



Results of the public consultation on SCHEER's preliminary Opinion on Biological effects of UVC radiation relevant to health with particular reference to UVC lamps

A public consultation on this opinion was opened on the website of the scientific committees from 29 July to 30 September 2016. Information about the public consultation was broadly communicated to national authorities, international organisations and other stakeholders.

Eleven contributors (in total 51 contributions and 140 comments) participated in the public consultation providing input to different parts of the Opinion. Among the organisations participating in the consultation, there were universities, institutes of public health, NGOs and public authorities.

Each submission was carefully considered by the SCHEER and the Opinion has been revised to take account of relevant comments. The literature has been accordingly updated with relevant publications.

The SCHEER expresses its thanks to all contributors for their comments and for the literature references provided during the public consultation.

The table below shows all comments received on different chapters of the Opinion and the SCHEER 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 SCHEER preliminary Opinion on
"Biological effects of UVC radiation relevant to health with particular reference to UVC lamps"**

No.	Name of individual/organisation	Table of content to which comment refers	Submission	Reference provided	Reply
1.	Public Health England, marina.khazova@phe.gov.uk, United Kingdom	1.1.4 Regulations and standards for workers	<p>p 4, line 3. Spectrum is missing after (UVR): should read .(UVR) spectrum</p> <p>p4, 28-29. Incorrect interpretation of legal requirements for protection of workers. Exposure of workers is controlled by the EU Directive 2006/25/EC which has been implemented into national legislation of all EU member states. This Directive lays down the minimum safety requirements regarding the exposure to risks arising from artificial optical radiation, including UV-C. It places a responsibility on employers to assess exposure levels, adopt preventative measures and arrange for the provision of information and training for their workers. The Directive gives priority to reducing risks at source, through preventative measures related to work equipment design, procedure and methods</p> <p>p4, 30. Replace intendedly with intentionally</p> <p>p4, 39. It is operation not condition: should read ...UVR exposure of the user in normal operation</p> <p>p5, 2-3. The International Commission on Illumination in 2010 completed a review of UV-C photocarcinogenesis risks from germicidal lamps (CIE 187). It is not clear why this important review is not included</p> <p>p9, 10. Suggest to add sources that emit to the text for clarity: ...use of sources that emit UV-C radiation...</p> <p>p9, 9-13. Text should be amended to include reference to the Directive 2006/25/EC (Artificial Optical Radiation Directive) which places a duty on employers to assess exposure levels and gives priority to reducing risks at source, through preventative measures related to work equipment design, procedures and provision of personal protective equipment</p> <p>p9, 18. Incorrect reference. Insect control systems (referred as "bug zappers") are UV-A sources, not UV-C</p> <p>p9, 31-33. Reference to the authoritative source of scientific background should not be to information on web-sites of equipment manufacturers but to internationally recognised and peer-reviewed documents such as ICNIRP Guidelines on limits of exposure to</p>		<p>The text was amended.</p> <p>The text was amended.</p> <p>No change is required.</p> <p>The text was amended.</p> <p>The reference list was updated.</p> <p>The text was amended.</p> <p>The text was amended.</p> <p>The text was amended.</p> <p>The text was amended.</p>

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			<p>ultraviolet radiation of wavelengths between 180 nm and 400 nm.</p> <p>p9, 34-37. Incorrect interpretation. Exposure to the UV-C in all incidents referred in this paragraph happened due to the fittings of wrong lamps (UV-C instead of UV-A), not because of inadequate information which should prevent the risk of overexposure. The following paragraph (lines 39-40 on p9 and lines 1-4 on p10) implicitly identified this problem</p> <p>p9, 39-40. It is not clear what is the relevance of reference to the lamps with higher than 55W rated power</p> <p>p10, 5. Incorrect reference. Insect killers incorporate UV-A sources, not UV-C</p> <p>p10, 32-34. Repetition of lines 26-27</p> <p>p10, l 36-37. Exposure of the workers is controlled by the EU Directive 2006/25/EC which has been implemented into the national legislation of all EU member states.</p> <p>p10, 37 and footnote 9. Correct reference is ISO 15858:2016</p> <p>p11, 8-15. Incorrect interpretation. Exposure of the workers is controlled by the EU Directive 2006/25/EC which has been implemented into the national legislation of all EU member states. This Directive includes exposure limits for the full range of optical radiation, i.e. 180 nm to 3 microns; exposure limits are based on ICNIRP Guidelines. Lines 19-22 refer to Directive 2006/25/EC: it is not clear why priority is given to the ISO standard</p> <p>p11, 13. Correct reference is ISO 15858:2016</p> <p>p11, Fig 1. This figure is based on continuous exposure at constant level and could be misleading. Time-weighted averaging is an important concept in risk assessment and is not represented here (for example a high irradiance for a long exposure duration). The limit is expressed in terms of the radiant exposure over 8 hours</p> <p>p13, footnote 15. Misleading interpretation. Exposure to the UV-C in these incidents happened due to installing incorrect lamps (UV-C instead of UV-A)</p>		<p>The text was amended.</p> <p>No change is required.</p> <p>The text was amended.</p> <p>The text was amended.</p> <p>The text was amended.</p> <p>The footnote was deleted.</p> <p>The text was amended.</p> <p>The text was amended.</p> <p>The figure caption was amended.</p> <p>The text was amended.</p>
2.	Sjømoen, Tone-Mette, Norwegian Radiation Protection Authority, nrpa@nrpa.no, Other, Norway	1.1.4 Regulations and standards for workers	<p>This is a comment to section 1.1.3, but it was not possible to select 1.1.3 in the table of contents:</p> <p>The European standard EN 62471, Photobiological safety of lamps and lamp systems provides e.g. definitions, rules for measurement and safety classifications for all</p>		The text was amended.

