, repeated ultraviolet exposures resulted in increased epidermal pigmentation and thickness. The ultraviolet sensitivity for erythema decreased on average by 75%. The cyclobutane pyrimidine dimer formation was reduced on average by 60%. According to Cui 2007: A protein known as the "master watchman of the genome" for its ability to guard against cancer-causing DNA damage has been found to provide an entirely different level of cancer protection: By prompting the skin to tan in response to ultraviolet light from the sun, it deters the development of melanoma skin cancer, the fastest-increasing form of cancer in the world…. There is even the possibility that p53 protects against skin damage in a second — and previously unsuspected — way. The protein not only causes skin to tan in response to sunlight, it may also underlie people's desire to spend time in the sun. The same process that causes POMC to produce α-MSH also leads to the production of β-endorphin, a protein that binds to the body's opiate receptors and may be associated with feelings of pleasure. According to Mason 2012; The photoprotective effects of vitamin D compounds against thymine dimers and apoptosis demonstrated in mouse and	The list of references was updated. No changes in the Opinion are needed.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				human skin, and protection against photoimmune suppression and photocarcinogenesis in mice has led to the proposal that photosynthesis of vitamin D from UVB in skin and its local conversion to the active hormone 1,25(OH)2D3 is an adaptive mechanism for cellular defense against further UV exposures. Summary mechanistic studies – Page 56 – line 3 to 16 After reviewing the information in this sections, excessive and overexposure, and sunburns are the major problem. That changing spectral output away from natural sunlight has also contributed. Since the 50's sunscreens have done this, by only blocking UVB light. It only been since the late 90's that this changed has been made to control parts of the UVA spectrum. The improper use of sunscreens (Lazovich 2012) – application – SPF15 would only be an SPF of 5 show how harmful a product can be if not used or applied properly. Than the indoor tanning industry starts in the mid 70's and with pure UVB lamps (because of benefits vitamin D), then moving to UVA lamps and high pressure lamps. At the same time, researchers like the Wolff brothers, come out with a lamp that mimic sunlight at noon. Then there is a move to higher UVB push for fluorescent lamp and high UVA, High Pressure lamps without UVB. As new research now states there is a problem with both UVA & B, so the industry adapts and goes back to a natural mix of UVA and UVB, and more controlled dose. Control or dosage seems to be what needs to be looked at. That skin needs to adapt to it environment in a controlled manner. That Skin Type 1's should be banned because of the inability to tan (IARC N2012). As research evolves both positive and negative reactions will be found on a genome level. The one thing that always comes out is sunburning and the ability to tan. Natural photoprotection along with chemical sunscreens should be recommended and sunburning should be avoided at all cost. That abstinence from UV light should never be	

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				recommended, due to the high risk of sunburning, this creates un-photoadapted skin. All skin cancers have been related to sunburning exposure. Cui 2007 full research paper is to large of a file to upload	
187.	No personal data provided	7.3.3 Mechanistic studies: Susceptibility		§ 7. Health effects, p52, line 25 Comment: The authors refer to studies showing the formation of double-strand breaks in DNA as the result of exposure to UVA. Other researchers have shown that this is not a direct effect. This should be made clearer in order to prevent a wrong comparison between UVA and ionizing radiation.	Text of the Opinion was changed for clarity.
188.	Dr. Richarz Frank, IEC TC61 / MT16 'Biological effects of optical radiation', MT16@richarz-consulting.de, Germany	7.3.3 Mechanistic studies: Susceptibility		page 50 line 33 Pleasance, Nature, 2010 reference is missing page 50 line 41 de Gruijl and Rebel, 2008 reference is missing page 51 line 4 Wang 2009 reference is missing page 51 line 11 Brash 2015 reference is missing page 51 line 21 Huang 2013 reference is missing page 51 line 21 Horn 2013 reference is missing page 51 line 27 + 30 A 2009 reference should not be done with a 2005 study Brenner 2005. page 54 line 18 - 22 Moriwaki reports primarily repair by BER base excision repair and NER nucleotide excision repair. SCENIHR only handles NER in this Opinion. page 56 line 4 - 16 The general positive influence of UVR on repair mechanism has not been considered by SCENIHR.	The reference list was updated. Text of the Opinion was changed. The SCHEER didn't see the relevancy of papers showing that UVR positively influences repair mechanisms. No changes are needed.
189.	de Gruijl Frank, representing none, degruijl@planet.nl, Netherlands	7.3.3 Mechanistic studies: Susceptibility		7.3.3 Mechanistic studies - pg 51, lines 14 -15, A > T at codon 600 in Braf not likely a UVA mutation; UVA mutations are either of UVB type or oxidative type. A > T is more a mutation resulting from alkylation. This type op mutation is also found in melanomas stemming from the dark - non-	The SCHEER agrees with the general comment. No changes in the Opinion are needed. Three mutations in the promotor of the TERT gene (Huang: 2),

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				illuminated - part of the inner eye (de Lange MJ et al, PLoS One. 2015 Sep 14;10(9):e0138002) pg 51, line 19, "three" or 2? pg 51, line 21, in 71% ! pg 51, lines 45-47, UVB does this even more effectively, as mentioned in the same paper pg 52, line 7, this conclusion of melanin offering "some protection" is way overboard! Some protection? Cancer risk in pigmented skin considerably lower, and DNA damage in melanocytes lower than in fibroblast or keratinocytes pg 52, lines 16-17, opposite to UVB effect: UVB immunosuppressive and antimicrobial pg 52, lines 28 - 29, Ikehata cs wrote down their results a bit awkward, but they did not find that " UVA induces C→ T mutations at me-CpG sites more frequently than UVB", but UVA mutated me-CpG sites with far more preference that UVB did. (UVA almost exclusively mutates me-CpG sites, whereas UVB also mutates unmethylated sites). pg 52, line 30, UVA is known to be far less carcinogenic than UVB, also confirmed by Ikehata. Summary mechanistic studies pg 56, line 9, An overstated conclusion: UVB is orders of magnitude more carcinogenic. UVA does result in some different responses compared to UVB, but no (experimental) data show UVA to be	Horn (1). Comment on Ikehata et al, accepted and corrected. This comment is unclear. No changes to the Opinion are required in relation to the comment. The SCHEER agrees with the comment. This paragraph focuses on UVA. The SCHEER agrees with the comment: *'some protection'* was replaced by *'limited protection'.* No changes in the text are needed. SCHEER agrees with the comment. The text was changed. No changes in the text are needed. The SCHEER agrees with the comment. The text was changed.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				more important than UVB in genesis of sun/UV related skin cancers. (in particular, see paper by Ikehata et al).	
190.	Dr. Richarz Frank, IEC TC61 / MT16 'Biological effects of optical radiation', MT16@richarz-consulting.de, Germany	7.4.1 Internal cancers		page 57 line 20 - 22 A 30% reduction of breast cancer should be mentioned more prominently.	Data are already given. No change in the Opinion is needed.
191.	Lipman Gary, The Sunbed Association, garylipman.tsa@gmail.com , United Kingdom	7.4.1 Internal cancers		Page 57, Line 24 : The relationship between Vitamin D levels and all-cause mortality not sunbed use per se.	The text of the Opinion was changed for clarity.
192.	de Gruijl Frank, representng none, degruijl@planet.nl, Netherlands	7.4.1 Internal cancers		7.4.1 Internal cancers - pg 57 lines 27 – 28, remarkable! Confounding by natural sunlight not an issue with skin cancers? pg 57 lines 37 – 38, sun bathing vacation more reliably estimated than other sun/UV exposures?	No change in the Opinion is needed. Results are similar after additionally controlling for these variables.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
193.	Gilroy Steven, Joint Canadian Tanning Association JCTA, info@TanCanada.org, Canada	7.4.2 All cause mortality	 Lindqvist_2014_-_Avoidance_of_sun_expo	7.4 Other cancers – page 56 – line 17 7.4.2 All-cause mortality– page 57 – line 23 Page 57 - line 37 to 39 A large cohort study by Lindqvist study in 2014 reported that use of sunbeds reduces all-cause mortality risk by 33%. This large cohort study followed 29,518 Swedish women for 20+ years. The study found that women who used sunbeds and sunbathed during summer or on holiday, had a greatly reduced risk for all-cause mortality. The study concluded: The mortality rate amongst avoiders of sun exposure was approximately twofold higher compared with the highest sun exposure group, resulting in excess mortality with a population attributable risk of 3%. The results of this study provide observational evidence that avoiding sun exposure is a risk factor for all-cause mortality. Following sun exposure advice that is very restrictive in countries with low solar intensity might in fact be harmful to women's health. Summary – Page 58 – line 14 Page 58 Line 17-19 The Lindqvist 2014 cohort study shows that sunbeds are associated with a 33% decreased risk and lower all-cause mortality.	The reference list was updated. The text of the Opinion was changed.
194.	de Gruijl Frank, representing none, degruijl@planet.nl, Netherlands	7.4.2 All cause mortality		No mention of: avoidance of sun exposure was found associated with increase risk of all-cause mortality, as was sunbed exposure with a decrease of all-cause mortality risk (Lindqvist et al, 2014).	The reference list was updated. The text of the Opinion was changed.
195.	No personal data provided	7.4.3 Ocular melanoma		§ 7. Health effects, p57, line 40 - ocular melanoma Comment: The authors mention several times in the text the role of UV in ocular melanoma. Nevertheless, the mechanistic link is not as strongly established than in the case of cutaneous melanoma, this point should be underlined.	The SCHEER agrees with the comment. The text of the Opinion was changed accordingly: "There is a lack of mechanistic studies that support the causal link between ocular melanoma and UV radiation."
196.	Dr. Richarz Frank, IEC TC61 / MT16 'Biological effects of optical radiation', MT16@richarz-	7.4.3 Ocular melanoma		page 58 line 5 Schmidt-Pokrzywniak 2009 reference is missing	The list of references was updated.

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	consulting.de, Germany				
197.	Lipman Gary, The Sunbed Association, garylipman.tsa@gmail.com , United Kingdom	7.4.3 Ocular melanoma		In addition to my extensive comments for page 5 lines 41-43 submitted separately. Page 58, lines 1-13: This is not substantive compelling scientific research, merely a self-administered postal survey. As such, should not have been included in a scientific review.	The study met the inclusion criteria. No change in the Opinion is needed.
198.	de Gruijl Frank, representing none, degruijl@planet.nl, Netherlands	7.4.3 Ocular melanoma		7.4.3 Ocular melanoma - pg 58 line 8, none of it significant, so what is the substance? Summary - pg 58 lines 19 – 21, none of it significant, so what is the substance?	The text of the Opinion was changed for clarity.
199.	Gilroy Steven, Joint Canadian Tanning Association, info@TanCanada.org, Canada	7.5 Risk characterization (dose response in humans and animals by age and other factors)	Petitti_D_response_to_Wehner_2014_in_F Chang_Kuehn_Feb._17_2015_Response_t CDC-Sunburn___Sun_issue_MMWR_May_ Bataille_2005_-_A_multicentre_epidemiolo	7.5 Risk characterization (dose response in humans and animals by age and other factors) – Page 58 – line 22/23 Page 58 Line 29-32 Petitti 2016 reports in PubMed "The meta-analytically derived estimate of the prevalence of ever exposure to indoor tanning for adults in Northern and Western Europe based on the studies identified by Wehner et al. (2014) is meaningless; the estimate of the number of skin cancers attributable to indoor tanning in Northern and Western Europe based on this meaningless estimate is meaningless. The accuracy of the Wehner research (2012, 2014) has been called into question through a Rapid Response letter by Chang & Kuehn (Feb. 17, 2015). It reported that: "crude categorization of ever vs. never exposure results in conflation of different levels of exposure with, presumably, different degrees of risk."Chang & Kuehn went on to say: "We found that prevalence estimates from the majority of these studies were based on highly selected or non-representative populations. These source populations call into question whether the results from these studies can be generalized to the entire populations of the United States, Northern and Western Europe, or Australia. Furthermore, low participation rates and non-randomized sampling methods in many studies	The comment has been considered and the respective changes in the Opinion have been made.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				likely resulted in biased findings. Publication bias was also evident, with preferential publication of studies reporting a higher prevalence of indoor tanning, further undermining the validity of the meta-analysis results." They reported: "The annual cancer incidence estimates also have inherent uncertainty, although confidence intervals appear not to have been reported by the sources relied upon by Wehner et al. Thus, the reported 95% confidence intervals around the estimated number of skin cancer cases attributable to indoor tanning are not true confidence intervals because they do not incorporate the uncertainty in the relative risk and cancer incidence estimates. Furthermore, as stated earlier, the meta-analysis confidence intervals describe only statistical error; they do not describe the extent of study heterogeneity. In other words, the estimates of attributable skin cancer cases are much more uncertain and unstable than reported and do not provide a valid estimate of the true prevalence (if there is a single prevalence) of indoor tanning in the general population." In addition to the issues outlined by Chang & Kuehn regarding the accuracy of the Wehner research there are further issues. The tanning industry has not been increasing as Wehner states with an absolute increase in past year exposure of 3.4% in adults, 2.1% in university students and 1.7% in adolescents. The American Suntanning Association reported January 7, 2016 that the 10% federal excise tax from 2010 has devastated the tanning industry in the USA by closing 10,000 businesses with the loss of 100,000 jobs. Studies included by Wehner in their prevalence analysis from the NCI and CDC support this trend. Past year exposure by adults, NCI 2005 – 8%, NCI 2007 – 9%, CDC and NCI 2012 – 6%. Based on these national studies, tanning by adults has reduced by 39% since 2007. The past year prevalence for adults in United States by Wehner of 13% is double the CDC/NCI 2012 study of 5.6%.	

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				This would indicate that Wehner's prevalence analysis is severely overstated which would reduce the overall impact greatly. According to this report on page 24 – line 1 to 9 the National Youth Risk Behaviour Surveys (Guy 2014) showed a decrease in the use of sunbed for student where states had restrictions. So this would be another confounder for both Wehner 2012 and 2014. This would back up the NCI and not Wehner numbers.	
200.	Gilroy Steven, Joint Canadian Tanning Association JCTA, info@TanCanada.org, Canada	7.5 Risk characterization (dose response in humans and animals by age and other factors)	 Bataille_2005_-_A_multicentre_epidemiolo	Page 59 - line 3-10 The largest European case-control study (Bataille 2005) investigating the association between sunbed use and melanoma found that sunbed use provided a reduction in melanoma of 10% (OR 0.90, 95% CI 0.71-1.14) Page 59 line 15-17 The 76% risk as reported by Cust was based on Australian data and cases which were not using the new 0.3 European lamp and also had high outdoor UV which could confound these numbers. Out of 604 cases, only 137 or 22% "Ever" used a sunbed. The study reported 78% of the cases or 467 cases never used a sunbed. So 100% of their melanoma was from 'other causes'. But for the young sunbed users, 76% of their melanoma was attributed to sunbeds. A UK study using the same questionnaire and method of analysis as the Australian study by Cust et al. (2011) by Elliott (2012) found a non-significant ever-use risk of sunbeds of 6% (OR 1.06, 95% CI 0.83–1.36). In addition, Elliott (2012) reported age at first use of sunbeds showed a small non-significant increased risk for use of 16%(OR 1.16, 95%CI 0.84–1.62).	The comment has been considered and the respective changes in the Opinion have been made.

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201.	Dr. Richarz Frank, IEC TC61 / MT16 'Biological effects of optical radiation', MT16@richarz-consulting.de, Germany	7.5 Risk characterization (dose response in humans and animals by age and other factors)	 11-Autier-UVA-sunbeds-sunscreens-melan  10_-_Diffey_-_A_model_to_calculate_sun	page 58 line 33 - 40 All indoor numbers should be compared to outdoor numbers as well. page 58 line 41 - page 59 line 2 Following Autier 2011 two forms of melanoma can be distinguished. Therefore the transfer of incidence/mortality ratios would only be allowed if the two types of melanoma would have been calculated separately. SCENIHR should at least discuss this. page 58 line 27 - page 59 line 17 "The risk characterization does not include the risk of under exposure with UVR as shown in the WHO disease burden report from 2006. The file WHO solaruvradfull_180706 was too big to upload and is send to the SCENIHR office by mail."	This is a personal view. No change in the Opinion is needed. The SCHEER is aware of this hypothesis, which cannot be applied to this kind of calculation. The SCHEER disagrees with the comment.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
202.	de Gruijl Frank, representing none, degruijl@planet.nl, Netherlands	7.5 Risk characterization (dose response in humans and animals by age and other factors)		7.5 Risk characterization (dose response in humans and animals by age and other factors) pg 58 lines 27 – 28, may not "negligible" but in %% marginal at most, especially for melanoma. If estimates would proof reliable added absolute risks of BCC and SCC would be more of a concern. pg 58 line 45 – pg 59 line 2, dubious assumption, and estimated mortality probably not true pg 58 lines 5 – 8, considering the focus here on the marginal percentage, it would be far better to address the problem of the large majority of melanoma, among which a majority related to sun exposure. pg 58, line 13, again dubious framing of a relative risk relative risk in younger cohort, especially women, that started sunbed use before the age of 35, but still with a low absolute risk (at < 60 years); melanoma incidences are high in the elderly, especially men, a comparison which would put everything in proper perspective. pg 58, lines 15 -17, a relatively large fraction of an exceedingly small risk at ages under 30 years with vanishingly small mortality rates.	The SCHEER disagrees with the comment. No change in the Opinion is needed. This is a personal view. No change in the Opinion is needed. The SCHEER agrees with the comment, but the focus of the mandate is on the exposure from sunbeds. The SCHEER agrees with the comment, but the focus of the mandate is on the exposure from sunbeds. This is a personal view. The Opinion does not exclusively refer to mortality rate below the age of 30. No change in the Opinion is needed.
203.	Levy Joseph, American Suntanning Association, joe@smarttan.com, United States	7.5 Risk characterization (dose response in humans and animals by age and other factors)	 _Petitti_-_Wehner_Review_.pdf	7.5 Risk characterization (dose response in humans and animals by age and other factors) – Page 58 – line 22/23, and Line 29-32 Dr. Diana Petitti, a former vice chair of the U.S. Preventative Services Task Force and a champion of women's health issues, has reviewed the Wehner et al reports that are used in the SCENIHR report as a basis to establish the prevalence of sunbed use and the risk from sunbed use. Dr. Wehner's review (attached) believes this paper to be so incapable of producing conclusions that she calls its conclusions "meaningless." She states, "The meta-analytically	The comment has been considered and the respective changes in the Opinion have been made.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				derived estimates of prevalence of ever-exposure to indoor tanning for adults in Northern and Western Europe is meaningless" and "The estimate of the number of skin cancers attributable to indoor tanning in Northern and Western Europe based on this estimate is meaningless." As supplied in my power point presentation to the SCENIHR committee, the massive 8-fold variation in reported skin cancer incidence from country to country in Europe (WHO data supplied) -- with no corresponding significant difference in mortality data from country to country -- make definite conclusions about environmental risk factors impossible, as the default explanation for such a range has to first be differences in reporting and detection rather than differences in actual disease. Because none of the input studies used in Wehner et al are capable by design of differentiating non-burning UV exposure from exposure that results in a burn, this analysis cannot be used as a sound basis for any policy.	