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			incoherent sources of optical radiation. The standard should be mentioned in Section 1.1.3 and its contents should be taken into account in the whole text of the opinion.		
3.	Sjømoen, Tone-Mette, Norwegian Radiation Protection Authority, nrpa@nrpa.no, Other, Norway	1.1.4 Regulations and standards for workers	<p>Comment to page 11, line 11: Not stated that the radiant exposure (and other terms) is un-weighted. The irradiance values presented in fig. 1 is claimed to be "effective", but seem to be un-weighted. Tentative explanation: value at 1 s is 60000 mW/m², or 60 J/ m², which can be assumed to be similar to the limit value from ICNIRP with a $s(\lambda)$ equal to 0.5 at 254 nm.</p> <p>Proposed change: Make it clear, also in the text of Fig. 1 for irradiance, if the radiant exposure is weighted (i.e. if the intended meaning is Ultraviolet hazard radiant exposure, as defined in EN 14255 part 1 and 4) and provide information on the weighting function applied. The same comment applies to weighted irradiance (or the expression effective irradiance which is also used in the opinion).</p>		The figure caption was amended.
4.	Sjømoen, Tone-Mette, Norwegian Radiation Protection Authority, nrpa@nrpa.no, Other, Norway	1.1.4 Regulations and standards for workers	<p>Comment to page 12, line 3: ICNIRP limit values are also determined for the unprotected skin. Proposed change in line 3: ...protection of skin and eyes are...</p> <p>Comment to page 12, line 5: $S(\lambda)$ should be defined. Use multiplication symbol in the equation.</p>		<p>The text was amended.</p> <p>The text was amended.</p>
5.	Dr. Udovicic, Ljiljana, Federal Institute for Occupational Safety and Health (BAuA) udovicic.ljiljana@baua.bund.de, Germany	1.1.4 Regulations and standards for workers	<p>Page 4, lines 27-29</p> <p>Page 10, lines 36-37</p> <p>Page 11, lines 7-11</p> <p>Page 24, lines 22-25</p>	 Exposure_Limit_Vi es.pdf	<p>The text was amended.</p> <p>The text was amended.</p>
6.	Dr. Udovicic, Ljiljana, Federal Institute for Occupational Safety and Health udovicic.ljiljana@baua.bund.de, Germany	1.1.4 Regulations and standards for workers	<p>Page 5, lines 43-46</p> <p>(this chapter cannot be selected)</p>	<p>Thresholds.pdf</p>  Thresholds.pdf	The text was amended for clarity.
7.	Dr. Udovicic, Ljiljana, Federal Institute for Occupational Safety and Health udovicic.ljiljana@baua.bund.de, Germany	1.1.4 Regulations and standards for workers	Additional information	<p>AKNIR_Statement.pdf</p>  AKNIR_Statement.p df	The text was amended accordingly.

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8.	O'Hagan, John, International Commission on Illumination, joh.hpa@btinternet.com, Austria,	1.1.4 Regulations and standards for workers	<p>8 - Suggest that a hyphen should be used in UV-A, UV-B and UV-C and used in both the ISO standard on terminology and the CIE International Lighting Vocabulary.</p> <p>11 - It is important to recognise that the limits for exposure to ultraviolet radiation are time-weighted averages to ensure that the spectrally-weighted (where appropriate) radiant exposure limit is not exceeded for an 8-hour day.</p> <p>1.2 - it is not clear that questions 2 and 3 are answered in the opinion.</p>		<p>The text was changed accordingly.</p> <p>This is already mentioned in the text. No change is required.</p> <p>The questions are answered in the Opinion section.</p>
9.	Ivanova, Mihaela, National Center of Public Health and Analyses	1.1.4 Regulations and standards for workers	Directive 2006/25/EC considered in the text is not mentioned in the abstract - legal background. It could be concluded that there are only standards in this field and The Directive on General Products safety and Low Voltage Directive.		The text was amended.
10.	Public Health England, marina.khazova@phe.gov.uk, United Kingdom,	2. METHODOLOGY	<p>General comments.</p> <p>It is not clear that questions 2 and 3 have been addressed in the Opinion.</p> <p>It is suggested that the International Commission for Illumination and International Organization for Standardization notation for the UV bands, i.e. UV-A, UV-B and UV-C, should be used throughout the opinion.</p> <p>PHE supports the position that UV-C is possibly detrimental to human health. While it is true that there are limited data on UV-C exposure in humans, there has been a great deal of investigation into the biological effects of UV-C on cells and animals. It is surprising that the authors appear to be unaware of it, referring to information on web-sites of equipment manufacturers for authoritative sources of scientific background rather than peer-reviewed literature. It is not clear why greater reference has not been made to the ICNIRP Guidelines on limits of exposure to ultraviolet radiation of wavelengths between 180 nm and 400 nm, published in 2004, which includes spectral weighting functions for UV-C in addition to the exposure limits in this spectral range.</p> <p>The authors describe case studies of accidental exposures, but apart from interesting anecdotes which highlight failures in risk assessment, they appear to be descriptions, without synthesis and conclusions. Interpretation of the legal framework on protection of protection of workers from overexposure to the UV-C is incorrect. It is outlined using compliance with product standards, including prEN documents, rather than the requirements of European Union Directive 2006/25/EC on the minimum health and safety requirements regarding the exposure of workers to risks arising from physical agents (Artificial Optical Radiation) implemented in national legislation by all EU Member states.</p> <p>The structure of the draft report is not concise and suffers from unnecessary repetition.</p>		<p>The questions are answered in the Opinion section.</p> <p>The text was amended.</p> <p>The sources of literature reviewed in the document are clearly stated.</p> <p>The text has been amended and the Directive 2006/25/EC is appropriately cited.</p> <p>The aim of each</p>