Results of the public consultation on the preliminary Opinion on biological effects of ultraviolet radiation relevant to health with particular reference to sunbeds for cosmetic purposes

Comments 204-275

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204.	Zeyen Thierry, European Glaucoma Society Foundation, thierry.zeyen@telenet.be, Belgium	8. Opinion	MacularDegenerationRefs.pdf	lines 24-25. The European Glaucoma Society calls for macular degeneration to be added to this sentence due to the permanent nature of the visual impairment. We supply the same reference file as in previous section.	Comment accepted. The new section on eyes includes: "The association of age-related macular degeneration (AMD) with UV exposure is more controversial". Text of the Opinion was amended.
205.	Baldermann Cornelia, German Federal Office for Radiation Protection, cbaldermann@bfs.de, Germany	8. Opinion		This paper covers the current state of science and technology in relation to the biological effects of UV radiation. The German Federal Office for Radiation Protection (BfS) agrees completely with the "Preliminary Opinion on Biological effects of ultraviolet radiation relevant to health with Particular reference to sunbeds for cosmetic purposes" of the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), and notes that due to scientific knowledge basis the marketing of this carcinogen should be banned - according to the example of Brazil and Australia.	The SCHEER acknowledges the agreement with the Opinion.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
206.	Gilroy Steven, Joint Canadian Tanning Association, info@TanCanada.org, Canada	8. Opinion	Radack_2015_A_Review_of_the_Use_of Cui_2007_Melanoma_and_Tanning_benef Cui_Fisher_2007_-_Science_Daily_-_Guarc de_Winter_2001_-_Solar-Simulated_Skin_/ Mason_2012_-_Sunlight_Vitamin_D_and_ Mason_2010_-_Photoprotection_by_125-I	8. OPINION Page 60 – line 1 to 13 ANSWERS TO TERMS OF REFERENCE Research has evolved to show that there is a risk with excessive and overexposure, both in the UVA and UVB range. That Skin Type 1 (always burn, never tan) should be excluded from indoor tanning. That there is benefits and risk for UV exposure. That the lack of UVB from sunlight in northern climate – UVI below 3 should be a concern. That people from northern countries that take sunny vacation should adapt their skin to a tropical climate to reduce the risk of overexposure. Most research on immune suppression has been with high dose of either UVB (according to IARC 2012) or UVA or in combination. Most of the sources do not mimic sunlight or a sunbed. That sometime immune suppression is required, for example MS and other autoimmune diseases. There are a number of doctors that recommend phototherapy and when there is no medical phototherapy, a sunbed can be recommended. A group dermatologist (Radack 2015) completed a full review of the use of tanning beds for dermatological treatment and are recommending that tanning beds can be used for treatment. The study reported that many patients are unable to reach dermatologic facilities regularly and that tanning bed facilities could represent a more convenient means to obtain UV therapy. They found studies validating the use of tanning facilities for psoriasis treatment and as a treatment option for atopic dermatitis, mycosis fungoides, acne, scleroderma, vitiligo, and pruritus, as well as other UV sensitive dermatoses. They concluded; Unsupervised sun exposure	No changes in the Opinion are needed. The text on diet and Nordic natural sunlight has been amended. The SCHEER disagrees with the comment. In a human model, wavelength-specific (narrow band) immunosuppression occurs from 300 mJ/cm2 UVA, and the Opinion states that this effect is lost at higher doses. Immunosuppression by UV-A from sunbeds for medical conditions is outside the mandate. Treatment of medical conditions by sunbeds is outside the scope of the mandate. No changes in the Opinion are needed.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				is a standard recommendation for some patients to obtain phototherapy. Selected use of commercial tanning beds in the treatment of dermatologic conditions may be another useful and effective treatment for those patients with an inability to access office-based or homebased phototherapy. Furthermore, the risks of treatments that would be used as an alternative to tanning beds should also be considered, as many medications, such as methotrexate, carry the risk of severe side effects. Although there are significant risks associated with tanning beds, completely discounting its use may be a disservice to patients who have poor access to in-office and home phototherapy. As research evolves, even the Vitamin D researcher are now admitting that vitamin d deficiency maybe an indicator of sunlight deficiency. Since there are so many more photoproducts being produce from light, example nitric oxide from UVA light for the reduction of blood pressure. There is consistent evidence that overexposure to UV is related to CMM, SCC and moderately to BCC skin cancer. That the inability to tan, increases the risk of skin cancer. That photoprotection (tan) reduces the risk of CMM (IARC 2012, De Winter, Mason, Cui). That only SCC has an excessive risk factor, but sunburning could not be ruled out of the excessive exposure. Australian studies should not be used due to their high ambient UV index and ozone deletion over the country. Most of the European countries do not have high UV index year round. Page 61 – line 2 to 10 Since the latest research shows no threshold levels of UV-irradiance and UV–dose, and that human require sunlight to survive, the recommendation should be to stay below	The Opinion clearly states that sunbeds can enhance vitamin D status, and the Opinion has been amended to include the effect on blood pressure. Incorrect citation of IARC. There is no general agreement that having a tan may reduce CMM risk.

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				erythema levels. That Skin Type 1 (always burn, never tan) should be restricted from using sunbed and should be told to stay out of the sun. For those that can tan - Skin Type 2 and above, they should be advised to adapt their skin to new UV environments when traveling, especially to tropical destinations. This would align with guidance information for alcohol consumption and food – example produced meats. They all have similar risks.	Advice on outdoor sun exposure is outside the mandate. No change in the Opinion is needed.
207.	Petri Aspasia, Greek Atomic Energy Commission (EEAE), aspasia.petri@eeae.gr, Greece	8. Opinion		lines 31 - 33. A full stop is probably missing.	Text of the Opinion was corrected.
208.	de Gruijl Frank, representing none, degruijl@planet.nl, Netherlands	8. Opinion		8. OPINION ANSWERS TO TERMS OF REFERENCE – pg 60, lines 19 – 20, a false conclusion (see the work of Ikehata et al). UVA is definitely mutagenic but not as strongly as UVB, not by a long shot (ref. Ikehata et al, quoted in this respect, stated this quite explicitly)	Text was slightly modified for clarity. The high UVA content of sunbeds makes up for this.
				- pg 60, lines 24 – 25, the evidence for UV causing uvea melanoma is very weak (non-significant increases), and if there would be such an effect it would be more likely caused by blue light/UVA1	The comment has been considered. This aspect had already been described in the Opinion. No changes of the text are needed.
				- pg 60, lines 29 – 30, not true in winter time in temperate climates: not enough UVB, which results in a reduction in vitamin D status, more dependent of diet which is generally insufficient in vitamin D	The text on sunlight and diet has been amended.
				- pg 60, line 32, " and lack of such UVA effects at high dosages and even counter effects on UVB induced immunosuppression".	This has been mentioned in the paragraph on immunosuppression. No changes in the chapter "Opinion" are needed.
				- pg 60, lines 43 – 44, where the absolute risk is exceedingly small,	The SCHEER disagrees with the comment. No change is needed.
				- pg 61, lines 1 -2, if these assessments turn out to be reliable, the added absolute risks of	The SCHEER disagrees with the comment. No

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				SCC and BCC would be more of a concern than that of melanoma (reliability is likely to be hampered by closely related behaviours of sunbed use and sun bathing). - pg 61, lines 15 – 16, as is the case for sun exposure. - pg 61, line 25, but not in skin where UVB is actually more hazardous.	change is needed. The SCHEER disagrees with the comment. No change is needed. The text has been amended.
209.	Olofsson Katarina, Swedish National Electrical Safety Board/Swedish Radiation Safety Authority, katarina.olofsson@elsakerhetsverket.se, Sweden	8. Opinion		In section 8, concerning UV-irradiance limit levels, we would like to make one additional comment. Even though there are no safe limit it is important to have limits that are reasonably low in order to decrease the risk of accidental overexposure.	Calculation of reasonably low limits is problematic because the cancer induction is a stochastic process. There are insufficient data to calculate a backward extrapolation of dose-response to a dose level of no concern. Limiting risk of accidental overexposure is a risk-management issue, outside the scope of the mandate.
210.	Zeyen Thierry, European Glaucoma Society Foundation, thierry.zeyen@telenet.be, Belgium	9. Recommendations for further work	 solaruvradfull_OECD_EDIT.pdf	The European Glaucoma Society Foundation would like to draw attention to the fact that, in its 2006 report on solar ultraviolet radiation, the OECD report calls for further evaluation on the causative links between excess UV exposure and AMD in future burden of disease assessments despite the fact that the authors classify the evidence of a link between AMD and uv as inconclusive. We understand that this may not be the scope of this Opinion paper however we call for the Scientific Committee to consider undertaking some efforts for such evaluation given the popularity of sun beds and the permanent visual impairment of the disease. The risk of the disease is particularly high for the people aged over 40s as we noted elsewhere in the consultation. We include the OECD report. Please note that the uploaded document is only a section of the full report due to file size restrictions for uploading.	Ten years later (2016), there is evidence of a relation between UV radiation and AMD. The SCHEER supports any research that would give insight in the mechanisms.

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211.	Gilroy Steven, Joint Canadian Tanning Association JCTA, info@TanCanada.org, Canada	9. Recommendations for further work		9. RECOMMENDATIONS FOR FURTHER WORK – Page 62 – line 1 There seems to be a lack of research on animal studies as it relates to UV exposure from a sunbed, especial with the 0.3 lamps being introduce in 2007. Further studies are required to see the effects on skin cell when exposed to normal sunbed levels – risks and benefits. Further research should be on the type of location where sunbeds are located, more so about who controls the equipment. Is risk reduced when trained operators are controlling the equipment. Not just that they are in a commercial facility. Further research should be done on the reason why a tan reduces your risk of melanoma and other skin cancers. There is already new research showing vitamin D reducing the risk of melanoma and other skin cancers. Supplement don't seem to have this effect, since it not on the skin at time of exposure and skin cell can convert to the active hormone calcitriol themselves. Further research is required to find out why the P53 gene not only activates a tan but also activates the production of β-endorphin. UV exposure seem to be the same as food, water and air, activation of feeling good. This response seems to indicate we should be getting some exposure without excess. Further research is required to whether a sunbed has further benefits than just vitamin D production, example nitric oxide, other photoproducts, before the product is condemned because of myopic research on skin without looking at the whole body. It is well known that the further a person lives away from the equator the higher the risk of cancer and all disease mortality.	These experiments are not expected to change the general opinion that UVR is a complete carcinogen. There is no doubt of the importance of vitamin D in relation to health and disease. The benefits of exposure to UV from sunlight are outside the scope of the Opinion. Effects of artificial UV on other organ systems than skin have been discussed in the Opinion. The relation between latitude and health & disease is complex. The comment is a purely speculative one: the ecological studies mentioned in the comment are just indicative and not strong evidence. In addition, it is as yet unclear what role sunbeds could play.

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212.	No personal data provided	9. Recommendations for further work		The French Agency for Food, Environmental and Occupational Health & Safety (Anses) and the French Institute for Public Health Surveillance (InVS) totally agree with the Scenihr conclusions. The document is well documented and provides very strong conclusions. The overall document presents an exhaustive up-to-date evaluation of the scientific knowledge both from human and animal studies on the potential risks from sunbed use. Anses and InVS propose to add a recommendation for further reflexing on regulation: In a context of rapid expansion of the marketing and use for cosmetic purposes of radiation-emitting devices with a proven carcinogenic effect, and moreover without any beneficial effect on health, associated with the reduced effectiveness of the regulation to ensure protection for the health and safety users of tanning device, ANSES believes that the European regulation constitutes only a partial and insufficient response in light of the proven risk of skin cancer for their users. Indeed, regulations governing the methods of public access to tanning devices for cosmetic purposes are unable to prevent the health impact of artificial UV rays. Given the health data already presented, it would be preferable for the authorities to alert the European Commission concerning the safety of use of tanning devices. Since 2012, ANSES therefore recommends the cessation, ultimately, of all commercial use of tanning by artificial UV rays and of the sale of appliances emitting artificial UV rays for cosmetic purposes (see OPINION of the French Agency for Food, Environmental and Occupational Health & Safety relating to a draft decree concerning the sale and provision to the public of certain tanning devices that use ultraviolet radiation available online in English: https://www.anses.fr/en/system/files/AP2012sa0263EN.pdf).	The SCHEER acknowledges the agreement with the Opinion. The recommendation by ANSES is a risk management issue and therefore outside the scope of the mandate.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
213.	Grant William, Sunlight, Nutrition and Health Research Center, wbgrant@infionline.net, United States	9. Recommendations for further work	 49-Endometrial_cancer_sun_Epstein.pdf  012-Vit_D_sun_type_2_diabetes_Lindqvis  906-Vitamin_D_thrombotic_Lindqvist.pdf  64-UV_lymphoma_Boffetta.pdf  64-Breast_cancer_UV_Ssweden_Yang.pdf	p. 62, lines 3-5. There are reports of health benefits from indoor tanning in Europe: Boffetta P, van der Hel O, Kricker A, Nieters A, de Sanjosé S, Maynadié M, Cocco PL, Staines A, Becker N, Font R, Mannetje A', Goumas C, Brennan P. Exposure to ultraviolet radiation and risk of malignant lymphoma and multiple myeloma--a multicentre European case-control study. Int J Epidemiol. 2008 Oct;37(5):1080-94. Epstein E, Lindqvist PG, Geppert B, Olsson H. A population-based cohort study on sun habits and endometrial cancer. Br J Cancer. 2009 Aug 4;101(3):537-40. Lindqvist PG, Olsson H, Landin-Olsson M. Are active sun exposure habits related to lowering risk of type 2 diabetes mellitus in women, a prospective cohort study? Diabetes Res Clin Pract. 2010 Oct;90(1):109-14. Lindqvist PG, Epstein E, Olsson H. Does an active sun exposure habit lower the risk of venous thrombotic events? A D-lightful hypothesis. J Thromb Haemost. 2009 Apr;7(4):605-10. Yang L, Veierød MB, Löf M, Sandin S, Adami HO, Weiderpass E. Prospective study of UV exposure and cancer incidence among Swedish women. Cancer Epidemiol Biomarkers Prev. 2011 Jul;20(7):1358-67.	The SCHEER has carefully considered the references. Most have already been discussed in the preliminary Opinion and several studies are on natural sunlight. No changes in the Opinion are needed.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
214.	Nilsen Lill Tove, Norwegian Radiation Protection Authority, Lill.Tove.Nilsen@nrpa.no, Norway	9. Recommendations for further work		Page 62, line 5: We disagree that there is no need for future work. 1) We would like to see studies that can show whether it is UVB and/or UVA being more carcinogenic. This is particularly relevant as many countries allow only UV type 3 sunbeds, and some countries do not regulate this. UV type 3 sunbeds allow limited irradiance in both UVB and UVA wavelength range, but the large amount of UVA that is allowed makes these sunbeds very little "sunlike". UV type 1 and 2 sunbeds are even less "sunlike" with primarily UVA. 2) We would like to see studies on the importance of dose rate versus dose. 3) We would like to see more epidemiological studies that also consider the actual doses and dose rates, as well as compliance with existing exposure limits. We are aware of the fact that this Opinion does not consider risk management. However, assessing health hazard from a certain irradiance level is difficult without considering the compliance with this level and also how the devices are used.	While further scientific research on the biologic effects of UVR is highly appreciated by SCHEER, estimation of which wavelength (UVA or UVB) is more carcinogenic is of minor importance in the context of the Opinion. For sunbeds it is relevant that both radiations are complete carcinogens. Studies on dose rate vs. dose are of importance in radiation biology, but are outside the present mandate. New studies on sunbed usage for cosmetic purposes would not be a priority for future work since there is a large body of consistent evidence which has established the adverse health effects and limited beneficial effects associated with the use of sunbeds.
215.	de Gruijl Frank, representing none, degruijl@planet.nl, Netherlands	9. Recommendations for further work		- pg 62, lines 4 – 5, this statement is ridiculous and totally unsubstantiated; very few studies have actually addressed this issue which would imply that data and proper studies are sorely missed. And remember: "the absence of proof is not the same as the proof of absence".	No additional information is expected – the UVR is carcinogenic. While research on UVR is highly welcomed, the SCHEER does not see a priory in relation to sunbeds for cosmetic purposes. This is a correct statement.
216.	Khazova Marina, Public Health England, marina.khazova@phe.gov.uk, United Kingdom	9. Recommendations for further work		Further research is required in a number of areas of UVR, including effects of intermittent high exposures on melanoma induction, effects of UVR exposure on cardiovascular health and the required level of exposure to produce Vitamin D. In short, further evidence to quantify the burden of disease from excessive/insufficient UVR exposure and to optimise UVR exposure.	The SCHEER welcomes research on the role of UVR in health and disease, but it does not see a priory for sunbeds for cosmetic purposes. The treatment of medical conditions is outside the scope of the mandate.

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217.	Rutkowski Piotr, Polish Society of Surgical Oncology, Maria Sklodowska-Curie Memorial Cancer Center and Institute of Oncology, Warsaw, Poland, piotr.rutkowski@coi.pl, Poland	ABSTRACT		I completely agree with the Opinion, particularly that "Sunbed use is responsible for a 29 noticeable proportion of both melanoma and non-melanoma skin cancers and for a large 30 fraction of melanomas arising before the age of 30". It should lead to the conclusion about necessary legal regulations and restrictions in all EU Member coutries on access of persons up to 18 years old to sunbeds.	The SCHEER acknowledges the supportive comment.
218.	Zeyen Thierry, European Glaucoma Society Foundation, thierry.zeyen@telenet.be, Belgium	ABSTRACT	 _UV_macular_degeneration_2.pdf  risk_factor_AMD_3.pdf  Ultraviolet_light_and_ocular_diseases_1.p  Outdoor_Activity_Cataract_Rural_Popula	lines 15-25: The European Glaucoma Society Foundation (EGS) understands that this Opinion is primarily focussing on the cancers linked to UV, however it is important that visual impairment as a result of UV exposure must be added in the section of non-cancer health effects. There is sufficient and strong scientific evidence for age related macular degeneration (AMD), cortical cataract, photokeratitis, climatic droplet keratopathy (CDK), and pterygium. The EGS would like to draw particular attention to AMD because of the IRREVERSIBLE damage caused by the disease. Admittedly the association between AMD and UV radiation has remained controversial. However a systematic review and meta-analysis suggests that the controversiality regarding AMD and UV stems from heterogeneity between studies which is due to study-specific covariates, including latitude and gross domestic product (GDP) per capita. The review suggests that risk for early AMD is increased in subjects exposed to high UVR, but also to low UVR, by comparison with medium exposures. Although such information will not alter the overall view regarding the harmful impact of UV in health, it also highlights that the methodology in choosing the evidence base for such important Opinion papers has to be strengthened in general. The EGS elaborates further on this point in the relevant section.	A chapter on the potential effects on the eyes has been added.

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219.	Harbusch Frank, European Sunlight Association a.s.b.l., frank.harbusch@europeansulnlight.eu, Belgium	ABSTRACT		Page 4, lines 35-36 UV index 12 is not equivalent to midday tropical sun. UV index 12 is equivalent to midday mediterranean sun.	The text was amended to say equatorial sun.
220.	Keller, Dr. Birgit, Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety, birgit.keller@bmub.bund.de, Germany	ABSTRACT		The present report highly reflects the current scientific state of knowledge. The contained statements and conclusions agree with those of the "Strahlenschutzkommission", the scientific advisory board of the German Federal Ministry for Environment in issues of radiation protection. This commission confirms in its latest recommendation, which will soon be published, the risk of the use of sunbeds related to melanoma and other UV-induced damages. I also would like to support the statements, that there is no need to use sunbeds to induce Vitamin D and no indications for threshold levels of UV-radiation. In 2009 Germany has adopted the Act on the Protection against Non-ionising radiation including a ban of the use of sunbeds for minors. The Ordinance on the Protection against harmful effects of artificial ultraviolet radiation (UV-Protection-Ordinance) of 2012 contains specific obligations f proper health and safety information and the need for properly trained staff being available at all times the sunbed is in operation. The overall conclusion of this Opinion with regard to risks associated with UV radiation in general and with sunbeds in particular reaffirms the strong necessity for a strict legislation.	Thank you for the comment. The SCHEER acknowledges the supportive information.

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221.	Baldermann Cornelia, German Federal Office for Radiation Protection, cbaldermann@bfs.de, Germany	ABSTRACT		Page 5 / line number 15 – 25: This section and the associated chapters 1.4 and 7.1 are discussing only vitamin D, immunosuppression and skin aging as "non-cancer health effects". A balanced consideration of all acute and chronic non-cancer effects would be appropriate to point out that in addition to the positive effect of the UV radiation (the initiation of the vitamin D synthesis) a large number of negative effects has to be taken into account for health risk estimation - especially concerning the use of sunbeds. Regarding vitamin D synthesis, the summarizing statement that even on cloudy days usual solar UV exposure to face and hands is sufficient to achieve a sufficient vitamin D level is not deducible from the detailed explanations in chapter 7.1.1. Recent publications on UV-induced vitamin D synthesis indicate that on sunny days in the summer at an approximate UV index of 7 (Manchester summer, s. Publication of Webb and Rhodes 2010 and 2011) a UV exposure for half of the time in which a sunburn for fair skinned people arise (0.5 MED) may form sufficient vitamin D blood serum level of 50 nmol/l. Depending on the extent, cloudiness reduces UV irradiance and thus the UVB irradiance and in conclusion the efficiency of vitamin D synthesis. Accordingly, the statement "even on cloudy days" should be specified.	Text on blood pressure, eyes, internal cancers and general mortality has been added. The text on vitamin D has been modified.
222.	Ministry of Health, Welfare and Sports, Netherlands	ABSTRACT	 Comments_on_the_SCENIHR-report_april_	The title indicates that the report is focused on artificial UV-sources, but not entirely restricted to: "with particular reference to sunbeds" for cosmetic purposes" - Would it not be better to replace sunbeds by "artificial UV-sources" - It is good that the title also allows for the broader UV-exposure and UV-radiation protection to at least be indicated ABSTRACT General comment: We've noticed the report doesn't elaborate on	The SCHEER has decided to use the term 'sunbeds' for practical purposes and to focus on their cosmetic (tanning) purposes. Comment acknowledged. Within the mandate, the SCHEER has focused on the effects from sunbeds. Especially in the discussion of the epidemiological studies, the (draft) Opinion has attempted to distinguish this from the overall (mainly sunlight-UV) exposure. See above: a full discussion on solar UV exposure and its regulation is outside the scope of the

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				age limits. In fact, it ignores former recommendations of 2006. For the current report many field studies and meta-studies were used. However, these studies all apply to the use of tanning beds prior to the SCCP report of 2006. The question remains to what extent applying the recommended measures (0.3 W/m2 and the age limit) from 2006 will add to the current findings. This is not reflected in the report. The main description and conclusions that UV is a complete carcinogen, both an initiator and a promoter is fully justified based on existing knowledge and this view is fully in line with IARC's classification of solar radiation, UV-radiation and UV-emitting tanning devices as (proven) carcinogens to humans: class I carcinogens. The problem should be framed more clearly: Sin cancer incidences are rising rapidly in many countries (and more rapidly than expected due to ageing or growing of the populations). This should be indicated in the abstract. Furthermore, it should be indicated that skin cancer risks are related to the overall UV-exposure, including both exposures to solar UV and artificial UV-sources. Since the full scope of SCENIHR is broader than just the SCCS (Consumer Products) it is a missed opportunity if not some attention is drawn to the fact that skin cancer risks rapidly rise in many countries in the western world (more rapid than any other cancer in at least several countries) and could be influenced by increased efforts regarding UV-radiation protection from both solar and artificial exposures. The contribution of exposure to artificial sources to present skin cancer incidence is estimated at 5-6%. The big majority of the	mandate. This is explained in the Opinion. This confounding is discussed in the epidemiological studies. Unfortunately, there are no data (yet) to support this assumption. The text on vitamin D has been modified. The SCHEER acknowledges the comment, but sees no need for changes in the text. The paragraph on risk characterisation was rephrased in the Executive Summary. The paragraph on solar radiation was rewritten.

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				remaining risk is most probably related to solar UV-exposure. The explanation for rising risks is probably an increase in solar and artificial exposures! Page 6 section Risk characterization Agreement with the risk estimates given in this section (5-6% of present incidence), although it could be that some correlation with solar exposure behavior occurs (studies have tried to adjust for that, but it is extremely difficult to correct for this in view of the fact that full life time exposure records would be required to do so). Also, please add: Since exposure to artificial sources probably increased in the past decades, it might be expected that the absolute contribution to future risks increases (because of the lag time between exposure and the occurrence of skin cancers). Page 6 Lines 19-23 The sentence starting with the "The increase… amounts to 15%.... " is unclear. In the first part of the sentence the difference with the 5.4% in line 16 is unclear. Suggestion to rephrase to: "For the group in the general population that exposed themselves to artificial UV the melanoma risk was increased with 15% compared to those that were not exposed to artificial sources, and if the exposure to artificial UV sources started at an age below 35 the increase is 75% compared to those that did not expose themselves to artificial sources. Page 10 section 1.4 There is clearly some scientific debate on the minimum vitamin D levels required and certainly about the optimal levels. Skin production of vitamin D in winter time solar UV is hardly existing (in temperate zones), meaning that the summer production and/or	Calculation of reasonably low (or maximum allowable) dose limits is problematic because the cancer induction is a random process. Defining an acceptable risk is outside the mandate of the Opinion. See answer to comment 209. The text of the Opinion has been amended. This risk-management issue is outside the mandate. The effect of banning sunbed use for people under the age of 18 is briefly mentioned in Chapter 6.

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				diet contribution should be sufficient to avoid too low values in late winter. I do agree with the statement that the sunbed exposure spectrum is far from ideal to make up for the winter dip. Page 19 Section Solar radiation Nice to know that the solar spectrum peaks at 550 nm, but a description of the solar UV-spectrum at ground level is more relevant for this report. Some clarification is needed in lines 23-31 and lines 32-40 have some flaws/errors. Lines 23-31 suggestion instead of The solar UV-spectrum is strongly influenced by the atmosphere due to strong wavelength dependent absorption and scattering. Due to the strong absorption by ozone the shorter UV-wavelengths are strongly reduced when the sun is at a low elevation, compared to the overhead sun. This leads to a strong dependence of the UV-index with time of the day, the season and the geographical latitude. In addition to the total ozone column, clouds and aerosols and the presence of reflective surfaces (like snow) can influence UV-irradiance levels relevant for expsures. Page 19 Lines 32-40 Solar UV-irradiaton at the ground is measured by spectroradiometers or broadband detectors (the latter require regular checks against spectraradiometers). Also satellites use spectroradiometers to measure reflectance spectra from the atmosphere, and from that ozone and UV-irradiance levels at the ground can be calculated with UV-transfer models (the latter require regular checks versus ground based measurements). It is true that the spectral UV-irradiance increases very strongly with increasing wavelengths in th range from 290 to 320 nm, however the number (factor of 5) mentioned	A full discussion on vitamin D levels and its supplementation is outside the scope of the mandate.

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				is totally wrong. The irradiance levels at 290 nm is only measurable with very sensitive instruments and at high solar elevations and the intensity is more than 10000-100000 times lower than at 320 nm. Irradiance levels at 290 nm are, because of the very low values not relevant at all for biological effects. I would suggest to give a comparison between irradiance at 300 and 320 nm which differ 100-fold (at solar elevations of 60 degrees) or more at lower solar elevation. Page 60 Answers to terms of reference Page 61 question 2 It is true that no absolute safe levels can be indicated with respect to erythemally weighted irradiance levels, or more important the doses (irriadiance x exposure time). The additional risk that is caused by the use of artificial sources is also influenced by the solar UV-exposure of the individual (relationships are non-linear with dose). It might be advisable to also add a limit on the dose rather than the irradiance level. However, this dose should probably be depending on the skin type. The presently set limit of the erythemally effective irradiance of 0,3 W/m2 is higher than the maximum solar irradiance level in (most of) Europe. It is equivalent to UV-index 12 and for instance in western Europe a UV-index of 7 or 8 is at the high end around solar noon (in southern Europe around 10). However, the dose received is determining the potential effect. There could be some further addition on the inclusion of maximum doses, and at least to avoid (severe) burning of the skin. Page 61 question 3 The level of 0,003 W/m2 effectively weighted in the UVC range, implies that the UVC is not relevant in the actual exposure spectrum if the source.	

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				No comment is given in the report on the age-limit for users of artificial tanning devices. I think this is an omission, and it should be emphasized that postponing the start of exposures to artificial sources to a later age is highly important. Also: more emphasis should be put on the combined effort to limit solar and artificial sources. Page 62 Recommendation for further work The committee basically gives no advice here. I would suggest that in the view of ongoing discussions on the rapidly rising skin cancer risks on the one hand and the debate regarding minimal and optimal levels of vitamin D it would be wise to further investigate UV-exposure habits from both the sun and artificial sources. Investigations into the optimization of UV-exposure from a broad health perspective would be very welcome. Such studies relating to vitamin D should of course include vitamin D intake through food and supplements. An integrated approach in this field might be beyond the scope of this report, however it is of large public health interest	
223.	Gilroy Steven, Joint Canadian Tanning Association (JCTA), info@TanCanada.org, Canada	ABSTRACT		Introduction page 4 - lines 6 to 9. The reference to Group 1, carcinogenic to humans, should be clarified since the IARC Monograph of 2012 (100D) states this to the reader of the Monograph on page 1 - The term 'carcinogenic risk' in the IARC Monographs series is taken to mean that an agent is capable of causing cancer. The Monographs evaluate cancer hazards, despite the historical presence of the word 'risks' in the title. Inclusion of an agent in the Monographs does not imply that it is a carcinogen, only that the published data have been examined. The IARC Monograph states an agent could be a cancer causing, not that it is. This is a very important piece of information missed in the Abstract since most	The SCHEER disagree. This is a personal view. No change in the Opinion is needed.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				people read the abstracts only. This document reports "There is no difference in the biological (and general health) effects induced by UV radiation in respect to their origin, the natural solar UV or artificial UV from e.g. tanning devices. UV-radiation (UVA, UVB, UVC) from the sun or from tanning devices has been classified by IARC (2009) as carcinogenic to humans (class 1, IARC). (Page 60, *. Opinion, Line 15-18)." The sun and solar UV has been included in IARC Group 1 since 1992. UV from sun or sunbeds is the same and has the same risks and the same benefits. Colantonio 2014, the largest and most current meta-analysis reviewing sunbed risk and melanoma had the following concerns regarding the study evidence: "The quality of evidence contributing to review results ranges from poor to mediocre." Colantonio did not use MacKie 1989 – Women and Veierod 2003. MacKie was reviewed and discarded and Veierod 2003 was replaced by Veierod 2010. Colantonio was the first research paper to identify the quality of the research done on sunbeds. If this report is reviewed by lawmakers, they should know the quality of the research which is being presented in the full report. 1145 Page 4 Exposure – lines 34 to 36 This report states that "the modern tanning appliance corresponds to an UV index of 12".It should be noted that this change was made in 2007. The research used in this report, with the exception of one study, has been based on sunbed equipment before the equipment was changed over to the 0.3 lamp and therefore the results would not apply to the new 0.3 lamp equipment. The 0.3 lamp was based on the recommendation of 2006 European Commission report. This report should fully disclose this fact to readers.	Please see the answer to comment 29. See answer to comment 222.

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224.	Gilroy Steven, Joint Canadian Tanning Association (JCTA), info@tancanada.org, Canada	ABSTRACT	Chang_Kuehn_Feb_17_2015_Response_t Petitti_D_response_to_Wehner_2014_in_t	Page 5 Exposure – line 3-14 The accuracy of the Wehner research (2012, 2014) has been called into question through a Rapid Response letter by Chang & Kuehn (Feb. 17, 2015). It reported that: "crude categorization of ever vs. never exposure results in conflation of different levels of exposure with, presumably, different degrees of risk."Chang & Kuehn went on to say: "We found that prevalence estimates from the majority of these studies were based on highly selected or non-representative populations. These source populations call into question whether the results from these studies can be generalized to the entire populations of the United States, Northern and Western Europe, or Australia. Furthermore, low participation rates and non-randomized sampling methods in many studies likely resulted in biased findings. Publication bias was also evident, with preferential publication of studies reporting a higher prevalence of indoor tanning, further undermining the validity of the meta-analysis results." They reported: "The annual cancer incidence estimates also have inherent uncertainty, although confidence intervals appear not to have been reported by the sources relied upon by Wehner et al. Thus, the reported 95% confidence intervals around the estimated number of skin cancer cases attributable to indoor tanning are not true confidence intervals because they do not incorporate the uncertainty in the relative risk and cancer incidence estimates. Furthermore, as stated earlier, the meta-analysis confidence intervals describe only statistical error; they do not describe the extent of study heterogeneity. In other words, the estimates of attributable skin cancer cases are much more uncertain and unstable than reported and do not provide a valid estimate of the true prevalence (if there is a single prevalence) of indoor tanning in the general population." Petitti 2016 reports in PubMed "The meta-analytically derived estimate of the	Please see the answers to comments 2 and 67.

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				prevalence of ever exposure to indoor tanning for adults in Northern and Western Europe based on the studies identified by Wehner et al. (2014) is meaningless; the estimate of the number of skin cancers attributable to indoor tanning in Northern and Western Europe based on this meaningless estimate is meaningless. In addition to the issues outlined by Chang & Kuehn regarding the accuracy of the Wehner research there are further issues. The tanning industry has not been increasing as Wehner states with an absolute increase in past year exposure of 3.4% in adults, 2.1% in university students and 1.7% in adolescents. The American Suntanning Association reported January 7, 2016 that the 10% federal excise tax from 2010 has devastated the tanning industry in the USA by closing 10,000 businesses with the loss of 100,000 jobs. Studies included by Wehner in their prevalence analysis from the NCI and CDC support this trend. Past year exposure by adults, NCI 2005 – 8%, NCI 2007 – 9%, CDC and NCI 2012 – 6%. Based on these national studies, tanning by adults has reduced by 39% since 2007. The past year prevalence for adults in United States stated by Wehner of 13% is double the CDC/NCI 2012 study of 5.6%. This would indicate that Werner's prevalence analysis is severely overstated which would reduce the overall impact greatly. According to this report on page 24 – line 1 to 9 the National Youth Risk Behaviour Surveys (Guy 2014) showed a decrease in the use of sunbed for student where states had restrictions. So this would be another confounder for both Wehner 2012 and 2014. This would back up the NCI and not Wehner numbers.	

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225.	Gilroy Steven, Joint Canadian Tanning Association (JCTA), info@tancanada.org, Canada	ABSTRACT		Page 5 – line 17/18 According to Dr. M. Holick in 2016 the statement above is incorrect. He states the following about the production of vitamin D from UVB; there are 2 things going on simultaneously both 7-dehydrocholesterol and previtamin D are absorbing ultraviolet radiation. The previtamin D3 will photoisomerize to lumisterol and tachysterol. At the same time 7-dehydrocholesterol will be converted to previtamin D and thus the amount of previtamin D3 does not decrease. It is in a photoequilibrium. Therefore total pre-vitamin D3 levels would not be degraded by excess UV exposure. Page 5 – line 18 to 22 Regular sunbed use has been proven to provide 25(OH)D levels of 95 nmol/L which were higher than the levels people achieved who received lots of sun exposure (Schwalfenberg 2010). This is due to the fact that sunbed exposure of UVB is provided to a much higher percentage of the body skin area, up to 100%. Sunbed use has not been endorsed by health agencies who continue to be influenced by the risks of UV such as skin cancer vs the benefits such as vitamin D. Cancer Care Ontario, in Canada, reported that the melanoma risk for intermittent UV exposure from outdoor solar UV was 61% (IARC 2012) and the risk from UV-emitting Indoor tanning devices was 15% (IARC 2006). This report is suggesting solar outdoor UV exposure for vitamin D production over sunbed, which has a 4X higher risk for melanoma. Vitamin D levels at higher latitudes drop in winter. In Canada, 25% of the population does not meet Health Canada and the Institute of Medicine's vitamin D guidelines of 50 nmol/L in the summer and this rises to 40% in the winter (Janz 2013). In Europe, a recent study has found that 40.4% of the population does not meet a 25(OH)D blood level of 50 nmol/L (Cashman 2016). This proves that the current recommendation of usual exposure of face	The text on vitamin D has been modified. See also the answer in comments 3 and 109. The Opinion clearly states that UV-B from sunbeds can raise vitamin D levels. A full discussion on appropriate vitamin D levels and about adequate intake is outside the scope of the mandate. Treatment of medical conditions is outside the scope of the mandate. No changes in the Opinion are needed.