No.	Name of individual/organisation	Table of content to which comment refers	Submission	Reference provided	Reply
			<p>The same case-reports are repeated in Sections 4 and 5: these sections should be combined to avoid unnecessary repetition.</p> <p>Information given in Section 3.2 is widely available, excessive and often over-simplistic; its relevance to the health effects of UV-C is unclear.</p> <p>The International Commission on Illumination (CIE) published a review of UV-C photocarcinogenesis risks from germicidal lamps in 2010 (CIE 187). No reference is made to this important review.</p> <p>Many of the adverse health effects discussed in the opinion are not specific to UV-C and may be attributable to UV generally. Where that is the case, it is important that the text is clear.</p> <p>A number of the incidents related to exposure of people to UV-C are due to incorrect lamps being fitted into equipment, such as electrical insect killers. One key contribution to reducing the risk of such incidents in the future would be for product standards to require different fittings for UV-C (germicidal) lamps compared with other lamps. A strong recommendation from SCHEER could help to achieve this objective.</p>		<p>section is clear and different from each other. No change in the text is required.</p> <p>No change in the text is required.</p> <p>The reference list was updated.</p> <p>In these cases the text clearly refers to UVR instead of UV-C.</p> <p>The SCHEER agrees that this was indeed the case and this is clearly indicated in the text. The text was amended.</p>
11.	Public Health England, marina.khazova@phe.gov.uk, United Kingdom,	3. DEFINITION AND USE OF UVC DEVICES	<p>p15, lines 8-12. This description does not include emission from lasers and LEDs and mis-interprets emission of low pressure lamps (such as the majority of UV-C lamps).</p> <p>p15, Table 1. Incorrect spectral range of visible light: it should be 780 – 380 nm or 3.8.10¹⁴ – 7.5.10¹⁴ Hz, which correctly overlaps with UV-A.</p> <p>p.15, lines 21-22. It is not clear why an ISO standard (given without complete reference) is used instead of CIE International Lighting Vocabulary.</p> <p>p16, line 2. Sunlight is also scattered by the atmosphere; the shorter the wavelength of the UV radiation the more it scatters. Amend to: Sunlight is absorbed and scattered....</p> <p>p16, line 11. Pure mercury is not solid at room temperature. Delete solid</p> <p>p16, line 26. Replace hazard with risk</p> <p>p16, line 28. Replace their with the. Lines 28 and 32. Lamp envelope is not glass, it is quartz or fused silica.</p>		<p>The text was amended.</p> <p>The table is correct. See comment 17 below. No changes in the text are required.</p> <p>No changes in the text are required.</p> <p>No change in the text is required.</p> <p>The text was amended.</p> <p>No change in the text is required.</p> <p>The text was amended.</p>

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			<p>p17, line 2. Although it may be, in some cases, appropriate to refer to commercial product information, trade web-sites cannot be considered as a source of authoritative scientific reference material.</p> <p>p17, lines 4-9. It is unclear what the relevance of this information is to the health effects of UV-C.</p> <p>p18, line 1. They are not necessarily cheap and/or environmentally friendly.</p> <p>p18, line 2. 40% of what?</p> <p>p18, line 23. Use of punctuation. Amend as follows:.... of the user in normal operation; and for the other applications, the radiation is</p>		<p>No change in the text is required.</p> <p>It is relevant to lamp maintenance. No change in the text is required.</p> <p>The text was amended.</p> <p>The text was amended.</p> <p>No change in the text is needed.</p>
12.	Halbritter, Werner, OSRAM GmbH, w.halbritter@osram.com, Germany,	3. DEFINITION AND USE OF UVC DEVICES	<p>There is a general mismatch between the headline of the chapter and the sub-titles.</p> <p>In general, on component level (lamps, LED) the industry is very well regulated by standards.</p> <p>We do not see any action field for Lamps or LED.</p> <p>Regulatory is needed for UVC Devices (Fixtures, Apparatus, wherein UVC Lamps or LED are used).</p> <p>Today, such fixtures has to be design under general lighting standards. As the purpose of these standards (general illumination) is far away from most product purposes, a unique standard should be created for UVC devices. We recommend to define Device classes for several Applications.</p>		<p>No change in the text is required. Recommendations for risk management are outside the remit of SCHEER.</p>
13.	Asmuss, Monika, Federal Office for Radiation Protection masmuss@bfs.de, Germany,	3.1 Definition of UVR and physical properties	<p>p 16 line 6</p> <p>Add to last sentence: "The amount and spectrum of UV Radiation that reaches the Earth ´s surface varies widely around the globe and varies with altitude, season, time of day, atmospheric ozone and cloudiness.</p>		<p>The text was amended.</p>
14.	Asmuss, Monika, Federal Office for Radiation protection, masmuss@bfs.de, Germany,	3.1 Definition of UVR and physical properties	<p>p 16 line 6</p> <p>Add to last sentence: "... time of day, atmospheric ozone and cloudiness."</p>		<p>The text was amended.</p>
15.	Sjømoen, Tone-Mette, Norwegian Radiation Protection Authority, nrpa@nrpa.no, Other, Norway	3.1 Definition of UVR and physical properties	<p>Comment to the table on page 15, line 14:</p> <p>Light is an expression of visible radiation. Proposed change: Use the term "Infrared radiation" in the first column.</p>		<p>The table was amended.</p>