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				and hands to UVR from the sun and common diet does NOT provide sufficient vitamin D levels for 40% of the population. It should be noted that other groups recommend higher vitamin D blood levels than Health Canada and the IOM. The Endocrine Society in the USA recommend a 25(OH)D level of 75 nmol/L (Holick 2011). A group of 50 of the top vitamin D scientists, researchers and doctors through GrassrootsHealth recommend that for optimal health everyone maintain a 25(OH)D level of between 100-150 nmol/L. In Canada 90% of the population is below 100 nmol/L (Langlois 2010). People with malabsorption syndrome (Holick 2007) cannot absorb vitamin D from diet or supplements. Holick recommends: Exposure to sunlamps that produce UVB radiation is an excellent source for producing vitamin D3 in the skin and is especially efficacious in patients with fat malabsorption syndromes.In northern latitudes, vitamin D can only be made through solar UVB exposure near midday in the summer months when the UVI is above 3 and your shadow is shorter than your height. The Canadian Arm Forces uses sunbed in the arctic bases for vitamin D production – CFS Alert base (see attachment). Some provincial regulations for the indoor tanning in Canada actual have a medical exemption. One province stated the reason was the lack of phototherapy equipment in the Northern parts of Canada. The reason I note this is that Health Canada and other radiation committee rely on IEC recommendation for harmonization.	

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226.	Gilroy Steven, Joint Canadian Tanning Association JCTA, info@TanCanada.org, Canada	ABSTRACT	 Freedman_2000_-_Mortality_from.pdf  Van_der_Mei_2003_-_Past_exposure_to_f  Baarnhielm_2012_-_Sunlight_is_associete  Bjornevik_2014_-_Sun_exposure_and_mu  Islam_2007_-_Childhood_sun_exposure_i  Becklund_2011_-_UV_radiation_suppresse	Page 5 – line 23 - 24 According to the IARC Monograph of 2012 (100D), this is not the case, it states the following on page 87; The major steps of UV-induced immune suppression have been determined but it should be noted that, in many instances, these details were obtained following a single or a few exposures of a rodent model or human subjects to UVR and that the dose chosen was sufficient to cause burning. In addition, the source used to emit UVR frequently contained more than 50% UVB (wavelength 280–315 nm), considerably more than natural sunlight. In addition, immunosuppression may have health benefits particularly for modulating the immune system. There is compelling evidence that suggests that higher levels of sun exposure are associated with decreased risk and disease activity in autoimmune diseases like MS, probably through both vitamin D and non-vitamin D pathways (Lucas 2015). Occupational studies have found that outdoor work in an area of high sunlight could reduce the risk of MS mortality by 76% (Freedman 2000). Higher sun exposure during childhood and early adolescence is associated with a 69% reduced risk of MS (Van der Mei 2003). A study from Sweden reported that subjects with low UVR exposure had a 2X increased risk of MS (Baarnhielm 2012). Frequent sunscreen use between birth and the age of 6 was associated with a 44% increased risk of MS in Norway (Bjornevik 2014). A study of twins found that the risk of MS was 60% lower for the twin who spent more time suntanning (Islam 2007). Studies have indicated that UVR is likely suppressing MS independent of vitamin D production and that vitamin D supplementation alone may not replace the ability of sunlight to reduce MS susceptibility (Becklund 2010). Health effects: Melanoma, Non-melanoma skin cancer, other cancers	No change in the Opinion is needed. See also the answer to comment 3. Effects of artificial UV on other organ systems than skin have been discussed in the Opinion. The relation between latitude and health and disease is complex, and it is as yet unclear what role sunbeds could play.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
			 Lindqvist_2014_-_Avoidance_of_sun_exp	Page 5 – Line 26 Page 5 – line 30 to 34 The three most recent cohort studies referenced above were not based on the new 0.3 lamps introduced in 2007 and therefore do not represent the relative risk for the new 0.3 W/m2 devices. In addition, the new meta-analysis research reports show that the estimated risk for using a sunbed at a younger age is reducing. For example, the IARC 2006 increased risk for under age 35 was 75%, Boniol 2012 reported the relative risk of 59% for those under age 35, and Colantonio 2014 the most recent and up to date analysis reported a 35% relative risk for people under age 25 and an 11% relative risk for people over age 25. Page 5 – line 39 That statement is untrue. A large cohort study by Lindqvist study in 2014 reported that use of sunbeds reduces all-cause mortality risk by 33%. This large cohort study followed 29,518 Swedish women for 20+ years. The study found that women who used sunbeds and sunbathed during summer or on holiday, had a greatly reduced risk for all-cause mortality. The study concluded: The mortality rate amongst avoiders of sun exposure was approximately twofold higher compared with the highest sun exposure group, resulting in excess mortality with a population attributable risk of 3%. The results of this study provide observational evidence that avoiding sun exposure is a risk factor for all-cause mortality. Following sun exposure advice that is very restrictive in countries with low solar intensity might in fact be harmful to women's health. Page 5 – line 41 to 43 Readers of this report should know the specific of the research. Was this about improper use of eyewear or no eyewear being used? Lucas 2014 not able to upload to large	See answer to comment 223. In addition: "risk for using a sunbed at a younger age is reducing" is a personal view not supported by scientific evidence. No change in the Opinion is needed.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
227.	Gilroy Steven, Joint Canadian Tanning Association, info@TanCanada.org, Canada	ABSTRACT	 Cancer_Risk_Factors_in_Ontario_-_Ultravi  Chang_Kuehn_Feb._17_2015_Response_i	Page 6 – line 16 to 19 Confounder in the research paper – genetic - MC1R and BRAF mutations. These people should be excluded since no matter what UV exposure they receive their risk is there. Alcohol consumption, drinking more than 2.8 drinks per week increase the risk of melanoma by 69%. The CDC after discussions with the American Suntanning Association about confounders removed any percentage risk factors relating to sunbed usage. This would indicate that an estimate for attributable incidence and mortality would be impossible to calculate and at best a guess. The estimated number is before the 0.3W/m2 devices were introduced in 2007 Page 6 – line 19 to 23 These lines and the 15% ever use risk and 75% risk for people under age 35 from IARC should be updated to the largest meta-analysis by Colantonio. Colantonio published in 2014 reported an ever use risk of 16% and before the age of 25 (35%) and after age 25 - 11%. It should be noted that this risk represents the risk of unsupervised sunbed use in homes and other locations which have no control on usage. In addition, confounder in the data by people who have burning exposure and for skin type 1 people who should never use a sunbed. The 76% risk as reported by Cust was based on Australian data and cases which were not using the new 0.3 W/m2 devices and also had high outdoor UV which could confound these numbers. Out of 604 cases, only 137 or 22% "Ever" used a sunbed. The study reported 78% of the cases or 467 cases never used a sunbed. So 100% of their melanoma was from 'other causes'. But for the young sunbed users, 76% of their melanoma was attributed to sunbeds. A UK study using the same questionnaire and method of analysis as the Australian study by Cust et al. (2011) by Elliott (2012) found a non-significant ever-use risk of sunbeds of 6% (OR 1.06, 95% CI 0.83–1.36). In addition, Elliott (2012)	Confounders are discussed in the text of the Opinion. In addition, according to Cancer Research UK, the evidence linking heavy drinking and melanoma isn't strong enough. No change in Abstract necessary. Colantonio is discussed in the Opinion. No change necessary in the Abstract.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				reported age at first use of sunbeds showed a small non-significant increased risk for use of 16%(OR 1.16, 95%CI 0.84–1.62). Cancer Care Ontario, in Canada, reported that the melanoma risk for intermittent UV exposure from outdoor solar UV was 61% (IARC 2012) and the risk from UV-emitting Indoor tanning devices was 15% (IARC 2006). Indoor sunbed exposure is one quarter the risk of uncontrolled outdoor UV exposure. In addition, the 15% risk for sunbeds is lower than the recent risk reported by IARC for processed meats of 18% which was recently added to Group 1. Overall Conclusion Page 6 line 24 Page 6 - Line 25-26 Research has proven that this is not the case. If this was true the more UV exposure you received the more skin cancer you would have. A large meta-analysis reported in IARC 2012 found that chronic UV exposure, defined as continuous regular exposure, had a 5% reduced rate of melanoma. In addition, studies of outdoor workers who receive the most daily UV have less melanoma skin cancer.	The SCHEER disagrees. No change in the Opinion is needed.
				Page 6 - Line 26-28 Evidence is weak that sunbeds cause melanoma. Colantonio the most recent and largest meta-analysis reports a small 16% risk for melanoma and greatly reduced younger age risk of 35% for under age 25 and 11% for over age 25. These results have bias for burning exposure, home use, and skin type 1 use. For comparison, processed meats have a higher cancer risk at 18%.	The SCHEER disagrees. No change in the Opinion is needed.
				Page 6 Line 29-31 Chang & Kuehn (2015) found that prevalence estimates from the majority of these studies were based on highly selected or non-representative populations.	The SCHEER disagrees. No change in the Opinion is needed.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
228.	Gilroy Steven, Joint Canadian Tanning Association JCTA, info@TanCanada.org, Canada	ABSTRACT	Lindqvist_2014_-_Avoidance_of_sun_exp Baggerly_2015_-_Sunlight_and_Vitamin_D	Page 6 – line 32 to 37 The higher vitamin D levels achieved by tanners would help reduce the burden of disease and increase life expectancy (Baggerly 2015). A large cohort study in 2014 reported that use of sunbeds reduces all-cause mortality risk by 33% (Lindqvist 2014). UV overexposure does not reduce vitamin D levels but reaches equilibrium, the body regulates and ensures excessive vitamin D is not produced (Holick). Sunbeds have a 4X reduced risk of melanoma compared to outdoor solar UV (IARC 2012).	See answers to comments 50, 193, 194.
229.	Harbusch Frank, European Sunlight Association a.s.b.l., frank.harbusch@europeansunlight.eu, Belgium	ABSTRACT	EN16489-1_EN.pdf EN16489-2_EN.pdf EN16489-3_EN.pdf	Page 4, lines 29-33 It seems that SCENIHR were not aware, when compiling this Opinion, that an accredited pan European Standard for Tanning Salon training was launched in 2015. This is EN16489. We rather suspect that, if the authors of the Preliminary report had known the depth of knowledge and training required for delegates to reach the Standard required, it would have nullified many of the concerns outlined.	This plan falls in the risk management field.
230.	Harbusch Frank, European Sunlight Association a.s.b.l., frank.harbusch@europeansunlight.eu, Belgium	ABSTRACT		Page 5 – line 30 to 34 The mentioned cohort studies all fall short in taking into account the different confounders (especially skin type I, which should not use a sunbed, and natural sun exposure).	Confounders are discussed in the Opinion. No change in the Opinion is needed.
231.	Harbusch Frank, European Sunlight Association a.s.b.l., frank.harbusch@europeansunlight.eu, Belgium	ABSTRACT		Page 5, line 17-18 We would like SCENIHR to rephrase the sentence and write 'does induce vitamin D'. We also find this sentence being tendentious writing as it did not answer the question of the EC but tries to gives an	Text of the Opinion was amended.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				additional negative, unnecessary comment regarding photodegradation, which might be an effect, but has no health consequences at all. Page 6 - Line 25-26 With a given carcenogen the question is still if there are thresholds or doses when such a carcenogen will cause disease burdens for the population. Also the cause of the carcenogen often has positive health effects. In low doses it may be a medicine, in higher doses it may be a poison. This was exactly what was questioned by EC and has not been answered by stating again just the starting point. Page 6, line 15 When referring to 'skin cancer', to be objective, the SCENIHR must always differentiate in this Opinion between melanoma and non-melanoma as to conflate skin cancers is disingenuous and misleading. There are two main categories of skin cancer - melanoma and non-melanoma. Melanoma (also known as 'malignant melanoma') is less common than non-melanoma cancers, but is the most dangerous. Non-melanoma skin cancers are mainly comprised of 'Basal Cell Carcinoma' (BCC) and 'Squamous Cell Carcinoma' (SCC). BCC is the most common and the least dangerous. BCC and SCC were formerly known as 'lesions' as they are not cancerous at all, in that they do not metastasize and spread. As such, whilst unfortunate, BCC and SCC are generally not life threatening. In more recent years, BCC and SCC were effectively renamed as 'non-melanoma skin cancer (NMSC). This is to ensure that the public obtains a medical inspection by a dermatologist and this has led to a vast increase in reported incidences. Fortunately, circa 97% of biopsies are benign. It is therefore essential not to conflate melanoma and NMSC as to do so often leads to confusion.	The SCHEER disagrees. No change in the Opinion is needed. The figures quoted refer only to melanoma. No change needed.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
232.	FITE Johanna, ANSES - French Agency for Food, Environmental and Occupational Health & Safety, johanna.fite@anses.fr, France	ABSTRACT		p4, lines 7-9, p9, lines 10-12 It should be reminded that the full UV spectrum UVA, UVB, UVC was evaluated by IARC based on much more data stemming from human and animal studies. The level of evidence for such an association is particularly high and IARC classified the whole UV spectrum as carcinogen. Because of the specific emission of artificial tanning devices, which are emitting particularly intense UV exposure, and based on several human and animal studies which are covered by SCENIHR report, the IARC added also UV-emitting devices in the group classification.	Supportive statement acknowledged by the SCHEER.
233.	FITE Johanna, ANSES - French Agency for Food, Environmental and Occupational Health & Safety, johanna.fite@anses.fr, France	ABSTRACT		Abstract, p5, Health effects: non-cancer health effects AND p10 Executive summary; Chapter 1.4 Health Effects: Non-cancer health effects AND p31-34 Main report; Chapter 7 Health Effect, Introduction and Summary of the chapter 7.1 Non-cancer health effects Comment: The SCENHIR Opinion is a very substantial review on the adverse effects (vitamin D and immunosuppression). However, some of them are poorly described or not at all: - Effects on the eyes; - Effects on the skin; - Metabolic effect; - Behavior, Addiction; - Other. We propose some references to argue these elements, there may be others (this list is not exhaustive): Anses. Rayonnements ultraviolets – état des connaissances sur l'exposition et les risques sanitaires [internet]. Anses. Maisons-Alfort. 2005. [cited 2016 Mar 25]. Available from:https://www.anses.fr/fr/system/files/AP2004et7183Ra.pdf Ernst A, Grimm A, Lim	The text of the Opinion was updated and a chapter on eyes was added.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				HW. Tanning lamps: health effects and reclassification by the Food and Drug Administration. J Am Acad Dermatol. 2015 Jan;72(1):175-80. doi: 10.1016/j.jaad.2014.10.016. Hickle A, Forster J, Lazovich D, et al. Sanitarians' work with indoor-tanning businesses: findings from interviews in two major metropolitan areas. J Environ Health. 2005;67(8):30-36, 54. International Agency for Research on Cancer, World Health Organization. Exposure to Artificial UV Radiation and Skin Cancer. Lyon, France: International Agency for Research on Cancer; 2006. http://www.iarc.fr/en/publications/pdfs-online/wrk/wrk1/ArtificialUVRad&SkinCancer.pdf. Accessed July 10, 2013 Lucas RM, McMichael AJ, Armstrong BK, et al. Estimating the global disease burden due to ultraviolet radiation exposure. Int J Epidemiol. 2008;37(3):654-667. National Electronic Injury Surveillance System, All Injury Program. National estimates for tanning bed/booth-related injuries, 2003–2012. Analyzed by National Center for Injury Prevention and Control and National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention. Unpublished data, analyzed 2014. World Health Organization. Ultraviolet radiation and the INTERSUN programme: the known health effects of UV. World Health Organization website. http://www.who.int/uv/faq/uvhealtfac/en/index1.html . Accessed December 3, 2013. Effects on the eyes: UV exposure can have adverse effects on the eyes, affecting surface tissues and internal structures (cornea and lens) with acute and chronic effects. Short-term eye damages including eye irritation, photokeratitis (sunburn of the eye) and conjunctivitis can occur, but also acute corneal perforation, pterygium and solar retinopathy. Long-term eye damages include the formation of cataracts, but also macular	