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			Write "Wavelength (nanometers, nm)" on the top of the second column. Use multiplication symbol in front of the power of 10 in the frequency column.		
16.	Ivanova, Mihaela, National Center of Public Health and Analyses (Team of Prof. Michel Israel, PhD), Mihaela_1970@abv.bg, Bulgaria,	3.1 Definition of UVR and physical properties	line 8 The word "intensity" should be removed, because as it is written the definition of "spectrum" is not correct.		The text was amended.
17.	O'Hagan, John, International Commission on Illumination, joh.hpa@btinternet.com, Austria,	3.1 Definition of UVR and physical properties	Table 1 - The CIE definition for visible light extends down to 380 nm; i.e. there is overlap of visible and UV in the wavelength range 380 to 400 nm.		No change in the text is required.
18.	Sjømoen, Tone-Mette, Norwegian Radiation Protection Authority, nrpa@nrpa.no, Other, Norway	3.2.2 Excimer technology	Editorial comment to page 17, line 28: Use Space character between 222nm and between 282nm. Editorial comment to page 17, line 37: Use comma character after gallium phosphide (GaP),		The text was amended.
19.	Sjømoen, Tone-Mette, Norwegian Radiation Protection Authority, nrpa@nrpa.no, Other, Norway	3.2.3 UVC Light emitting diodes (UVC-LEDs)	Editorial comment to page 17, line 37: Comma character is missing after gallium phosphide (GaP),		The text was amended.
20.	Asmuss, Monika, Federal Office for Radiation Protection masmuss@bfs.de, Hungary,	3.3 UVC lamp applications	The preliminary opinion concentrates on the use of UVC emitting lamps for the purposes of water disinfection, air disinfection and insect killers. The surface disinfection is only marginally mentioned and an example of a volunteer study is given in section 5.1.2. But: The so called "disinfection wands" for surface disinfection are broadly advertised via Internet as hand held consumer products. The distance to skin and eyes by hand held consumer products is much shorter than to UVC lamps that are fixed at the ceiling. In most cases, it is unclear, to what extent and how the user is protected against the emitted UV-radiation. Moreover it is also unclear if these UVC sources are childproof or not. As far as I know, no specific standard exists for this kind of UVC-emitting lamps. (At least in Germany, DIN EN ISO 15858:2014-09 exists only as draft). I suggest to add more weight on this type of application. p 19, line 3 add: "So called disinfection wands are broadly advertised via Internet as Hand Held consumer products for the disinfection of surfaces, for instance toilet seats, clothes or computer keyboards". And in 1.1.3, p 10, line 34 "For some areas of application, e.g. for so called disinfection wands, used for the disinfection of surface areas, no applicable product standard exists up to now."		The text was amended.

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21.	No agreement to disclose personal data	3.3 UVC lamp applications	Surface Disinfection is missing as general Application field. Surface Disinfection (in Food and Beverage Sector) means the Disinfection of Packaging, transport systems, tools and not only the irradiation of foods. It is also used in hospitals as a very effective way to fight MRSA directly. As it is permitted to irradiate food in general we recommend to work on this path, as we see very positive impacts abroad, by using UVC.		The text was amended to include this application. This is outside the scope of the SCHEER.
22.	No agreement to disclose personal data	3.3 UVC lamp applications	Also there is a trend to nail curing with UVC. The necessity of standards, wherein maximum dose and intensity is defined, should be investigated. Same for other home appliance products, like vacuum cleaner with UVC, or smartphone disinfection units.		No changes in the Opinion are required because the literature does not refer to UVC.
23.	Sjømoen, Tone-Mette, Norwegian Radiation Protection Authority, nrpa@nrpa.no, Other, Norway	3.3 UVC lamp applications	Editorial comment to page 18, line 36: Space character is missing afterlaboratories, Editorial comment to page 18, line 37: Comma character is missing after chromatography (TLC),		The text was amended.
24.	MIRKOVA, EKATERINA, National Center of Public Health Protection, Sofia, Bulgaria - Associate Professor of Toxicology, Senior Research Scientist (until 2011); Independent Scientific Expert (Toxicology, Scientific Human Health Risk Assessment), EU Risk Assessment Advisory Structure of Scientific Committees and Experts European Commission / DG EMPL / SCOEL Member (2009 - 2015); European Commission / DG (SANCO) SANTE / EFSA / ERWG Member (2009-2016); European Commission / DG SANTE / SCCS External Expert (2015-2016); Reserve List:	3.3 UVC lamp applications	3.1 - paragraphs 5-7, page 15; p.p. 2-6, page 16 3.3 - page 18 6., 61, 6.1.1- paragraphs 6-21, page 29; pp 1-3. 11-34, page 30, pp 1-13 page 31	 Mirkova_Comments_SCHEER_Preliminary_  __rkova_Comments_SCHEER_Preliminary_  __rkova_Comments_SCHEER_Preliminary_	No change in the text is required. The secretariat contacted the contributor asking to submit those docs that