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				degeneration or pinguecula. Wearing sunglasses that fit properly and have 100% UVA and UVB protection is the best way to protect eyes from UV damage. Closing the eyelids cannot replace eye protection with UV filtration. Effects on the skin: In addition to increasing the risk of skin cancer, UV exposure can have other adverse effects on the skin. Excessive UV exposure can cause premature skin aging, including wrinkling, mottled pigmentation (freckling or lentigines), and loss of elasticity. Excessive UV exposure can increase the risk of actinic keratosis; it is also known as solar keratosis. Quatresooz P, Henry F, Paquet P, et al. Photoaging under recreational sunbeds. Skin Res Technol. 2011;17(3):309-313.	
234.	FITE Johanna, ANSES - French Agency for Food, Environmental and Occupational Health & Safety, johanna.fite@anses.fr, France	ABSTRACT		Abstract, p5, Health effects: non-cancer health effects AND p10 Executive summary; Chapter 1.4 Health Effects: Non-cancer health effects AND p31-34 Main report; Chapter 7 Health Effect, Introduction and Summary of the chapter 7.1 Non-cancer health effects Comment: The SCENHIR Opinion is a very substantial review on the adverse effects (vitamin D and immunosuppression). However, some of them are poorly described or not at all: - Effects on the eyes; - Effects on the skin; - Metabolic effect; - Behavior, Addiction; - Other. Metabolic effect: Excessive UV exposure may reduce the effectiveness of folic acid supplements, which has potential health consequences for pregnant women and women of childbearing age. Borradale D, Isenring E, Hacker E, et al. Exposure to solar ultraviolet radiation is associated with a decreased folate status in women of childbearing age. J Photochem Photobiol B. 2014;131(5):90-95. Behavior, Addiction: Behavior and addictions were not included in the searches for the literature review (cf. annex 1, p 66). The authors cited Hillhouse JJ et al for the prevalence of sunbeds among teenagers in	The text of the Opinion was updated and a chapter on eyes was added.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				USA (cf. Annex III, page 79) but not for evaluating a measure of tanning abuse and dependence, the purpose of this study. Hillhouse JJ et al developed the Structured Interview for Tanning Abuse and Dependence (SITAD) modified items from the Structured Clinical Interview for DSM-IV Axis I Disorders that focus on opiate abuse and dependence. More recently, Heckman and colleagues (2014) have also introduced another instrument called the Tanning Pathology Scale (TAPS) to identify cases of tanning dependence. The newly developed SIDAT and TAPS criteria should also be tested. They could possibly provide researchers with more valid alternatives to the commonly used mCAGE score, often used to prove the existence of tanning dependence, which does not appear to be a valid instrument. There is enough scientific evidence that tanning can be also included in the spectrum of addictive behaviors. However, other studies are required to determine the validity of an addiction diagnosis and to explore pharmacologic and cognitive therapeutic options for affected persons. Further controlled studies must be performed, especially in neurobiology and imaging, to improve our understanding of tanning dependence. We propose some references to argue these elements, there may be others (this list is not exhaustive): Ashrafioun L, Bonar EE. Tanning addiction and psychopathology: Further evaluation of anxiety disorders and substance abuse. J Am Acad Dermatol. 2014 Mar;70(3):473-80. doi: 10.1016/j.jaad.2013.10.057. Heckman CJ1, Darlow S, Kloss JD, Cohen-Filipic J, Manne SL, Munshi T, Yaroch AL, Perlis C. Measurement of tanning dependence. J Eur Acad Dermatol Venereol. 2014 Sep;28(9):1179-85. Hillhouse JJ, Baker MK, Turrisi R, et al. Evaluating a 17 measure of tanning abuse and dependence. Arch Dermatol. 2012; 148:815–819 Kourosh AS, Harrington CR, Adinoff B. Tanning as a	The comment has been considered and a paragraph added in the section on mood and behaviour.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				behavioral addiction. Am J Drug Alcohol Abuse. 2010 Sep;36(5):284-90. doi: 10.3109/00952990.2010.491883. Petit A, Lejoyeux M, Reynaud M, Karila L. Excessive indoor tanning as a behavioral addiction: a literature review. Curr Pharm Des. 2014;20(25):4070-5. Reed DD. Ultra-violet indoor tanning addiction: a reinforcer pathology interpretation. Addict Behav. 2015 Feb;41:247-51. doi: 10.1016/j.addbeh.2014.10.026. Other: In addition, indoor tanning can cause burns to the skin and if tanning devices are not properly sanitized, skin infections. Russak JE, Rigel DS. Tanning bed hygiene: microbes found on tanning beds present a potential health risk. J Am Acad Dermatol. 2010;62(1):155- 157.	
235.	FITE Johanna, ANSES - French Agency for Food, Environmental and Occupational Health & Safety, johanna.fite@anses.fr, France	ABSTRACT		Abstract, p6 line21, p11 line 40, p59 lines 12-14 Comment: The updated meta-analysis by Boniol et al. (2012), reported an increased risk of 59% of cutaneous melanoma attributable to sunbed use for first use of sunbed before the age of 35, slightly lower than the initial evaluation by IARC in 2006. Because Boniol et al. (2012) meta-analysis is more recent, includes more studies, and has been conducted by the same team as IARC 2006, it would be preferable to report the figure of 59% instead of 75%. Based on figures in the meta-analysis of Boniol et al. (2012) with a relative risk of 1.59, this fraction would be 37% of melanoma cases caused by sunbeds use among individuals who exposed themselves to sunbeds before the age of 35.	The comment has been considered and the text amended.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
236.	FITE Johanna, ANSES - French Agency for Food, Environmental and Occupational Health & Safety, johanna.fite@anses.fr, France	ABSTRACT		Abstract, p6, lines 25-37 - Overall conclusion Comment: Anses agrees with the overall Scenihr conclusion. Since 2012, ANSES therefore recommends the cessation, ultimately, of all commercial use of tanning by artificial UV rays and of the sale of appliances emitting artificial UV rays for cosmetic purposes (see OPINION of the French Agency for Food, Environmental and Occupational Health & Safety relating to a draft decree concerning the sale and provision to the public of certain tanning devices that use ultraviolet radiation available online in English: https://www.anses.fr/en/system/files/AP2012sa0263EN.pdf).	The SCHEER acknowledges the agreement.
237.	FITE Johanna, ANSES - French Agency for Food, Environmental and Occupational Health & Safety, johanna.fite@anses.fr, France	ABSTRACT		Abstract, p6 lines 30-31, p11 lines 41-42, p12 lines 4-5, p59 lines 15-17, p60 lines 41-44 Comment: There is a misunderstanding of the aetiologic fraction which corresponds to the fraction of cases caused by sunbed use among exposed population. The age level of 35 corresponds to the age at exposure and not the age at diagnosis of melanoma. The estimation of 76% in Cust et al. (2011) and 43% in Boniol et al. (2010), is therefore to be interpreted as an estimation of the proportion of melanoma cases caused by sunbeds among those individuals who exposed themselves to sunbeds for the first time before the age of 35.	The comment has been considered and the text on risk characterisation has been amended.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
238.	FITE Johanna, ANSES - French Agency for Food, Environmental and Occupational Health & Safety, johanna.fite@anses.fr, France	ABSTRACT		Abstract, p6, lines 32-34 - Overall conclusion Comment: You write that 'the small potentially beneficial effects of sunbed use are more than outweighed by the many severe adverse effects' but you do not indicate the potentially beneficial effects. Which are they? We find this sentence ambiguous. Beneficial effects, if any, should be clearly stated and described. Anses agree with this statement: 'There is no need to use sunbeds […]'. It has been published that the exposure of 6-10% of the body surface (hands, arms and face) to half of a MED (5 min, skin-type-2 adult) two or three times a week is more than adequate. Doses needed to synthesize vitamin D are not enough to get a tan. Moreover, external vitamin D supplements can help, lowering the need for UVR exposure. We propose some references to support these elements, there may be others (this list is not exhaustive): Egan KM, Sosman JA, Blot WJ. Sunlight and reduced risk of cancer: is the real story vitamin D? J Natl Cancer Inst. 2005 Feb 2;97(3):161-3. Holick MF. Sunlight Dilemma: risk of skin cancer or bone disease and muscle weakness. Lancet. 2001 Jan 6;357(9249):4-6	Text was changed for clarity.
239.	Pedersen Ronny, Norwegian Tanning Association, ronny@mida.no, Norway	ABSTRACT	 Ungdomsunders_kelse_solingsvaner_2014	page 6 line 14-35 The Norwegian Cancer Society made a survey in 2014 among young people between 15-24 years of age. 90 % of the individuals in that age group answered that they had yearly sunburns. Only 2 % answered that they had ever burned in a tanning device, the rest were from outdoor tanning. There is a widespread consensus that burning when tanning increases the risks of developing melanomas. The survey from the Norwegian Cancer Society clearly shows where the efforts should be addressed, namely outdoor tanning.	Although the SCHEER acknowledges its importance, advice on outdoor tanning is outside the mandate of the Opinion.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
240.	Wunsch Alexander, Medical Light Consulting, praxis@alexanderwunsch.de, Germany	ABSTRACT	 1.pdf  2.pdf  3.pdf  4.pdf  5.pdf  6.pdf	P5/18-20: "There is widespread consensus that it is not necessary to use sunbeds to enhance vitamin D levels even in winter." This claim is based upon the old concept regarding sufficient vitamin D levels defined as the absence of rickets and osteomalacia. In fact, there is actually no consensus concerning the optimal vitamin D level. A growing body of evidence suggests that sufficient vitamin D levels are much higher than previously estimated. (1.pdf) P5/18-20: "There is widespread consensus that it is not necessary to use sunbeds to enhance vitamin D levels even in winter." The fact that several papers with the objective "Vitamin D photosynthesis via sunbed use" have been published proves on its own that there is no "widespread consensus that it is not necessary to enhance vitamin D levels even in winter", because these researchers investigated exactly the opposite: the potential of sunbed use for elevating vitamin D levels in winter. (2.pdf - 9.pdf) P5/20-21: "Usual exposure of face and hands to UVR from the sun (even on cloudy days) and common diet are sufficient to achieve a sufficient vitamin D level." Recommendations with regard to face and hand exposure for maintaining a sufficient vitamin D level are skin tumor promoting themselves, since these body areas are predilection zones for BCC and SCC, also dubbed as "sun terraces". According to Ann Webb/CIE the recommendation for cutaneous vitamin D production is to expose large areas of the body for a short time, ideally around noon time. In European countries with mostly fair-skinned population, cutaneous VD3 photosynthesis is only achievable in summer half-year due to the solar elevation angle. (10.pdf) P5/22: " If needed, dietary supplements for vitamin D are available." Diets providing sufficient vitamin D supply are mostly based on seafish, which is contaminated with mercury. The	The Opinion clearly states that sunbeds can enhance vitamin D levels. The issue is whether this is the way forward to intervene in cases of low vitamin D levels from a public health point of view. Sufficient levels are still a matter of debate – a full discussion on vitamin D levels is outside the scope of the mandate. The text on sun exposure for vitamin D has been modified. A discussion on the safety of seafood is outside the scope of the mandate. The risk of vitamin D overdose and recommendations from public health authorities about vitamin D supplementation are outside the scope of the mandate. The text on internal cancers and all-cause mortality has been modified.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
			7.pdf 8.pdf 9.pdf 10.pdf 11.pdf 12.pdf	recommendation to supplement VD3 via seafish consumption is linked to the risk of long term mercury intoxication.(11.pdf) Vitamin D can be administered orally, however, this is linked to the risk of overdosage. Overdosage is impossible for cutaneous VD3 photosynthesis. There is currently no consensus, that oral administration of VD3 is fully equivalent to the cutaneous VD3 photosynthesis pathway with regard to biological efficacy and galenics. (12.pdf, 13.pdf) P5/37-43: "There was no evidence from recent studies of an increase in incidence of internal cancers associated with sunbed use. The current evidence does not suggest a decreased risk in all-cause mortality associated with sunbed use; the only available cohort study suggests an increased risk of death from all cancers taken together. There is an increased risk of ocular melanoma associated with sunbed use especially if exposure starts at an early age." The OPINION statement: "There was no evidence from recent studies of an increase in incidence of internal cancers associated with sunbed use." suggests that UVR has no systemic effects on the immune system which would act as a tumor promoter. Otherwise, all types of cancer - external and internal forms - would show an increase, since immunosuppression results in elevated incidence of many cancer forms. This indicates also a possible misinterpretation of the causal function of UVR regarding ocular melanoma, because the optical media of the eye, even in adolescents, absorb UVR very efficiently: UVR does not reach the retinal structures in significant levels. Therefore (due to the lack of local effects), only systemic effects could contribute to this kind of melanoma, but these effects seem to be absent for internal cancers. (14.pdf)	It is not within the scope of the Opinion to address vitamin D supplementation. A discussion on the safety of seafood is outside the scope of the mandate. The risk of overdose and recommendations from public health authorities on vitamin D supplementation are outside the scope of the mandate. The text on internal cancers and all-cause mortality has been modified.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
			13.pdf 14.pdf		
241.	Wunsch Alexander, Medical Light Consulting, praxis@alexanderwunsch.de, Germany	ABSTRACT	OCEBM.pdf	P6/26-28: "There is strong evidence that sunbed exposure causes skin melanoma, squamous cell carcinoma and, to a lesser extent, basal cell carcinoma, more especially when first exposure takes place in younger ages." According to the Oxford Centre for Evidence-Based Medicine, "The Oxford 2011 Levels of Evidence" (http://www.cebm.net) the estimations regarding the carcinogenity of UV either from sunbeds or natural sunlight provide no strong evidence. The evidence level of retrospective, interrupted times series, case-control studies, cohort studies with controls, and health service research adjusting for likely confounding variables is only =L4. In the context of epidemiological studies it is difficult to claim for strong evidence, which can only be expected from the highest evidence level possible (=L1), which is demonstrated by systematic reviews of randomized controlled trials only.	The definition of strong, moderate or weak weight of evidence used in this Opinion is described in the section "Approach to the development of this Opinion".

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
242.	Dr. Richarz Frank, IEC TC61 / MT16 'Biological effects of optical radiation', MT16@richarz-consulting.de, Germany	ABSTRACT		MT16 'Biological effects of optical radiation' as the standardization body of sunbeds responsible to transfer scientific knowledge into safety requirements of sunbeds in the IEC TC 61 'Household Appliances' would have expected SCENIHR to take into account the current European standard and especially the changes in the standard following the SCCP Opinion of 2006, when assessing a risk assessment on European sunbeds. - The draft Opinion does not show any assessment of the effects of the changes of the standard. - The draft does not take into account the effect of all the information and warnings to the user - The draft displays IEC requirements wrongly as EN requirements - The draft displays spectra not associated with current European sunbeds - The draft misses to answer the questions of the mandate	The SCHEER takes note. This is not possible, at least not within the context of the epidemiological studies thus far.
243.	Dr. Richarz Frank, IEC TC61 / MT16 'Biological effects of optical radiation', MT16@richarz-consulting.de, Germany	ABSTRACT		The primary purpose of a sunbed is to provide a tan. Even if a tan is a fashion and beauty habit it is a natural response on UV radiation regardless of the source. In a risk assessment of product it should be taken into account which alternatives are available to fulfill the users demand for a product, a service or an effect. Therefore the risk assessment for sunbeds might include a comparison of the risks of getting a tan by 1. Sunbeds 2. Natural sun in the home environment 3. Natural sun during vacations to the south 2./3. might be differentiate between with or without use of sunscreens	The scope of the mandate is on the effects from sunbeds. A formal risk-assessment in view of sun-exposure guidelines and limits would be a totally different undertaking – if feasible.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
244.	Dr. Richarz Frank, IEC TC61 / MT16 'Biological effects of optical radiation', MT16@richarz-consulting.de, Germany	ABSTRACT		Page 4, lines 35-38 SCENIHR failed to provide any proof that sunbeds have been evolving towards higher UVA irradiance in recent years. Furthermore the UVA/UVB ratio of todays European sunbeds is equivalent to natural sunlight in afternoon hours and the purely natural midday ratio is not possible to achieve in some European countries, since natural sun corresponds to UV type 4, which is forbidden by law e.g. in France, Finland, Iceland, Sweden, Norway, Austria. page 5 line 6 Students mainly USA, Wehner 2014 gives reference to Monfrecola 2000 and shows students in Europe with much lower prevalence (figure 3) Page 5, line 1-14 The numbers presented are biased by the studies performed in USA and Australia. In Europe a decrease of sunbed prevalence is clearly shown in figure 7 of Wehner 2014. Page 5, lines 16-18 SCENIHR gives no reference for the photo degradation of vitamin D in the ongoing document. The only study (Webb 1989) suggesting such mechanism was a chemical lab result. This has never been established in human studies.	See answer to comment 82. Main text has been amended. The text on degradation has been modified.
245.	Harbusch Frank, European Sunlight Association a.s.b.l., frank.harbusch@europeansunlight.eu , Belgium	ABSTRACT		Page 5, lines 16-22 To facilitate its work ESA provided SCENIHR with a scientific reference list of 143 recent studies from the last decade. SCENIHR only found 11 studies from this list worth mentioning with most of the time its own selective conclusions or by either ignoring or with downplaying any positive effects. Referenced by the SCENIHR working group: Epidemiological studies: 0 from 12!, UV	The working group conducted its own independent literature search. ESA provided SCENIHR/SCHEER with a reference list of 143 recent studies (some redundant, cited more than once). Below is an analysis of the matches between the two literature searches. ESA list was classified as: A. Epidemiological studies showing the importance of moderate sun/UV

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				exposure and health effects: 1 from 49!, Indoor exposure and Vitamin D: 2 from 17!, UV exposure and melanoma: 8 from 65 (only adverse effects). We believe that ignoring the provided evidence for positive effects of UV and sunbed use demonstrates a clear selection bias in this preliminary Opinion. Page 5, lines 39-40 The research used is not reflecting the current situation in the European Indoor tanning market after professional sunbeds have been changed to the 0,3 W/m2 irradiation limit from 2007 onwards. In fact, the preliminary Opinion is based on out-dated data mostly from outside of Europe where irradiation limits for sunbeds are much higher and where skin-types are not adapted to the environment (e.g. Australia). Most research used is not applicable for Europe or is nor reflecting the changes in the market after 2007! Page 6, lines 15-23 No research has been done on non-burning exposure for sunbed use within the 0,3 W/m2 irradiation limit! All these statements are therefore irrelevant and are not reflecting the current situation in Europe. We find it strange that SCENIHR is using very precise figures (from the US!) here and then using the word "may" with it every time. This looks very much like Opinion making rather then providing facts.	exposure for good health. 12 refs. All related to sun/UV exposure. None related to UV exposure from sunbeds. B. UV exposure and health effects. 49 refs. Not all peer-reviewed published research articles (book chapters, position papers, guidelines, web sites…). Most related to sun/UV/vitamin D and diseases, not directly relevant to the scope of the Opinion. 1 cited. C. Indoor UV exposure and vitamin D3. 17 refs. Most related to vitamin D and diseases, not directly relevant to the scope of the Opinion. 2 cited. D. UV exposure and melanoma. 65 refs. Some more than 10 years old and cited in SCCP 2006. Not all peer reviewed research articles. Most related to sun exposure, genetics, and mechanistic pathways. 5 cited. 1 could have been missed (Gandini, 2013: sun exposure and melanoma Breslow thickness, no association with sunbed exposure). E. Other published peer-reviewed studies stressing the importance of sun/UV exposure for maintaining good health. 38 additional references. Mostly related to sun exposure/vitamin D and various diseases, not relevant. 4 cited. The SCHEER disagrees.
246.	de Gruijl Frank, representing none, degruijl@planet.nl, Netherlands	ABSTRACT		Pg 4, lines 6 - 9: Curiously, different from the IARC 1992 monograph, where sunlight was put Group 1, but not UV (Group 2A) – contrary to general consensus, especially among experts in dermatology and photobiology -, despite all already available overwhelming experimental and molecular-	This comment addresses IARC classification, not the present Opinion.