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	2016-2021 term of office., e.mirkova@gmail.com, Bulgaria			could not be opened, but no answer was received by the time of the publication of this document.	
25.	Public Health England, marina.khazova@phe.gov.uk, United Kingdom	3.4 UV lamps maintenance	This excessive description does not provide a link to the increased/decreased risk of human exposure to UV-C. Furthermore, lines 18-38 suggest a decrease of accessible emission while lines 10-17 refer to the mercury release due to the cracks in lamp envelope but not to an increase of emission leakage.		The section is given to stress the reason for regular maintenance which can result in potential exposure to UV-C. No change in the text is required.
26.	Sjømoen, Tone-Mette, Norwegian Radiation Protection Authority, nrpa@nrpa.no, Other, Norway	3.4 UV lamps maintenance	Comment to page 19, line 31 and 34: Use UV radiation instead of UV light.		The text was amended.
27.	Public Health England, marina.khazova@phe.gov.uk, United Kingdom	4. EXPOSURE	p20, lines 3-7. Reference should be given to ICNIRP guidelines and Exposure Emission Limits (ELVs) should be used instead of MPE. UV-A ELVs are irrelevant to the subject of this document. Text on lines 4-5 is misleading and should be changed to: radiant exposure is expressed in joules per square meter and spectrally weighted with S(l). Exposure limits of Directive 2006/25/EC are applicable only to workers, not the general public. Sections 4.1 and 4.2 are repetition of the same case studies presented in Section 5. p20, line 24. Delete eventual p20, lines 41-46 and p21, lines 1-6. This case study of 1991 describes incorrectly fitted UV-C and non-standard lamps into equipment designed for UV-A sources. p21, lines 8-10. This case study also describes exposure from UV-A equipment with wrongly fitted UV-C lamps. Do measurements done by a particular instrument have an impact on a risk of exposure? It is unclear the relevance of irradiance in 200-600 nm for the assessment of UV-C exposure. Presented irradiance level is only relevant to a risk in combination with exposure duration; 8h exposure at 30 cm is extremely unlikely. Why erythema weighted UV-C irradiance is compared with the southern European summer sun which doesn't contain UV-C at all?		The text was amended. However, these case studies are presented from a different point of view. No change in the text is required. The text was amended. No change in the text is required. The text cites the exposure reported. No change in the text is required. The typos were

No.	Name of individual/organisation	Table of content to which comment refers	Submission	Reference provided	Reply
			<p>p21, lines 19, 25, 29 and 30. W/m2 should be Wm-2</p> <p>p22, line 1. Incorrect interpretation of occupational exposure limits. UV ELVs are given for radiant exposure, i.e. product of irradiance and exposure duration; limiting irradiance is only relevant to the continuous 8h exposure at constant irradiance level.</p> <p>p22, line 3. Statement "rather high" is subjective and ambiguous.</p>		<p>corrected.</p> <p>Exceedance of the ELV is separately mentioned. No change in the text is required.</p> <p>The text was amended.</p>
28.	Halbritter, Werner, OSRAM GmbH, w.Halbritter@osram.com, Germany	4. EXPOSURE	<p>Surface Disinfection is missing as general Application field. Surface Disinfection (in Food and Beverage Sector) means the Disinfection of Packaging, transport systems, tools and not only the irradiation of foods. It is also used in hospitals as a very effective way to fight MRSA directly.</p> <p>As it is permitted to irradiate food in general we recommend to work on this path, as we see very positive impacts abroad, by using UVC.</p> <p>Also there is a trend to nail curing with UVC. The necessity of standards, wherein maximum dose and intensity is defined, should be investigated. Same for other home appliance products, like vacuum cleaner with UVC, or smartphone disinfection units.</p>		<p>The text was amended to mention this application. Risk management measures are not in the remit of SCHEER.</p>
29.	Dr. Udovicic, Ljiljana, Federal Institute for Occupational Safety and Health udovicic.ljiljana@baua.bund.de	4. EXPOSURE	Page 20, lines 3-6	 ELV_and_MPE.p	The text was amended.
30.	O'Hagan, John, International Commission on Illumination, joh.hpa@btinternet.com, Austria	4. EXPOSURE	Many of the sources of exposure are due to inappropriate actions during maintenance - for example fitting incorrect (germicidal) lamps in devices designed to use UV-A lamps. Suggest that this should be clearer in this chapter.		The text is clear on this issue. No change is required.
31.	Halbritter, Werner, OSRAM GmbH, w.halbritter@osram.com, Germany	4.1 WATER DISINFECTION	<p>Strong regulated in DVGW / ÖVGW and other national standards worldwide.</p> <p>1 European standard appreciated.</p>		The section is about exposure quantification for risk assessment and not risk management. No change in the text is required.
32.	No agreement to disclose personal data	4.2 AIR DISINFECTION AND INSECT KILLERS	There is no connection between Air Disinfection and Insect Traps. Insect Traps are using blue light, in some cases near UVA light to attract insects. UVC Air Disinfection is based on inactivation of bacteria, spores and viruses by radiation.		Their connection is that the lamps radiate to the environment and not