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				epidemiologic proof. Later on, sunbeds provide no stronger evidence than sun exposure did before. According to the IARC criteria in 1992, the conclusion for IARC 2009 for sunbeds should be: the use of sunbeds (contact with disinfectants?) is carcinogenic to humans, Group 1, but UV is probably carcinogenic to humans, Group 2A. Pg 4 line 36, in tropics UV-index > 20 was measured. 12 is more characteristic of midday max in subtropics/Mediterranean areas (https://www.niwa.co.nz/sites/niwa.co.nz/files/import/attachments/Liley_2.pdf) Pg 5, line 9; very selective representation of increasing sunbed use; Telegraph.co.uk 28 june 2013, Kathy Young reports on a study of Simple Business: "The study, based on 750,000 quote requests, revealed a steep decline in tanning salons of 29 per cent since 2012, suggesting that the dangers associated with sunbeds have finally hit home." (http://www.simplybusiness.co.uk/about-us/press-releases/tanning-salons/) (see also Boyle et al, Br J Dermatol 2010;163:1269-75). Also, reports on already low sunbed use in Australia declining, and among female students in the US: "From 2009 to 2013, tanning decreased among female students (from 25.4 percent to 20.2 percent), .. " (Gery P. Guy, et al. Trends in Indoor Tanning Among US High School Students, 2009-2013. JAMA Dermatology, 2014; DOI: 10.1001/jamadermatol.2014.4677) pg 5, line 9, "absolute increases" in %%? pg 5, line 18, loss of vitD by "excessive exposure" (what is excessive?) not measured in vivo, and certainly not in sunbed users who show net increases upon exposure sunbeds with 1 – 2% UVB in the UV band	Text has been amended. Identical to comment 19. This sentence refers only to Wehner's study. Decrease in sunbed use in some countries is reported in the main text. See answer to comment 19. The text on vitamin D production has been modified.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				pg 5 lines 19 – 22, these sentences show a lack of UV-vitamin D expertise: if there is any consensus then it is over the inadequacy of the Western diet to provide sufficient vitamin D (numerous papers and reports). The question is whether the drop in vitamin D status in winter has any (adverse) health effects. The premise that vitamin D supplement can (safely) replace UV exposures in beneficial effects is debated among experts, and would only be defendable if UV's beneficial effects are fully attributable to vitamin D (and the digestive route would equal the one from UV-generated in the skin – also debatable considering newly identified vitamin D metabolites). pg 5, lines 30 -31, increased relative melanoma risk from sunbed use before 35 years of age, mostly from studies that first of all detected an effect from ever use of sunbeds – Dr. Hoel pointed out that this introduces a hidden publication bias. pg 5, line 32 - 33, adjustments for risk from sun exposure variable and either poor or even irrelevant in proxy of dosimetry; resulting highly likely in "cross over" of sun exposure risk into determined "sunbed exposure" risk. Adjustments, applied or not, or variable, are a neglected issue anyway in meta-analyses, undermining their crediblity. Concluding that sunbed exposure, as assessed by the available studies, adds independently from sun exposure to the risk is therefore dubious. to be continued	The text onvitamin D production has been modified. The SCHEER disagrees. This comment refers to the 3 cohort studies analysed in the main text. An introductory paragraph has been added. Analyses of all 3 cohorts were actually adjusted for host factors and sun exposure.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
247.	de Gruijl Frank, representing none, degruijl@planet.nl, Netherlands	ABSTRACT		- pg 5 line 36, as the absolute risk of squamous cell carcinoma (SCC) is higher than that of melanoma to begin with, and the assessed relative risk from sunbed use is higher that that of melanoma, it is curious that so much emphasis is put on the marginal increase in melanoma risk (overall +10 to 20%) from sunbed use (mostly in young cohorts without any established effect on mortality). Scientifically, it would be more logical to be concerned over SCC instead of melanoma in relation to sunbed use (but also for SCC risk from sun exposure leaks into the derived risk from sunbed exposure which has never been adequately analysed). - Pg 5 line 37, it is remarkable that a percent increase in risk of basal cell carcinomas (BCC) from sunbed use (around 10%) comparably marginal to that of melanoma (10 – 20%) is considered negligible while the absolute risk is much higher and therefore the added absolute risk would also be much higher than that estimated for melanoma. Again, a remarkable unbalance in presenting and interpreting the risks. - Pg 5, lines 40 – 41, an incorrect and incomplete summary of sun / sun bed exposures on all-cause mortality. - Pg 6, line 2, UVA only successful in pigmented transgenic mice prone to develop melanoma, but less effective than UVB per unit energy (results in fish by the "Setlow group" could not be reproduced in a more solid study). - Pg 6 lines 7 – 10, stating that " UVA is at least as much involved as UVB in DNA damage and mutations" is misleading because UVB is orders of magnitudes more efficient than UVA which implies that even in sunlight UVB still dominates (despite the abundance of UVA; UVA/UVB = 20). Also confirmed by Ikehata et al referred to in this SCENIHR document. - Pg 6 line 15, 5% may not be negligible (although the errors in this estimate probably drown in the noise of statistics on melanoma incidence) but is	See also 209. Text of the Opinion was modified for clarity.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				certainly marginal; a more neutral and balanced presentation would be scientifically appropriate and more suitable for an official SCENIHR report. In all, as most recent (meta-) studies, IARC reports, and perpetuated in this draft document, far too much focus is put on sunbeds, distracting from the main culprit on population base: the sun! Not a sign of any serious consideration in this Abstract (and not in the main document). - Pg 6, line 18, projecting relative risks from sunbed risk on melanoma mortality is without substance: no data, there is no evidence of any increase in mortality – on the contrary sun/UV-related melanoma appear to have a better prognosis than melanoma in general. - Pg 6 lines 21 – 23, 43 to 76% of the melanoma risk before 30 years of age if a fraction from a (very) very low risk, with a vanishingly small risk of lethality. Proper mentioning of absolute risks would be in order; especially in the perspective that melanoma incidence and mortality is in large part attributable to elderly men (despite dominant use of sunbeds by (young) women). - Pg 6 lines 26 - 28, sunbed may not really "cause" (initiate) these skin cancers but increase the risk (e.g. by promoting their outgrowth). And the relative risk for BCC is hardly less than that of melanoma, and in added absolute risk it would be considerably greater. - Pg 6, line 29, if uveal melanoma risk is related to sunbed use (weak evidence) it is more likely to be related to blue light/UVA1 which should be no problem with proper use of goggles. - Pg 6, line 31, large fraction of an exceedingly small risk, and a vanishingly small mortality for ages under 30 years. Mind absolute risk, and do not frame everything in misleading relative risks.	See also 209. Text of the Opinion was changed for clarity.

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248.	Annendijck Kurt, Kom op tegen Kanker, kurt.annendijck@komoptegenkanker.be, Belgium	ABSTRACT		Kom op tegen Kanker would like to express its full endorsement of the findings and conclusions of the SCENIHR Preliminary Opinion on Biological effects of ultraviolet radiation relevant to health with particular reference to sunbeds for cosmetic purposes. The important causal link between sunbed use and skin cancer are is fully recognised in this report, the conclusion that "there is no safe limit for UV irradiance from sunbeds", is in line with our position. The message in the European Code against Cancer (www.cancercode.eu), a joint initiative of the World Health Organization's International Agency for Research on Cancer (IARC) and the European Commission, which is dedicated to UV exposure advises to "avoid too much sun, especially for children. Use sun protection. Do not use sunbeds". In line with the SCENIHR Opinion, IARC also notes that the use of sunbeds exposes the individual to unnecessary excess UV and should be avoided at all times. In conclusion, we fully support the findings of the SCENIHR Preliminary Opinion on Biological effects of ultraviolet radiation relevant to health, with particular reference to sunbeds for cosmetic purposes, in particular the link to increased skin cancer incidence. Kom op tegen Kanker would like to see this scientific Opinion used in the future as an evidence base for legislation or policy. It is important that these conclusions are can already be used to inform consumers, in particular those under 30, of cancer and other health risks associated with sunbed use.	The supportive comment is acknowledged.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
249.	Lipman Gary, The Sunbed Association, garylipman.tsa@gmail.com, United Kingdom	ABSTRACT	 Vit_D_Synthesis_in_relation_to_latitude__	Page 4, lines 6-9: In 1992 IARC classified sunlight as carcinogenic to humans (Group 1). In 2009 there was no new evidence on sunbeds reviewed; it was merely a 'housekeeping' exercise to add UV emitting devices.	
			 Vitamin_D_toxicity.pdf	Page 4, lines 26-28 Can the SCENIHR please identify where in Europe the Standard is not applied.	No changes in the Opinion are needed.
			 UVB_photoprotectoin_immune_effects_Na	Page 4, lines 35-38: By declaration of LVD-AdCo and the EC of 22. January 2007, all sunbeds supplied new or traded second-hand, should not exceed a maximum UV emission level of 0.3W/m2 as from 22. July 2007. LVD-AdCo did not implement a retrospective initiative for sunbeds already in the marketplace. As such, the consequence was that it was harder to convince the industry to comply.	The word widespread has been deleted. SCHEER is not aware of any European (public) health or health professional organisation that recommends such use.
			 Koutia_et_al__28233_29_2001_Gastroent	The SCENIHR report clearly states that 'the value for Mediterranean midday sun is 0.43W/m2' (Page 28, line 37). As such, to give the impression that sunbeds in Europe emit an output equal to midday tropical sun is incorrect and misleading. Page 4, lines 35-38 (Continued)	The text on vitamin D from sunlight has been modified.
				The Standard (EN60335-2-27) defines output in so far as spectrum and intensity. Sunbed manufacturers have adhered to the Standard and all new sunbeds produced since 2007 have limited output to 0.3W/m2. WIthin this defined limit no 'large variations' are possible anymore. Any such large variations, as stated, is outdated data.	This has already been answered.
				Page 5, line 1: Can the SCENIHR define 'varies greatly' and provide supporting evidence. US studies are irrelevant when addressing usage in Europe. The method of usage in the US is very different to Europe as the sunbed output levels are higher in the US	

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				and there are other variables. Page 5, lines 16-18 It is incorrect to state that excess exposure using sunbeds leads to photo degradation of pre-vitamin D3 in the skin. Overexposure, leading to burning, from any source of UV, not just sunbeds must be avoided. Page 5, lines 18-19: It is disingenuous in the extreme to state that 'There is widespread consensus that it is not necessary to use sunbeds to enhance vitamin D levels even in winter'. Page 5, lines 20-22: In Northern latitudes it is not possible for the body to synthesise Vitamin D production between October and April. Exposing the face and hands is only of benefit for Vitamin D production in summer months and requires circa 20 minutes of sunlight per day. Vitamin D synthesis is at best restricted and generally not possible in Europe on cloudy days, as suggested. We suggest the data regarding 'cloudy days' in the report is from Australia. Page 5, lines 20-22 (contd): Dietary supplements do not provide ideal efficacy. Vitamin D naturally synthesised by the body as a result of exposure to UV is absorbed better and can be stored by the body. Vitamin D from dietary supplements can also cause toxicity whereby naturally produced Vitamin D cannot. As stated in the title, while this paragraph should focus on health effects, it actually questions the "necessity" of sunbeds to enhance Vit D levels. (There is also widespread evidence that dietary supplements are not necessary and present some risks.) SCENIHR should refrain from suggesting alternatives, which are containing possible other risks, without providing data of a comparable risk assessment of the different sources of Vitamin D. Page 5, lines 23-24: The possibility of UV induced immunosuppression, whether from	The text is self-evident. No changes are needed. The word widespread has been deleted. The SCHEER is not aware of any European (public) health or health professional organisation that recommends such use. The text on vitamin D from sunlight has been modified. The text on vitamin D supplementation has been modified. The doses are mentioned in the Opinion. (note PJC: see earlier remark: how much UV-A in j/m2) from a typical sunbed exposure ? Immunosuppression is documented at 300 – 1000 J/m2). The SCHEER disagrees.

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				UVA, or UVB, would be as a result of over exposure (burning) as opposed to 'exposure'. Page 5, line 25: Photo aging of the skin is caused by over chronic over exposure (burning) and not exposure per se. Nevertheless, this would be a cosmetic issue, not a health concern and therefore outside the remit of the SCENIHR. contd/...	
250.	Lipman Gary, The Sunbed Association, garylipman.tsa@gmail.com, United Kingdom	ABSTRACT	 Grant-IARC-sunbed-epub.pdf  Highlighted_Leeds_Report_-_Intl_Journal  Boniol_et_al-2013-International_Journal_  Elliott_et_al-2013_Response_to_Boniol-Ir  Papas__Grant_summary_of_IARC_report	P2 of comments for Abstract section Page 5, lines 27-31: It is too simplistic to isolate sunbeds and say they are dangerous. It is an unproven direct causal link. The cause of melanoma is a mixed and complex subject. It is misleading to state that meta-analyses provide definitive evidence of risk. Risk expressed as a relative risk may be perceived to be larger than the same risk presented as both an absolute risk reduction or as a number needed to treat. The authors have presented studies that, at first glance, appear to corroborate each other. Sadly, all the studies present an incorrect conclusion, as they all use the same flawed data source. A meta-analysis can be a powerful statistical tool, but it cannot compensate for poorly designed or carried out studies. In other words, to borrow a phrase from computer science, garbage in, garbage out. The studies in the meta-analyses provided were by no means all garbage, but they were not perfect either as their conclusions are misleading. The research provided by the authors of the report and the research authors themselves assert these papers as evidence of a link between sunbed use and melanoma. That would be acceptable if they only used sunbeds in their research. By including UV devices for medical use and home devices in the data source used in the meta-analysis, the resultant extrapolation is skewed and therefore flawed. Where sunbeds alone have been tested (Luxembourg Health Institute published in the European Journal of Cancer	Please see the answer to comment 23. No change in the Opinion is needed. The analyses have been presented in the main text.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				41 (2005) 2141–2149 and International Journal of Cancer published research from Faye Elliott, Section of Epidemiology and Biostatistics, Leeds Cancer Research UK Centre, Leeds Institute of Molecular Medicine and Cancer Genetics (10.1002/ijc.26347)) no such link was found. Autier and Boniol questionned the authors of this report bu the authors defended their study and its conclusion. The conclusion of the Leeds report said 'In summary, we have found no evidence for sunbed use as a risk factor for melanoma in the UK; although we cannot exclude a small effect of ever sunbed use, nor risk associated with use in early life, we can exclude a large effect'. The conclusion of the Luxembourg report said 'The results indicate that if an association between sunbed use and melanoma truly existed, then it must be marginal'. Independent scientific analysis of this data source used in these types meta analyses as used by IARC and the others referred to in this section irrefutably clarifies that any increased risk is associated with medical use UV equipment - at a staggering 96% - and to a much lesser degree home use equipment but NOT with professional sunbeds. Meta-analyses carry the weight of all of the studies that they summarise. This credence makes it imperative that meta-analysis can be trusted to be an impartial tool and makes the validity of meta-analytic summary a far more important issue than measurement error. Their data can often be skewed by some weighted data and thereby obscures the result. As such, in my Opinion, meta-analyses are a crude blunt tool that can and do lose important detail. In 2009 Dermato-Endocrinology published A Critique of the International Agency for Research on Cancer's meta-analyses of the association of sunbed use with risk of cutaneous malignant melanoma (1:6, 1-7;). The conclusion was 'This meta-analysis of the association of CMM risk with respect to sunbed use by the IARC	

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				does not support the evidence that sunbed use is a risk factor for CMM when the confounding factors of skin phenotype and latitude are considered. The IARC study only claims association, not causality, and the criteria for causality do not appear to be satisfied'. contd/...	
251.	Lipman Gary, The Sunbed Association, garylipman.tsa@gmail.com, United Kingdom	ABSTRACT	 Grant-IARC-sunbed-epub.pdf  Papas__Grant_summary_of_IARC_report  Papas_2011_Abstract_3rd_North_America  suntan_poster_4-final-Montreal.pdf	Page 3 of comments for Abstract section Page 5, lines 27-31 (contd): Meta-analyses carry the weight of all of the studies that they summarise. This credence makes it imperative that meta-analysis can be trusted to be an impartial tool and makes the validity of meta-analytic summary a far more important issue than measurement error. Their data can often be skewed by some weighted data and thereby obscures the result. As such, in my Opinion, meta-analyses are a crude blunt tool that can and do lose important detail. In 2009 Dermato-Endocrinology published A Critique of the International Agency for Research on Cancer's meta-analyses of the association of sunbed use with risk of cutaneous malignant melanoma (1:6, 1-7;). The conclusion was 'This meta-analysis of the association of CMM risk with respect to sunbed use by the IARC does not support the evidence that sunbed use is a risk factor for CMM when the confounding factors of skin phenotype and latitude are considered. The IARC study only claims association, not causality, and the criteria for causality do not appear to be satisfied'. Referring back to the IARC report, research was published at the North American Congress of Epidemiology in Montreal, Canada in June 2011 showing 'Differential Risk of Malignant Melanoma by Sunbed Exposure Type' by Mia A. Papas, PhD, Anne H. Chappelle, PhD, William B. Grant, PhD. The conclusion stated 'When professional sunbed	Please see the answer to comment 24. No change in the Opinion is needed.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				usage is considered independent of home and medical exposures there is no association with melanoma'. The reports failed to disclose is that the data from the studies they examined also showed: 1. There was no statistical connection between indoor tanning usage and melanoma for people with skin types dark enough to tan. (Grant WB, "Critique of IARC Meta-Analysis of the Association of Sunbed Use with the Risk of Melanoma. Dermato-Endocrinology 1:6, 1-7; Nov./Dec. 2009) The only connection was with people with "Skin Type I" (fair/sensitive skin) who use home tanning units for therapeutic reasons, but crucially, are screened from tanning in professional sunbed salons. 2. Closer analysis of data from the IARC report -- when separated by unsupervised home usage of UV equipment verses usage in professional sunbed facilities and medical usage of medical UV equipment in hospitals and clinics -- reveals that no statistically significant increase in relative risk* (6 percent) was attributable to commercial tanning facility usage, while larger increases (40 percent and 96 percent) were attributable to home and medical usage of UV equipment. By removing skin type 1, the relative risk is insignificant. The often quoted '75% (or 59% (Boniol)) increase' is an amalgamation of all the studies and therefore should never have been attributed solely to professional sunbeds. It must be reiterated that only vulnerable groups (for example those with sensitive skin who burn easily and rarely tan, so called skin type 1) have a relative risk of 6%. This group is screened out by professional tanning salons.	

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252.	Lipman Gary, The Sunbed Association, garylipman.tsa@gmail.com, United Kingdom	ABSTRACT	Sam_Shuster_-PANIC_NATION_CHAPT_2 EJC_Multicentre_epidemiological_study_d Highlighted_Leeds_Report_-_Intl_Journal Boniol_et_al-2013-International_Journa_ Elliott_et_al-2013_Response_to_Boniol-Ir Grant_Nordic_cancer_occup__2_.pdf	Page 4 of comments for Abstract Page 5, lines 30-34 "There are two main categories of skin cancer - melanoma and non-melanoma. Melanoma (also known as 'malignant melanoma') is less common than non-melanoma cancers, but is the most dangerous. Non-melanoma skin cancers are mainly comprised of 'Basal Cell Carcinoma' (BCC) and 'Squamous Cell Carcinoma' (SCC). BCC is the most common and the least dangerous. BCC and SCC were formerly known as 'lesions' as they are not cancerous at all, in that they do not metastasise and spread. As such, whilst unfortunate, BCC and SCC are generally not life threatening. In more recent years, BCC and SCC were effectively renamed as 'non- melanoma skin cancer (NMSC). This is to ensure that the public obtains a medical inspection by a dermatologist and has led to a vast increase in reported incidences. Fortunately, circa 97% of biopsies are benign. It is therefore essential not to conflate melanoma and NMSC as to do so often leads to confusion. There is no clinical data relating sunbed use with melanoma, only interview based recollections. The authors imply that there is evidence showing direct melanoma causation isolated as attributable to sunbed use to the exclusion of sunlight. I ask the authors to provide proof on this, as I am confident that none exists. Indeed two recent studies attempted to prove a link between sunbeds and melanoma and both found no association. In 2005, the European Journal of Cancer 41 (2005) 2141–2149 published A multicentre epidemiological study on sunbed use and cutaneous melanoma in Europe, that sought to prove a causal relationship between sunbed use and melanoma. The conclusion was 'In conclusion, sunbed and sun exposure were not found to be significant risk factors for melanoma in this case–control study performed in five European countries'. In 2011 the International Journal of Cancer published	Partly identical to comment 23. No change in the Abstract needed. In addition, it is not true that BCC and SCC "are not cancerous at all". Although less malignant that melanoma, SCC does metastasize and may even be life threatening.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				research from Faye Elliott, Section of Epidemiology and Biostatistics, Leeds Cancer Research UK Centre, Leeds Institute of Molecular Medicine and Cancer Genetics (10.1002/ijc.26347). The conclusion of the report stated: 'In summary, we have found no evidence for sunbed use as a risk factor for melanoma'. Messrs Autier and Boniol questioned the authors' findings but the authors defended their study and conclusion. These studies set out to prove a link between sunbed use and melanoma. The SCENIHR authors seem to dismiss both of these large case controlled studies, or any such studies. Page 5, lines 34-37 Chronic over exposure to UV in general can be a risk factor for squamous cell carcinoma and basal cell carcinoma, not sunbeds in particular Page 5, lines 38-39 There has never been any incidence of internal cancers associated with sunbed use. Indeed the reverse is true as there is compelling evidence that sufficient Vitamin D levels assist the body to suppress disease. contd/...	Chronic sun exposure is a risk factor for SCC, not for BCC and melanoma. Studies are generally adjusted for sun exposure. No change in Abstract needed. The studies are analysed in the main text.
253.	Lipman Gary, The Sunbed Association, garylipman.tsa@gmail.com, United Kingdom	ABSTRACT	Lin_et_al-2012-International_Journal_of_ Grant_2009_-_decreased_risk_of_cancer_	Page 5 of comments on Abstract Page 5, lines 39-40: There is compelling evidence linking sunbed use and Vitamin D synthesis. It is disingenuous in the extreme to state 'an available cohort study suggests an increased risk of death from all cancers taken together' as the only consideration is melanoma and the studies shown earlier negate that theory. Indeed, research shows that people exposed to more sunlight had a significantly lower risk of many types of cancer, including melanoma. A study that correlated exposure to sunlight with cancer risk found that people exposed to more sunlight had a significantly lower risk of many types of cancer (Lin, 2012). This study followed more than 450,000 white, non-Hispanic subjects aged 50-71 years from	Vitamin D synthesis in relation to sunbed use is discussed in the main text. No change in the Abstract needed. The SCHEER is aware of the Lin et al. 2012 study, but discussion of ecological associations between solar UV exposure and cancer risks are outside the mandate. Association between sunbed exposure and ocular melanoma is discussed in the main text. No change in the Abstract needed.