No.	Name of individual/organisation	Table of content to which comment refers	Submission	Reference provided	Reply
			<p>Missing standards on:</p> <ul style="list-style-type: none"> - Measuring procedure on UVC leaks - Research and standards on minimum Intensity values needed (mainly only Dose defined) - In case of cracking material by UVC => check on fine dust exploration - Emission of Ozone (NOx + UV => O3) 		<p>to a closed system. The aetiology of exposure to UV-C from insect traps is clearly mentioned. The section is about exposure quantification for risk assessment and not risk management. No change in the text is required.</p>
33.	Halbritter, Werner, OSRAM GmbH, w.halbritter@osram.com, Germany	4.2 AIR DISINFECTION AND INSECT KILLERS	<p>There is no connection between Air Disinfection and Insect Traps. Insect Traps are using blue light, in some cases near UVA light to attract insects. UVC Air Disinfection is based on inactivation of bacteria, spores and viruses by radiation.</p> <p>Missing standards on:</p> <ul style="list-style-type: none"> - Measuring procedure on UVC leaks - Research and standards on minimum Intensity values needed (mainly only Dose defined) - In case of cracking material by UVC => check on fine dust exploration - Emission of Ozone (NOx + UV => O3) 		<p>Their connection is that the lamps radiate to the environment and not to a closed system. The aetiology of exposure to UV-C from insect traps is clearly mentioned. The section is about exposure quantification for risk assessment and not risk management. No change in the text is required.</p>
34.	Sjømoen, Tone-Mette, Norwegian Radiation Protection Authority, nrpa@nrpa.no, Other, Norway	4.2 AIR DISINFECTION AND INSECT KILLERS	<p>Editorial comments to page 21:</p> <p>Line 2: Comma character missing after Forsythe in ref.</p> <p>Several places on the page: "2" is not written in superscript in W/m² and J/m².</p> <p>Between line 21 and 22: Put in open line.</p>		<p>The text was amended.</p>
35.	Ivanova, Mihaela, National Center of Public Health and Analyses (Team of Prof. Michel Israel), Mihaela_1970@abv.bg, Bulgaria	4.2 AIR DISINFECTION AND INSECT KILLERS	<p>There are cases of bactericidal lamps for air disinfection which are placed in housing (barred cover) with forced ventilation system (or natural ventilation) where the proper mounting (orientation of the barred cover) could help to avoid the exposure to personnel. May be this type of air disinfection sources should be mentioned in the text.</p> <p>Electromagnetic Fields in Biology and Medicine, Chapter 20</p> <p>edited by Marko S. Markov, CRC Press Taylor&Francis Group, International Standard</p>		<p>Exposure assessment in the provided reference is not explained sufficiently to be included. No change in the text is required.</p>

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36.	Public Health England, marina.khazova@phe.gov.uk, United Kingdom	5. HUMAN HEALTH EFFECTS	<p>Book Number-13:978-1-4822-4851-7</p> <p>p23, lines 5 and 6. Incorrect numbers: more 365 nm than 297 nm penetrates to the viable cell layer. This statement is also in contradiction with Figure 3.</p> <p>p23-24. Repetition of the case studies described in Chapter 4.</p> <p>p24, lines 32-40. UVR Exposure limits are product of irradiance and exposure duration; irradiance is only relevant if exposure duration is known.</p> <p>p25, lines 4-5. What does "UV-B irradiation was not observed upon UV-C exposure" mean?</p> <p>p25, lines 12-22. Very unclear and confusing description; was exposure of 400-500 J/m² related to 222 nm source or 280-315nm? Spectral measurements, e.g. measurements of spectral irradiance, are carried out by the calibrated instrument by default. MEDs of 400-500 J/m² erythema effective radiant doses are not low; MED for skin types I-II doesn't exceed 250 J/m².</p> <p>p25, lines 30-31. Very unclear sentence: does it refer to visible bright light or UVR (where the term light is not applicable)? If it is visible light, what is the relevance to the health effects of UV-C? If UVR, bright light should not be used.</p> <p>p25 line 33. What does broadened mean? And how does effect a risk to human health?</p> <p>p25, line 37 and p26, line 17. There are no ocular hazards for welders, if appropriate personal protective equipment is used; all reported cases are dated or due to inadequate protection. There should be an explicit statement to emphasise this. It is also stated in lines 14-16 on p26 that presented studies are not UV-C specific.</p> <p>p25, line 42. UV-C can't cause lens damage as it is absorbed by the cornea.</p> <p>p27, line 6. Incorrect terminology, UVR is not light or lights.</p> <p>p27, line 7. What was the emission spectrum this irradiance refers to?</p>		<p>The text was amended.</p> <p>However, these case studies were presented from a different point of view. No change in the text is required.</p> <p>No change in the text is required.</p> <p>It means that the effect reported for UV-B irradiation was not observed for UV-C irradiation. No change in the text is required.</p> <p>The peer-reviewed reference is available in the publications list. The text was amended.</p> <p>The text clearly mentions UVR and not "UV light". No change in the text is required.</p> <p>The text was amended for clarity.</p> <p>Risk management is not in the remit of SCHEER. No change in the text is required.</p> <p>Nowhere in the text is this claim made.</p>

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			<p>p27, line 16. Delete or off at the end of sentence</p> <p>p27, line 26. Should unblended be unblinded?</p> <p>p27, line 30. Amend to: ... unclear in which period they occurred.</p> <p>p28, line 25. Which one study?</p> <p>p28, line 41-45. Exposure to UV-C can't increase a risk of cataract because of limited penetration depth to the ocular media, as shown in Figure 2 and explained by the text on p29. Other ocular and skin pathologies given in this paragraph are not UV-C specific.</p>		<p>No change in the text is required.</p> <p>The text was amended.</p> <p>The reference is available in the publication list. No change in the text is required.</p> <p>The text was amended.</p> <p>The text was amended.</p> <p>The text was amended.</p> <p>Zaffina et al, 2012. No change in the text is required.</p> <p>Nowhere in the text is such a claim made. No change in the text is required.</p>
37.	Sjømoen, Tone-Mette, Norwegian Radiation Protection Authority, nrpa@nrpa.no, Other, Norway	5. HUMAN HEALTH EFFECTS	<p>Comment to page 23, line 3:</p> <p>UVC radiation may be more or less damaging depending on the exposure condition and the target organ. Proposed change: Modify to e.g. ...most chemically reactive to DNA and proteins...</p> <p>Comment to page 23, line 5 and 6:</p> <p>Penetration of UVA and UVB are incorrect. According to table 4 in Bruls et al., the % values should be 15 % for UVB and 50 % for UVA.</p>		<p>The text is clear. No change in the text is required.</p> <p>The text was amended.</p>
38.	O'Hagan, John, International Commission on Illumination,	5. HUMAN HEALTH	We are not aware of any evidence for cancer caused by UV-C in humans. CIE published a review of this topic. The details and abstract are below:		SCHEER concludes that from basic