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			 Table_1_-_Ocular_Melanoma_Study_Anal  Lutz_et_al_2005.pdf  Monnarez-Espino_-_Occupation_as_a_risk	diverse geographic areas in the US. Researchers correlated the calculated ultraviolet radiation (UVR) exposure in these different areas with the incidence of a variety of cancers. The diverse sites included six states (California, Florida, Louisiana, New Jersey, Pennsylvania, and North Carolina), and the metropolitan areas of Atlanta and Detroit. They followed these subjects over a period of nine years in the study and eliminated other known risk factors for cancer such as smoking, body mass index, and physical activity. This was the first prospective study (participants were actively observed for the duration of the study) to look at the relationship of sunlight to cancer. A total of 75,000 participants in the study contracted cancer. The study found that 12 types of cancer were reduced in those subjects exposed to more sunlight. These included cancers of the lungs, prostate, pancreas, colon, thyroid and many other types. This confirmed a previous study that showed a decreased incidence of cancer to sun exposure (Grant, 2012). Page 5, lines 41-43: Sunbed users have to wear eye protection goggles, so this is an irrelevant point. Indeed, even if the assertion had merit, melanoma of the eye usually occurs where light cannot penetrate in the choroid region (see below). The retinal hazard zone is between 400-1400nm. Sunbeds emit UVA (315-400nm) and UVB (280-315mn). The alleged link between sunbeds and eye melanoma is created by confusion with high intensity UV light generated by welding equipment. There is a coherent body of evidence in relation to welding and ocular melanoma. Welding, particularly arc-welding, is an intense source of ultraviolet radiation to which welders work in close proximity. They are also exposed to welding fumes which may contain known carcinogens, such as hexavalent chromium and to radioactive	Association between sunbed exposure and ocular melanoma is discussed in the main text. No change in the Abstract needed.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				materials such as thorium oxide. In 2012 the International Agency for Research in Cancer (IARC), in a review of the risks of radiation (100D), concluded that there was sufficient evidence that (occupational) welding was carcinogenic in relation to ocular melanoma, but that it was unclear whether this was a reflection of high exposures to ultraviolet radiation or to other incurred exposure(s). The authors stated that this Opinion would not be expected to change after a full review of welding in a subsequent Monograph. The evidence base examined by IARC comprises seven case-control studies, the findings of which are summarised in Table 1. In addition two further studies (Monárrez- Espino et al., 2002, Lutz et al., 2005) identified through a literature search by IIAC's Research Working Group, are included. There is no evidence linking sunbed use and ocular melanoma, however, over exposure to UV in general can lead to cataracts, so it is important to wear sunglasses in sunlight and professional tanning salons provide eye protection in the form of goggles. contd/...	
254.	Lipman Gary, The Sunbed Association, garylipman.tsa@gmail.com, United Kingdom	ABSTRACT	A_quantitative_estimate_of_melanoma_m bmj_-_study_correction.pdf	Page 6 of comments on Abstract Page 5, lines 45-46/ Page 6, lines 1-13: These 'animal studies' refer to mice and deep sea fish. Mice are nocturnal animals covered in fur which avoid the light, so one must be cautious about extrapolating from these experiments to humans. More commonly, the mice used in such experiments/research are genetically modified so as to be more susceptible to cancer. That helps to accelerate the process, but also distorts the test results. The same can be said for deep sea fish. Their environment will have extremely low UV. As such, when they are used for this type of research, their reaction to UV is extreme. Once again, one must be cautious about extrapolating from these experiments to humans and it is suggested using this data is done with the intention of worrying the reader. Page 6, lines 15-19: It is not possible	

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				to prove direct causation was isolated as attributable to a sunbed to the exclusion of sunlight. Therefore these types of models use a method called Monte Carlo random sampling. This method utilises conjecture in the absence of factual evidence. In the UK, for example, it is often quoted in the media that 'sunbeds are responsible for 100 deaths per year'. This figure is taken from 'A quantitative estimate of melanoma mortality from ultraviolet A sunbed use in the U.K by B.L. Diffey in 2003. The report stated that the author used the Monte Carlo random sampling. Moreover, the conclusion was: "Sunbed use could be regarded as a relatively minor self-imposed detriment to public health compared with other voluntary pleasurable activities associated with significant mortality, such as smoking and drinking alcohol. While cosmetic tanning using sunbeds should be discouraged, prohibition is not warranted especially as exposure to the sun, which cannot be regulated, remains the major contributory factor to the risk of melanoma." Page 6, lines 19-23: The figure quoted (+75%) has been subsequently reduced and amended in an update published in the British Medical Journal stating 'Corruption of a data file led to the publication of an incorrect summary estimate in this Research paper by Boniol and colleagues (BMJ 2012;345:e4757, doi:10.1136/bmj.e4757). The summary relative risk for first exposure to sunbed use starting before age 35 years is 1.59 (95% confidence interval 1.36 to 1.85) [not 1.87 (1.41 to 2.48)] with no evidence of heterogeneity (I2=3% [not 0%]). The conclusions and the estimation of the burden of sunbed use in Europe remain unchanged' (BMJ 2012;345:e8503). The revised lower figure is still widely disputed due to the flawed data set used in the meta-analysis. contd/...	

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
255.	Lipman Gary, The Sunbed Association, garylipman.tsa@gmail.com, United Kingdom	ABSTRACT	Christophers_1998_-_Melanoma_is_not_c Sam_Shuster_-PANIC_NATION_CHAPT_2	Page 7 of Abstract comments Page 6, lines 25-28: Same comments as Page 5, lines 27-31. I am surprised that such a group in the medical fraternity would make such a conclusion that 'UV is a complete carcinogen'. For an organisation whose work is predicated on fact, that is extraordinary conjecture. Humans evolved in the horn of Africa, close to the equator over 30,000 years ago. They spent their days out in the full sun, with no clothing, hunting and gathering food. Their skin pigment evolved and protected them from sun burns and allowed the production of vitamin D through the skin. Nature never intended for humans to live and work indoors, in offices and factories without daily sunshine exposure. This is why it is logical we take action to ensure we achieve natural, evolutionary, vitamin D levels. We need to balance the fact that too little sunshine is as concerning for health as is over exposure, leading to burning. Anyone with a modicum of knowledge of physics would know that the Bunsen-Roscoe law of reciprocity states that a certain biological effect is directly proportional to the total energy dose irrespective of the administered regime. Dose is the product of intensity and the duration of exposure and thus the time required to deliver a certain dose is influenced by the intensity of the source and whether the exposure is continuous or fractionated. Allen J Christophers confirmed that there is no link between melanoma and sunshine in his study 'Melanoma is not caused by sunlight (Mutation Research 422 (1998) 113-117) in which his conclusion was 'The fact that melanoma has little or nothing to do with sun exposure becomes obvious when comparisons are made of the three main skin tumours (SCC, BCC and melanoma). This approach to the data makes it clear that sun exposure is the predominant factor in the aetiology of SCC, is a somewhat less significant factor in BCC and has little or no involvement in	A "complete" carcinogen is one which affects tumour cells in all stages of development. This is true for UV which is a mutagen, a carcinogen and a promoter.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				melanoma.' It is established that BCC and SCC are known as NMSC (non-melanoma skin cancer) and not cancers at all, but benign lesions. There is no such thing as artificial UV. A photon is a photon and there is no difference between sunshine that reaches the earth's surface and the output of a sunbed. A modern day sunbed should not have an output (intensity) in excess of 0.3W/m2, this equates to the midday sun in the Mediterranean. Commercial sunbeds emit a controlled combination of UVA and UVB rays that imitate natural sunlight. Sunlight is essential for good health. To suggest that a sunbed session is not safe when used responsibly and by appropriate people without any contra-indications to tanning, defies medical science, reason and common sense. Indeed, burnt skin is skin damage. However, pre-erythema tanning is entirely natural and no burning or damage occurs at all. Dr. Sam Shuster, Emeritus Professor of Dermatology at Norfolk and Norwich University states "The dogma, now fossilised in print, is that any tan is a sign of skin damage. Tell that to Darwin. Pigmented melanocytes in the skin are a system that protects it from excessive UV, which evolved long before the advent of sunscreens. Even if there was hard evidence that melanoma was UV-induced it would be all the more important to keep a protective tan". contd/...	
256.	Lipman Gary, The Sunbed Association, garylipman.tsa@gmail.com, United Kingdom	ABSTRACT	Monnarez-Espino_-_Occupation_as_a_risk Lutz_et_al_2005.pdf	Page 8 of Abstract comments Page 6, lines 25-28 (contd): Tanning is the body's natural protection against sunburn — it is what your body is designed to do. Dermatology industry representatives have myopically referred to this process as "damage" to your skin, but calling a tan "damage" is a dangerous oversimplification. Here is why. Calling a tan damage to your skin is like calling exercise damage to your muscles. Consider this, when one exercises you are actually tearing tiny muscle fibres in your body. On the surface, examined at the micro-level, that could be	The comment does not correspond to text p. 6 lines 25-28. No change in the opinion is needed.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
			Highlighted_Leeds_Report_-_Intl_Journal Boniol_et_al-2013-International_Journa_ Elliott_et_al-2013_Response_to_Boniol-Ir 2016-Weller-Sunlight-CVD-independent-of	called "damage." But that damage on the micro-level is your body's natural way on the macro-level of building stronger muscle tissue. So to call exercise "damaging" to muscles would be terribly deceiving. Page 6, lines 28-29 There is no evidence linking sunbed use and ocular melanoma. The only research refers to UV from welding. Page 6, lines 29-31 The research referred to is the same meta analyses discussed earlier whereby the data source is flawed (Page 5, lines 27-31). Indeed, the 2011 International Journal of Cancer published research from Faye Elliott, Section of Epidemiology and Biostatistics, Leeds Cancer Research UK Centre, Leeds Institute of Molecular Medicine and Cancer Genetics (10.1002/ijc.26347) quoted earlier stated 'Age at first use and years since first use showed no significant associations with melanoma risk'. It is accepted that pre-pubescent skin can be more sensitive to sunlight and therefore could burn more easily. As such, to ensure that children do not use sunbeds, professional tanning salons restrict usage to over 18 year olds. Page 6, lines 32-33 "It is disingenuous to state that there are only small beneficial effects of sunbed use. Sunbed use causes the body to synthesise Vitamin D and there is compelling evidence of the related health benefits. All-cause mortality should be the primary determinant of public health messages. Sunlight is a risk factor for non-melanoma skin cancer, but sun avoidance may carry more of a cost than benefit for overall good health. Dermatologist Richard Weller has identified the fact that the skin contains significant stores of nitrogen oxides, which can be converted to NO (Nitric Oxide) by UV radiation and exported to the systemic circulation. Human studies show that this	 See answer to comment 197. Partly identical to comment 154. See main text for description of the Elliott study and a critique of the adequacy of its design. See main text for a discussion of all-cause mortality.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				pathway can cause arterial vasodilatation and significantly reduced blood pressure. Indeed, in his research paper entitled 'Sunlight has Cardiovascular Benefits Independently of Vitamin D' (Blood Purif 2016;41:130–134 DOI: 10.1159/000441266) he states 'Public health advice on sunlight exposure is at the crossroads. Almost a century of data has confirmed the carcinogenic effects of UV radiation on the skin, and delineated the mechanisms by which this occurs. There is however a remarkable absence of any evidence that UV reduces lifespan, in sharp contrast to other risk factors (e.g. hypertension, smoking, alcohol) on which we advise. A substantial body of evidence shows that sunlight has health benefits and that these are independent of vitamin D and thus cannot be reproduced by oral supplementation. 'The UV-induced reduction of cutaneous nitrate and its export to the systemic vasculature, which I have helped delineate, is an additional mechanism by which sunlight may exert beneficial effects on health, but other mechanisms surely exist. All- cause mortality and its reduction should be the primary aim of physicians, not the narrow avoidance of skin cancer'. Page 6, lines 33-34 Indeed, over exposure, not usage per se can reduce the Vitamin D levels. Over exposure (burning) is avoided with well trained staff in professional salons. contd/...	Paragraphs on vitamin D synthesis in the skin following UVB exposure have been rewritten in the main text.
257.	Lipman Gary, The Sunbed Association, garylipman.tsa@gmail.com, United Kingdom	ABSTRACT	 Vit_D_Synthesis_in_relation_to_latitude__	Page 9 of Abstract comments Page 6, lines 35-36: Humans need to balance sunshine exposure. Too little and chronic over exposure both carry health risks. In northern latitudes, Vitamin D can only be synthesised by the body between May and September on sunny days. This can lead to Vitamin D insufficiency in the winter months. When a client visits a professional tanning salon with well trained, informed staff, their skin type will be assessed and their suitability will be	Paragraphs on vitamin D synthesis in the skin following UVB exposure have been rewritten In the main text.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
			 EN16489-1_EN.pdf  64-Melanoma_Crete_2c_Germany_Kasithi	examined. Those from vulnerable groups, such as those with sensitive skin will be screened out. An appropriate session time will be provided to the client to help ensure that they do not exceed the recommended dosage. Client details will be registered and usage will be recorded to prevent excessive use. Salon staff across Europe can now receive accredited Tanning Salon training to the EN16489 Standard. The issue is not the sunbed. The issue is chronic over exposure to UV in general. Statistically speaking, more people sunbathe in the sun (and burn) than a sunbed and that is where the issue lies. Page 6, line 37: If this were true, then this would also apply to sunshine. There is evidence that people who live in sunny climates have less melanoma, so this assertion needs to be examined. Page 6 line 35-37: The mission for SCENIHR was to look at new scientific evidence after the SCCP report on sunbeds from 2006. Most studies refered to by SCENIHR are either irrelevant, because not applicable for Europe, or outdated as original studies are mostly older than 2006. This report has failed to provide any new evidence that would allow the conclusion that there is no safe limit for sunbed use. Indeed, the 0.7 W/m2 irradiation limit as suggested for in the draft report by the reputable SCCP working group in 2006 still stands unchallenged. SCCP at the time changed to 0.3 W/m2 in the final report so to be on the very safe side, also because of heavy criticism by cancer leagues, but without providing any scientific reason for lowering the limit in the final report.	The SCHEER disagrees. The SCHEER disagrees.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
258.	Khazova Marina, Public Health England, marina.khazova@phe.gov.uk, United Kingdom	ABSTRACT		p 5, lines 1-14. Exposure to sunbeds is taken in isolation from sun exposure, occupational and recreational; in particular, intermittent very high exposure during beach holidays which are increasingly prevalent in Northern Europe in last few decades. There is a need to provide more of this context. B Petersen et al (B Petersen, E Thieden, P A Philipsen, J Heydenreich, A R Young and H C Wulf. A sun holiday is a sunburn holiday. Photodermatology, Photoimmunology & Photomedicine, v 29, no 4, pp 221–224, 2013) reported that Danish holidaymakers received daily 9.4 SEDs and accumulated 57 SEDs during 6 days holidays in the Canary Islands in March 2010 which is likely to be higher than the annual dose from sunbed exposure. The numbers on prevalence of sunbeds use presented in this report are strongly biased by the older studies and studies from USA and Australia and not representative for Europe. Thus, B Koster et al (B Koster et al Sunbed use in Danish population in 2007: a cross-sectional study, Preventive Medicine, 48, 2009, 288-290) showed in Table 1 that only 9% of respondents used sunbeds more often than once a month in previous year and 70 % either didn't use sunbeds in last 12 month or at all. These numbers are significantly lower than reported in this draft. p5, lines 16-22. Although PHE supports the position that sunbeds should not be used for improvement of VitD status, arguments presented in this draft report are unconvincing and often based on unsupported and unrealistic assumptions; hands and face have too small skin area to synthesise sufficient level of VitD by exposure to sub-erythema doses. Bogh et al showed that higher doses are needed if small area of the body is exposed (MK Bogh, AV Schmedes, PA Philipsen et al. Vitamin D production after UVB exposure depends on baseline vitamin D and total cholesterol but not on skin pigmentation. J Invest Dermatol, 2010,	The SCHEER acknowledges that outdoor exposure to UV when it is excessive, either intentionally (e.g. sunbathing) or unintentionally (e.g. some professions), is of public health concern. Nevertheless, the (draft) Opinion is on the effects of exposure from sunbeds per se, whereby in the discussions of the available studies the confounding by outdoor sun exposure is taken into account.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				130:546-553); most of modelling is based on 35% exposed body area. Furthermore, the UK usually experience only 5 cloud-free days per year, most of which occur in the winter when the solar spectrum doesn't contain a VitD effective component. p5, lines 23-25. Erythema weighting used throughout this draft report for the assessment of risk from sunbeds masks the contribution of UVA to health effects (other than erythema) due to very low spectral weighting (6.8 10-4 at 350nm and 1.7 10-4 at 390nm). p6, lines 28-29. The report doesn't present conclusive evidence of an increase of ocular melanoma due to use of sunbeds.	
259.	Dr. Richarz Frank, IEC TC61 / MT16 'Biological effects of optical radiation', mt16@richarz-consulting.de, Germany	ABSTRACT		The submitted comments and statements of IEC TC61 / MT16 ‚Biological effects of optical radiation' are representing the view of the majority of the maintenance team. The members from NRPA Norway, STUK Finland, FDA USA and Prof. Sliney do just support the comments on the content of the standard text in chapter 5. These members might submit own comments by their home organization.	Note has been taken of this important disclaimer.
260.	Zeyen Thierry, European Glaucoma Society, thierry.zeyen@telenet.be, Belgium	ANNEXES	 MacularDegeneration Refs.pdf	Annex 1. page 66 Lines 10-11: The term 'macular degeneration' does not appear amongst the terms used in the searches and presented in this table. The European Glaucoma Society Foundation notes that the time limit for such searches is post 2006. We provide references regarding evidence on ultraviolet radiation as serious risk factor for macular degeneration from 2011.	References submitted were considered, and a paragraph has been added in the text.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
261.	Zeyen Thierry, European Glaucoma Society Foundation, thierry.zeyen@telenet.be, Belgium	ANNEXES	 risk_factor_AMD_3.pdf	page 67, lines 1-11: It was acknowledged earlier on Section 5. Technical Background in lines 1-16 that definitions around UV vary. But so do the abbreviations used to refer to UV. Using the combination ultraviolet and UV eliminated references which use UVR as abbreviation. We attach such reference here. Lines 9-10: combining therms with specific terms such as sunbeds, sunlamps, indoor tanning brings social bias which prevents the finding of studies that have been carried out with ordinary sun exposure and associated with GDP. Although such references do not alter the main findings of the Opinion paper, they do highlight a gap in methodology in how evidence is collected. Such gap must not be overlooked and it must be addressed for future Opinion papers. Leaving out of the evidence base eye disease compromises the safety of the consumer who must be properly informed products. This is particularly important when the visual loss is irreversible.	References submitted were considered, and a paragraph has been added in the text.
262.	Baldermann Cornelia, German Federal Office for Radiation Protection, cbaldermann@bfs.de, Germany	REFERENCES		The citation "Schmidt-Pokrzywniak 2009" is missing.	The Schmidt-Pokrzywniak reference has been added in the list.
263.	Petri Aspasia, Greek Atomic Energy Commission (EEAE), aspasia.petri@eeae.gr, Greece	REFERENCES		lines 33 - 34: Petri A, Karabetsos E. Effective ultraviolet irradiance measurements from artificial tanning devices in Greece. Radiat Prot Dosimetry 2015;167(4):490-501. doi: 10.1093/rpd/ncu346.	The correct reference has been included in the reference list.
264.	Baldermann Cornelia, German Federal Office for Radiation Protection, cbaldermann@bfs.de, Germany	Response 1		Page 60 / line number 25: Behind "Melanoma" should be set a point instead of a colon. Because of the statements in Section 7.4.3 the statement made here seems to be to go too far. It se ems more appropriate to state: UV radiation is "a risk factor" instead of "a main risk factor". Page 60 / line number 26 - 28: The sentences "Although there ...", and "There is widespread consensus ...", should be combined. In scientific view it would be necessary to	The text was amended.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				complement that due to the scientific proved adverse health effects of UV radiation (solar and artificial) the exposure with artificial UV radiation in addition to not avoidable exposure with solar UV radiation should be strictly avoided. Page 60 / line number 28 - 30: The sentence „Short (minutes to half of an hour) daily exposures to solar UV of unprotected (e.g., no sunscreens applied) face and hands have been shown to build up and restore sufficient levels of vitamin D." is a too short summary of the associated statements made in this Opinion. To avoid misinterpretation it is proposed to use the following formulation which is part of the world's first interdisciplinary joint recommendation regarding "UV exposure for endogenous vitamin D synthesis" of scientific authorities, expert associations, and professional bodies concerned with health, assessment, medical care, and nutritional science, published in 2014 on the websites of the Federal Office for Radiation Protection http://www.bfs.de/vitamind: "Based on current scientific knowledge, sufficient vitamin D synthesis is achieved when exposing the face, hands, and arms uncovered and without sunscreen to half of the minimum erythemal UV dose (0.5 MED) two to three times a week, i.e. half the time it would usually take unprotected skin to develop a sunburn. In purely mathematical terms, this would correspond to about 12 minutes of exposure to high erythemal UV irradiation (UV index 7), taking skin type II as an example." In addition to the remarks on the topic "sunbed use / vitamin D synthesis", it could be further stated that - neither the sunbed operators nor the sunbed users know the given UV spectrum (particularly in relation to the vitamin D synthesis initiating UVB portion) or the real erythemal UV irradiance	The text on vitamin D was amended. The SCHEER does not think it is necessary to further elaborate on this sentence because all the information is already given in the full report.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				of the used sunbed. Checks based on the German Ordinance for protection against the harmful effects of artificial ultraviolet radiation (UV protection ordinance) showed that the required maximum erythemal UV irradiance of 0.3 W/m2 can be exceeded as well as be undercut. Accordingly, in sunbeds occur uncontrolled UV irradiation. There is no comprehensible statement possible, whether and to what extent the blood serum vitamin D levels are affected when using a sunbed. Since vitamin D is doubtless very important for health, the issue "Optimal vitamin D status" should be treated with the necessary seriousness and placed under medical control. - the vitamin D metabolism is extremely complex. It cannot be excluded that suboptimal vitamin D blood serum levels may also be due to a disturbance of the vitamin D metabolism. In this case, the vitamin D blood serum value cannot be increased by an additional UV exposure. Volunteer studies showed repeatedly that the vitamin D blood serum levels of single test persons did not arise despite of adequate UV exposure. - in the studies conducted so far regarding the health effects of vitamin D, the vitamin D fed to volunteers in form of vitamin D supplements caused the desired increase in vitamin D blood serum levels without exception. Thus, vitamin D supplements are effective. It is therefore incomprehensible that in terms of maintaining an optimal vitamin D blood serum levels, only the UV-induced vitamin D synthesis is promoted.	These aspects are already considered in the main body of the report. These aspects have been already mentioned in the main body of the report.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
265.	ANSES	Response 1		§ 8- Opinion, p60, lines 15-45 – Question 1 Comment: In addition to increasing skin cancer risk, immunosuppression and skin–aging, indoor tanning can cause acute and chronic eye diseases (if eye protection is not used), addiction, burns to the skin and, if tanning devices are not properly sanitized, skin infections. To preserve the integrity of the genetic code, repair enzymes are activated almost immediately to correct the damage. In cells where extensive or irreparable injury occurs, these cells switch on the pathway for controlled self-destruction (apoptosis). Extensive data demonstrate that DNA damage or DNA repair intermediates are powerful signals that initiate melanogenesis. Tanning is a biological signal by the skin that reflects the presence of DNA impairment.	These aspects had already been discussed in different sections of the report.
266.	Frank de Gruijil Representing none, degruijl@planet.nl Netherlands	Response 1		Acknowledgements: - Pg.3, lines 6 - 18: with all due respect, unfortunately no one from EU bodies has a proper background in photobiology or UV cancer risks - Pg 3, lines 20 – 22: only two proper and reputed experts on the subject of UV and skin cancer, but both very outspoken on the subject of active regulation of UV exposure, which evidently is only possible for sunbeds not for sun bathing. The document is clearly framed along these lines. This is not a sound basis for a balanced presentation of data and well informed judgment (more experts from different 'schools of thought' would have been desirable). The Opinion on sunbeds should have been put in proper context where skin cancer incidences are concerned, particularly melanoma incidences, and where sun exposure is concerned, with a more balanced evaluation of health effects, including beneficial ones (dismissing observational studies.	This Opinion is based on metadata analysis and literature review carried out by a group of experts to answer the questions of the specific mandate on the effects of exposure from sunbeds per se, whereby in the discussions of the available studies the confounding by outdoor sun exposure is taken into account. The expertise of scientists involved in this Opinion, both in the working group and the Committee, covers a broad range of areas and fully enables the collective group to tackle all aspects of the mandate: UV natural or artificial radiation, physics, statistics, health care engineering, field measurement and dosimetry, photobiology, photochemistry, dermatology, toxicology, public health, epidemiology, anthropometry, cancer, molecular mechanisms of UV-induced skin cancer, the role of epidermal stem cells in skin carcinogenesis, epigenetic regulation of epidermal stem cells and cancer stem cells, the role of miRNAs in UV-induced skin cancer, exposure assessment, modelling, risk assessment and other areas. Beneficial effects are also included in the Opinion.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
267.		Response 1		In addition it could be stated that it is not sufficient to give specific information. Due to the fact that no threshold levels of UV-irradiance and UV-dose for the carcinogenic effect of UV radiation exist, the limit value of the erythemal irradiation in sunbeds should be dropped down to 0.0 W/m2.	No change in the text is needed because the erythema is a deterministic effect while cancer is a stochastic one.
268.	Lipman Gary, The Sunbed Association, garylipman.tsa@gmail.com, United Kingdom	Response 1	 Vit_D_Synthesis_in_relation_to_latitude__	Page 60, lines 27-30 Exposing the face and hands a few minutes to half an hour, as stated omits the fact that this calculation is based upon daily exposure all year round. In Northern Europe it is not possible for the body to synthesise Vitamin D between October and May. Page 60, lines 31-33 It is accepted by the SCENIHR that it is excessive or over exposure to UV that causes health concerns, not exposure per se. It is therefore disingenuous to state that UV light (UVA as well as UVB) has an immunosuppressive effect on the skin and also a systemic immunosuppressive effect. Context is important when statements like these are made. In so far as photo aging, this is a cosmetic issue and not a health concern and therefore, in my Opinion, outside the remit of the SCENIHR. Nevertheless, it is clear that it is accepted that it is excessive or chronic exposure that can lead to health concerns, not exposure per se.	The text on UV for vitamin D has been amended. The UV-A dose for immunosuppression is clearly described in the Opinion. The SCHEER sees this as a biological effect of UV, which is a very gradual process, accelerated by high exposure.
269.	Baldermann Cornelia, German Federal Office for Radiation Protection, cbaldermann@bfs.de, Germany	Response 2		§ 8- Opinion, p61, lines 12-16 – Question 2 Comment: We propose that some elements discussed in the abstract or the main report may be added in the response: From the Abstract, Overall conclusion: "The SCENIHR concludes that UV is a complete carcinogen, both an initiator, and a promoter. There is strong evidence that sunbed exposure causes skin melanoma, squamous cell carcinoma and, to a lesser extent, basal cell carcinoma, more especially when first exposure takes place in younger ages. There is moderate	No changes in the Opinion are needed.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
				evidence that sunbed exposure may also cause ocular melanoma. Sunbed use is responsible for a noticeable proportion of both melanoma and non-melanoma skin cancers and for a large fraction of melanomas arising before the age of 30." Because of evidence of the carcinogenic effects of artificial UV exposure and of the nature of skin cancer induction, we agree that there is no safe limit for UV irradiance from UV lamps, especially sunbeds. So, no threshold levels of UV-irradiance and UV–dose can be specified for the protection of the health and the safety of users. "The UV emission of a modern tanning appliance corresponds to an UV index of 12, i.e. equivalent to midday tropical sun." (cf. § 6.2 UV exposure from sunbeds –trends in UV irradiance, page 26). In this case, the level of protection is not sufficient to ensure the health and safety of users. By setting sunbeds to a high UV index (usually 12 equivalent to midday tropical sun), it is expected to reach maximal UV damage. Unlike sun exposure, indoor tanning provides concentrated UV exposure regardless of geographical location, time of year, or time of day. Indoor tanning also exposes areas of the body not normally exposed to intense UV radiation, further increasing risk. Indoor tanning should therefore be completely avoided. Prevention messages should aim to that goal in addition to those used to reduce sun exposure.	
270.	Lipman Gary, The Sunbed Association, garylipman.tsa@gmail.com, United Kingdom	Response 2		Page 61, lines 12-16: The SCENIHR have failed to demonstrate that sunbeds per se are carcinogenic. Like most things, it is excessive or chronic over exposure to UV in general that causes health concerns. To state 'no limit can ensure protection for the health and safety of users' is myopic to the point of blindness. It is an accepted fact that too little exposure to UV is as unhelpful to good health as is chronic over exposure. A balance needs to be found.	The studies discussed in the Opinion show the carcinogenicity of exposure to UV through the use of sunbeds. The SCHEER acknowledges that excessive outdoor UV exposure is a public health concern.