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	joh.hpa@btinternet.com, Austria	EFFECTS	<p>UV-C Photocarcinogenesis Risks from Germicidal Lamps</p> <p>CIE 187:2010</p> <p>ISBN 978 3 901906 81 7</p> <p>Increasingly, UV-C (100 nm – 280 nm) mediated air disinfection (principally 254 nm radiant energy from low-pressure mercury lamps) is being used as a building environmental control to provide human protection from transmission of airborne pathogens such as tuberculosis bacteria, influenza viruses and other aerosolized agents. Some uses of UV-C energy require direct exposure of the volume room air in a horizontal plane directly above the heads of occupants. In these settings there is the potential of reflected or scattered UV-C radiation that could result in human exposure. Known side effects of overexposure to UV-C radiation include transient corneal and conjunctival irritation (photo-keratoconjunctivitis) and skin irritation (erythema), which disappear within a 24 – 48 hour period, not currently known to produce lasting biological damage. The ACGIH and ICNIRP threshold limit for 8 hour continuous exposure to UV-C radiation at 254 nm is 6 mJ·cm⁻² (60 J·m⁻²), and proper installation of well-engineered UV-C systems meet this criteria. However, there have been incidents of poor installations resulting in accidental UV-C overexposures. General statements that all UVR is carcinogenic have raised safety concerns of open air UV-C systems. Although, from basic biophysical principles, UV-C radiation is carcinogenic for the same reason that it is an effective germicidal agent, the attenuation provided by the stratum corneum and epithelial tissues of the skin greatly reduces the risk relative to UV-B radiation. UV germicidal irradiation can be safely and effectively used for upper air disinfection without a significant risk for long term delayed effects such as skin cancer.</p>		<p>biophysical principles, UV-C radiation is carcinogenic, but nowhere in this section is it mentioned that there is evidence of UV-C alone causing cancer. No change in the text is required.</p>
39.	Hofmann, Frank, NARVA Lichtquellen GmbH & co. KG, f.hofmann@narva-bel.de, Germany	5.1.1 CASE REPORTS	<p>The third paragraph (dealing with the case in Botswana) contains the following sentence: "In the office, UV measurements at eye level and looking directly at the UV lamp ranged from a low of 0.2 J/m² when seated to a high of 0.49 J/m² when standing." The quantity dose (J/m²) is wrong in this content, since it should be irradiance (W/m²). By applying the formula H=E*t one yields the same times as stated at the end of the paragraph (120s .. 300s).</p> <p>An additional, general note: within the whole study deuterium lamps as a common UVC source are not mentioned. Deuterium lamps exhibit a smooth spectral emission in the area 200nm..400nm (maybe also below 200nm) in contrast to the 254nm peak emission (Hg line) of discharge lamps.</p>		<p>The text was amended.</p> <p>The text was amended.</p>
40.	Sjømoen, Tone-Mette, Norwegian Radiation Protection Authority, nrpa@nrpa.no, Other, Norway	5.1.1 CASE REPORTS	<p>Editorial comments to page 24:</p> <p>Line 6: Space character missing between 36W.....</p> <p>Line 16: Year missing in Zaffina ref.</p>		<p>The text was amended.</p> <p>The citation was</p>

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					amended.
41.	Ivanova, Mihaela, National Centre of Public Health and Analyses (Team of Prof. Michel Israel), Mihaela_1970@abv.bg, Bulgaria	5.1.1 CASE REPORTS	line 22: We propose the following change in the sentence: It should be noted that in order to keep the dose below 60 J/m ² as it is recommended by ACGIH the duration of exposure to the 254 nm UVC radiation should not exceed 21.4 s.		The text was amended.
42.	Sjømoen, Tone-Mette, Norwegian Radiation Protection Authority, nrpa@nrpa.no, Other, Norway	5.1.2 VOLUNTEER STUDIES	Editorial comment to page 25, line 3: Write UVB instead of UV-B.		It was decided to use the dash. See comment 10 above.
43.	Sjømoen, Tone-Mette, Norwegian Radiation Protection Authority, nrpa@nrpa.no, Other, Norway	5.1.2 VOLUNTEER STUDIES	Editorial comment to page 25, line 3: Write UVB instead of UV-B.		It was decided to use the dash. See comment 10 above.
44.	Sjømoen, Tone-Mette, Norwegian Radiation Protection Authority, nrpa@nrpa.no, Other, Norway	5.2 STUDIES OF WELDERS	Comment to page 25, line 34: Distance is not determined. Distance from where, and is it plausible that the distance from the source influences the observed spectral distribution, unless filtering takes place?		The sentence expresses the UV absorption law in air. No change in the text is required.
45.	O'Hagan, John, International Commission on Illumination, joh.hpa@btinternet.com, Austria,	5.2 STUDIES OF WELDERS	Current exposure of welders to UV is considerable lower than it would have been 10 years ago. Personal protective equipment is now the accepted by welders.		No changes in the text are required.
46.	Public Health England, marina.khazova@phe.gov.uk, United Kingdom	6. BIOLOGICAL EFFECTS	p29, lines 12-19. Text refers to the damage of ocular tissues by UV-A and UV-B, not UV-C. Only lines 19-21 are relevant to the UV-C interaction. It is important not to cause confusion where the subject of the report is UV-C and not all UV. p29, line 16. Incorrect terminology, UVR is not light p29, line 17. Replace larger with longer p29, Figure 2. References taken from commercial web-sites should not be considered as a source of internationally accepted scientific evidence. Suggest peer-review literature should be referenced and/or reports/guidance from CIE or ICNIRP. p30, line 1. Mixture of terminology: there is no horny layer shown in Figure 3		The text is clear. No changes are required. The text was amended. The text was amended. No change in the text is required. Literal translation of "stratum corneum" into English is "horny layer". No change is required.
					But it does explain