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				The SCEHIHR Opinion calls out for appropriate training for salon staff. From December 2015 salon staff across Europe can now receive accredited Professional indoor UV exposure services training to the EN16489 Standard. When a client visits a professional tanning salon with well trained, informed staff, their skin type will be assessed and their suitability will be examined. Those from vulnerable groups, such as those with sensitive skin will be screened out. An appropriate session time will be provided to the screened client to help ensure that they do not exceed the recommended dosage. Client details will be registered and usage will be recorded to prevent excessive use. For those who desire to sunbathe, a professional tanning salon with well trained staff is infinitely safer than sunbathing in sunshine on the beach.	This risk management issue is outside the scope of the mandate.
271.	Lipman Gary, The Sunbed Association, garylipman.tsa@gmail.com, United Kingdom	Response 2	 EN16489-1_EN.pdf	To this answer it could be added that due to the fact that no threshold levels of UV-irradiance and UV-dose for the carcinogenic effect of UV radiation exist, the wavelength range for which the total erythemal irradiance should be negligible to minimize the risks of developing skin cancer due to the use of sunbeds should be 100 nm to 400 nm.	No change in the text is needed because the erythema is a deterministic effect while cancer is a stochastic one.
272.	Baldermann Cornelia, German Federal Office for Radiation Protection, cbaldermann@bfs.de, Germany	Response 3		§ 8- Opinion, p61, lines 23-29 – Question 3 Comment: The authors discussed the minimal irradiance and wavelength mostly in terms of UVC radiation. The latter wavelength range may not be the most relevant. UVC is readily absorbed by the DNA of cultured cells and induces numerous damage and mutations. However, the situation is different in full skin. Indeed, the stratum cornea absorbs most of the UVC which reaches the nucleated cells of the epidermis only in minute amount. The minimal wavelengths to consider are more likely the most energetic UVB.	The text on UVC was amended.

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273.	ANSES	Response 3		§ 8- Opinion, p61, lines 31-32 – Question 3 Comment: All wavelength of UV are dangerous. Ultraviolet radiations (bandwidth 100–400 nm, encompassing UVC, UVB and UVA) are carcinogenic to humans according to the IARC. UV radiations are a complete carcinogen, both an initiator, and a promoter. So, there is no safe limit for UV irradiance from UV lamps.	The SCHEER agrees with the comment. No change in the Opinion is needed.
274.	Lipman Gary, The Sunbed Association, garylipman.tsa@gmail.com, United Kingdom	Response 3		Page 61, lines 21-23: The mission for SCENIHR was to look at new scientific evidence after the SCCP report on sunbeds from 2006. Most studies refered to by SCENIHR are either irrelevant, because not applicable for Europe, or outdated as original studies are mostly older than 2006. In addition, the title of the SCENIHR report is with reference to sunbed use for cosmetic purposes. Many of the reports referenced in the Draft Opinion included data from sources other than professional sunbeds, which should preclude their inclusion in this report. This report has failed to provide any new evidence that would allow the conclusion that there is no safe limit for sunbed use. Indeed, the 0.7 W/m2 irradiation limit as suggested for in the draft report by the reputable SCCP working group in 2006 still stands unchallenged. SCCP at the time changed to 0.3 W/m2 in the final report so to be on the very safe side, also because of heavy criticism by cancer leagues, but without providing any scientific reason for lowering the limit in the final report.	The SCHEER disagrees with the comments. All new studies published after 2006 have been considered and the relevant ones for the scope of the mandate have been included. There is new evidence provided about DNA damage by UVA which is a stochastic effect. No limit value of either irradiance or dose (irradiance x time of exposure) can be given.

No.	Name of individual/organisation	Table of content to which comment refers	Reference provided	Submission	Committee's Comment
275.	Lipman Gary, The Sunbed Association, garylipman.tsa@gmail.com, United Kingdom	Response 3	 Grant-IARC-sunbed-epub.pdf  Papas__Grant_summary_of_IARC_report_		Grant's critique is mentioned in the text.

Results of the public consultation on the preliminary opinion on biological effects of ultraviolet radiation relevant to health with particular reference to sunbeds for cosmetic purposes

Contributions received through email (276-284)

No.	Name of individual/organisation	Comment	SCENIHR Response
276.	Alexander Wunsch	 9C1C1104-C3FD-4F7D-9D7D-8886EA26D0  sunbeds_96141513-ac04-421f-969a-8b7f	Please see the response to comment 13, above.
277.	ANSES	 2016-03-20_Consultation Scenihr.doc	Please see the responses to comments 8-11, 30, 51-53, 111, 166-169, and 187 above.
278.	Dutch Sunbed Association, Samenwerking Verantwoord Zonnen (SVZ)	 Comment on the draft opinion SVZ 27-(	The terms of reference constitute the mandate that SCHEER received from the European Commission. As to your question about the effectiveness of implementing specific measures, the SCHEER cannot comment because these are pertinent to risk management, which is outside of the remit of SCHEER which should perform risk assessment.
279.	Holick, Michael F	 Holick SCENIHR Letter 042716.pdf	 Response_to_M_F_Holick.docx

280.	Joint Canadian Tanning Association	 List of research papers and reference	The SCHEER acknowledges the receipt of the list of publications. It has examined all of them, but has considered in the final document only those which originated from the peer-reviewed literature and were pertinent to the mandate (see SCENIHR Memorandum on weight of evidence).
281.	American Suntanning Association		It is reminded here that: 1. A full discussion on the association between outdoor sunlight exposure (which is different from exposure from sunbeds), latitude and various health parameters (including vitamin D and other health effects) is complex and outside the scope of the mandate, which is on exposure to sunbeds per se. 2. The Opinion reviews all documented effects from the exposure to sunbeds per se. 3. The treatment of medical conditions is outside the scope of the mandate.
282.	Laurent & Laurent AB	 Scenihr Comments on public hearing on s	 Response_to_R_Laurent.xlsx

283.	Sunday's Nederland BV	 Sundays for Luxemburg 2016.04.:  Rob Bontje comments .msg Page 5, line 19 A very subjective line about a widespread consensus. In The Netherlands there's a widespread consensus that we have too little sun to get sufficient vitamin D. The sunbed, if used properly is a good alternative. Sunday's has many doctors among the clients that tan for vitamin D. Once again, also a widespread consensus among our customers. Page 32, line 10 Please find attached page 5. After 5 tanning sessions people with very low vitamin D levels doubled it! S5, S9, S23, S28, S30 and S31 were all persons with a big deficit. They tanned on an 0,3 sunbed for less than 20 minutes. This cannot be harmful.	It should be noted that tanning practice and the measures for it are not in the remit of the SCHEER, because being a risk management issue. The text of the Opinion has been amended. Treatment of medical conditions is outside the scope of the mandate. Research not published in peer-reviewed literature cannot be considered by the SCHEER.
284.	Prof. Dr. med. J. Reichrath	 Jör-SCENIHR-comments-27-4.doc	 Response_to_Reichrath_and_Vogt.docx