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			<p>p30, Figure 3. Stratum Lucidum layer shown in this figure is only present in the skin of the soles of the feet and palms of hands. It does not explain the practical relevance of UV-C exposure of the soles of the feet.</p> <p>p30, lines 11-15. Harmful effects of UVR exposure listed in this paragraph are not UV-C specific. Suggest this could be shortened to only cover UV-C harmful effects, to emphasise that they are few.</p> <p>p30, lines 32-34 and p31, lines 11-13. This interpretation contradicts to the scientific evidence that reciprocity law applies to erythema.</p> <p>p31, lines 24 and 30. What does ultrastructural mean?</p> <p>p31, lines 27-28. Replace dosage with dose. Given exposure doses (28 SEDs, 56 SEDs and 86 SEDs) are extremely high and would cause severe burns for humans; direct translation of this results to health effects is questionable.</p> <p>p31, line 30. Replace dosage with dose and exposal with exposure</p> <p>p31, lines 39-47 and p32, lines 1-4. Repetition of the case study presented in 5.1.2, p25, lines 12-22.</p>		<p>the relevance for other parts of the body. No change in the text is required.</p> <p>This is clearly stated in the text. No change is required.</p> <p>The reported results are given in the text together with the citations. No changes are required.</p> <p>Refers to the ultrastructure of a biological specimen. Can be looked up in a medical dictionary.</p> <p>The text was amended.</p> <p>The text was amended. Study described from a different aspect. It belongs to both sections. No changes are required in the text.</p>
47.	Ivanova, Mihaela, National Center of Public Health and Analyses (Team of Prof. Michel Israel), Mihaela_1970@abv.bg, Bulgaria	6.1.1 GENERAL OVERVIEW	<p>page 30, line 11: Proposal for changes of the sentence: The harmful effects of UV radiation include acute (deterministic) effects on human skin, like as well as chronic and stochastic effects...</p> <p>The biological effects of radiation on human body, are generally divided into two categories:</p> <p>"deterministic effects" and "stochastic effects". So, in our opinion, here should be mentioned that generally the acute effects are deterministic (with threshold), and the</p>		The text was amended.

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			parallel acute - stochastic effect is not so correct.		
48.	Public Health England, marina.khazova@phe.gov.uk, United Kingdom	7. OPINION	p34, lines 3-5. This statement contradicts ICNIRP Guidelines on limits of exposure to ultraviolet radiation of wavelengths between 180 nm and 400 nm which includes spectral weighting functions for UV-C and exposure limits in this spectral range. No justification is given to support this statement.		The text was amended for clarity.
49.	O'Hagan, John, International Commission on Illumination, joh.hpa@btinternet.com, Austria	8. RECOMMENDATIONS FOR FURTHER WORK	It is suggested that the greatest contributor to reducing risk from artificial sources is to provide collective protection (shielding and containment) where this is practicable. It is also important to recognise that some practices are returning, such as the use of ambient sterilisation processes with UV-C sources in medical facilities, for example in operating theatres. These practices had been phased out due to the serious damage to plastics in the environment.		The text was amended.
50.	Sharon Miller , PhD Office of In vitro Diagnostics & Radiological Health Center for Devices & Radiological Health US Food and Drug Administration		I know it is past the official deadline for comments on the UVC document, but I noticed that there appears to be an error on line 5 of page 23 where it says that the transmittance of skin (from Bruls 1984 paper) is 15% at 365 nm. IF you look at Figure 1 in Bruls' paper, it appears to be closer to 75%.		The text was amended.
51.	David Sliney, Ph.D. (Biophysicist/ Medical Physicist)		<p>Dear Ana Proykova, Theodoros Samaras, Renate Krätke, Rodica Mariana Ion and Colleagues:</p> <p>This e-mail is to provide a comment to the Scientific Committee on Health, Environmental and Emerging Risks SCHEER, Preliminary opinion on Biological effects of UVC radiation relevant to health with particular reference to UVC lamps.</p> <p>I am not sure exactly how a copy of the subject report arrived in my mailbox, but it was interesting to review. Perhaps it came to me as Chair of the IESNA Photobiology Committee or as Associate Director of CIE Division 6 (Photobiology) or as Convener of IEC TC76/WG1 (Lasers and Optical Radiation Safety). My particular concern was the lack of references to UV-C exposure limits, past work in this area, and in particular the failure to even mention the international technical report from the CIE on this very subject, Report CIE 187:2010, "UV-C Photocarcinogenesis Risks from Germicidal Lamps."</p> <p>I think that your report suggests a much higher uncertainty and higher perceived risk of UV-C radiation that is justified. Certainly, the shorter wavelengths of UV-C do not penetrate through the stratum corneum and certainly not to the basal level of the epidermis. You may want to review: http://www.cie.co.at/index.php/index.php?i_ca_id=718</p>		The text was amended.